UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

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

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

For the fiscal year ended September 30, 2016

OR

☐ **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: 001-37759

ONCOBIOLOGICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**38-3982704**
(State or other jurisdiction of incorporation or organization)	***(I.R.S. Employer Identification No.)***

7 Clarke Drive
Cranbury, New Jersey 08512
(609) 619 - 3990
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, $0.01 par value per share	**NASDAQ Global Market**
Series A warrants, $0.01 par value per share	**NASDAQ Global Market**
Series B warrants, $0.01 par value per share	**NASDAQ Global Market**

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 ☐ No ☒

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

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 than the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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 (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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 the 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. ☒

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 definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act (check one):

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☒

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

The registrant did not have a public float on the last business day of its most recently completed second fiscal quarter because there was no public market for the registrant's common equity as of such date.

As of December 28, 2016, the registrant had 23,578,942 shares of common stock, par value $0.01 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement, or the Proxy Statement, for the 2017 Annual Meeting of Stockholders of the registrant are incorporated by reference into Part III of this Annual Report on Form 10-K. The Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended September 30, 2016.

ONCOBIOLOGICS, INC.
ANNUAL REPORT ON FORM 10-K

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In this report, unless otherwise stated or as the context otherwise requires, references to "Oncobiologics," "the Company," "we," "us," "our" and similar references refer to Oncobiologics, Inc. The Oncobiologics logo and other trademarks or service marks of Oncobiologics, Inc. appearing in this report are the property of Oncobiologics, Inc. This report also contains registered marks, trademarks and trade names of other companies. All other trademarks, registered marks and trade names appearing in this report are the property of their respective holders.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than statements of historical facts are "forward-looking statements" for purposes of these provisions, including those relating to future events or our future financial performance and financial guidance. In some cases, you can identify forward-looking statements by terminology such as "may," "might," "will," "should," "expect," "plan," "anticipate," "project," "believe," "estimate," "predict," "potential," "intend" or "continue," the negative of terms like these or other comparable terminology, and other words or terms of similar meaning in connection with any discussion of future operating or financial performance. These statements are only predictions. All forward-looking statements included in this Annual Report on Form 10-K are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Any or all of our forward-looking statements in this document may turn out to be wrong. Actual events or results may differ materially. Our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks, uncertainties and other factors. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K in greater detail under the heading "Item 1A — Risk Factors." We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

PART I

Item 1. Business

Overview

We are a clinical-stage biopharmaceutical company focused on identifying, developing, manufacturing and commercializing complex biosimilar therapeutics. Our current focus is on technically challenging and commercially attractive monoclonal antibodies, or mAbs, in the disease areas of immunology and oncology. A mAb is a type of protein that is produced by a single clone of cells or cell line and made to bind to a specific substance in the body. Our strategy is to develop these biosimilars in a cost-effective manner on an accelerated timeline, which is fundamental to our success and we believe positions us to be a leading biosimilar company. We have leveraged our team's biopharmaceutical expertise to establish fully integrated in-house development and manufacturing capabilities, which we refer to as our BioSymphony Platform. We believe this platform addresses the numerous complex technical and regulatory challenges in developing and commercializing mAb biosimilars and has been designed to provide significant pricing flexibility. We have identified eight biosimilar product candidates for further development and have successfully advanced two of these product candidates through Phase 1 clinical trials and into preparations for Phase 3 clinical trials: ONS-3010, a biosimilar to adalimumab (Humira®), and ONS-1045, a biosimilar to bevacizumab (Avastin®).

We were founded by a team of industry veterans with decades of cumulative experience in biologics development and commercialization. Our leadership team has been instrumental in obtaining global regulatory approval for multiple complex biologics at leading multinational biopharmaceutical companies. In addition, our scientific team has specific experience in process development for complex biologics, protein manufacturing and analytical research and development, which are essential components for the development and manufacturing of complex biosimilars.

Escalating healthcare costs and healthcare reform have been major drivers for the advancement of the biosimilar market as payors continue to seek ways to reduce costs. By gaining the "highly similar" regulatory designation for an approved biologic, or reference product, less-expensive biosimilars provide the opportunity to reduce treatment costs without sacrificing the quality of care. We believe the significant pricing flexibility provided by our BioSymphony Platform gives us an additional competitive advantage in potentially capturing market share. The loss of multiple reference product patent exclusivities in the coming years will create significant opportunities for the biosimilar industry. There are more than 30 reference products facing loss of patent exclusivity in one or more major markets through 2020. According to the SNS Report entitled "The Biosimilar Drugs Market: 2015-2030 Opportunities, Challenges, Strategies & Forecasts", mAbs are the largest segment of the biologic market, and worldwide sales of mAb biosimilars are expected to grow from approximately $1.4 billion in 2015 to $56.5 billion by 2030.

Our most advanced product candidate, ONS-3010, an adalimumab (Humira) biosimilar, targets the tumor necrosis factor alpha, or TNFα, which is a potent inflammation mediator. In the first quarter of 2015, ONS-3010 met its primary and secondary endpoints in a Phase 1 clinical trial. In addition, ONS-3010 demonstrated a lower rate of injection site reactions than that of Humira. We have initiated Phase 3 preparatory activities for ONS-3010 and expect to commence enrollment in 2017 upon receipt of additional funding. Our second product candidate, ONS-1045, a bevacizumab (Avastin) biosimilar, interferes with tumor growth by binding to vascular endothelial growth factor, or VEGF, a protein that stimulates the formation of new blood vessels. In October 2015, ONS-1045 met its primary and secondary endpoints in a Phase 1 clinical trial and we are preparing to commence enrollment for a Phase 3 clinical trial in 2017 upon finding a development partner or receipt of additional funding.

In addition to our clinical candidates, we have six preclinical biosimilar product candidates in active development. Our most advanced preclinical product candidate, ONS-1050, a trastuzumab (Herceptin®) biosimilar, interferes with the human epidermal growth factor receptor 2, or HER2, a protein that stimulates cell proliferation, and when overexpressed, can cause certain cancers. ONS-4010 is a biosimilar to denosumab (Prolia®/Xgeva®), which is a fully human mAb with affinity and specificity for human RANKL (receptor activator of nuclear factor kappa-B ligand), and used for the treatment of osteoporosis, treatment-induced bone loss, bone metastases and giant cell tumor of the bone. Commencement of Phase 1

clinical trials of ONS-1050 and ONS-4010 are dependent on successful completion of comparative analytical and in vitro functional studies, receipt of necessary regulatory authorizations and additional funding. In addition to these preclinical products, we plan to expand our pipeline of complex biosimilar product candidates as additional products approach the loss of their respective patent exclusivities.

Our Strategy

Our goal is to utilize the BioSymphony Platform to identify, develop, manufacture and commercialize technically challenging and commercially attractive mAb biosimilars on an accelerated timeline in a cost-effective manner, initially in the disease areas of immunology and oncology. The key elements of our strategy include:

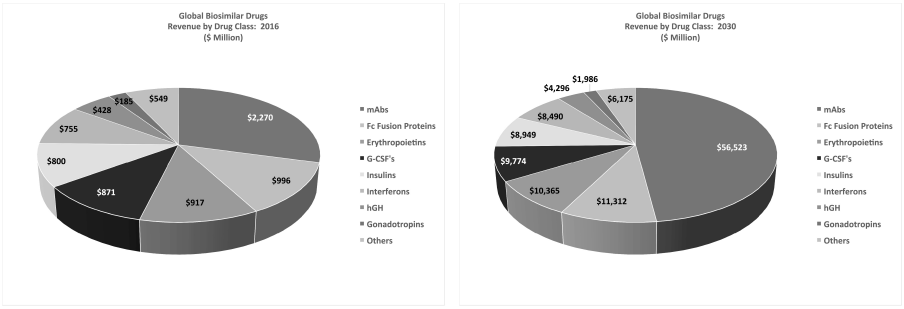
- ***Rapidly advancing our lead product candidates through late-stage clinical development and continuing to advance our preclinical pipeline.*** ONS-3010 and ONS-1045 are our most advanced clinical-stage product candidates. In the first quarter of 2015, ONS-3010 met its primary and secondary study endpoints in a Phase 1 clinical trial and we are preparing to commence enrollment in a confirmatory Phase 3 clinical trial in 2017. Our second product candidate, ONS-1045, met its primary and secondary study endpoints in a Phase 1 clinical trial in October 2015 and we expect to commence enrollment in a Phase 3 clinical trial of ONS-1045 upon finding a development partner or receipt of other additional funding. In addition to our advanced product candidates, we have identified six preclinical candidates. Our most advanced preclinical candidates, ONS-1050 and ONS-4010, are expected to commence Phase 1 clinical trials pending successful completion of comparative analytical and in vitro functional studies and receipt of additional funding.
- ***Employing our expertise in product development to further expand our pipeline.*** We use a comprehensive approach to identify both near-term and future biosimilar targets that will further enhance and sustain our growth. In particular, we periodically evaluate approved complex biologics using multi-faceted selection criteria to identify reference products that we believe have potential for significant commercial opportunity.
- ***Cost effectively developing and manufacturing mAb biosimilars in an accelerated timeframe.*** Our internal capabilities allow us to employ a seamless transition between development and manufacturing, significantly reducing the time and cost of biosimilar development. We employ single-use technology that reduces costs of manufactured goods as compared to traditional manufacturing methods. These integrative features of our in-house capabilities permit us to initiate current good manufacturing practice, or cGMP, manufacturing within six weeks of completion of process development compared to traditional technology transfers that can take six months or more. We believe that these cost reductions will enable significant pricing flexibility, and will be fundamental to establishing long-term leadership in the biosimilar industry.
- ***Continuing to invest in and expand our in-house manufacturing capabilities.*** We believe our in-house manufacturing capabilities offer us competitive advantages in the biosimilar industry. Our current manufacturing facilities and infrastructure are sufficient to support the clinical development of our current pipeline and the commercialization of our two most advanced product candidates. Further, given the modular nature of our facilities and infrastructure, we believe we can rapidly and cost effectively expand our capacity to support our future manufacturing needs as we continue to expand our pipeline of product candidates.
- ***Maximizing the value of our pipeline via co-development partnerships and/or licensing the development and commercialization rights where appropriate.*** We currently intend to enter into strategic collaborations and partnerships with biotechnology and pharmaceutical companies in the United States and other regions. We believe this strategy will allow us to maximize the impact of our financial resources and result in increased commercial value of our development programs.

The Biosimilar Industry

Background

Biologic products are produced by living cells and have been approved for the treatment of various disease states. Biosimilars are the approved “copies” of such reference products. According to a recent report from

ESPICOM, an international health research and publishing company, the 2014 global biologics market represented approximately $175 billion in sales while IMS projects the global biologics market will reach $221 billion in sales by 2017, with virtually the entire market composed of branded biologic products. Additionally, more than 280 potential novel biologic therapies have been identified in the clinical pipeline, almost half of which are being evaluated for oncology indications. Multiple patents for many commercially successful biologic products are expected to expire during the next five years, providing an unprecedented opportunity for reductions in the cost of biologics through the introduction of biosimilars. There are over 30 biologic products that face loss of market exclusivity in at least one major market through 2020. According to published reports, global sales of biologics are estimated to reach more than $200 billion by the end of 2016. Biologic reference products with estimated global sales of $100 billion will come off patent by 2020, and between 2009 and 2019, $50.0 billion of the market value of biologics in the United States alone will lose patent protection. There are currently 45 mAbs on the market worldwide, with revenues in excess of $40.0 billion. The overall biosimilar market is projected to reach global sales of approximately $7.8 billion ($2.3 billion of which is associated with mAbs) during 2016, eventually accounting for approximately $118 billion by 2030 ($56.5 billion of which is associated with mAbs). As demonstrated in the following graphic, revenue from global sales of mAbs are expected to account for nearly 29% of the global sales in 2016, with European sales expected to account for 24%.

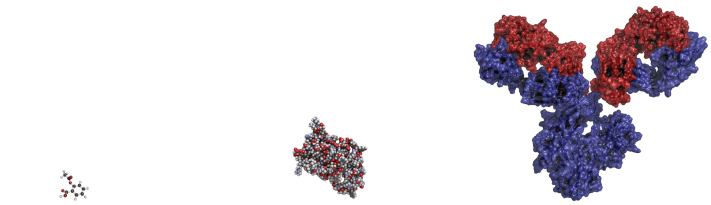


"The Biosimilar Drugs Market: Opportunities, Challenges, Strategies & Forecasts"; SNS Research Ltd.

A major driver for the advancement of the biosimilar market is the increasing and disproportionate amount of healthcare spending by governments and private payors on biologic therapeutics. The high costs for biologic treatments have led to an increasing financial burden on these payors. We believe this market dynamic has created opportunities for biosimilar developers in two key respects. First, the high costs of branded biologic products have created a growing demand for lower-cost biosimilars that can offer patients the same benefits as the reference products without sacrificing quality of care. Express Scripts projects U.S. healthcare savings of approximately $250 billion between 2014 and 2024 if biosimilars for just 11 existing biologic drugs that are the most likely candidates for biosimilars were to come to market. Second, because biosimilars, especially complex biosimilars, are more costly and challenging to develop and manufacture than the generic versions of small-molecule drugs, we expect fewer companies will be able to successfully overcome the technical and regulatory complexities of biosimilar development.

Technical Challenges

Unlike small molecules, such as aspirin, or simple biologics, such as human growth hormone, mAbs are much larger and correspondingly complex. MAbs consist of four polypeptide chains of amino acids and perform a vast array of functions within living organisms. The specific amino acid sequence of each mAb dictates the folding of the protein into a specific three-dimensional structure that determines its activity. The following image compares a mAb to human growth hormone and aspirin. The complexity of a molecule increases with its size as defined by molecular weight, or number of atoms.



Aspirin Molecule
180 Daltons

Human Growth Hormone
849 Daltons

Monocional Antibody
150,000 Daltons

MAbs are derived from living cells and are produced through a series of complex processing steps that define their overall structure. Accordingly, they cannot be chemically synthesized nor fully characterized by a few analytical techniques. MAbs are also known to contain sugar side-chains, which are attached through a process referred to as glycosylation. These sugar chains confer structural stability, improve solubility, and can impact the function of the protein in vivo.

The complexities of mAbs require a specialized skill set for development. A biosimilar developer must have the necessary expertise in cell and molecular biology, protein biochemistry and biochemical engineering to overcome the following particular technical challenges:

- ***Reference Product:*** A protein therapeutic exists as a mixture of various molecular forms that together impart its mechanism of action. In order to understand the structure and function of the reference product, the biosimilar developer must conduct many analytical studies to reverse engineer the multiple quality attributes that govern the reference product's protein structure and function. Due to the inherent variability that results from cellular production techniques, many production lots of reference product must be analyzed to understand the batch to batch variability and set the target product profile for the biosimilar candidate.
- ***Similarity:*** Biosimilar developers must create their own cell line and unique manufacturing process as they do not have access to the reference product manufacturer's cell lines or manufacturing know-how. As a result, only similar, but not exact, copies of the reference product are feasible. During production, mAbs commonly can degrade to form aggregates, when two or more mAb units bind to each other to form larger structures. These larger structures can lead to changes in activity, or immunogenicity (provoke an immune response). Finally, mAbs may also undergo other chemical degradation events during purification and during storage, each of which can impact potency. Producing biomolecules that are highly similar to the reference product requires a significant interdisciplinary effort that involves a number of iterative cycles between cell line and process development, and analytical characterization.
- ***Manufacturing:*** The quality profile of a biologic can change when the manufacturing process scale is increased to commercial size or when processes are modified to fit a facility. The ability to manufacture highly similar molecules must be demonstrated reproducibly at commercial scale. In order to enable pricing flexibility, the manufacturer must minimize costs related to depreciation of its capital investment, raw materials and operations, while maintaining high quality and yield.

Regulatory Challenges

The regulatory requirements for the development of biosimilars in many countries, including the United States, Canada, the EU and Japan, differ from the requirements for developing the reference products. For example, the analytical data package required to initiate clinical trials of biosimilars is more exhaustive due to the prerequisite to generate initial similarity data to the reference product. This process requires multiple qualified methods to ensure that the data generated for similarity testing are reproducible and comprehensive. On the other hand, the non-clinical and clinical programs for biosimilars tend to be more streamlined than for innovator molecules if shown to be analytically similar at the outset and can be supported by the reference product data. The regulatory expectations surrounding biosimilars are still evolving as new draft and final guidance documents are being made public across regulatory authorities.

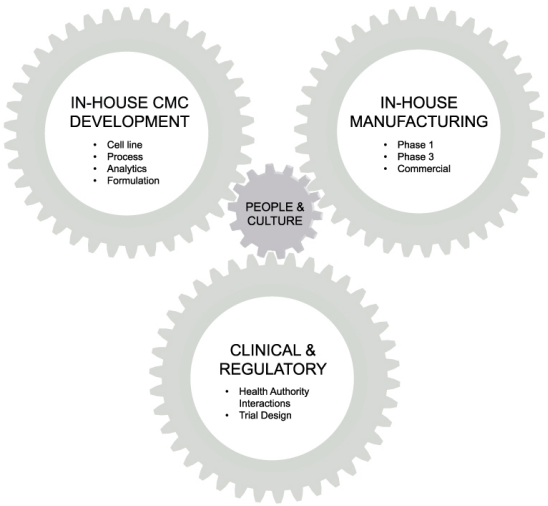
Regulatory hurdles associated with biosimilar development include:

- demonstrating to regulators that specific analytical differences of the biosimilar do not have clinical impact;
- complying with individual regulatory authority requirements for in vivo preclinical studies to enable development and registration in planned markets;
- anticipating and responding to changes in regulatory requirements that could involve additional technical work;
- demonstrating extrapolation for an indication that can drive market share;
- addressing questions during regulatory review of marketing applications to prevent a delay in approval; and
- designing global clinical trials to meet the different regulatory requirements to avoid duplicative studies and additional expense.

Any deficiency in regulatory approach could result in inconsistencies in the final data package for the submission and could lead to a delay or rejection of a product candidate's approval in certain markets.

Our BioSymphony Platform

Escalating healthcare costs and healthcare reform initiatives have been major drivers for the advancement of the biosimilar market. Our BioSymphony Platform is designed to address the technical challenges and regulatory dynamics of the complex biologics industry by developing high quality mAb biosimilars on an accelerated timeline and in an efficient and cost-effective manner. The BioSymphony Platform, driven by our entrepreneurial culture, leverages our fully integrated in-house 48,000 square foot development and manufacturing facility and our team's clinical and regulatory expertise. We believe this model enables significant pricing flexibility, providing us with competitive advantages, and positions us to be a leading biosimilar company. The key elements of our BioSymphony Platform are depicted in the following figure.



MAb development presents high technical hurdles, and the success of our development efforts is dependent on an experienced and knowledgeable workforce. We were founded by a team of industry veterans with decades of cumulative experience in biologics development and commercialization. Our team has been instrumental in obtaining global regulatory approval for multiple complex biologics at leading multinational biopharmaceutical companies. We have hired accomplished scientists, engineers and business leaders since our inception, who together foster an entrepreneurial culture that has enabled agility, teamwork and rapid decision-making at Oncobiologics. Together, this has resulted in a highly collaborative approach, which has been critical to the efficient and sustainable operation of our BioSymphony Platform.

Technical Platform

In-House CMC Development Capabilities

We have established a research and development laboratory, which we believe enables the rapid development of high-quality mAb biosimilars. By establishing this infrastructure in-house, we have shortened the typical time required to perform the mandatory interdisciplinary iterative steps to develop mAb biosimilar products, which we believe reduces the cost of development. Our platform provides us with a differentiated approach to the following compulsory steps required to develop biosimilars:

- ***Reference Product Characterization and Cell Line Development:*** We initially reverse engineer the amino acid sequence and identify the critical quality attributes of the reference product that in turn provides the criteria for the clone selection process. We utilize automated technologies to enable thousands of clones to be screened in an accelerated timeline.

- ***Bioprocess:*** We utilize high-throughput mini bioreactors to assess the screened clones and media components to determine which clone and bioreaction process will produce a biosimilar candidate with the closest match to the reference product. We have developed purification technology, including a platform of chromatography techniques that are strategically combined to maximize product-yield while meeting the critical quality attributes of the reference product.

- ***Formulation:*** The formulation that best preserves the stability of the biosimilar candidate may be different than the actual formulation of the reference product. We use high-throughput techniques to screen and evaluate many formulation variations to identify the most effective stable formulation.

- ***Analytical Characterization and in vitro Similarity:*** We utilize numerous advanced analytical techniques and instruments to enable us to interpret the chemical and structural similarity between our biosimilar candidate and the reference product. We apply a rigorous analytical approach to characterize attributes such as structure (primary, secondary and tertiary), size and glycosylation, among others. We test up to approximately 60 quality attributes with approximately 45 analytical methods. The biological characterization assays support establishing the in vitro similarity. Our in-house capabilities provide an expeditious and thorough assessment of biochemical, biophysical and functional attributes.

To pursue development and commercialization of additional mAb biosimilar candidates, we intend to expand our development capacity by an additional 82,000 square feet in our current industrial complex. We also plan to build-out additional state-of-the-art development infrastructure, which we will occupy in phases as needed. Our plan is to add to our scientific team as our development programs expand.

In-House Manufacturing Capability

We have established a state-of-the-art manufacturing facility capable of simultaneously producing multiple biosimilar candidates. Our manufacturing platform utilizes single-use technology, including the use of the largest single-use bioreactor available, which eliminates the need for rigorous cleaning and sterilization procedures, and related operational requirements necessary for manufacture in traditional stainless-steel based facilities. We have been able to construct single-use based antibody manufacturing plants in approximately four months as compared to the few years required for de novo biotechnology manufacturing facilities. We have developed and execute a quality system that meets U.S. and EU standards

and have successfully completed two Qualified Person, or QP, audits resulting in cGMP declaration for both Phase 1 and Phase 3 manufacturing. We believe we have sufficient manufacturing capacity until 2018 and will be able to expand capacity in our current location once we build-out our new development infrastructure.

Development-Manufacturing Integration

We believe we have successfully and seamlessly unified our development capabilities and manufacturing processes to minimize time lapses and risks that are frequently encountered in drug development. Our internal processes eliminate the need to transfer technology and processes to third-party manufacturers. Technology transfers are commonly performed through formal procedures consisting of the transfer of know-how, followed by manufacturing process gap assessments, and then finally replication and scale-up of the development process at manufacturing scale. These technology-transfer proceedings can take upwards of six months or longer, and could have an adverse effect on product quality. Our platform gives us the ability to initiate manufacturing within approximately six weeks of process development completion.

Regulatory and Clinical Approach for a Successful Global Launch

The regulatory requirements for the development of complex biosimilars are significantly different from those for novel biologic therapeutics. These biosimilar regulatory expectations are still evolving with new drafts and final guidance being made public by regulatory authorities worldwide. Due to the limited number of biosimilar regulatory approvals and developing guidance, prior regulatory feedback may not reflect the current expectations of the applicable regulatory authorities. We have developed a global regulatory risk mitigation strategy that we believe allows us to ask the right questions at the right time, enables us to ask probing questions to explore regulatory boundaries, provides the potential to set precedence and assures alignment with regulatory authorities. We believe the key prongs to this strategy include: checking in at certain key milestones to confirm continued acceptability, adjusting our programs with an understanding of evolving requirements, approaching key health authority agencies to discuss development plans and reviewing regulatory guidance and published information.

Our interactions with the U.S. Food and Drug Administration, or FDA, and European Medicines Agency, or EMA, provide us with a better understanding of relevant regulatory requirements and build our overall regulatory knowledge base for other upcoming product candidates. We augment these interactions by meeting with key health authorities, selected based on known expertise with biotechnology products or the established rapporteur to the reference product. These additional interactions are used to provide national input for risk mitigation for the clinical trial applications and also additional expert input on our development programs. This knowledge creates efficiencies in our development program by reducing the need to duplicate experiments or clinical trials. We have retained regulatory consultants in other countries to obtain advice on how to approach the regulatory agencies to optimally design our global development plans to meet the relevant local and regional regulatory requirements.

An important aspect of our regulatory development strategy is to design our confirmatory trials to maximize the potential commercial success in order to meet the requirements for extrapolation to other indications and to enable us to seek an interchangeability designation for at least some of our current and future product candidates. Our goal is to develop trial designs that will enable us to extrapolate to all approved indications without additional clinical data. We will also assess the ability for our product candidates that are either self-administered or used chronically in order to seek an interchangeability designation, which allows substitution for the reference product by a pharmacist without the intervention of the healthcare provider who prescribed the reference product. We may also develop trial designs to demonstrate clinical advantages of our biosimilar product candidates over reference products.

Data from in vivo animal studies may not be required to initiate human clinical trials for biosimilars, and as such we only conduct animal studies if it is deemed necessary to meet regulatory requirements or to address safety questions. Our approach to confirm that there is no clinically meaningful impact of any observed analytical differences is to conduct a Phase 1 clinical trial in healthy volunteers, followed by a single Phase 3 confirmatory clinical trial in a sensitive population. Based on regulatory guidance as well as our recent interactions with regulatory bodies, we believe this approach will continue to be acceptable to the regulatory bodies. Because regulatory bodies generally do not require a repeat of the original efficacy and safety trials,

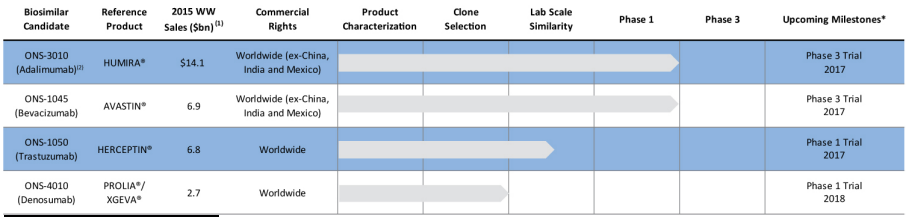
we continue to explore the potential of novel approaches to trial design that can confirm similarity in shorter duration of treatment and/or with smaller patient numbers, which can result in shortened timelines to registration. In certain cases, we may even be able to demonstrate that our biosimilar product candidates are more effective or safer than the reference products.

Our People and Culture

MAb development presents high technical hurdles, and the success of our development efforts is dependent on an experienced and knowledgeable work-force. We were founded by a team of industry veterans, with decades of cumulative experience in biologics development and commercialization at some of the leading biopharmaceutical companies including Eli Lilly and Company, Bristol-Myers Squibb Company, Genentech, Inc. and Amgen. Our leadership team has built a platform with the goal of expeditiously identifying, developing, manufacturing and commercializing mAb biosimilars in an efficient and cost-effective manner. We have fostered a culture of agility, collaboration and efficient decision-making with a focus on scientific rigor, which we believe forms the core of our BioSymphony Platform.

Our Product Candidate Portfolio

We are currently developing a portfolio of eight commercially attractive mAb biosimilars, for which the corresponding reference products generated an aggregate of approximately $37.8 billion in global revenue in 2015. We have also identified additional mAb biosimilars for which we expect to initiate development in 2017. The product candidates in our pipeline were selected on the basis of an internal evaluation process that relies on a weighted criteria comprised of the following factors: (i) future commercial potential; (ii) alignment of the reference product's patent expiry against the requisite development timelines; (iii) probability of technical success; and (iv) global competitive landscape. Our current pipeline of mAb biosimilars for which we have completed clone selection is described in the following chart.



* Subject to recept of additional funding and/or securing development partners.

(1) According to recent filings with the Securities and Exchange Commission, where available, EvaluatePharma and manufacturers' reports.

(2) We currently have an arrangement with Huahai for the co-development and joint commercialization of ONS-3010 in certain major developed markets, including the United States and EU. Assuming Huahai funds its proportionate share of development costs incurred after completion of the "Phase-3 Ready Package" for ONS-3010, we will have a 49% value ownership interest with Huahai having a 51% value ownership interest in ONS-3010.

ONS-3010 — Adalimumab (Humira) Biosimilar

Humira, the reference product for ONS-3010, is a subcutaneous injectable mAb that binds to TNFα. TNFα belongs to a family of pro-inflammatory cytokines, or soluble protein mediators, that are key initiators of immune-mediated inflammation in many different diseases, such as rheumatoid arthritis, psoriatic arthritis, psoriasis, ankylosing spondylitis, Crohn's disease and ulcerative colitis. Several biologic agents, including Humira, have been developed to inhibit the inflammatory activity of TNFs in the context of these diseases and are collectively referred to as the anti-TNF class of therapeutics.

Market Opportunity

Worldwide sales of Humira were $14.1 billion in 2015, with approximately $8.4 billion in the United States and projected to grow to $18.0 billion worldwide by 2020, and it is one of the world's bestselling drugs.

Humira has been approved by the FDA and the EMA for the treatment of 10 and 12 indications, respectively. Humira is currently approved in the United States for the following indications: rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult crohn's disease, pediatric crohn's disease, ulcerative colitis, plaque psoriasis, hidradenitis suppurativa and uveitis. We initially intend to seek approval of ONS-3010, a subcutaneous injectable, for the treatment of plaque psoriasis, and will pursue extrapolation of ONS-3010 across all eligible approved indications in order to maximize the commercial potential for ONS-3010. We have also designed our Phase 3 clinical trial for ONS-3010 in a way that we believe will enable us to also seek an interchangeability designation in the United States and have reviewed our trial design with the FDA and the EMA.

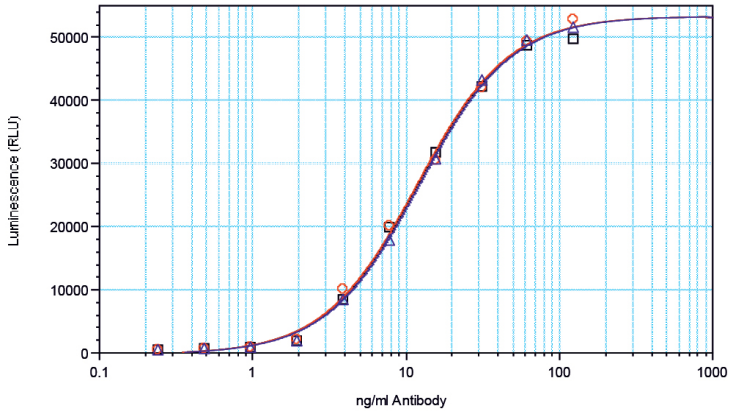
Chemistry Manufacturing Controls, or CMC, Status

We have manufactured and characterized a master cell bank from a selected clone and demonstrated its stability in accordance with global regulatory guidelines. We have also completed development of the ONS-3010 commercial manufacturing process. A novel formulation of similar stability was developed and used in the Phase 1 clinical trial and this same formulation is expected to be used for the planned Phase 3 clinical trial.

We have confirmed that the amino acid sequence of ONS-3010 matches Humira. Extensive analytical characterization and in vitro studies comparing ONS-3010 to both the U.S. and the EU versions of Humira were completed and a representative overlay demonstrating equivalent potency is shown in the following figure. Luminescence is a highly sensitive method for assaying cell proliferation and cytotoxicity. Potency is measured based on a comparison of the dose dependent response of the test article to the reference article. Based on the result of this assay and numerous analytical and in vitro characterization data, we initiated a Phase 1 clinical trial to assess pharmacokinetics, or PK, and safety. PK means how the body affects the molecule.

Comparative Potency of ONS-3010 versus Humira (U.S. and EU)

ONS-3010 (triangles), U.S.-Humira (squares), EU-Humira (circles).



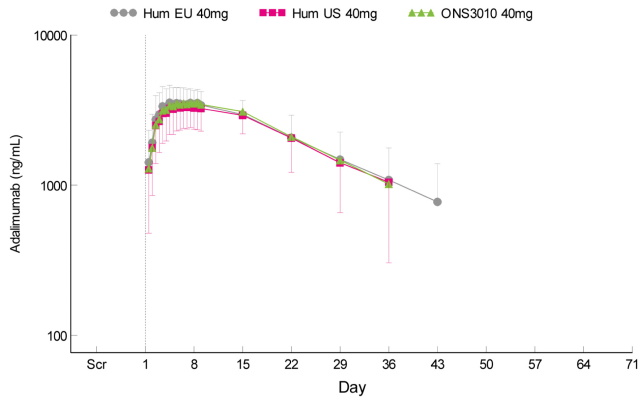
Using our commercial scale process at our manufacturing facility, we are manufacturing sufficient supply of ONS-3010 for Phase 3 clinical testing. We have contracted with a large U.S.-based pharmaceutical fill-finish facility to package ONS-3010 into a single-use, pre-filled syringe. We have also selected a partner for the development of an auto-injector to be used as an additional commercial delivery device.

Clinical Development Status and Clinical Trial Data

We have successfully completed a randomized, double-blind, single-dose and single-center Phase 1 clinical trial comparing ONS-3010 to Humira in 198 subjects receiving a 40 mg dose in three treatment arms: ONS-3010, U.S.-Humira and EU-Humira. This Phase 1 clinical trial was performed at the Center for

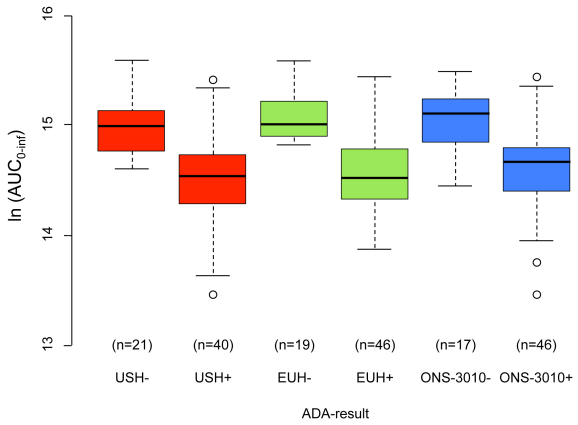
Human Drug Research in Leiden, The Netherlands under the auspices of the Stichting Beoordeling Ethiek Biomedisch Onderzoek. In this trial, ONS-3010 met its primary and secondary endpoints, demonstrating a similar PK profile, as well as an immunogenicity profile equivalent to both U.S.- and E.U.-Humira across all three treatment arms. ONS-3010 was well tolerated and demonstrated a favorable safety profile, which was similar to the safety profile for both U.S.- and E.U.-Humira, and demonstrated a lower injection site reaction rate than both U.S.- and E.U.-Humira. The following figure demonstrates the mean concentration-time profile of U.S.-Humira, EU-Humira and ONS-3010. The vertical line at day one denotes dosing. These results suggest a high degree of similarity between the three products.

Primary PK Endpoint (AUC0-∞)



The following figure demonstrates the effect of anti-drug antibodies on the concentrations (AUC, or area under the curve) for the three products. There were no significant differences in either the amount of anti-drug antibodies formed or their effect on concentration between the three products, which again suggest a high degree of similarity between the three products.

Effect of ADA-result on AUC0-inf



The following table reports the most frequently reported adverse events regardless of relationship. The most frequent occurring adverse event was local administration site irritation (either burning sensation or pain upon injection at the injection site), which was observed less frequently in the ONS-3010 treatment group.

Adverse Event	ONS-3010 N (%)	EU-Humira N (%)	U.S.-Humira N (%)
Burning sensation	12(18.2)	29(43.9)	31(47.0)
Headache	29(43.9)	20(30.3)	27(39.4)
Nasopharyngitis	12(18.2)	19(28.8)	12(18.2)

Regulatory Status and Development Plan

Prior to commencement of our Phase 1 clinical trial in 2014, we received feedback from both FDA and EMA, which provided guidance for the design of the clinical trial and our similarity testing approach. Since completion of the Phase 1 clinical trial, we had additional regulatory meetings with the FDA and the EMA, as well as other national regulatory agencies such as the Medicines and Healthcare Products Regulatory Agency, or MHRA, and the Swedish regulatory authority, and obtained further guidance on the Phase 3 clinical trial design in plaque psoriasis and the general similarity development plan for registration. We have completed a site feasibility study to identify global sites (North and South America, Europe, Australia and New Zealand) in preparation for the commencement of our planned Phase 3 clinical trial. We have designed our Phase 3 clinical trial for ONS-3010 in a way that we believe will enable us to also seek an interchangeability designation in the United States and have reviewed our trial design with the FDA and the EMA.

ONS-1045 — Bevacizumab (Avastin) Biosimilar

Avastin, the reference product for ONS-1045, is a mAb administered by infusion that interferes with tumor growth by binding to VEGF, a protein that stimulates the formation of new blood vessels.

Market Opportunity

Worldwide sales of Avastin were approximately $7.0 billion in 2014 and 2015 and are projected to remain relatively flat through 2019. Avastin has been approved by the FDA and the EMA for the treatment of seven and eight indications, respectively. Avastin is currently approved in the United States for the following indications: metastatic colorectal cancer, with intravenous 5-fluorouracil-based chemotherapy for first- or second-line treatment; metastatic colorectal cancer, with fluoropyrimidine- irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line Avastin containing regimen; non-squamous non-small cell lung cancer, with carboplatin and paclitaxel for first line treatment of unresectable, locally advanced, recurrent or metastatic disease; glioblastoma, as a single agent for adult patients with progressive disease following prior therapy; metastatic renal cell carcinoma with interferon alfa; cervical cancer, in combination with paclitaxel and cisplatin or paclitaxel and topotecan in persistent, recurrent, or metastatic disease; platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, in combination with paclitaxel, pegylated liposomal doxorubicin or topotecan. We initially intend to seek approval of ONS-1045, which will be delivered by infusion, for the treatment of non-squamous non-small cell lung cancer, and will pursue extrapolation across all approved indications, in order to maximize the commercial potential for ONS-1045.

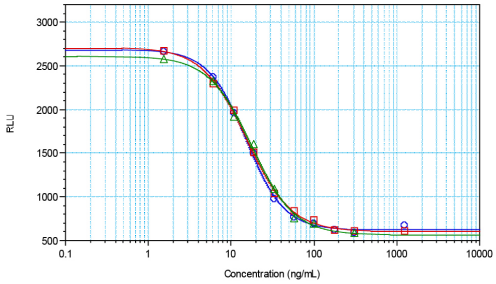
CMC Status

We have manufactured and characterized a master cell bank from a selected clone and demonstrated its stability in accordance with global regulatory guidelines. In addition, we have completed development of the ONS-1045 commercial manufacturing process.

We have confirmed that the amino acid sequence of ONS-1045 matches Avastin. Extensive analytical characterization and *in vitro* studies comparing ONS-1045 to both the U.S. and the EU-Avastin were completed and a representative overlay demonstrating equivalent potency is shown in the following figure.

Comparative Potency of ONS-1045 versus Avastin (U.S. and EU)

ONS-1045 (triangles), U.S.-Avastin (circles), EU-Avastin (squares)

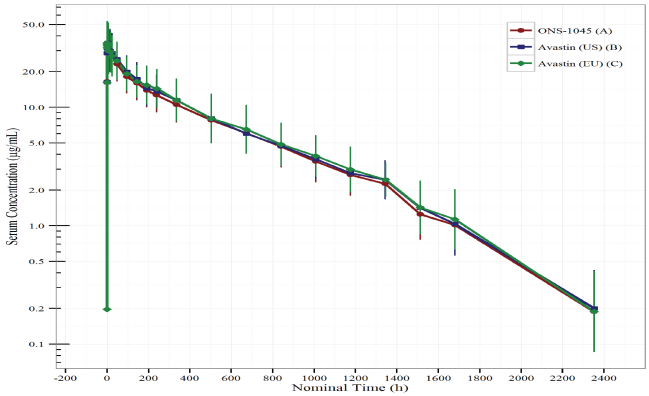


In preparation for producing Phase 3 clinical supplies, we are manufacturing ONS-1045 using our commercial scale process at our manufacturing facility. These batches will be filled into vials at a contracted U.S.-based commercial fill-finish facility.

Clinical Development

We have completed a randomized, double-blind, single-dose and single-center Phase 1 clinical trial comparing ONS-1045 to U.S.-licensed Avastin and EU-licensed Avastin in 135 subjects. This Phase 1 trial was performed at the Center for Human Drug Research in Leiden, The Netherlands under the auspices of the Stichting Beoordeling Ethiek Biomedisch Onderzoek. PK data, safety and immunogenicity were collected for a total of 98 days after a single 2.0 mg/kg dose. In this trial, ONS-1045 met its primary and secondary endpoints demonstrating a similar PK profile, as well as an immunogenicity profile equivalent to both U.S.- and EU-Avastin. Safety was comparable across all three groups. Immunogenicity was low with only one subject in the EU-licensed Avastin arm developing an anti-drug antibody, or ADA, at day 98. No neutralizing antibodies were detected in any arm. The following figure demonstrates the concentration-time profile of ONS-1045, U.S.-licensed Avastin, and EU-licensed Avastin as the mean. The vertical line at time zero denotes dosing. These results suggest a high degree of similarity between the three products.

Primary PK Endpoint (AUC0-∞)



Regulatory Status and Development Plan

Prior to the commencement of a Phase 1 clinical trial in 2015, we received feedback from both the FDA and the EMA, which provided guidance for the clinical trial design and similarity testing approach. We have

completed the next series of our regulatory interactions to obtain further guidance on our confirmatory trial design. Based on input from the FDA, EMA, MHRA and the Danish Health and Medicines Agency, we believe we have designed the appropriate confirmatory trial. We have also begun preparatory planning with the intention to discuss our Japanese development strategy with Japan's Pharmaceuticals and Medical Devices Agency.

Initiating the Phase 3 clinical trial for ONS-1045 is dependent on our completing negotiations with a co-development or licensing partner to assist in the further development and commercialization of ONS-1045.

ONS-1050 — Trastuzumab (Herceptin) Biosimilar

Trastuzumab (Herceptin), the reference product for ONS-1050, is a mAb administered by infusion that binds to HER2. Herceptin has been shown to inhibit the proliferation of human tumor cells that overexpress HER2.

Market Opportunity

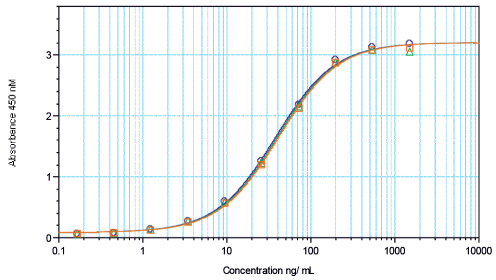
According to the Roche Annual Report for 2015, worldwide sales of Herceptin totaled approximately $6.8 billion in 2015. Herceptin is currently approved for HER2+ breast cancer and HER2+ metastatic gastric cancer in both the United States and the EU, as well as HER2+ gastroesophageal junction cancer in the United States. Worldwide sales of Herceptin are projected to grow to $7.1 billion by end of 2016. We have not yet determined the indication for which we will initially seek approval of ONS-1050. However, we will pursue extrapolation of ONS-1050 across all approved indications, in order to maximize the commercial potential for ONS-1050, and will deliver ONS-1050 by infusion.

CMC Status

A clone with a highly similar profile to Herceptin has been chosen for further process development. We have demonstrated the stability of the cell line, and characterization of the master cell bank. Manufacturing process development for ONS-1050 is nearing completion. We have confirmed that the amino acid sequence of ONS-1050 matches Herceptin. Extensive analytical characterization and *in vitro* functionality studies comparing ONS-1050 to Herceptin are underway and expected to support the biosimilarity assessment required to initiate clinical trials. A representative overlay demonstrating equivalent potency of ONS-1050 to U.S. and EU-Herceptin is shown in the following figure.

Comparative Potency of ONS-1050 versus Herceptin (U.S. and EU).

ONS-1050 (squares), U.S.-Herceptin (circles), EU-Herceptin (triangles)



We are planning to manufacture ONS-1050 for a Phase 1 PK study using our commercial scale process at our manufacturing facility. This batch is expected to be vialed at a U.S. pharmaceutical filling facility.

Regulatory Status and Development Plans

We received initial EMA guidance in the second quarter 2014 that supports our approach to the initial Phase 1 trial design. In accordance with our regulatory strategy and in advance of initiating Phase 1 clinical trials, we plan to interact with FDA, as well as other national regulatory agencies such as MHRA and the

Federal Institute for Drugs and Medical Devices, to also obtain further guidance on study design. We expect to be ready to commence our Phase 1 clinical trial upon securing either a co-development or licensing partner for ONS-1050 or additional funding.

Preclinical Biosimilar Pipeline

In addition to the product candidates we are currently advancing through clinical development, we are leveraging our BioSymphony Platform to develop additional preclinical candidates. Further development of such preclinical product candidates is subject to ongoing commercial analysis, among other items. We have not yet determined the initial indications for which we will seek approval for such preclinical product candidates. Our strategy will be to seek initial approval for an approved indication of the reference product, which will be determined in consultation with regulatory authorities regarding clinical trial and study design, and then seek to expand such approval to the same indications as the reference product. We also intend to deliver our biosimilars in the same manner as the reference product.

Two biosimilar product candidates, ONS-4010, a biosimilar to denosumab (Prolia/Xgeva), and ONS-1055, a biosimilar to cetuximab (Erbitux®), have cell lines developed and ONS-4010 has clone selection completed. Denosumab is a fully human mAb with affinity and specificity for human RANKL. Prolia is a subcutaneous injectable currently approved in the United States for treatment (i) of postmenopausal women with osteoporosis at high risk for fracture, (ii) to increase bone mass in men with osteoporosis at high risk for fracture, (iii) to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer and (iv) to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. Xgeva is a subcutaneous injectable currently approved in the United States for prevention of skeletal-related events in patients with bone metastases from solid tumors, treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity, and treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy. Erbitux, administered by infusion, is currently approved in the United States for the following head and neck cancer treatments: locally or regionally advanced squamous cell carcinoma of the head and neck in combination with radiation therapy, recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck in combination with platinum-based therapy with 5-FU, and recurrent or metastatic squamous cell carcinoma of the head and neck progressing after platinum-based therapy; and for the following colorectal cancer treatments: K-Ras wild-type, EGFR-expressing, metastatic colorectal cancer as determined by FDA-approved tests in combination with FOLFIRI for first-line treatment, in combination with irinotecan in patients who are refractory to irinotecan-based chemotherapy, and as a single agent in patients who have failed oxaliplatin- and irinotecan-based chemotherapy or who are intolerant to irinotecan. We have completed preliminary characterization and the reverse engineering of the amino acid sequences of the reference products. We plan to complete process development for ONS-4010 in 2017 to prepare for commencement of a Phase 1 clinical trial. We plan to complete lab scale similarity of ONS-1055 in 2017. According to manufacturers' reports and recent filings with the Securities and Exchange Commission, 2015 worldwide sales of Prolia/Xgeva and Erbitux were approximately $2.7 billion and $2.0 billion, respectively.

Three additional biosimilar product candidates, ONS-3030, a biosimilar to tocilizumab (Actemra®/Roactemra®), ONS-3035, a biosimilar to golimumab (Simponi®), and ONS-3040, a biosimilar to ustekinumab (Stelara®), are in early development. According to manufacturers' reports, 2015 worldwide sales of Actemra/Roactemra, Simponi and Stelara were $1.5 billion, $1.3 billion and $2.5 billion, respectively. We are focused on reverse engineering the reference product characteristics and developing cell lines for clone selection. In 2017, we anticipate completing clone selection for ONS-3030, and reference product characterization for each of ONS-3035 and ONS-3040.

Commercialization, Sales and Marketing

Our commercialization strategy is to maximize the revenue potential of our biosimilar product candidates along with seeking and securing selective licensing opportunities to fund the development of our assets. We currently intend to enter into strategic collaborations and partnerships with biotechnology and pharmaceutical companies in the United States and other regions to maximize the commercial value of our pipeline. Our intent is to enter into partnerships that result in economic and transactional efficiencies by

including upfront and post-Phase 1 development payments that would, in large part, offset global Phase 3 clinical development costs for each biosimilar product candidate. For example, we have a joint participation agreement in place for ONS-3010 with Zhejiang Huahai Pharmaceutical Co., Ltd., or Huahai, whereby we share post-Phase 1 development costs with Huahai, and proportionately share the revenues from commercialization of ONS-3010 in the United States, Canada, EU, Japan, Australia and New Zealand. We could also be required to form a joint venture to further develop and commercialize ONS-3010 with Huahai in the agreed countries, if so requested by Huahai. However, we do not have any other development and commercialization agreements for the United States or for major ex-U.S. markets, such as the EU and Japan. In 2012 and 2013, we established early country-specific partnerships for ONS-3010 and ONS-1045 in China with Huahai, in India with IPCA Laboratories Limited, or IPCA, and in Mexico with Laboratories Liomont, S.A. de C.V., or Liomont. In each of these smaller ex-U.S. markets, we have identified potential synergies between our partner's strategy to enter the biologics marketplace and access to our biosimilar development platform. These partnerships have resulted in $24.0 million in payments to us as of September 30, 2016, and are expected to result in high single-digit or low teens royalty streams for two of our licensed products, ONS-3010 and ONS-1045.

The United States and the EU are expected to be the largest and economically most attractive biosimilar markets and we plan to actively pursue licensing partners for both the United States and the EU. If required, we intend to build our commercialization infrastructure through an option to outsource the sales and marketing work force via a contract sales organization. As such, we have engaged a consulting company to evaluate our options and to assist with the development of a U.S. sales and marketing strategy. We also recently entered into a strategic collaboration agreement with Premier Healthcare Alliance, L.P., or Premier, a developer of a network of U.S. hospitals and healthcare providers, focused on data-gathering and cost-reduction strategies to improve the outcome of its members.

Under the agreement, we are partnering with Premier to share knowledge and strategize about how to most efficiently deliver our innovative and cost-effective mAb biosimilars in the U.S. market. We currently focus on those critical success factors associated with commercial success, namely the identification and interactions between (i) payors, (ii) providers, (iii) pharmacy benefit management organizations, (iv) patients and (v) physicians. We are currently developing a strategic roadmap that entails (i) developing and validating our commercialization strategy; (ii) exploring/establishing a distribution and commercialization relationship; and (iii) eventually developing our own sales and marketing force.

We believe that the U.S. biosimilar market adoption and penetration rates for each biosimilar will be determined primarily by four key factors: (1) the prevalence of payor incentives to drive substitution, (2) the physician and patient share influence relative to the payor in the prescribing decision, (3) rapidity of feedback on the safety and efficacy of the drug based on the totality of the patient response and (4) patient criticality (the degree of severity in the patient's condition).

Collaboration and License Agreements

We enter into collaboration and license agreements in the ordinary course of our business. We have in-licensed certain technology from Selexis SA, or Selexis, that we are using to research and develop our biosimilar product candidates. For biosimilar product candidates developed using the Selexis technology, we enter into commercial license agreements with Selexis that give us rights to commercialize, file INDs and enter into collaborative arrangements with third parties for the further development and commercialization of such biosimilar product candidates. Our commercialization strategy is to potentially retain U.S. rights to select biosimilar product candidates while entering into additional strategic collaborations and partnerships in other regions to maximize the commercial value of our pipeline. Although we do not yet have any such agreements for major ex-U.S. markets, such as the EU or Japan, we have licensing and collaboration agreements with select partners for smaller ex-U.S. markets where we would not otherwise intend to commercialize our biosimilar product candidates, including India, Mexico and China, which agreements have collectively provided an aggregate of $24.0 million in payments as of September 30, 2016.

Selexis — Humira (ONS-3010), Avastin (ONS-1045) and Herceptin (ONS-1050)

In October 2011, we entered into a research license agreement with Selexis SA, or Selexis, pursuant to which we acquired a non-exclusive license to conduct research internally or in collaboration with third parties to develop recombinant proteins from mammalian cells lines created using the Selexis expression technology, or the Selexis Technology. The original research license had a three-year term, but on October 9, 2014, was extended for an additional three-year term through October 9, 2017. We may sublicense our rights with Selexis' prior written consent but are prohibited from making commercial use of the Selexis Technology or the resultant recombinant proteins comprising our biosimilars in humans, or from filing an investigational new drug, or IND, absent a commercial license agreement with Selexis covering the particular biosimilar product candidate developed under the research license.

In connection with the entry into the research license, we paid Selexis an initial fee of CHF 100,000 (approximately $0.1 million) and agreed to make additional annual maintenance payments of the same amount for each of the three years that the research license agreement term was extended. As of September 30, 2016, we have paid Selexis an aggregate of approximately $0.4 million under the research license agreement.

Selexis also granted us a non-transferrable option to obtain a perpetual, non-exclusive, worldwide commercial license under the Selexis Technology to manufacture, or have manufactured, a recombinant protein produced by a cell line developed using the Selexis Technology for clinical testing and commercial sale. We exercised this option in April 2013 and entered into three commercial license agreements as described more fully below.

Either party may terminate the research license in the event of an uncured material breach by the other party or in the event the other party becomes subject to specified bankruptcy, winding up or similar circumstances. Either party may terminate the research license under designated circumstances if the Selexis Technology infringes third party proprietary rights. Although we have the right to terminate the research license at any time for our convenience, we agreed with our other collaborator parties to whom we have sublicensed the Selexis Technology not to exercise such right without their consent, which agreements are described below.

Commercial License Agreements

On April 11, 2013, following the exercise of our option to enter a commercial license under the Selexis research license, we entered into commercial license agreements with Selexis for each of the ONS-3010, ONS-1045 and ONS-1050 biosimilar product candidates that were developed under the research license (which agreements were subsequently amended on May 21, 2014). Under the terms of each commercial license agreement, we acquired a non-exclusive worldwide license under the Selexis Technology to use the cell lines developed under the research license and related materials, to manufacture and commercialize licensed and final products, with a limited right to sublicense.

We were required to pay an upfront licensing fee of CHF 65,000 (approximately $0.1 million) to Selexis for each commercial license and also agreed to pay up to CHF 365,000 (approximately $0.4 million) in milestone payments for each licensed product. In addition, we are required to pay a single-digit royalty on a final product-by-final product and country-by-country basis, based on worldwide net sales of such final products by us or any of our affiliates or sublicensees during the royalty term. The royalty term for each final product in each country is the period commencing from the first commercial sale of the applicable final product in the applicable country and ending on the expiration of the specified patent coverage. At any time during the term, we have the right to terminate our royalty payment obligation by providing written notice to Selexis and paying Selexis a royalty termination fee of CHF 1,750,000 (approximately $1.8 million). As of September 30, 2016, we have paid Selexis an aggregate of approximately $0.3 million under the commercial license agreements.

Each of our commercial agreements with Selexis will expire in its entirety upon the expiration of all applicable Selexis patent rights. The licensed patent rights consist of two patent families. The first patent family relates to methods of transferring cells, and is filed in the United States, Australia, Canada, Europe, Japan and Singapore. This patent family will begin to expire worldwide in 2022. The second patent family claims DNA compositions of matter useful for having protein production increasing activity. This patent

family is filed in the United States, Australia, Canada, China, Europe, Hong Kong, Israel, India, Japan, South Korea, Russia, Singapore and South Africa. This patent family will begin to expire worldwide in 2025. Either party may terminate the related agreement in the event of an uncured material breach by the other party or in the event the other party becomes subject to specified bankruptcy, winding up or similar circumstances.

Either party may also terminate the related agreement under designated circumstances if the Selexis Technology infringes third-party intellectual property rights. In addition, we have the right to terminate each of the commercial agreements at any time for our convenience; however, with respect to the agreements relating to ONS-3010 and ONS-1045, this right is subject to Liomont's consent pursuant to a corresponding letter we executed in conjunction with the standby agreement entered into between Selexis and Liomont on November 11, 2014. The standby agreement permits Liomont to assume the license under the applicable commercial agreement for Mexico upon specified triggering events involving our bankruptcy, insolvency or similar circumstances.

Ex-U.S. Collaboration and License Agreements

Aside from our joint participation agreement in place for ONS-3010 with Huahai, whereby we agreed to share post-Phase 1 development costs, and proportionately share the revenues from commercialization of ONS-3010 in the United States, Canada, EU and Japan, among other markets, and under which we could be required to form a joint venture with Huahai for ONS-3010 if so requested by Huahai, we do not have any commercial license or development agreements for the United States or for major ex-U.S. markets, such as the EU or Japan. We currently have collaboration and license agreements for smaller ex-U.S. markets where we would not otherwise intend to commercialize our biosimilar product candidates, which we entered into to help offset some of our development costs. Collectively, such agreements have provided an aggregate of $24.0 million in payments as of September 30, 2016 for our most advanced biosimilar product candidates. Our contracts include agreements with IPCA (for ONS-3010, ONS-1045 and ONS-1050 in India and other regional markets), Liomont (for ONS-3010 and ONS-1045 in Mexico), and Huahai (for ONS-3010 and ONS-1045 in China). Our arrangements with these partners generally include a strategic license for a defined territory for agreed biosimilar product candidates, and may also include agreements to assist with research and development to assist our contract counterparty in establishing their own mAb research, development and manufacturing capabilities. Under our existing strategic licensing agreements, we generally received an upfront payment upon execution, and have the ability to earn additional regular milestone payments and the right to receive royalties (generally a mid-single digit to low-teens percentage rate) based on net sales in the agreed territory. Our existing agreements to assist with research and development also included an upfront payment upon execution, and we have the ability to earn additional regular milestone payments, and the right to receive royalties (generally a mid-single digit to low-teens percentage rate) based on net sales in the agreed territory.

Generally, our agreements expire on a product-by-product basis on the date of the expiration of the royalty revenue term for all products in the territory. The royalty revenue term is 10 years from the date of first commercial sale and any renewal is subject to good faith negotiation. The license term for the agreed territory is perpetual. Either party may terminate the agreement in its entirety or with respect to a particular product if the other party materially breaches the agreement, subject to specified notice and cure periods. In addition, we have the right to terminate the agreement in connection with any interference, opposition or challenge of our patent rights. If the agreement is terminated due to our breach, our contract counterparty is generally free to use all applicable technology and know-how that we have provided under the agreement.

As noted above, our collaboration agreements with Huahai also includes a joint participation agreement, which provides for the co-funding of development of ONS-3010 in the United States, Canada, EU, Japan, Australia and New Zealand and the proportionate sharing of the revenues from commercialization of ONS-3010 in the agreed countries, and also provides for the formation of a joint venture with Huahai to further develop and commercialize ONS-3010 with Huahai in the agreed countries, if so requested by Huahai. We had the option to terminate this joint participation agreement by exercising the option prior to December 23, 2015 and paying Huahai a total of $28.0 million, consisting of an $11.0 million initial payment within seven business days of exercise, and four additional installment payments of $4.25 million payable over the course of the following year. We did not make the $11.0 million initial payment within the time frame required.

In the event Huahai funds its proportionate share of development costs incurred after completion of the "Phase-3 Ready Package," Huahai would be entitled to retain its 51% value ownership, with us entitled to retain our 49% value ownership, of ONS-3010 in the agreed countries. To maintain its 51% value ownership of ONS-3010 as of September 30, 2016, Huahai is required to make a payment to us of approximately $13.0 million. Similarly, revenues from the commercialization of ONS-3010 in the agreed countries (including major markets such as the United States and the EU, among others), would also be shared based on such proportional ownership interests. In the event that Huahai does not fund its proportionate share of such development costs, the joint participation agreement provides for a proportionate adjustment to our respective value ownership interests based on our respective investments in such development costs, which would increase our value ownership interest in ONS-3010.

Throughout the term of the joint participation agreement, we and our affiliates are prohibited from, directly or indirectly, conducting or having conducted or funding any discovery, research, development, regulatory, manufacturing or commercialization activity, alone or in collaboration with a third party, of any biosimilar product having the same reference product as the ONS-3010 compound or corresponding products, for use in the United States, Canada, EU, Japan, Australia and New Zealand, other than ONS-3010 with Huahai pursuant to the joint participation agreement.

Unless terminated early upon mutual agreement of the parties, or due to a material breach of either party that is uncured, the joint participation agreement will terminate upon entry into a mutually acceptable collaboration agreement between us and Huahai for ongoing development and commercialization of ONS-3010 in the agreed countries, or we and Huahai enter into an agreed license with a third party for such ongoing development and commercialization of ONS-3010 in the agreed countries. If the joint participation agreement is terminated for cause due to our breach, we could be required to refund Huahai any amounts funded by Huahai to develop ONS-3010, as well as pay Huahai a 6% royalty on net sales made by us or an affiliate, as well as 25% of revenues we receive from a sublicensee for commercial sales of ONS-3010 until the aggregate of such payments is equal to 10 times the amount Huahai funded for the development of ONS-3010.

Furthermore, if we were to file a voluntary petition in bankruptcy, or have an involuntary petition filed that we could not dismiss within 120 days, then Huahai would be granted an exclusive license to continue the development and commercialization of ONS-3010 in the agreed countries.

As of September 30, 2016, we have received an aggregate of $5.0 million of payments from IPCA under our various agreements, an aggregate of $3.0 million of payments from Liomont under our various agreements, and an aggregate of $16.0 million of payments from Huahai under our various agreements, $10.0 million of which were pursuant to the joint participation agreement.

Competition

Biosimilars have become a significant growth area for the biopharmaceutical industry, attracting large pharmaceutical companies as well as small niche players. Biosimilars of complex mAbs have limited competition to those industry players who have a high technical capability. The large players who have successfully taken mAb products into Phase 3 clinical trials include Pfizer Inc., or Pfizer, Amgen Inc., or Amgen, Sandoz, Inc., or Sandoz, Boehringer Ingelheim, or Boehringer, and Samsung Bioepis, Ltd., or Bioepis, while smaller niche players with clinical assets include us, Coherus Biosciences, Inc., or Coherus, Momenta Pharmaceuticals, Inc. and Celltrion, Inc., or Celltrion, as well as other regional developers.

Additionally, companies developing novel products with similar indications, and the innovator companies that are implementing protection strategies are expected to influence our ability to penetrate and maintain market share. Competition from generic small molecule manufacturers may also arise although these companies are less likely to have the technical, regulatory and clinical expertise required to succeed in this market unless they partner or acquire experienced biotech entities.

Our principal mAb biosimilar competitors include both companies with biologic reference products, such as AbbVie, Inc. (the holder of rights to Humira), Genentech Inc. (the holder of rights to the Avastin and Herceptin), as well as those with biosimilar products and/or reference products, such as Pfizer (pipeline, which includes five biosimilar candidates), Amgen (pipeline, which includes at least six biosimilar candidates), Sandoz (as a biosimilar company with two FDA-approved biosimilar products), and Merck &

Co., Inc., or Merck (through its joint venture collaboration aimed at developing and commercializing biosimilar candidates). Companies principally engaged in biosimilar development include Samsung-Bioepsis (pipeline, which initially includes six biosimilar candidates), Coherus (pipeline, which includes at least three biosimilar candidates), Momenta (pipeline, with seven biosimilar programs), and Celltrion (pipeline, with an FDA-approved biosimilar and at least five other biosimilar candidates). Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and greater experience in the discovery and development of mAb product candidates, obtaining FDA and other regulatory approvals of treatments and commercializing those treatments. Accordingly, our competitors may be more successful than us in obtaining approval for mAb biosimilars and achieving widespread market acceptance. Our competitors' treatments may be more effectively marketed and sold than any products we may commercialize that may cause limited market share before we can recover the expenses of developing and commercializing any of our product candidates.

Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These activities may lead to consolidated efforts that allow for more rapid development of mAb biosimilar candidates than us.

These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, the ability to work with specific clinical contract organizations due to conflict of interest, and also the conduct of trials in the ability to recruit clinical trial sites and subjects for our clinical trials.

We expect any products that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, price and the availability of reimbursement from government and other third-party payors. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are viewed as safer, more convenient or less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Intellectual Property

Our commercial success depends in part on our ability to avoid infringing the proprietary rights of third parties, our ability to obtain and maintain proprietary protection for our technologies where applicable and to prevent others from infringing our proprietary rights. We seek to protect our proprietary technologies by, among other methods, evaluating relevant patents, establishing defensive positions, monitoring EU oppositions and pending intellectual property rights, preparing litigation strategies in view of the U.S. legislative framework and filing U.S. and international patent applications on technologies, inventions and improvements that are important to our business. As of September 30, 2016, we own two pending international applications that were filed under the Patent Cooperation Treaty, or PCT, which relate to formulations developed for ONS-3010, as well as methods of antibody purification. We also own six provisional patent applications related to methods for purifying antibodies to separate isoforms, reducing high molecular weight species, and modulating afucosylated species, as well as buffer formulations for enhanced antibody stability and methods for determining the amino acid sequence of antibodies. Any patents that may eventually issue claiming priority to these six provisional patent applications are expected to expire in 2036 and 2037. The PCT is an international patent law treaty that provides a unified procedure for filing patent applications to protect inventions in each of its contracting states. Thus, a single PCT application can be converted into a patent application in any of the more than 145 PCT contracting states, and is considered a simple, cost-effective means for seeking patent protection in numerous regions or countries. This nationalization (converting into an application in any of the contracting states) typically occurs 18 months after the PCT application filing date. Our first PCT application was nationalized in April 2016 in Australia, Canada, China, Europe, Japan, Mexico and the United States. Our second PCT application is due to be nationalized in July 2017. We have not determined what countries to nationalize in. If granted, patents issuing from our two PCT applications are expected to expire in 2034 and 2036, absent any adjustment or extensions. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary position.

The term of individual patents depends upon the legal term of the patents in countries in which they are obtained. In most countries, including the United States, the patent term is generally 20 years from the earliest date of filing a non-provisional patent application in the applicable country. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office in examining and granting a patent or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date.

Regulatory

Government Regulation and Product Approval

Government authorities at the federal, state and local level in the United States and in other countries extensively regulate, among other things, the research, development, testing, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export of biopharmaceutical products such as our product candidates. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

FDA Approval Process for Biosimilars

All of our current product candidates are subject to regulation in the United States by the FDA as biological products, or biologics. The FDA subjects biologics to extensive pre- and post-market regulation. The Public Health Service Act, or PHSA as amended by the Patient Protection and Affordable Care Act, or Affordable Care Act, and the Biologics Price Competition and Innovation Act, or BPCIA, govern the regulatory pathway for biosimilar products. In addition, other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and import and export of biologics. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve a pending biologics license application, or BLA, withdrawal of approvals, clinical holds, untitled and warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal penalties.

Under the BPCIA, a biologic may be demonstrated to be "biosimilar" if data show that the product is "highly similar" to a reference product. This is demonstrated through extensive analytical studies, animal studies (if deemed necessary), and clinical trials in a sensitive patient population to confirm that "residual uncertainties" do not have clinically meaningful impact. Developing the data to satisfy FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Similar to innovator products, FDA requires submission of an Investigational New Drug application, or IND, prior to testing biosimilar investigational products in humans. The IND is composed of the clinical protocol and other documentation such as non-clinical and CMC data to assure the safe conduct of the study. The sponsor submits an IND to FDA to place the IND into effect. A 30-day waiting period after the submission of the IND is required prior to the commencement of clinical testing. If during the 30-day waiting period the FDA does not raise concerns or questions related to the safety of the proposed clinical trials or other data submitted by imposing a clinical hold, the clinical trial may begin.

Prior to IND submission of a biosimilar candidate, if previous human data are not available or if the analytical data warrant, in vivo preclinical tests may be required to assess the safety of the product. Other preclinical tests include laboratory evaluation of product chemistry, formulation and in vitro functional testing. This preclinical work is highly dependent on the development of robust analytical tests. An IND must become effective before United States clinical trials may begin.

Clinical trials for biosimilars involve the administration of the new investigational product to healthy volunteers or patients with the condition under investigation, all under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance

with good clinical practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if, among other things, it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unreasonable and significant risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements or may impose other conditions. The study sponsor may also suspend a clinical trial at any time on various grounds, including a determination that the subjects or patients are being exposed to an unacceptable health risk.

Clinical trials for biosimilar development are typically conducted in two sequential phases. In Phase 1, the investigational product is initially compared to the reference product by dosing healthy human subjects or patients to assess PK, pharmacological actions, and safety. In the case of some products for severe or life-threatening diseases, such as cancer treatments, initial human testing may be conducted in the intended patient population. A Phase 3 clinical trial is then undertaken to obtain additional information about clinical efficacy and safety, typically at geographically dispersed clinical trial sites. These Phase 3 clinical trials are intended to demonstrate that any residual uncertainty about biosimilarity which may exist after conducting prior trials does not have clinical impact in light of the totality of the evidence for the product candidate. Well-designed and well-conducted trials conducted outside of the United States in accordance with GCP are also acceptable to the FDA in support of product licensing if the FDA is able to validate the data from the study through an onsite inspection, if necessary. Other clinical study designs may be acceptable to regulators if justified.

After successful completion of the required clinical testing in accordance with all applicable regulatory requirements, detailed information regarding the investigational product is prepared and submitted to the FDA in the form of a BLA requesting approval to market the product for one or more of the reference product's indications. FDA review and approval of the BLA is required before marketing of the product may begin in the United States. The BLA must include the results of all preclinical, clinical and other testing and a detailed compilation of data relating to the product's pharmacology and CMC and must demonstrate the safety, purity and potency of the product based on these results. The cost of preparing and submitting a BLA is substantial. Under Biosimilar User Fee Act of 2012, or BsUFA, the sponsor must submit initial and annual biological product development fees, an application fee at the time of submission of the BLA and establishment and product fees if the product is approved. These fees are typically increased annually and will total several million dollars over the product's market life.

The FDA has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of biosimilar BLAs. The FDA's stated goal for fiscal year 2017 is to review 90% of original biosimilar biologic applications within ten months from the receipt date of the application. Although the FDA can meet its user fee performance goals, the review process is often extended by requests for additional information or clarification. The FDA reviews a biosimilar BLA to determine, among other things, whether the product candidate has no clinically meaningful differences from the reference product, and the manufacturing process and facility meet standards designed to assure the product candidate's continued safety, purity and potency. Before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the product candidate is manufactured. The FDA will not approve the product candidate unless it verifies compliance with cGMP and the BLA contains adequate data that provide substantial evidence that the product candidate meets the requirement of "highly similar" to the reference product.

After the FDA evaluates the BLA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction, the FDA will issue an approval letter. For fiscal year 2017, the FDA has committed to reviewing 90% of resubmissions of biosimilar BLAs within six months of receipt. FDA approval is never guaranteed, and the FDA will not approve a BLA if applicable regulatory criteria are not satisfied.

The approval of our product candidates may be significantly more limited than requested in the application, including limitations on the dosage forms (if multiple forms are filed) or the indications for use, which could restrict the commercial value of the product. In addition, as a condition of BLA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to minimize any risk associated with the product. REMS can include medication guides, communication plans for healthcare professionals and Elements To Assure Safe Use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the product. Moreover, post-approval testing and surveillance to monitor the product's safety or efficacy may be required as a condition of approval. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Abbreviated Licensure Pathway of Biologics as Biosimilar or Interchangeable under 351(k)

The BPCIA amended the PHSA by adding section 351(k) that created an abbreviated approval pathway for biologics shown to be highly similar to an FDA-licensed reference biologic. Under the BPCIA, a biologic may be demonstrated to be "biosimilar" if data show that, among other things, the product is "highly similar" to a reference product. This is demonstrated through extensive analytical studies, animal studies (when deemed necessary), and clinical trials in a sensitive patient population to confirm that "residual uncertainties" do not have clinically meaningful impact. Developing the data to satisfy FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. In addition, an application submitted under the 351(k) pathway must include information demonstrating that the proposed biosimilar product and reference product have the same route of administration, dosage form and the strength and the biosimilar product utilizes the same mechanism of action for the condition(s) of use approved in the proposed labeling to the extent the mechanism(s) of action are known for the reference product.

Biosimilarity under the BPCIA means that the biologic is highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there are no clinically meaningful differences between the biologic and the reference product in terms of the safety, purity and potency of the product. Therefore, in addition to a complete CMC data submission as required for a 351(a) BLA, an application submitted under section 351(k) is required to include data supporting the analytical similarity of the proposed biosimilar product to the reference product.

If a manufacturer intends to use data from an animal study or a clinical study comparing its proposed biosimilar product to a non-U.S.-licensed product to address, in part, the requirements under section 351(k), the sponsor must provide adequate data or information to scientifically justify the relevance of these comparative data to an assessment of biosimilarity and establish an acceptable bridge to the U.S.-licensed reference product. The type of bridging data that is required includes data from analytical studies that directly compare all three products, i.e., the proposed biosimilar product, the U.S.-licensed reference product and the non-U.S.-licensed comparator product, and is likely to also include bridging clinical PK and/or PD study data for all three products. FDA makes a final determination about the adequacy of the scientific justification and bridge during the review of the application.

Moreover, the BPCIA provides for a designation of "interchangeability" between the reference and biosimilar products, whereby the biosimilar may be substituted for the reference product without the intervention of the healthcare provider who prescribed the reference product. After the assessment of biosimilarity, the higher standard of interchangeability must be demonstrated by information sufficient to show that the proposed product is expected to produce the same clinical result as the reference product in

any given patient and for a product that is administered more than once to an individual, the risk to the patient in terms of safety or diminished efficacy of alternating or switching between the biosimilar and the reference product is no greater than the risk of using the reference product without such alternation or switch. FDA's implementation of the 351(k) approval pathway is still evolving, and the acceptance for filing and review of a 351(k) application is subject to the same refusals to file or approve that are described above for 351(a) BLAs. In addition, the FDA may accept a 351(k) application for filing but deny approval on the basis that the sponsor has not demonstrated biosimilarity, in which case the sponsor may choose to conduct further analytical, preclinical or clinical trials to demonstrate such biosimilarity under section 351(k) or submit a BLA for licensure as a new biologic under section 351(a).

The timing of final FDA approval of a biosimilar for commercial distribution depends on a variety of factors, including whether the manufacturer of the reference product is entitled to one or more statutory exclusivity periods, during which time the FDA is prohibited from approving, or accepting applications for, any product candidates that are purportedly biosimilar to the reference product. The FDA cannot approve a biosimilar application for 12 years from the date of first licensure of the reference product. Additionally, a biosimilar product sponsor may not submit an application under the 351(k) pathway for four years from the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency. Therefore, one must determine whether a subsequent application for a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity, or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the "first licensure" of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

A reference product may also be entitled to exclusivity under other statutory provisions. For example, a reference product designated as an orphan drug may be entitled to seven years of exclusivity, in which case no product that is biosimilar to the reference product may be approved until either the end of the 12-year biologic reference product exclusivity period or the end of the seven year orphan drug exclusivity period, whichever occurs later. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent and thus block §351(k) applications from being approved on or after the patent expiration date. In addition, the FDA may under certain circumstances extend the exclusivity period for the reference product by an additional six months if the FDA requests, and the manufacturer undertakes, studies on the effect of its product in children, a so-called pediatric extension.

The first biosimilar product determined to be interchangeable with a reference product for any condition of use is also entitled to a period of exclusivity, during which time the FDA may not determine that another product is interchangeable with the reference product for any condition of use. This exclusivity period extends until the earlier of: (i) one year after the first commercial marketing of the first interchangeable product; (ii) 18 months after resolution of a patent infringement suit against the applicant that submitted the application for the first approved interchangeable product, based on a final court decision regarding all of the patents in the litigation or dismissal of the litigation with or without prejudice; (iii) 42 months after approval of the first interchangeable product, if a patent infringement suit instituted against the applicant that submitted the application for the first interchangeable product is still ongoing; or (iv) 18 months after approval of the first interchangeable product if the applicant that submitted the application for the first interchangeable product has not been sued for patent infringement.

Post-Approval Regulatory Requirements

Once a BLA is approved, a product will be subject to continuing post-approval regulatory requirements relating to recordkeeping, periodic reporting, testing requirements, manufacturing, distribution, advertising and promotion and reporting of adverse experiences with the product. For instance, the FDA closely regulates post-approval marketing and promotion concerning communications for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Failure to comply with these regulations can result in significant penalties, including the issuance of untitled and warning letters directing a company to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA and federal and state civil and criminal investigations and prosecutions.

Biologics, like other pharmaceutical products, may be marketed only for the approved indications and in accordance with the provisions of the approved conditions specified in the BLA. After approval, changes to the information submitted in the BLA may require submission to the FDA. Generally, there are three types of filing mechanisms to the approved application: prior approval supplement, changes being effected supplement and annual report. The filing type is dictated by the assessment of the potential to impact quality, efficacy and/or safety and each holds specific review and/or approval timelines. For example, a new indication would be filed as a prior approval supplement because assessment of efficacy and safety would be necessary with the targeted 10 month review clock. Whereas, a minor change in manufacturing process, which, among other things, would not affect specification limits or modifications in potency, sensitivity, specificity or purity of the product, may be filed in the BLA annual report, and can be implemented once the company's quality unit has approved the use through appropriate documentation. There are also continuing annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

Adverse event reporting and submission of periodic safety reports are required following FDA approval of a BLA. As a condition of the BLA approval, the FDA also may require additional information that may include additional analytical or clinical studies and a REMS or other conditions to assess and/or monitor the quality and safety of the approved product.

All manufacturing operations, including manufacturing, testing, packaging, labeling, storage and distribution procedures must continue to meet cGMP requirements after approval. Product manufacturers and certain of their subcontractors are also required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must have dedicated resources in the areas of production, quality control, and quality assurance to maintain compliance with cGMP.

Discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency or with manufacturing processes or failure to comply with regulatory requirements, may result in the withdrawal of the product approval, product recall or marketing restrictions through labeling changes or product removals. A change in the safety profile may result in revisions to the approved labeling to update safety information; post-market studies or clinical trials to assess new safety risks; or distribution restrictions or other requirements under a REMS program.

Other U.S. Healthcare Laws and Compliance Requirements

Although we currently do not have any products on the market, our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may expose us to broadly applicable healthcare regulation and enforcement by the federal government and the states and foreign governments in which we conduct our business. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and physician sunshine laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in cash or in kind, either to induce or award the referral of an individual, for an item or service or the purchasing, recommending or ordering of a good or service, for which payment may be made under federal healthcare

programs such as the Medicare and Medicaid programs. The Anti-Kickback Statute is subject to evolving interpretations. In the past, the government has enforced the Anti-Kickback Statute to reach large settlements with healthcare companies based on, in certain cases, sham consulting and other financial arrangements with physicians. Further, the Affordable Care Act, among other things, amends the intent requirement of the federal Anti-Kickback Statute and the criminal statute governing healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to commit a violation. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties statute. The majority of states also have anti-kickback laws that establish similar prohibitions and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Additionally, the federal false claims and civil monetary penalties laws, including the civil False Claims Act prohibit, among other things, knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government, or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. The federal government has used the False Claims Act, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other illegal sales and marketing practices. The government has obtained multi-million and multi-billion dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, imposes requirements regarding the privacy and security of individually identifiable health information, including mandatory contractual terms, for covered entities, or certain healthcare providers, health plans, and healthcare clearinghouses, and their business associates. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Affordable Care Act, among other things, via the Physician Payments Sunshine Act, imposes new reporting requirements on certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, for payments made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information to the Centers for Medicare & Medicaid Services, or CMS, may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1.0 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Such manufacturers must submit reports by the 90th day of each subsequent calendar year.

Certain states also mandate implementation of commercial compliance programs, impose restrictions on pharmaceutical manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians. Additionally, analogous state and foreign 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. State laws may also apply that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, as well as state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The shifting commercial compliance environment and the need to build and maintain robust systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may violate one or more of the requirements. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Healthcare Reform

The Affordable Care Act has had, and is expected to continue to have, a significant impact on the healthcare industry. The Affordable Care Act was designed to expand coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, among other things, the Affordable Care Act expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare prescription drug benefit. There have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future particularly in the light of the pending change in administrations following the U.S. presidential election. We continue to evaluate the effect that the Affordable Care Act has on our business. Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. For example, through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, following passage of the Bipartisan Budget Act of 2015, will remain in effect through 2025 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers. In addition, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. In the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the success of our product candidates. The Affordable Care Act, as well as other federal, state and foreign healthcare reform measures that have been and may be adopted in the future, could harm our future revenues.

International Regulation

In addition to regulations in the United States, foreign regulations also govern clinical trials, commercial sales and distribution of product candidates within their jurisdiction. The regulatory approval process varies from country to country and the time to approval may be longer or shorter than that required for FDA approval. In the European Union, the approval of a biosimilar for marketing is based on an opinion issued by the European Medicines Agency and a decision issued by the European Commission. However, substitution of a biosimilar for the innovator is a decision that is made at the local (national) level on a country-by-country basis. Additionally, a number of European countries do not permit the automatic

substitution of biosimilars for the reference product. Many countries also have published their own legislation outlining a regulatory pathway for the development and approval of biosimilars. In some cases, countries have either adopted European guidance or are following guidance issued by the World Health Organization. Although similarities are apparent across these various regulatory guidances, there is also the potential for additional country-specific requirements.

Pharmaceutical Coverage, Pricing and Reimbursement

In the United States and other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third-party payors, including government health administrative authorities, managed care providers, private health insurers and other organizations. Third-party payors are increasingly examining the medical necessity and cost effectiveness of medical products and services in addition to safety and efficacy and, accordingly, significant uncertainty exists as to the reimbursement status of newly approved therapeutics. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Obtaining and maintaining adequate reimbursement for our product candidates, once approved, may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement compared to existing approved biologics and other therapies. There may be significant delays in obtaining coverage and reimbursement for newly approved drugs in the United States, and coverage may be more limited than the indications for which the product is approved by the FDA or similar regulatory authorities outside the United States. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures and adoption of more restrictive policies in jurisdictions with existing controls and measures could further limit our net revenue and results. Decreases in third-party reimbursement for our product candidates or a decision by a third-party payor to not cover our product candidates could reduce physician utilization of our products and have a material adverse effect on our sales, results of operations and financial condition.

Employees

As of September 30, 2016, we had 83 full-time employees, 39 of whom were primarily engaged in research and development activities and 18 of whom had an M.D. or Ph.D. degree. None of our employees are represented by a labor union or covered by a collective bargaining agreement.

Facilities

We occupy approximately 48,000 square feet of office and laboratory space in Cranbury, New Jersey, under a lease that expires in June 2021. Additionally, we entered into a lease for approximately 82,000 square feet of office and laboratory space in Cranbury, New Jersey, with lease payments that commenced in March 2016 and expire in March 2026.

Corporate Information

We initially incorporated in January 2010 in New Jersey as Oncobiologics, Inc., and in October 2015, we reincorporated in Delaware by merging with and into a Delaware corporation. Our headquarters are located at 7 Clarke Drive, Cranbury, New Jersey, 08512, and our telephone number at that location is (609) 619-3990. Our website address is www.oncobiologics.com. The information contained on, or that can be accessed through, our website is not part of, and is not incorporated by reference into this Annual Report on Form 10-K.

We file electronically with the Securities and Exchange Commission our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. We make available on

our website at www.oncbiologics.com, free of charge, through a hyperlink on our website, copies of these reports, as soon as reasonably practicable after electronically filing such reports with, or furnishing them to, the Securities and Exchange Commission. Further, a copy of this Annual Report on Form 10-K is located at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549-2736. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy and information statements and other information regarding our filings at www.sec.gov.

Item 1A. Risk Factors

You should consider carefully the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be adversely affected. The risks described below are not the only risks facing the Company. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may adversely affect our business, financial condition, results of operations and/or prospects.

Risks Related to Our Financial Condition and Capital Requirements

We have a limited operating history, have incurred significant losses and negative cash flows from operations since our inception and expect to continue to incur significant losses and negative cash flows from operations for the foreseeable future.

We are a biopharmaceutical company with a limited operating history and we have incurred net losses in each year since our inception in January 5, 2010, including net losses of $53.3 million and $47.4 million for the years ended September 30, 2016 and 2015, respectively.

We have devoted substantially all of our financial resources to identify, develop and manufacture our product candidates, including conducting, among other things, analytical characterization, process development and manufacture, formulation and clinical trials, regulatory filing and communication activities and providing general and administrative support for these operations. To date, we have financed our operations primarily through the sale of equity securities and debt financings, as well as to a limited degree, payments under our co-development and license agreements with Zhejiang Huahai Pharmaceutical Co., Ltd., or Huahai, Laboratorios Liomont, S.A. de C.V., or Liomont, and IPCA Laboratories Limited, or IPCA. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financing or strategic licensing or co-development collaborations.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- continue preclinical studies and clinical development of our identified product candidates;
- expand the number of our current clinical trials for our product candidates;
- advance our programs into larger global clinical trials;
- initiate additional preclinical, clinical or other studies for our product candidates;
- change or add clinical research service providers, testing laboratories, device suppliers, legal service providers or other vendors or suppliers;
- invest in, and maintain, our development and manufacturing facilities and infrastructure;
- seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- seek to identify, assess, acquire or develop other biosimilar product candidates that may be complementary to our product candidates;
- make upfront, milestone, royalty or other payments under any license agreements;
- seek to create, maintain, protect and expand our intellectual property portfolio;
- engage in litigation, including patent litigation, with originator companies or others that may hold patents to the reference products for which we are developing biosimilars, or to methods of manufacture or methods of use we may employ in the production of our biosimilars;
- seek to attract and retain skilled personnel;

- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts; and
- experience any delays or encounter issues with any of the above, including but not limited to failed clinical trials, conflicting results, safety issues or regulatory challenges that may require longer follow-up of existing studies, additional major studies or additional supportive studies in order to pursue marketing approval.

Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

As described in their audit report, our auditors have included an explanatory paragraph that states that we have incurred recurring losses and negative cash flows from operations since inception and have an accumulated deficit at September 30, 2016 of $147.4 million and $4.6 million of indebtedness that is due on demand. These matters raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. If we cannot continue as a viable entity, our securityholders may lose some or all of their investment in us.

We have never generated any revenue from product sales and may never be profitable.

Although we have received upfront and milestone payments from our license and collaboration agreements, we have no products approved for commercialization and have never generated any revenue from product sales. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize, one or more of our product candidates. We cannot predict when we will begin generating revenue from product sales, as this depends heavily on our success in many areas, including but not limited to:

- completing preclinical and clinical development of our product candidates;
- developing and testing of our product candidate formulations
- obtaining regulatory and marketing approvals for product candidates for which we complete clinical trials, including any delays as a result of petitions by reference product sponsors, or RPSs, or patent holders;
- obtaining extensions of approvals for our product candidates to other indications for which the reference product is approved and commercialized;
- developing a sustainable and scalable manufacturing process for any approved product candidates to support clinical development and the market demand for any such approved product candidates;
- launching and commercializing product candidates for which we obtain regulatory and marketing approval, either directly or with collaboration partners;
- obtaining adequate third-party coverage and reimbursements for our products;
- obtaining market acceptance of our product candidates as viable treatment options, including with respect to the efficacy, safety and biosimilarity of our product candidates to the reference products;
- addressing any competing technological and market developments;
- identifying, assessing and developing, or acquiring and in-licensing, new product candidates;

- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- establishing through litigation or otherwise that we are not violating the intellectual property rights of innovators of reference products for which we are developing biosimilars, or that of other third parties;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Even if one or more of the product candidates is approved for commercialization, we anticipate incurring significant costs to commercialize any such product. Our expenses could increase beyond our expectations if we are required by the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or the EMA, other regulatory agencies, domestic or foreign, or by any unfavorable outcomes in intellectual property litigation filed against us, to change our manufacturing processes or assays or to perform clinical, preclinical or other types of studies in addition to those that we currently anticipate. In cases where we are successful in obtaining regulatory approvals to market one or more of our product candidates, our revenue will be dependent, in part, upon:

- the size of the markets in the territories for which we gain regulatory approval;
- the number of biosimilar and other competitors in such markets;
- the market acceptance of our products, or biosimilars in general, over the reference products;
- novel therapies for the approved indications in our biosimilar market that erode uptake;
- the accepted price for the product and the ability to get reimbursement at any price;
- the nature and degree of competition from originators and other biosimilar companies (including competition from large pharmaceutical companies entering the biosimilar market that may be able to gain advantages in the sale of biosimilar products based on brand recognition and/or existing relationships with providers, pharmacy benefit managers and payors);
- the quality and performance of our products compared to the reference products or other competing products, including the relative safety and efficacy; and
- whether we own, or have partnered, the commercial rights for that territory.

If the market for our product candidates, or our share of that market, is not as large as we expect, the number of indications approved by regulatory authorities is narrower than we expect or the target population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products to become profitable. If we are unable to successfully complete development and obtain regulatory approval for our lead product candidates, namely ONS-3010, ONS-1045 and ONS-1050, our business will be harmed.

We will need to raise substantial additional funding to complete development of our product candidate pipeline. This additional funding may not be available on acceptable terms or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

We are currently advancing our product candidates through preclinical and clinical development. Developing product candidates is an expensive, risky and lengthy process, and we expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue and initiate clinical trials of, and seek marketing approval for, our product candidates, in particular ONS-3010, ONS-1045 and ONS-1050.

As of September 30, 2016, our cash was $2.4 million, including $8.4 million of proceeds from our October, November and December 2016 note and warrant issuances. We expect that our current cash will be sufficient to fund our operations through February 2017. We expect that we will require substantial additional capital to commercialize ONS-3010, and to commence clinical trials, obtain regulatory approval

for, and to commercialize, our product candidates, including our other preclinical product candidates and our future product candidates. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or a combination of these approaches. In any event, we will require additional capital to pursue preclinical and clinical activities, pursue regulatory approval for, and to commercialize, our longer term pipeline product candidates. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may negatively impact the holdings or the rights of our stockholders, and the issuance of additional securities, whether equity or debt, by us or the possibility of such issuance may cause the market price of our securities to decline. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. For example, our senior secured notes issued in December 2016 include restrictions on our ability to incur additional indebtedness and pay stockholder dividends, among other restrictions. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may harm our business, operating results and prospects. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or for specific strategic considerations.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our development programs or the commercialization of any product candidates. We may also be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could harm our business, financial condition and results of operations.

Raising additional capital may cause dilution to our securityholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity and debt financings, as well as selectively continuing to enter into collaborations, strategic alliances and licensing arrangements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a securityholder. 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, and may be secured by all or a portion of our assets.

If we raise funds by selectively continuing to enter into collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish additional valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. If we are unable to raise additional funds through collaborations, strategic alliances or licensing arrangements, we may be required to terminate product development or future commercialization efforts or to cease operations altogether.

Risks Related to the Discovery and Development of Our Product Candidates

We are heavily dependent on the success of our two most advanced product candidates, ONS-3010 and ONS-1045. All of our other product candidates are still in various stages of preclinical development. If we are unable to obtain regulatory approval for, or successfully commercialize, ONS-3010 and ONS-1045, our business will be harmed.

Biosimilar product development is a highly speculative undertaking and involves a substantial degree of risk. We have initiated preparatory activities for our confirmatory Phase 3 clinical trial of ONS-3010, our adalimumab (Humira) biosimilar candidate, and ONS-1045, our bevacizumab (Avastin) biosimilar candidate. It may be several years, if ever, before we complete Phase 3 clinical trials and have a product candidate ready to file for market approval with the relevant regulatory agencies. We will require additional funds to advance the development of ONS-3010 through Phase 3 clinical trials. Further, we will need to raise substantial additional capital, either through equity or debt issuances or through strategic collaborations to advance our other product candidates, including ONS-1045, into clinical trials. If we obtain regulatory approval to market a biosimilar product candidate, our future revenue will depend upon the size of any markets in which our product candidates may receive approval and our ability to achieve sufficient market acceptance, pricing, reimbursement from third-party payors and adequate market share for our product candidates in those markets. Even if one or more of our product candidates gain regulatory approval and are commercialized, we may never become profitable.

To date, we have invested substantially all of our efforts and financial resources to identify, develop and manufacture our product candidates. Our future success is dependent on our ability to develop, obtain regulatory approval for, and commercialize and obtain adequate third-party coverage and reimbursement for one or more product candidates. We currently do not have any approved products and generate no revenue from sales of any products, and we may never be able to develop or commercialize a marketable product.

Our product candidates are in varying stages of development and will require significant additional investment before we generate any revenue from product sales, if at all. Notably, we must continue clinical development, including managing preclinical and clinical manufacturing activities, obtain regulatory approvals, manufacture adequate commercial supplies, build a commercial organization and conduct significant marketing efforts. We have initiated Phase 3 preparatory activities for ONS-3010 and ONS-1045. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. We have not submitted any marketing applications for our product candidates to the FDA or comparable foreign regulatory authorities and any application we submit may not be approved.

We plan to seek regulatory approval to commercialize our product candidates in the United States, the European Union, or the EU, and in additional foreign countries where we or our partners have commercial rights. To obtain regulatory approval, we and our collaboration partners must comply with numerous and varying regulatory requirements of such countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical trials, commercial sales and pricing and distribution of our product candidates. Even if we are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. If we are unable to obtain approval for our product candidates in multiple jurisdictions, our revenue and results of operations could be negatively impacted.

We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

The development, manufacture and commercialization of biosimilar products under various global regulatory pathways pose unique risks. To our knowledge, there have been only four biosimilar product applications approved by the FDA under the 351(k) pathway to date.

United States Regulatory Framework for Biosimilars

We and our collaboration partners intend to pursue market authorization globally. In the United States, an abbreviated pathway for approval of biosimilar products was established by the Biologics Price Competition

and Innovation Act of 2009, or BPCIA, enacted on March 23, 2010, as part of the Patient Protection and Affordable Care Act. The BPCIA established this abbreviated pathway under section 351(k) of the Public Health Service Act, or PHSA. Subsequent to the enactment of the BPCIA, the FDA issued draft guidance regarding the demonstration of biosimilarity as well as the submission and review of biosimilar applications. To our knowledge, there have been only four mAb biosimilar product applications approved by the FDA under the 351(k) pathway to date. Moreover, market acceptance of biosimilar products in the United States is still in its infancy and continues to evolve.

Numerous states are considering or have already enacted laws that regulate or restrict the substitution by state pharmacies of biosimilars for reference products already licensed by the FDA. Market success of biosimilar products will depend on demonstrating to patients, physicians, payors and relevant authorities that such products are similar in quality, safety and efficacy as compared to the reference product.

The BPCIA requires a biosimilar applicant to demonstrate biosimilarity with respect to a reference product that has been approved by FDA in the United States. Biosimilars approved in the EU and other non-U.S. jurisdictions may not be approved in the United States without additional "bridging" studies demonstrating biosimilarity to an FDA-approved reference product. Biosimilars approved in the United States may also not be approved in foreign jurisdictions without additional bridging studies. The requirements for such bridging studies are not well defined, which may delay the global marketing of our product candidates.

We will continue to analyze and incorporate into our biosimilar development plans any final regulations or guidance issued by the FDA, pharmacy substitution policies enacted by state governments and other applicable requirements established by relevant authorities. The costs of development and approval, along with the probability of success for our biosimilar product candidates, will be dependent upon application of any laws and regulations issued by the relevant regulatory authorities.

Biosimilar products may also be subject to extensive patent clearances and patent infringement litigation, which may delay and could prevent the commercial launch of a product. Moreover, the BPCIA prohibits the FDA from accepting an application for a biosimilar candidate to a reference product within four years of the reference product's licensure by the FDA. In addition, the BPCIA provides reference biologics with 12 years of exclusivity from the date of their licensure, during which time the FDA cannot approve any application for a biosimilar candidate to the reference product. For example, the FDA would not be able to grant approval of any application submitted for a bevacizumab (Avastin) biosimilar or a trastuzumab (Herceptin) biosimilar, until 12 years after the original biologics license application or the BLAs, for these drugs were approved, which occurred on February 26, 2004 in the case of Avastin and September 25, 1998 in the case of Herceptin. However, in the past, legislative proposals have been introduced to cut this 12-year period of exclusivity down to seven years and prohibit additional periods of exclusivity due to minor changes in product formulations, a practice often referred to as "evergreening." In addition, the Federal Circuit has recently interpreted the BPCIA as requiring (under certain circumstances) the biosimilar applicant to give the RPS 180 days' notice of commercial launch after receiving approval from FDA. This could result in an additional six months of market exclusivity for the reference product. Patent infringement litigation under the BPCIA may also be complex and time-consuming. RPSs may seek preliminary injunctions barring launch during the pendency of such litigation, which could substantially delay market entry.

The BPCIA is complex and only beginning to be interpreted and implemented by the FDA and courts. As a result, its ultimate impact, implementation and meaning are evolving and subject to significant uncertainty. Future implementation decisions by the FDA or court decisions could result in delays in the development or commercialization of our product candidates or increased costs to assure regulatory compliance and could adversely affect our operating results by restricting or significantly delaying our ability to market new biosimilar products.

Regulatory Framework for Biosimilars Outside the United States

In 2004, the European Parliament issued legislation allowing the approval of biosimilar therapeutics. Since then, the European Commission has granted marketing authorizations for more than 21 biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. Because of their extensive experience in the review and approval of biosimilars, the EU has

more final guidelines than the FDA, including specific product data requirements needed to support approval.

Generally speaking, under current EU regulations, an application for regulatory approval of a biosimilar drug cannot be submitted in the EU until expiration of an eight year data exclusivity period for the reference product, measured from the date of the reference product's initial marketing authorization. Furthermore, once approved, the biosimilar cannot be marketed until expiration of a 10-year period following the initial marketing authorization of the reference product, such 10-year period being extendible to 11 years if the reference product received approval of an additional therapeutic indication within the first eight years following its initial marketing authorization, representing a significant clinical benefit in comparison with existing therapies. However, we understand that reference products approved prior to November 20, 2005 (which would include, for example, Humira, approved in the EU on August 9, 2003) are subject to a 10-year period of data exclusivity. While the data exclusivity periods for Humira have now expired in the EU, the reference product is presently still subject to unexpired patents.

In the EU, the approval of a biosimilar for marketing is based on an opinion issued by the EMA and a decision issued by the European Commission. Therefore, the marketing approval will cover the entire European Economic Area, or EEA. However, substitution of a biosimilar for the reference product is a decision that is made at the Member State level.

Additionally, a number of countries do not permit the automatic substitution of biosimilars for the reference product. Therefore, even if we obtain marketing approval for the entire EEA, we may not receive substitution in one or more European nations, thereby restricting our ability to market our products in those jurisdictions.

Other regions, including Canada, Mexico, China, Japan and Korea, also have their own legislation outlining a regulatory pathway for the approval of biosimilars. In some cases, other countries have either adopted European guidance (Singapore and Malaysia) or are following guidance issued by the World Health Organization (Cuba and Brazil). While there is overlap in the regulatory requirements across regions, there are also some areas of non-overlap. Additionally, we cannot predict whether countries that we may wish to market in, which do not yet have an established or tested regulatory framework, could decide to issue regulations or guidance and/or adopt a more conservative viewpoint than other regions. Therefore, it is possible that even if we obtain agreement from one health authority to an accelerated or optimized development plan, we will need to defer to the most conservative view to ensure global harmonization of the development plan. Also, for regions where regulatory authorities do not yet have sufficient experience in the review and approval of a biosimilar product, these authorities may rely on the approval from another region such as the United States or the EU, which could delay our approval in that region.

Due to our limited resources and access to capital, we have, and will continue to need to, prioritize development of certain product candidates; and these decisions may prove to have been wrong and may harm our business.

Because we have limited resources and access to capital to fund our operations, we must decide which product candidates to pursue and the amount of resources to allocate to each. We are currently primarily focused on the development of mAb biosimilars and, in particular, ONS-3010, ONS-1045 and ONS-1050. Our decisions concerning the allocation of research, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties in respect to certain product development programs may also prove not to be optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the market potential of our product candidates or misread trends in the biosimilar industry, our business, financial condition and results of operations could be harmed.

The evolving regulatory approval processes of the FDA, EMA and comparable foreign authorities are lengthy, time-consuming, rigorous and inherently unpredictable. If we and our collaboration partners are ultimately unable to obtain regulatory approval for our product candidates, our business will be harmed.

The research, development, testing, manufacturing, labeling, packaging, approval, promotion, advertising, storage, marketing, distribution, post-approval monitoring and reporting and export and import of biologic products are subject to extensive regulation by the FDA and other regulatory authorities in the United

States, by the EMA and Competent Authorities in the EEA, and by other regulatory authorities in other countries, where regulations differ from country to country. We are not permitted to market our product candidates in the United States until we receive approval from the FDA, or in the EEA until we receive European Commission or EEA Competent Authority approvals.

The exact amount of time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, may take years following the completion of clinical trials and depends upon numerous factors, which may not be within our control. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which could cause delays in the approval or the decision not to approve an application. We have not obtained regulatory approval for any of our product candidates, and it is possible that none of our current or future product candidates will ever obtain regulatory approval.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA, a biosimilar product application under the 351(k) pathway of the PHSA, a biosimilar marketing authorization under Article 6 of Regulation (EC) No. 726/2004 and/or Article 10(4) of Directive 2001/83/EC in the EEA or other submission or to obtain regulatory approval in the United States, the EEA or elsewhere;
- the FDA, EMA or other foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- the population studied in the clinical trial may not be sufficiently representative to assure safety in the full population for which we seek approval;
- the FDA, EMA or other foreign regulatory authorities may disagree with our interpretation of data from analytical and bioanalytical studies, preclinical studies or clinical trials;
- we may be unable to demonstrate to the FDA, EMA or other foreign regulatory authorities that our product candidate is highly similar to biological reference products already licensed by the regulatory authority pursuant to marketing applications, notwithstanding minor differences in clinically inactive components;
- we may be unable to extrapolate or obtain approval of other indication for which the reference product is approved by the FDA, EMA or other foreign regulatory authority to other indications for which the reference product is approved;
- we may be unable to obtain an interchangeability designation by the FDA or other foreign regulatory authority for our product candidate, which may deter physicians, providers and payors from prescribing our product candidates;
- the FDA or comparable foreign regulatory authorities may fail to deem our manufacturing processes, test procedures and specifications or our manufacturing facilities adequate for approval; and
- the approval policies or regulations of the FDA, EMA or other foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failure to obtain regulatory approval to market any of our product candidates, which would significantly harm our business. Moreover, any delays in the commencement or completion of clinical testing could significantly impact our product development costs and commercial return potential, and could result in the need for additional financing.

In addition, if we change the regulatory pathway through which we intend to seek approval of any of our product candidates, or alter their composition or method of manufacturing, we may have to conduct additional clinical trials, which may delay our ability to submit a marketing application for the product.

Even if we or our collaboration partners were to obtain approval for any of our product candidates, regulatory agencies may limit the scope of such approval for fewer or more limited indications than we request, may grant approval contingent on the completion of costly additional clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing could harm the commercial prospects for our product candidates.

If we are not able to demonstrate the biosimilarity of our product candidates to the satisfaction of regulatory authorities, we will not obtain regulatory approval for commercial sale of our product candidates and our future results of operations will be adversely affected.

Our future results of operations depend heavily on our ability to obtain regulatory approval for and to commercialize our biosimilar product candidates. To obtain regulatory approval for the commercial sale of these product candidates, we will be required to demonstrate to the satisfaction of regulatory authorities, among other relevant groups such as physicians and payors, that our biosimilar product candidates are highly similar to biological reference products already licensed by the regulatory authority pursuant to marketing applications, notwithstanding minor differences in clinically inactive components, and that there are no clinically meaningful differences as compared to the marketed reference products in terms of the safety, purity and potency of such reference products. Each jurisdiction may apply different criteria to assess biosimilarity, based on a preponderance of the data that can be interpreted subjectively in some cases.

Although we have had several interactions with both the FDA and EMA for our lead product candidates and will continue to meet with regulators as necessary, we cannot be assured that results from our scientific studies will meet the rigorous requirements for approval. In addition, we cannot be certain of potential future changes to regulatory requirements that may require additional work before approval can be granted. It is also uncertain if regulatory authorities will grant the full reference label to our biosimilar product candidates when they are approved. For example, an infliximab (Remicade®) biosimilar molecule was approved in the EU for the full reference label but did not receive the full reference label when approved in Canada. A similar outcome could occur with respect to one or more of our product candidates, which would have a negative impact on our ability to commercialize our products.

The structure of complex mAb biologics is inherently variable and highly dependent on the processes and conditions used to manufacture them. If we are unable to develop manufacturing processes that achieve a requisite degree of biosimilarity to the reference product, and within a range of variability considered acceptable by regulatory authorities, we may not be able to obtain regulatory approval for our products.

MAb biologics are inherently heterogeneous and their structures are highly dependent on the cell line and production process conditions. Products from one production facility can differ within an acceptable range from those produced in another facility. Similarly, physicochemical differences can also exist among different lots produced within a single facility. The physicochemical complexity and size of biologic therapeutics create significant technical and scientific challenges in the context of their replication as biosimilar products.

The inherent variability in the protein structure from one production lot to another is a fundamental consideration with respect to establishing biosimilarity to a reference product to support regulatory approval requirements. For example, the glycosylation of the protein, meaning the manner in which sugar molecules are attached to the protein when it is produced, can be critical to the half-life, efficacy, immunogenicity and safety of the therapeutic and is therefore a key consideration for biosimilarity. Also, small changes in the structure or folding of the protein backbone of a mAb can impact its affinity, specificity and immunogenicity. Defining and understanding the variability of a reference product in order to match its glycosylation profile and other critical quality attributes requires significant skill in cell biology, protein purification and analytical protein chemistry. Furthermore, manufacturing proteins with reliable and consistent product quality at scale is challenging and highly dependent on the skill of the cell biologist and process scientist.

There are extraordinary technical challenges in developing complex mAb biologics that not only must achieve an acceptable degree of similarity to the reference product in terms of structural characteristics, but also the ability to develop manufacturing processes that can replicate the necessary structural characteristics within an acceptable range of variability sufficient to satisfy regulatory authorities.

Given the challenges caused by the inherent variability in protein production, we may not be successful in developing our product candidates if regulators conclude that we have not achieved a sufficient level of biosimilarity to the reference product, or that the processes we use to manufacture our product candidates are unable to produce our product candidates within an acceptable range of variability. These challenges may result in a failure to obtain regulatory approval for our products and could harm our business.

Clinical drug development is a lengthy and expensive process and we may encounter substantial delays in our clinical trials or may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we and our collaboration partners must conduct clinical trials to demonstrate the safety and efficacy of the product candidates in humans.

We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. Events that may prevent successful or timely completion of clinical development include but are not limited to:

- inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of human clinical trials;
- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in obtaining required Institutional Review Board, or IRB, approval at each clinical trial site;
- imposition of a clinical hold by regulatory agencies, after review of an investigational new drug, or IND, application or amendment or equivalent filing, or an inspection of our clinical trial operations or trial sites, or as a result of adverse events reported during a clinical trial;
- delays in recruiting suitable patients to participate in our clinical trials;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA's good clinical practice, or GCP, requirements or applicable regulatory guidelines in other countries;
- delays in having subjects complete participation in a study or return for post-treatment follow-up, or subjects dropping out of a study;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical trials of our product candidates being greater than we anticipate;
- inability to obtain sufficient quantities of reference product for the comparator arm of our studies;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in us deciding or regulators requiring us to conduct additional clinical trials or abandon product development programs; and
- delays in manufacturing, testing, releasing, validating or importing/exporting and/or distributing sufficient stable quantities of our product candidates and reference products for use in clinical trials or the inability to do any of the foregoing.

Any inability to successfully complete preclinical studies and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional clinical trials to bridge our modified product candidates to earlier versions.

Clinical development of biosimilars is different and can be more complex than clinical development programs for the reference products.

Clinical trials to show comparability of a biosimilar candidate to an approved reference product are new and differ from the clinical trials to gain approval for a new biologic. This may lead to difficulties in designing, initiating and enrolling trials for our product candidates. Some of these difficulties include:

- finding eligible patients willing to participate in clinical trials for biosimilar drugs;
- finding investigators willing to participate in biosimilar trials and who have access to appropriate patients;
- accommodating changes to reference product formulations during the conduct of clinical trials;
- competition for sites and patients where new and competitive therapies are being tested;
- designing, enrolling and completing a clinical trial to demonstrate biosimilarity and, where appropriate, interchangeability; and
- working with investigators that are not as experienced in conducting biosimilarity or interchangeability trials, or with the regulations applicable to such clinical trials.

These requirements and difficulties may lead to data quality issues or an inability to start or finish a clinical trial, or may lead to significant delays, which in turn may lead to the inability to produce data for approval of our biosimilar product candidates.

The results of previous clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the FDA, EMA or other foreign regulatory agencies.

Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any of our current and future collaborators may decide, or regulators may require us, to conduct additional clinical or preclinical testing. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are as safe and effective for use in a specific patient population as the respective reference products before we can seek regulatory approvals for their commercial sale. Success in early clinical trials does not mean that future larger registration clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate equivalent safety and efficacy to the satisfaction of the FDA, EMA and other foreign regulatory agencies despite having progressed through initial clinical trials. Product candidates that have shown promising results in early clinical trials may still fail in subsequent confirmatory clinical trials. Similarly, the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial to support regulatory approval. In some instances, there can be significant variability in safety or efficacy results between different trials of the same product candidate due to numerous factors, including but not limited to changes in trial protocols, differences in size and type of the patient populations, adherence to the dosing regimen and the rate of dropout among clinical trial participants.

Further, our product candidates may not be approved even if they achieve their primary endpoints in Phase 3 clinical trials or registration trials. The FDA, EMA and other foreign regulatory agencies may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. In addition,

any of these regulatory authorities may change the requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a Phase 3 clinical trial that has the potential to result in FDA or other agencies' approval. We initially intend to seek approval for ONS-3010 for the treatment of plaque psoriasis and ONS-1045 for the treatment of non-squamous, non-small cell lung cancer. We have not yet determined the indication for which we will seek initial approval for ONS-1050 or our preclinical biosimilar product candidates. We plan to extrapolate to all indications in the approved product labeling of the reference product based on the sensitive population agreed by the FDA and EMA in the confirmatory clinical study. During review of the registration application, our justification for the extrapolation may not be accepted. Any of the regulatory authorities may approve a product candidate for fewer indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials. In addition, the FDA, EMA and other foreign regulatory agencies may not approve the additional indication extrapolations that we believe would be necessary or desirable for the successful commercialization of our product candidates.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if granted.

As with most pharmaceutical products, use of our product candidates could be associated with side effects or adverse events, which can vary in severity and frequency. Side effects or adverse events associated with the use of our product candidates may be observed at any time, including in clinical trials or when a product is commercialized. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other foreign authorities. Results of our studies could reveal a high and unacceptable severity and prevalence of side effects, toxicity or other safety issues, and could require us to perform additional studies or halt development or sale of these product candidates or expose us to product liability lawsuits that will harm our business. In such an event, we may be required by regulatory agencies to conduct additional animal or human studies regarding the safety and efficacy of our product candidates that we have not planned or anticipated or our studies could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny or withdraw approval of our product candidates for any or all targeted indications. There can be no assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or any other regulatory agency in a timely manner, if ever, which could harm our business, prospects and financial condition.

Additionally, product quality characteristics have been shown to be sensitive to changes in process conditions, manufacturing techniques, equipment or sites and other related considerations, and as such, any manufacturing process changes we implement prior to or after regulatory approval could impact product safety.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a Risk Evaluation and Mitigation Strategy plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

If we receive approval, regulatory agencies including the FDA, EMA and other foreign regulatory agency regulations require that we report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA, EMA or other foreign regulatory agencies could take action including but not limited to criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval or clearance of future products.

If other biosimilars of adalimumab (Humira), bevacizumab (Avastin) or trastuzumab (Herceptin) are determined to be interchangeable and our biosimilar product candidates for these reference products are not, our business would suffer.

The FDA or other relevant regulatory authorities may determine that a proposed biosimilar product is "interchangeable" with a reference product, meaning that the biosimilar product may be substituted for the reference product without the intervention of the healthcare provider who prescribed the reference product, if the application includes sufficient information to show that the product is biosimilar to the reference product and that it can be expected to produce the same clinical result as the reference product in any given patient. If the biosimilar product may be administered more than once to a patient, the applicant must demonstrate that the risk in terms of safety or diminished efficacy of alternating or switching between the biosimilar product and the reference product is not greater than the risk of using the reference product without such alternation or switch. To make a final determination of biosimilarity or interchangeability, regulatory authorities may require additional confirmatory information beyond what we plan to initially submit in our applications for approval, such as more in-depth analytical characterization, animal testing or further clinical trials. Provision of sufficient information for approval may prove difficult and expensive.

We cannot predict whether any of our biosimilar product candidates will meet regulatory authority requirements for approval as a biosimilar product or as an interchangeable product in any jurisdiction. Furthermore, legislation governing interchangeability could differ by jurisdiction on a state or national level worldwide.

The concept of "interchangeability" is important in the U.S. market, potentially the largest global market for biosimilars, because the first biosimilar determined to be interchangeable with a particular reference product for any condition of use is eligible for a period of market exclusivity with respect to other interchangeable biosimilars. The FDA may not designate a second or subsequent biosimilar product as interchangeable with the reference product until the earlier of: (1) one year after the first commercial marketing of the first interchangeable product; (2) 18 months after resolution of a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product; (3) 42 months after approval of the first interchangeable product, if a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product is still ongoing; or (4) 18 months after approval of the first interchangeable product if the applicant that submitted the application for the first interchangeable product has not been sued under 42 U.S.C. § 262(l)(6). Thus, a determination that another company's product is interchangeable with the reference biologic before we obtain such a designation may delay the potential determination that our products are interchangeable with the reference product, which could harm our results of operations and delay, prevent or limit our ability to generate revenue.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our current or future product candidates, and our existing insurance coverage may not be sufficient to satisfy any liability that may arise.

Drug-related side effects could affect patient recruitment for clinical trials, the ability of enrolled patients to complete our studies or result in potential product liability claims. We currently carry product liability insurance in the amount of $10.0 million per product candidate and we are required to maintain product liability insurance pursuant to certain of our license agreements. We may not be able to maintain insurance

coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. A successful product liability claim or series of claims brought against us could negatively impact our results of operations and business. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, withdrawal of clinical trial participants, costs due to related litigation, distraction of management's attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates and decreased demand for our product candidates, if approved for commercial sale. Furthermore, we may also not be able to take advantage of limitations on product liability lawsuits that apply to generic drug products, which could increase our exposure to liability for products deemed to be dangerous or defective.

Failure to obtain regulatory approval in any targeted jurisdiction would prevent us from marketing our products to a larger patient population and reduce our commercial opportunities.

We and our collaboration partners have not initiated marketing efforts in any jurisdiction. Subject to product approvals and relevant patent expirations, we or our collaboration partners intend to first market our products in the EU and Japan followed by the United States.

In order to market our products in the EU, the United States and other jurisdictions, we and our collaboration partners must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The EMA is responsible for the regulation and recommendation for approval of human medicines in the EU. This procedure results in a single marketing authorization that is valid in all EU countries, as well as in Iceland, Liechtenstein and Norway. The time required to obtain approval abroad may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval and we may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We or our collaboration partners may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products within the EU, the United States or in other jurisdictions. Failure to obtain these approvals would harm our business, financial condition and results of operations.

Approval in the United States requires a demonstration of biosimilarity to a U.S.-approved reference product. EMA approval requires a demonstration of biosimilarity to an EMA-approved reference product. Accordingly, for our global clinical program, bridging studies will be required in order to use the clinical testing in one jurisdiction in another. The bridging studies must demonstrate that the data demonstrating biosimilarity against the EMA-approved reference product are sufficient to demonstrate biosimilarity to the FDA-approved reference product, and vice versa. The need for such bridging studies may delay or limit our ability to market our products globally.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.

If our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturing facilities are required to comply with extensive FDA, and comparable foreign regulatory authority, requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices, or cGMP, regulations. As such, we will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any non-disclosure agreement, BLA or marketing authorization application, or MAA. Accordingly, we and our collaborators and suppliers must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we or our collaboration partners receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the

conditions of approval or may contain requirements for potentially costly additional clinical trials and surveillance to monitor the safety and efficacy of the product candidate. We will be required to report certain adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization or increased costs to assure compliance. We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we are not allowed to promote our products for indications or uses for which they do not have approval. If our product candidates are approved, we must submit new or supplemental applications and obtain approval for certain changes to the approved products, product labeling or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with an approved product, such as adverse events of unanticipated severity or frequency or problems with our manufacturing facilities or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue untitled and warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our manufacturing facilities; or
- seize or detain products or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be negatively impacted.

Adverse events involving a reference product, or other biosimilars of such reference product, may adversely affect our business.

In the event that use of a reference product, or other biosimilar for such reference product, results in unanticipated side effects or other adverse events, it is likely that our biosimilar product candidate will be viewed comparably and may become subject to the same scrutiny and regulatory sanctions as the reference product or other biosimilar, as applicable. Discovery of such unanticipated side effects or other adverse events in a reference product may result in changes to its approved labeling or indications, or even withdrawal of the reference product from the market. Additionally, if a biosimilar is approved for the same reference product as one of our product candidates and unanticipated side effects or other adverse events are associated with such third-party biosimilar in the future, the development and market for our product candidate could be adversely affected.

As a result, we may become subject to regulatory supervisions, clinical holds, product recalls or other regulatory actions for matters outside of our control that affect the reference product, or other biosimilar, as applicable, if and until we are able to demonstrate to the satisfaction of our regulators that our biosimilar product candidate is not subject to the same issues leading to the regulatory action as the reference product or other biosimilar, as applicable.

We may elect to seek licensure of our biosimilar products under the 351(a) (novel biologic) approval pathway instead of the 351(k) (biosimilar) approval pathway. This approval pathway may require us to undertake more expensive clinical trials and may present greater risk of failure than the 351(k) (biosimilar) approval pathway.

While we have elected to proceed under the 351(k) (biosimilar) approval pathway for ONS-3010, ONS-1045 and ONS-1050, we may elect for future products to pursue a 351(a) (novel biologic) approval pathway for a variety of clinical, regulatory and business reasons. The 351(a) (novel biologic) approval pathway generally requires three study phases (as contrasted with the two-study phases generally accepted by FDA for an application submitted under the 351(k) (biosimilar) pathway). Moreover, the 351(a) pathway generally does not allow for the possibility that a clinical trial in one indication can be extrapolated to multiple indications as is generally the case under the 351(k) (biosimilar) approval pathway. Pursuing licensure under the 351(a) (novel biologic) approval pathway may present disadvantages in terms of the requirements for additional clinical and nonclinical trials, clinical trial cost and failure risk, as well as the likelihood that multiple clinical trials would be required to obtain approval for all of the indications approved for the reference drug.

Risks Related to Commercialization of Our Product Candidates

We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced or more effective than ours. Other biosimilars or "biobetters" of the reference products we are targeting may be approved and successfully commercialized before ours, which may adversely affect our financial condition and our ability to successfully commercialize our product candidates.

We expect to enter highly competitive pharmaceutical markets. Successful competitors in the pharmaceutical markets have demonstrated the ability to effectively discover, obtain patents, develop, test and obtain regulatory approvals for products, as well as an ability to effectively commercialize, market and promote approved products. Numerous companies, universities and other research institutions are engaged in developing, patenting, manufacturing and marketing of products competitive with those that we are developing. Many of these potential competitors are large, experienced pharmaceutical companies that enjoy significant competitive advantages, such as substantially greater financial, research and development, manufacturing, personnel and marketing resources. These companies also have greater brand recognition and more experience in conducting preclinical testing and clinical trials of product candidates and obtaining FDA and other regulatory approvals of products.

We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies. Some of the pharmaceutical and biotechnology companies we expect to compete with include, for example, Sandoz International GmbH, or Sandoz, Hospira, Inc., or Hospira, Amgen Inc., Pfizer Inc., Boehringer Ingelheim GmbH, or Boehringer, Teva Pharmaceutical Industries, Ltd., Samsung Bioepis, Ltd. (a Merck/Biogen/Samsung biosimilar venture) and Hanwha Chemical Corporation, as well as other smaller companies such as Coherus Biosciences, Inc. and Celltrion, Inc. We are currently aware that such competitors are engaged in the development of biosimilar product candidates to adalimumab (Humira) – for which Amgen has received approval, bevacizumab (Avastin) and trastuzumab (Herceptin), and expect that some of these competitors will commercialize their biosimilar products prior to us, which could materially harm our ability to gain market share.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able to and may be more effective in selling and marketing their products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop; they may also obtain patent protection that could block our products; and they may obtain regulatory approval, product commercialization and market penetration earlier than we do. Biosimilar product candidates developed by our competitors may render our potential product candidates

uneconomical, less desirable or obsolete, and we may not be successful in marketing our product candidates against competitors. Competitors may also assert in their marketing or medical education programs that their biosimilar products demonstrate a higher degree of biosimilarity to the reference products than do ours or other competitor's biosimilar products, thereby seeking to influence healthcare practitioners to select their biosimilar products rather than ours or other competitors. Competitors may also develop "biobetter" versions of reference products we are targeting. A biobetter is a product that contains alterations to the reference product's chemical structure or delivery system that provide a clinical benefit over the original reference product. Biobetters developed by our competitors may compete advantageously against our products and limit our market success.

We expect additional companies to seek approval to manufacture and market biosimilar versions of Humira, Avastin and Herceptin, in some cases, in advance of our commercialization timeline. If other biosimilars of Humira, Avastin or Herceptin are approved and successfully commercialized before ONS-3010, ONS-1045 or ONS-1050, respectively, we may never achieve significant market share for these products, our revenue would be reduced and, as a result, our business, prospects and financial condition could be harmed.

If efforts by developers and manufacturers of reference products to delay or limit the use of biosimilars are successful, our sales of biosimilar products may suffer.

Many developers and manufacturers of reference products have increasingly used legislative, regulatory and other means to delay regulatory approval and to seek to restrict competition from manufacturers of biosimilars. These efforts may include or have included:

- settling patent lawsuits with biosimilar companies, resulting in such patents remaining an obstacle for biosimilar approval by others; submitting Citizen Petitions to request the FDA Commissioner to take administrative action with respect to prospective and submitted biosimilar applications;
- appealing denials of Citizen Petitions in United States federal district courts and seeking injunctive relief to reverse approval of biosimilar applications;
- restricting access to reference brand products for equivalence and biosimilarity testing that interferes with timely biosimilar development plans;
- attempting to influence potential market share by conducting medical education with physicians, payors, regulators and patients claiming that biosimilar products are too complex for biosimilar approval or are too dissimilar from reference products to be trusted as safe and effective alternatives;
- implementing payor market access tactics that benefit their brands at the expense of biosimilars;
- seeking state law restrictions on the substitution of biosimilar products at the pharmacy without the intervention of a physician or through other restrictive means such as excessive recordkeeping requirements or patient and physician notification;
- seeking federal or state regulatory restrictions on the use of the same nonproprietary name as the reference brand product for a biosimilar or interchangeable biologic;
- seeking changes to the United States Pharmacopeia, an industry-recognized compilation of drug and biologic standards;
- obtaining new patents covering existing products or processes that could extend patent exclusivity for a number of years or otherwise delay the launch of biosimilars; and
- influencing legislatures so that they attach special patent extension amendments to unrelated federal legislation.

If an improved version of a reference product, such as Humira, Avastin or Herceptin, is developed or if the market for the reference product significantly declines, sales or potential sales of our biosimilar product candidates may suffer.

Originator companies may develop improved, or "biobetter," versions of a reference product or change the product formulation as part of a life cycle extension strategy and may obtain regulatory approval of the

improved version under a new or supplemental BLA filed with the applicable regulatory authority. If the originator company succeeds in obtaining an approval of an improved biologic product, it may capture a significant share of the collective reference product market in the applicable jurisdiction and significantly reduce the market for the reference product and thereby the potential size of the market for our biosimilar product candidates. For example, AbbVie has obtained approval in the United States and Europe of an improved formulation of Humira that reduces injection pain, injection volume and potentially the number of injections a patient receives. Switching existing patients to biobetter versions reduces the available market size for a biosimilar. In addition, the improved product may be protected by additional patent rights that may subject our follow-on biosimilar product to claims of infringement.

Biologic reference products may also face competition as technological advances are made that may offer patients a more convenient form of administration or increased efficacy or as new products are introduced. As new products are approved that compete with the reference products to our biosimilar product candidates, sales of the reference products may be adversely impacted or rendered obsolete. If the market for the reference product is impacted, we may lose significant market share or experience limited market potential for our approved biosimilar products or product candidates, and the value of our product pipeline could be negatively impacted. As a result of the above factors, our business, prospects and financial condition could be harmed.

The commercial success of any current or future product candidate will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

Even with the requisite approvals from the FDA and comparable foreign regulatory authorities, the commercial success of our product candidates will depend in part on the medical community, patients and third-party payors accepting our product candidates as medically useful, cost-effective and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients, third-party payors and others in the medical community. The degree of market acceptance of any of our product candidates, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the safety and efficacy of the product as demonstrated to be “highly similar” in clinical trials, and potential advantages over competing treatments and the reference product;
- labeling or naming imposed by FDA or other regulatory agencies that suggest clinical differences between the product and the reference product;
- the publication of unfavorable safety or efficacy data concerning our product by third-parties;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product’s approved labeling;
- the clinical indications for which approval is granted;
- whether we achieve an interchangeability designation in the United States, and if such designation has a material effect on the perception of equivalence;
- the possibility that a competitor may achieve interchangeability and we may not;
- relative convenience and ease of administration as compared to the reference product;
- the extent to which our product may be more or less similar to the reference product than competing biosimilar product candidates;
- recognition and acceptance of our product candidates over our competitors’ products;
- prevalence of the disease or condition for which the product is approved;
- the cost of treatment, particularly in relation to competing treatments;
- the willingness of the target patient population to try biosimilar therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;

- the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations;
- publicity concerning our products or competing products and treatments;
- the extent to which third-party payors provide coverage and adequate reimbursement for our product candidates, if approved; and
- our ability to maintain compliance with regulatory requirements.

Moreover, the market success of a biosimilar product, including widespread patient and doctor acceptance, may ultimately depend on whether it receives an interchangeability designation. This is particularly true if one or more competing biosimilars receives such a designation. Future laws and drug formulary rules requiring or facilitating automatic substitution of biosimilars for reference products at the pharmacy level may also be limited to biosimilars that have received an interchangeable designation.

The labeling requirements for a biosimilar product have not been fully developed and there is uncertainty as to how much of the reference product label a biosimilar applicant may or must copy, and the extent to which the applicant must distinguish its product from the reference product. The naming of biosimilars is also subject to significant uncertainty, and it is unclear whether biosimilar products will be required to bear names that distinguish them from their reference products. Differences between the labels and names of the biosimilar and reference product may make it more difficult for us to achieve market uptake for our product.

Even if our product candidate displays an equivalent or more favorable efficacy and safety profile in preclinical and clinical trials, market acceptance of the product candidate will not be fully known until after it is launched and may be negatively affected by a potential poor safety experience and the track record of other biosimilar product candidates. If market acceptance of our product is less than that of the reference product or competing biosimilars, the price of the product may need to be reduced or we may need to implement additional marketing endeavors in order to accrue market share, which will negatively affect profitability. Our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, may be under-resourced compared to large well-funded pharmaceutical entities and may never be successful. If our product candidates are approved but fail to achieve an adequate level of acceptance by physicians, patients, third-party payors and others in the medical community, we will not be able to generate sufficient revenue to become or remain profitable.

We currently have no marketing and sales organization. If we are unable to establish sales and marketing capabilities in jurisdictions for which we choose to retain commercialization rights, we may be unable to generate any revenue.

We currently have no marketing or sales organization. Our products have not yet been approved for sale, and we, as a company, have no experience selling and marketing our product candidates. To successfully commercialize any products that may result from our development programs, we will need to develop these capabilities, either on our own or with others. If our product candidates receive regulatory approval, we intend to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates in major markets where we may choose to retain commercialization rights. Doing so will be expensive, difficult and time-consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our products. Further, given our lack of prior experience in marketing and selling biosimilar products, our initial estimate of the size of the required sales force may be materially more or less than the size of the sales force actually required to effectively commercialize our product candidates. As such, we may be required to hire substantially more sales representatives and medical support liaisons to adequately support the commercialization of our product candidates or we may incur excess costs as a result of hiring more sales representatives than necessary. With respect to certain geographical markets, we may enter into collaborations with other entities to utilize their local marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. If our future collaboration partners do not commit sufficient resources to commercialize our future products, if any, and we are unable

to develop the necessary marketing capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. If we are unable to establish sales and marketing capabilities for any approved product, whether on our own or through collaborations, our results of operations will be negatively impacted.

We may need to enter into alliances with other companies that can provide capabilities and funds for the development and commercialization of our product candidates. If we are unsuccessful in forming or maintaining these alliances on favorable terms, our business could be harmed.

Because we have limited or no internal capabilities for late-stage product development, manufacturing, sales, marketing and distribution, we have found it necessary to enter into alliances with other companies. For example, we entered into service agreements with InVentiv Health Clinical, LLC to assist us in conducting our Phase 1 and Phase 3 clinical trials for ONS-3010 and ONS-1045. Aside from our joint participation agreement with Huahai for ONS-3010, we do not have any agreements for the development and commercialization of our biosimilar product candidates for any major ex-U.S. markets, such as the EU and Japan. To date, we only have such agreements for smaller ex-U.S. markets. In particular, we entered into a co-development and license agreement with Huahai to co-develop ONS-3010 and ONS-1045 for Huahai to commercialize in the greater China region. We also entered into a license agreement with Liomont to develop and commercialize ONS-3010 and ONS-1045 in Mexico. Further, we entered into license and collaboration agreements with IPCA to develop and commercialize ONS-3010, ONS-1045 and ONS-1050 in India, Sri-Lanka, Myanmar, Nepal and Bhutan. In the future, we may also find it necessary to form other alliances or joint ventures with major pharmaceutical companies to jointly develop and/or commercialize specific biosimilar product candidates. In such alliances, we would expect our collaboration partners to provide substantial capabilities in regulatory affairs, as well as sales and marketing. We may not be successful in entering into any such alliances. Even if we do succeed in securing such alliances, we may not be able to maintain them if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. If we are unable to secure or maintain such alliances we may not have the capabilities necessary to continue or complete development of our product candidates and bring them to market, which may have an adverse effect on our business.

In addition to commercialization capabilities, we may depend on our alliances with other companies to provide substantial additional funding for development and potential commercialization of our product candidates. We may not be able to obtain funding on favorable terms from these alliances, and if we are not successful in doing so, we may not have sufficient funds to develop a particular product candidate internally or to bring product candidates to market. Failure to bring our product candidates to market will prevent us from generating sales revenue, and this will substantially harm our business. Furthermore, any delay in entering into these alliances could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market. As a result, our business and operating results may be harmed.

Policies and practices governing the naming of biosimilar product candidates are neither fully established nor fully harmonized and are subject to debate and change. Failure to achieve a nonproprietary name sufficiently close to the reference product or be competitively disadvantaged in this regard, could adversely affect the commercial performance of our biosimilar product candidate.

United States Adopted Name, or USAN, and International Nonproprietary Names, or INN, two important bodies involved in nonproprietary nomenclature, have no policy for the naming of biosimilar product candidates, and products are named on a case by case basis. Non-glycosylated proteins can follow the approach established for small molecule generics, which is to retain the same nonproprietary name if it is synthesized by a different route provided the substance is the same. Glycosylated proteins from different sources are given distinct names, as these proteins are expected to differ in their glycosylation profile. The same approach is valid for all other modifications to the protein that can occur in a cell after the cell has finished making the protein. A system currently under discussion at the World Health Organization that would enable the clear definition of all similar biotherapeutic proteins would include the INN of the reference product in the first part of the name, and some form of biological qualifier that could uniquely identify the substance. Currently the FDA and EMA have final authority regarding names in the United States and the EU, respectively, and it is unclear how they will handle nonproprietary nomenclature in the

future. However, recent draft FDA guidance has recommended an approach to distinguish product manufacturers of the reference biologic, biosimilars, interchangeables, and related biologics by establishing nonproprietary names that are distinct from the reference product. For the reference biologic, FDA intends to use as a "core name" the name adopted by the USAN Council for the drug substance. For a biosimilar, interchangeable, or related biologic, the core name is the name of the drug substance contained in the relevant previously licensed product.

Under FDA's proposed approach, the nonproprietary name designated for reference biologics, related biologics, and biosimilars will include a unique suffix in addition to the core name. FDA is seeking comment on whether the nonproprietary name for an interchangeable product should include a unique suffix, or should share the same suffix as its reference product. This policy could suggest to payors, providers and patients that our biosimilar product is different from the reference product, which may negatively affect the price we can charge, our sales and market share, which could harm our business. Notably, by affixing a random four letter suffix to the USAN, there is a potential for misuse that could cause misreporting of adverse events or otherwise to the wrong biosimilar product. If our biosimilars were wrongly reported as having caused adverse events or other negative outcomes, it could affect our brand and negatively harm our business.

The third-party coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

Pricing, coverage and reimbursement of our biosimilar product candidates, if approved, may not be adequate to support our commercial infrastructure. Our per-patient prices may not be sufficient to recover our development and manufacturing costs and potentially achieve profitability. The availability and adequacy of coverage and reimbursement by governmental and private payors are essential for most patients to be able to afford expensive treatments such as ours, if approved. Accordingly, sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid for by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations or reimbursed by government authorities, private health insurers and other third-party payors. If coverage and reimbursement are not available, or are available only at insufficient levels, we may not be able to successfully commercialize our product candidates. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Even if coverage is provided, the approved reimbursement amount may not be adequate to allow us to establish or maintain pricing sufficient to realize a return on our investment.

There is significant uncertainty related to third-party coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. The Medicare program covers certain individuals aged 65 or older or those who are disabled or suffering from end-stage renal disease. The Medicaid program, which varies from state to state, covers certain individuals and families who have limited financial means and/or certain disabilities. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our biosimilar product candidates, if approved. In addition, in the United States, no uniform policy of coverage and reimbursement for biologics exists among third-party payors. Therefore, coverage and reimbursement for biologics can differ significantly from payor to payor. As a result, the process for seeking favorable coverage determinations often is time-consuming and costly and may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have an adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Outside the United States, pharmaceutical businesses are generally subject to extensive governmental price controls and other market regulations. We believe the increasing emphasis on cost-containment initiatives in

the EU, Canada and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to control healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. While cost containment practices generally benefit biosimilars, severe cost containment practices may adversely affect our product sales. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes.

Our biosimilar product candidates, if approved, will face price competition from both the respective reference products and other biosimilars. This price competition could exceed our capacity to respond, negatively impacting our market share and revenue as well as adversely affecting the overall financial health and attractiveness of the market for the biosimilar.

Successful competitors in the biosimilar market will likely have the ability to effectively compete on price through payors and their third-party administrators who exert downward pricing pressure. It is possible our competitors' compliance with price discounting demands in exchange for market share could exceed our capacity to respond in kind and reduce market prices beyond our expectations. In addition, the RPS may compete effectively on price and limit our ability to accrue market share. Such practices may limit our and our collaboration partners' ability to increase market share and will also impact profitability.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our preclinical and clinical trials and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be harmed.

We have relied upon and plan to continue to rely upon CROs to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical and clinical trials and we can only control certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific requirements and standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with cGMP, GCP, and Good Laboratory Practices, or GLP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the EEA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections of study sponsors, principal investigators, study sites and other contractors. If we, any of our CROs, service providers or investigators fail to comply with applicable regulations or GCPs, the data generated in our preclinical and clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional preclinical and clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with products produced under cGMP regulations. Failure to comply by any of the participating parties or ourselves with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if our CROs or any other participating parties violate federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

If any of our relationships with any of these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. In addition, our CROs are

not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. CROs may also generate higher costs than anticipated. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Changing or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which can negatively impact our ability to meet our desired clinical development timelines. We may encounter challenges or delays in the future and these delays or challenges may have an adverse effect on our business, financial condition and prospects.

We manufacture bulk drug substance for preclinical and clinical supplies of our product candidates in our in-house facility. We also intend to manufacture bulk drug substance for commercial sale in our facility. Our business could be harmed if our facility is damaged or we otherwise fail to manufacture our product candidates at the necessary quantity or quality levels.

If we are unable to manufacture sufficient supplies of our product candidates, our development efforts would be delayed, which would adversely affect our business and prospects. In addition, our failure to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, 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 product candidates or any other product candidates or products that we may develop.

If any of our product candidates are approved, in order to produce the quantities necessary to meet anticipated market demand, we may need to increase our manufacturing capacity. If we are unable to produce our product candidates and in sufficient quantities to meet the requirements for the launch of these products or to meet future demand, our revenue and gross margins could be adversely affected.

Our manufacturing depends on our suppliers. For single-use technology, we depend on specialty-manufactured bags and our reliability on the supply of such bags can impact manufacturing. In addition, the quality of such bags may vary, and in certain rare circumstances, the bag components may leak into the product, which would make the product unsuitable. We also depend on the timely supply and quality of all raw materials, which are crucial to the successful manufacturing of our products. Further, we depend on our fill-finish partners to ensure quality products and our partners' failure to deliver a consistent supply of high-quality products is a risk to the business.

We have never manufactured commercial scale quantities in our facilities and we may face challenges in ensuring a consistent supply for global markets.

Any adverse developments affecting the manufacturing operations of our biosimilar product candidates could substantially increase our costs and limit supply for our product candidates.

The process of manufacturing our product candidates is complex, highly regulated and subject to several risks, including but not limited to:

- failure to establish contracts with fill-finish contract manufacturing organization or CMOs, and device vendors;
- product loss due to contamination, equipment failure or improper installation or operation of equipment or vendor or operator error;
- failure to maintain fermentation or other manufacturing conditions necessary to achieving biosimilarity to the reference product;

- infringing intellectual property rights of third parties relating to manufacturing and quality testing;
- failure to achieve or maintain compliance with FDA's requirements for acceptance of our manufacturing facilities; and
- labor shortages, natural disasters and power failures.

Even minor deviations from normal manufacturing processes for any of our product candidates could result in reduced production yields, product defects and other supply disruptions. In addition, if we require a change in CMO, this will add time along with financial and personnel resources to change manufacturing sites. If microbial, viral or other contaminations are discovered in our product candidates or in our manufacturing facilities, our facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

Any adverse developments affecting manufacturing operations for our product candidates may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls or other interruptions in the supply of our product candidates. We may also have to take inventory write-offs and incur other charges and expenses for product candidates that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

We expect to depend on third parties for the commercialization of our biosimilar product candidates, and their failure to commercialize in those markets could harm our business and operating results.

We will need to identify third-parties and then negotiate the terms of the development and commercialization agreements for the United States and major ex-U.S. markets, such as the EU and Japan. We may not be successful in identifying contract counterparties, and we may not be able to reach agreements with such parties on terms that are as favorable to our company as we would anticipate. We currently have in place only one licensing agreement for commercialization in the United States. Our other current arrangements are for smaller ex-U.S. markets where we would not otherwise intend to commercialize our biosimilar product candidates, such as China, Mexico and India, among others. If these entities fail to exercise commercially reasonable efforts to market and sell our products in their respective licensed jurisdictions or are otherwise ineffective in doing so, our business will be harmed and we may not be able to adequately remedy the harm through negotiation, litigation, arbitration or termination of the license agreements.

Moreover, any disputes with our collaboration partners concerning the adequacy of their commercialization efforts will substantially divert the attention of our senior management from other business activities and will require us to incur substantial legal costs to fund litigation or arbitration proceedings.

In the event that any of our license agreements terminate, we may need to find another partner in those markets to commercialize and in certain instances, manufacture our biosimilar product candidates. Further, upon any such termination, our contract counterparties may still have the right to commercialize these biosimilar product candidates in such markets, which may affect our ability to commercialize in the same markets.

We are required to co-fund the development of, and proportionately share in the revenue from, the commercialization of ONS-3010 in the United States, Canada, EU, Japan, Australia and New Zealand under a joint participation agreement with Huahai. We may also be required to form a joint venture to further co-develop and commercialize ONS-3010 with Huahai in the agreed countries, if so requested by Huahai.

We currently have a joint participation arrangement with Huahai that provides for the co-funding of the development of ONS-3010 in the United States, Canada, EU, Japan, Australia and New Zealand and the proportionate sharing of the revenue from commercialization of ONS-3010 in such countries. We could also be required to further co-develop and commercialize ONS-3010 with Huahai in the agreed countries pursuant to a joint venture, if so requested by Huahai, as contemplated by our joint participation agreement. Although we had the option to terminate this joint participation agreement by exercising our option to pay Huahai a total of $28.0 million, including an $11.0 million initial payment, we did not make

the $11.0 million initial payment within the time frame required. Under the joint participation agreement, assuming Huahai funds its proportionate share of development costs incurred after completion of the "Phase-3 Ready Package" for ONS-3010, we will have a 49% value ownership interest with Huahai having a 51% value ownership interest in ONS-3010. Accordingly, our share of any potential revenues from the successful commercialization of ONS-3010 in the agreed countries, including major markets such as the United States and EU, would also be in proportion to such ownership interests. While we anticipate that we will each act in accordance with the terms of our agreement for the joint development and commercialization of ONS-3010, we cannot control Huahai, nor can we predict with any certainty that our interests will be aligned and that we will successfully collaborate.

We entered into a lease for additional manufacturing and research and development space and our business may be interrupted if these facilities are not ready for occupation in time to implement our expansion efforts, which could impact our ability to advance our early-stage preclinical pipeline and any future product candidates.

We entered into a lease for a new facility in our current industrial complex, which commenced in March 2016. We intend to build-out this facility as an additional state-of-the-art development infrastructure, which we will occupy in phases, as needed. There can be no assurance that the new space will be prepared and ready in time for our move-in. Further, the expansion could disrupt our current development and manufacturing operations, resulting in an inability to meet our deadlines and leading to a slow realization of the efficiencies and capacity anticipated from such expansion. Adverse consequences resulting from a delay in the expansion could harm our relationships with our license and collaboration partners, and further affect our ability to develop and commercialize our biosimilar product candidates. In addition, such expansions of our manufacturing and research and development capabilities may increase our costs. Any of the above could delay regulatory approval and commercialization of our current early-stage preclinical and future biosimilar product candidates. All of the foregoing could result in substantial costs to us and could result in material interruption to our business and operations.

We currently engage single source suppliers for clinical trial services and multiple source suppliers for fill-finish manufacturing and product testing of our biosimilar product candidates. The loss of any of these suppliers, or any future single source suppliers, could harm our business.

Our current clinical stage biosimilar product candidates were fill-finished by Hospira and Ajinomoto Althea, Inc., or Althea. As such, we are heavily dependent on Hospira and Althea for supplying us with finished product candidates. Although we believe that there are alternate sources for this service, we cannot assure you that identifying and establishing new relationships would not result in significant delay in the development of our biosimilar product candidates. Additionally, we may not be able to enter into arrangements with alternative vendors on commercially reasonable terms, or at all. A delay in the development of our biosimilar product candidates or having to enter into a new agreement with a different third party on less favorable terms than we have with our current suppliers could negatively impact our business.

We are subject to significant regulation with respect to manufacturing our product candidates. Our manufacturing facilities may not continue to meet regulatory requirements or may not be able to meet supply demands.

Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP and other applicable regulations. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We must supply all necessary documentation in support of a BLA or MAA on a timely basis and must adhere to GLP and cGMP regulations enforced by the FDA and other regulatory agencies through their facilities inspection program. We have never produced a commercially approved pharmaceutical product at our facilities and therefore have not obtained the requisite regulatory authority approvals to do so. Our facilities and quality systems must pass a pre-approval inspection for compliance

with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect our manufacturing facility or our associated quality systems for compliance with the regulations applicable to the activities being conducted. If our facilities do not pass a pre-approval facility inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

The regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, the relevant regulatory authority may require remedial measures that may be costly and time-consuming for us to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of our facility. Any such remedial measures could harm our business.

If we fail to maintain regulatory compliance, the FDA or other applicable regulatory authority can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new biologic product, withdrawal of an approval or suspension of production. As a result, our business, financial condition and results of operations may be harmed.

These factors could cause us to incur higher costs and could cause the delay or termination of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates.

Risks Related to Intellectual Property

If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed. Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in large part on avoiding infringement of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the pharmaceutical industry, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the U.S. Patent and Trademark Office, or USPTO, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the pharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Our research, development and commercialization activities may infringe or otherwise violate or be claimed to infringe or otherwise violate patents owned or controlled by other parties. The companies that originated the products for which we intend to introduce biosimilar versions, such as AbbVie, Inc., or AbbVie, and Genentech, Inc., or Genentech, as well as other competitors (including other companies developing biosimilars) have developed worldwide patent portfolios of varying sizes and breadth, many of which are in fields relating to our business, and it may not always be clear to industry participants, including us, which patents cover various types of products, formulations, manufacturing processes or methods of use.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. We have conducted patent searches for third-party patents with respect to each of our lead product candidates, and are aware of third-party patent families with claims that, if valid and enforceable, could be construed to cover such product candidates or their respective methods of manufacture or use. Some of these patents have expiration dates that could extend reference product exclusivity past our anticipated product launch dates. We cannot guarantee that any of our analyses are complete and thorough, nor can we be sure that we have identified each and every patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of our product candidates. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents covering our product candidates. We have not yet completed freedom to operate

analysis on our early-stage pipeline or products we are evaluating for inclusion in our future biosimilar product pipeline and therefore, we do not know whether or to what extent these products may be subject to unexpired patents. The existence of any patent with valid and enforceable claims covering one or more of our product candidates could cause substantial delays in our ability to introduce a biosimilar candidate into the U.S. market if the term of such patent extends beyond our desired product launch date.

There may also be patent applications that have been filed but not published and if such applications issue as patents, they could be asserted against us. For example, in most cases, a patent filed today would not become known to industry participants for at least 18 months given patent rules applicable in most jurisdictions that do not require publication of patent applications until 18 months after filing. Moreover, we may face claims from non-practicing third-party entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. In addition, the scope of patent claims is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the asserted patent claims or that the claims are invalid and/or unenforceable, and we may not be successful.

Proving that a patent is invalid or unenforceable is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. In proceedings before courts in the EU, the burden of proving invalidity of a patent also usually rests on the party alleging invalidity. Even if we are successful in litigation, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted, which could harm our business. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

Third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial monetary damages. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. If a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. Ultimately, we could be prevented from commercializing a product or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on commercially acceptable terms or at all. If, as a result of patent infringement claims or to avoid potential claims, we choose or are required to seek licenses from third parties, these licenses may not be available on acceptable terms or at all. Even if we are able to obtain a license, the license may obligate us to pay substantial license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would likely involve substantial litigation expense and would likely be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may, in addition to being blocked from the market, have to pay substantial monetary damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, derivation or post-grant proceedings declared or granted by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or future products. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may also become involved in disputes with others regarding the ownership of intellectual property rights.

Third parties may submit applications for patent term extensions in the United States or other jurisdictions where similar extensions are available and/or Supplementary Protection Certificates in the EU states (including Switzerland) seeking to extend certain patent protection that, if approved, may interfere with or delay the launch of one or more of our biosimilar product candidates.

The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Patent litigation and other proceedings may fail, and even if successful, may result in substantial costs and distract our management and other employees. The companies that originated the products for which we intend to introduce biosimilar versions, as well as other competitors (including other biosimilar companies) may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace.

So called "submarine" patents may be granted to our competitors that may significantly alter our launch timing expectations, reduce our projected market size, cause us to modify our product or process or block us from the market altogether.

The term "submarine" patent has been used in the pharmaceutical industry and in other industries to denote a patent issuing from a U.S. application with an effective filing date prior to June 8, 1995 that was not published, publically known or available prior to its grant. Submarine patents add substantial risk and uncertainty to our business. Submarine patents may be issued to our competitors covering our biosimilar product candidates or our pipeline candidates and thereby cause significant market entry delay, defeat our ability to market our product candidates or cause us to abandon development and/or commercialization of a product candidate.

The issuance of one or more submarine patents may harm our business by causing substantial delays in our ability to introduce a biosimilar candidate into the U.S. market.

We may not identify relevant patents or may incorrectly interpret the relevance, scope or expiration of a patent, which might adversely affect our ability to develop and market our products.

We cannot guarantee that any of our patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete and thorough, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products or pipeline candidates. We may incorrectly determine that our products are not covered by a third party patent. Further, we may conclude that a well-informed court or other tribunal would find the claims of a relevant third-party patent to be invalid based on prior art, enablement, written description, or other ground, and that conclusion may be incorrect, which may negatively impact our ability to market our products or pipeline molecules.

Many patents may cover a marketed product, including but not limited to the composition of the product, methods of use, formulations, cell line constructs, vectors, growth media, production processes and purification processes. The identification of all patents and their expiration dates relevant to the production and sale of a reference product is extraordinarily complex and requires sophisticated legal knowledge in the relevant jurisdiction. It may be impossible to identify all patents in all jurisdictions relevant to a marketed product. We may not identify all relevant patents, or incorrectly determine their expiration dates, which may negatively impact our ability to develop and market our products.

Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop, market and commercialize our products.

We may become involved in lawsuits to protect or enforce any future patents, which could be expensive, time-consuming and unsuccessful.

Although we have no issued patents, when and if we do obtain issued patents, we may discover that competitors are infringing those patents. Expensive and time-consuming litigation may be required to

enforce our patents. If we or one of our collaboration partners were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including but not limited to lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone involved in the prosecution of the patent withheld relevant or material information related to the patentability of the invention from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly and decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy.

Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

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 any litigation we initiate to enforce our patents. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a negative impact on the market price of our securities. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ individuals and retain independent contractors and consultants and members on our board of directors who were previously employed at universities or other pharmaceutical companies, including our competitors or potential competitors. For example, our Chairman, President and Chief Executive Officer, Pankaj Mohan, Ph.D., our Chief Medical Officer, Kenneth M. Bahrt, M.D., our Senior Vice President of Business Strategy & Development, Stephen J. McAndrew, Ph.D., our Senior Vice President of Process Development & Manufacturing, Scott Gangloff, and our Vice President of Regulatory Affairs, Elizabeth A. Yamashita, are former employees of Bristol-Myers Squibb Company. Further, Dr. Mohan and Dr. Bahrt are former employees of Genentech, which is the reference product sponsor of bevacizumab (Avastin), for which we seek to develop ONS-1045 as a biosimilar, and trastuzumab (Herceptin), for which we seek to develop ONS-1050 as a biosimilar, and Kogan Bao, Ph.D., our Vice President of Analytical Sciences, is a former employee of Amgen, Inc., which is the reference product sponsor of denosumab (Prolia/Xgeva), for which we seek to develop ONS-4010 as a biosimilar. Additionally, Dr. McAndrew was a former employee of Roche. Two members of our board of directors, Scott Canute and Dr. Mohan, were former employees of Eli Lilly and Company and Ms. Yamashita was a former employee of ImClone Systems Inc., a subsidiary of Eli Lilly and Company, which is the reference product sponsor of cetuximab (Erbitux), for which we seek to develop ONS-1055 as a biosimilar. Although we try to ensure that our employees, consultants and

independent contractors do not use the proprietary information or know-how of others in their work for us and we are not currently subject to any claims that they have done so, we may in the future be subject to such claims. 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, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us asserting ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

We currently have no issued patents. If we are unable to obtain and maintain effective patent rights for our product candidates or any future product candidates, we may not be able to prevent competitors from using technologies we consider important in our successful development and commercialization of our product candidates, resulting in loss of any potential competitive advantage our patents may have otherwise afforded us.

While our principal focus in matters relating to intellectual property is to avoid infringing the valid and enforceable rights of third parties, we also rely upon a combination of patents, trade secret protection and confidentiality agreements to protect our own intellectual property related to our product candidates and development programs. Our ability to enjoy any competitive advantages afforded by our own intellectual property depends in large part on our ability to obtain and maintain patents and other intellectual property protection in the United States and in other countries with respect to various proprietary elements of our product candidates, such as, for example, our product formulations and processes for manufacturing our products and our ability to maintain and control the confidentiality of our trade secrets and confidential information critical to our business.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our products that are important to our business. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. There is no guarantee that any patent application we file will result in an issued patent having claims that protect our products; and, as a result, we may not be able to effectively prevent others from commercializing competitive products. Additionally, while the basic requirements for patentability are similar across jurisdictions, each jurisdiction has its own specific requirements for patentability. We cannot guarantee that we will obtain identical or similar patent protection covering our products in all jurisdictions where we file patent applications.

The patent positions of biopharmaceutical companies generally are highly uncertain and involve complex legal and factual questions for which legal principles remain unresolved. As a result, the patent applications that we own or license may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries for many reasons. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, considered or cited during patent prosecution, which can be used to invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patent claims being narrowed, found unenforceable or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competitors from using the technologies claimed in any patents issued to us, which may have an adverse impact on our business.

Patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant and, in addition, may be challenged before national courts at any time.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents and patent applications we hold, license or pursue with respect to our product candidates is threatened, it could threaten our ability to prevent third parties from using the same technologies that we use in our product candidates. In addition, recent changes to the patent laws of the United States provide additional procedures for third parties to challenge the validity of issued patents based on patent applications filed after March 15, 2013. If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to our current or future product candidates is challenged, then it could threaten our ability to prevent competitive products from using our proprietary technology. Further, because patent applications in the United States and most other countries are confidential for a period of time, typically for 18 months after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications. Furthermore, for applications filed before March 16, 2013 or patents issuing from such applications, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. If third parties have filed such applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third parties to determine whether our invention was derived from theirs.

We do not have any issued patents, but we have filed patent applications, which are currently pending, directed to various aspects of our product candidates. We cannot offer any assurances about which, if any, patents will be issued, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened or infringed by third parties. Any successful actions by third parties to challenge the validity or enforceability of any patents that may be issued to us could deprive us of the ability to prevent others from using the technologies claimed in such issued patents.

Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

While our business is based primarily on the timing of our biosimilar product launches to occur after the expiration of relevant patents, we have filed two patent applications directed to our own proprietary formulations and processes for our product candidates when we have believed securing such patents may afford a competitive advantage. For example, the companies that originated Humira and Avastin (AbbVie and Genentech, respectively) own patents directed to formulations for these products. Rather than wait for the expiration of these formulation patents, we have developed our own proprietary formulations for these products that we believe are not covered by valid claims of third party patents, including AbbVie or Genentech's formulation patents; and we have filed patent applications directed to our formulations. We cannot guarantee that our proprietary formulations will avoid infringement of third party patents. Moreover, because competitors may be able to develop their own proprietary product formulations, it is uncertain whether issuance of any of our pending patent applications directed to formulations of adalimumab (Humira) and bevacizumab (Avastin) would cover the formulations of any competitors. For example, we are aware that Sandoz is developing biosimilar versions of adalimumab (Humira) and has filed patent applications directed to formulations of adalimumab (Humira). We are also aware that Boehringer is developing a biosimilar version of adalimumab (Humira) and has filed a patent application directed to formulations of adalimumab (Humira). We have also filed patent applications, none of which have yet issued, directed to aspects of our downstream manufacturing processes for various biosimilars, including ONS-3010. In contrast to our patent applications directed to formulations of ONS-3010, the proprietary technologies embodied in our process-related patent filings, while directed to inventions we believe may provide us with competitive advantage, were not developed by us to avoid third-party patents. As in the case of our formulation patent filings, it is highly uncertain and we cannot predict whether our patent filings on process enhancements will afford us a competitive advantage against third parties.

Obtaining and maintaining our patent protection depends on compliance with various procedural requirements, document submissions, fee payment and other requirements imposed by governmental patent agencies. Our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. In many cases, an

inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, defending and enforcing patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may choose not to file patent applications in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or importing products made using our inventions into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but the ability to enforce our patents is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not being approved, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Governments of some foreign countries may force us to license our patents to third parties on terms that are not commercially reasonable or acceptable to us. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation, including the Leahy-Smith America Invents Act, or the America Invents Act, signed into law on September 16, 2011.

As of March 16, 2013, the United States transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications claiming the same invention are filed by different parties. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. The change to “first-to-file” from “first-to-invent” is one of the changes to the patent laws of the United States resulting from the America Invents Act. Among some of the other significant changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent in the USPTO via procedures including post-grant and inter partes review. These adversarial actions at the USPTO review patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts, and use a lower burden of

proof than used in litigation in U.S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a patent invalidated in a Patent Office post-grant review or inter partes review proceeding than invalidated in a litigation in a U.S. federal court. If any of our patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we or our licensors or collaborators will be successful in defending the patent, which would result in a loss of the challenged patent right. It is not yet clear what, if any, impact the America Invents Act will have on the operation of our business. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any issued patents, all of which could harm our business and financial condition.

Further, recent court rulings in cases such as Association for Molecular Pathology v. Myriad Genetics, Inc. (Myriad I); BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig., (Myriad II); and Promega Corp. v. Life Technologies Corp. have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations.

In addition to increasing uncertainty with regard to our 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 future actions by the United States 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 might obtain in the future.

If we are unable to maintain effective proprietary rights for our product candidates or any future product candidates, we may not be able to compete effectively in our markets.

While we have filed patent applications to protect certain aspects of our own proprietary formulation and process developments, we also rely on trade secret protection and confidentiality agreements to protect proprietary scientific, business and technical information and know-how that is not or may not be patentable or that we elect not to patent. However, confidential information and trade secrets can be difficult to protect. Moreover, the information embodied in our trade secrets and confidential information may be independently and legitimately developed or discovered by third parties without any improper use of or reference to information or trade secrets. We seek to protect the scientific, technical and business information supporting our operations, as well as the confidential information relating specifically to our product candidates by entering into confidentiality agreements with parties to whom we need to disclose our confidential information, such as, our employees, consultants, board members, contractors, potential collaborators and financial investors. However we cannot be certain that such agreements have been entered into with all relevant parties. 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, but it is possible that these security measures could be breached. 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. Our confidential information and trade secrets thus may become known by our competitors in ways we cannot prove or remedy.

Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed. We cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, 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.

Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may harm our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secret. We cannot guarantee that our employees, former employees or consultants will not file patent applications claiming our inventions. Because of the “first-to-file” laws in the United States, such unauthorized patent application filings may defeat our attempts to obtain patents on our own inventions.

We may be subject to claims challenging the inventorship of our patent filings and other intellectual property.

We may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patent applications or patents we may be granted or other intellectual property as an inventor or co-inventor. For example, we may have inventorship or ownership disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of or right to use valuable intellectual property. Such an outcome could harm our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

If we fail to comply with our obligations in the agreements under which we license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are party to a non-exclusive intellectual property license agreement with Selexis SA, or Selexis, pertaining to cell line expression technology, that is important to our business, and we expect to enter into additional license agreements in the future. Our license agreement with Selexis imposes, and we expect that future license agreements will impose, various milestone payments, royalty payments and other obligations on us. If we fail to comply with our obligations under these agreements or if we are subject to a bankruptcy, we may be required to make certain payments to the licensor of our license or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. Additionally, the milestone and other payments associated with these licenses will make it less profitable for us to develop our product candidates.

In the event we breach any of our obligations under these agreements, we may incur significant liability to our licensing partners. Disputes may arise regarding intellectual property subject to a licensing agreement, including but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patents and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates and that could harm our business.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

We currently have rights to certain intellectual property through licenses from third parties, including Selexis, to develop ONS-3010 and ONS-1045. Because we may find that our programs require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license compositions, methods of use, processes or other third party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater

clinical development and commercialization capabilities. 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 third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of that program and our business and financial condition could suffer.

Our ability to market our products in the United States may be significantly delayed or prevented by the BPCIA patent dispute resolution mechanism.

The BPCIA created a new, elaborate and complex patent dispute resolution mechanism for biosimilars that could prevent us from launching our product candidates in the United States or could substantially delay such launches. This mechanism has been referred to as the "patent dance." Uncertainty over how courts will construe the patent dance, for example whether it is the exclusive pathway for litigation involving 351(k) biosimilar applications, may cause our assumptions regarding the scope, timing and expense of patent litigation to be incorrect, and may cause delays in the launch of products subject to such litigation.

Currently, the patent dance is not mandatory, although this may change in the future. The patent dance mandates patent disclosure and briefing requirements that are demanding and time-sensitive. The following is an overview of the patent exchange and patent briefing procedures:

- Disclosure of the Biosimilar Application. Within 20 days after receiving a notice from the FDA that its application has been accepted for review, a 351(k) biosimilar applicant provides a copy of its application information to the RPS. Providing of this information begins the patent dance. If the 351(k) biosimilar applicant chooses not to disclose such information, or opts out of later steps of the patent dance, the RPS may bring an immediate suit for patent infringement that will proceed under the conventional procedural rules for patent infringement actions.
- Identification of Pertinent Patents. Within 60 days of the date of receipt of the application, the RPS must identify the patents owned or controlled by it that it reasonably believes could be asserted against the biosimilar applicant.
- Statement by the Biosimilar Applicant. Following the receipt of the RPS's patent list, the biosimilar applicant must state either that it will not market its product until the relevant patents have expired or alternatively provide its arguments of stating why the patents are invalid, unenforceable or would not be infringed by the proposed biosimilar product candidate. The biosimilar applicant may also provide the RPS with a list of patents it reasonably believes the RPS could assert against the biosimilar product.
- Statement by the RPS. In the event the biosimilar applicant has asserted that the patents are invalid, unenforceable or would not be infringed by the proposed follow-on product, the RPS must provide the biosimilar applicant with a response within 60 days. The response must provide the legal and factual basis of the opinion that such patent will be infringed by the commercial marketing of the proposed biosimilar.
- Patent Resolution Negotiations. If the RPS provides its detailed views that the proposed biosimilar would infringe valid and enforceable patents, then the parties are required to engage in good faith negotiations to identify which of the identified patents will be the subject of a patent infringement action. If the parties agree on the patents to be litigated, the RPS must bring an action for patent infringement within 30 days.
- Simultaneous Exchange of Patents. If those negotiations do not result in an agreement within 15 days, then the biosimilar applicant must notify the RPS of how many patents (but not the identity of those patents) that it wishes to litigate. Within five days, the parties are then required to exchange lists identifying the patents to be litigated. The number of patents identified by the RPS may not exceed the number provided by the biosimilar applicant. However, if the biosimilar applicant previously indicated that no patents should be litigated, then the RPS may identify one patent.

- Commencement of Patent Litigation. The RPS must then commence patent infringement litigation within 30 days. That litigation will involve all of the patents on the RPS's list and all of the patents on the biosimilar applicant's list. The biosimilar applicant must then notify the FDA of the litigation. The FDA must then publish a notice of the litigation in the Federal Register.

- Notice of Commercial Marketing. If the biosimilar applicant opts out of the patent dance, the BPCIA requires the biosimilar applicant to provide notice to the RPS after FDA licensure, and at least 180 days in advance of its first commercial marketing of its proposed follow-on biologic. It is not clear whether the biosimilar applicant must give notice if it complies with the patent dance, but courts may interpret the BPCIA to require such notice. If notice is not given, the RPS may immediately commence a patent infringement action on any patent that was listed (or listable) by the RPS during the dance, but not part of the first wave of patents being litigated. The RPS is allowed to seek a preliminary injunction blocking such marketing based upon any such patents. The litigants are required to "reasonably cooperate to expedite such further discovery as is needed" with respect to the preliminary injunction motion.

Biosimilar companies such as ours have the option of applying for U.S. regulatory approval for our products under either a traditional 351(a) BLA approval route, or under the recently enacted streamlined 351(k) approval route established by the BPCIA. The factors underpinning such a decision are extremely complex and involve, among other things, balancing legal risk (in terms of, e.g., the degree and timing of exposure to potential patent litigation by the RPS) against regulatory risks (in terms of, e.g., the development costs and the differing scope of regulatory approval that may be afforded under 351(a) rather than 351(k)).

A significant legal risk in pursuing regulatory approval under the 351(k) regulatory approval route is that the above-summarized patent exchange process established by the BPCIA could result in the initiation of patent infringement litigation prior to FDA approval of a 351(k) application, and such litigation could result in blocking the market entry of our products. In particular, while the 351(k) route is more attractive to us (rather than 351(a)) for reasons related to development time and costs and the potential broader scope of eventual regulatory approval for our biosimilar product candidates, the countervailing risk in such a regulatory choice is that the complex patent exchange process mandated by the BPCIA could ultimately prevent or substantially delay us from launching our products in the United States.

Preparing for and conducting the patent exchange, briefing and negotiation process outlined above will require extraordinarily sophisticated legal counseling and extensive planning, all under extremely tight deadlines. Moreover, it may be difficult for us to secure such legal support if large, well-funded RPSs have already entered into engagements with highly qualified law firms or if the most highly qualified law firms choose not to represent biosimilar applicants due to their long standing relationships with RPSs.

Furthermore, we could be at a serious disadvantage in this process as an RPS, such as AbbVie (in the case of ONS-3010) or Genentech (in the case of ONS-1045 or ONS-1050), may be able to apply substantially greater legal and financial resources to this process than we could.

Whether courts will view the BPCIA process as the sole avenue for a biosimilar entity and the RPS to identify and potentially litigate such patents remains uncertain, although a Federal Circuit panel has recently held that a biosimilar applicant may opt out of the patent dance. A binding and non-reviewable judicial determination to that effect could increase patent infringement risks for companies, including ours, seeking to introduce biosimilar versions of reference products.

If we file a 351(k) regulatory approval application for one or more of our products, we may consider it necessary or advisable to adopt the strategy of selecting one or more patents of the RPS to litigate in the above described BPCIA process (for example in the third and seventh steps of the process, as outlined above), either to assert our non-infringement of such patents or to challenge their validity; but we may ultimately not be successful in that strategy and could be prevented from marketing the product in the United States.

The complex, untested and uncertain rules of the BPCIA patent provisions, coupled with the inherent uncertainty surrounding the legal interpretation of any RPS patents that might be asserted against us in this new process, may significantly delay or defeat our ability to market our products in the United States.

Risks Related to Our Business Operations

We may not be successful in our efforts to identify, develop or commercialize additional product candidates.

Although a substantial amount of our effort will focus on the continued clinical testing, potential approval and commercialization of our existing product candidates, the success of our business also depends upon our ability to identify, develop and commercialize additional product candidates. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Our development efforts may fail to yield additional product candidates suitable for clinical development and commercialization for a number of reasons, including but not limited to the following:

- we may not be successful in identifying potential product candidates that pass our strict screening criteria;
- we may not be able to overcome technological hurdles to development or a product candidate may not be capable of producing commercial quantities at an acceptable cost, or at all;
- we may not be successful in identifying a reference product as to which we can determine how to create a biosimilar;
- we may not be able to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in preclinical or clinical testing;
- our potential product candidates may fail to show sufficient biosimilarity to reference molecules; and
- competitors may develop alternatives that render our product candidates obsolete or less attractive or the market for a product candidate may change such that a product candidate may not justify further development.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs or we may not be able to identify, develop or commercialize additional product candidates, which would harm our business and could potentially cause us to cease operations.

We expect to incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a newly public company, we expect to incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules subsequently implemented by the Securities and Exchange Commission, or SEC, and the NASDAQ Global Market, or NASDAQ, have imposed various requirements on public companies. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as “say on pay” and pay parity. Recent legislation permits smaller “emerging growth companies” such as us to implement many of these requirements over a longer period and up to five years from the date of pricing of our May 2016 initial public offering. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we will be required to perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report, commencing in our annual report on Form 10-K for the year ending September 30, 2017, on the effectiveness of our internal controls over financial reporting, if then required by Section 404 of the Sarbanes-Oxley Act, or Section 404. Our testing may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group and rely on independent contractors for control monitoring and for the preparation and review of our consolidated financial statements. We are actively seeking additional accounting and financial staff with appropriate public company experience and technical accounting knowledge to augment our current staff. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner or if we identify or our independent registered public accounting firm identifies deficiencies in our internal controls 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.

New laws and regulations as well as changes to existing laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act and rules adopted by the SEC and by NASDAQ, would likely result in increased costs to us as we respond to their requirements.

We are highly dependent on the services of our key executives and personnel, including our Chairman, President and Chief Executive Officer, Pankaj Mohan, Ph.D., and if we are not able to retain these members of our management or recruit additional management, clinical and scientific personnel, our business will suffer.

We are highly dependent on the principal members of our management and scientific and technical staff, particularly, our Chairman, President and Chief Executive Officer, Dr. Mohan. The loss of service of any of our management or key scientific and technical staff could harm our business. In addition, we are dependent on our continued ability to attract, retain and motivate highly qualified additional management, clinical and scientific personnel. If we are not able to retain our management and to attract, on acceptable terms, additional qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow.

We may not be able to attract or retain qualified personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future regulatory approvals, sales of our product candidates and our results of operations. Additionally, we do not currently maintain “key person” life insurance on the lives of our executives or any of our employees.

We will need to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations.

As of September 30, 2016, we had 83 full-time employees. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial, legal and other resources. Our management may need to divert a disproportionate amount of its attention away from our day-to-day operations and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational inefficiencies, loss of business opportunities, loss of employees

and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our current and potential future product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Two members of our board of directors, including our Chief Executive Officer, are directors of Sonnet Biotherapeutics, Inc. In addition, there is significant overlap between our current stockholders and the shareholders of Sonnet. Their interests may conflict with those of our other stockholders.

On April 6, 2015, pursuant to a contribution agreement, we contributed certain of our assets, unrelated to our biosimilar business, to Sonnet Biotherapeutics, Inc., or Sonnet, a company focused on the development of bi- or tri-specific antibody fragments that have potential utility in oncology, in exchange for all of Sonnet's outstanding equity interests. We then distributed the equity interests to our stockholders on a pro rata basis. Two of our current directors, Pankaj Mohan, Ph.D., who is also our Chairman, President and Chief Executive Officer, and Donald J. Griffith, our former Chief Financial Officer, currently serve as members of the board of directors of Sonnet. In addition, Mr. Griffith serves as the President, Chief Executive Officer and Treasurer of Sonnet. Neither Dr. Mohan nor Mr. Griffith intend to resign from their respective positions in Sonnet. In addition, Dr. Mohan currently holds greater than 50% of the outstanding capital stock of Sonnet. These relationships could result in conflicts of interest between their obligations to our company and Sonnet. In addition, there is significant overlap between our current stockholders and the shareholders of Sonnet. Sonnet's interests and the interests of its shareholders may be different from ours or those of our other stockholders and this could result in conflicts. The resolution of any of these conflicts may not always be in our or your best interest.

Healthcare legislative reform measures may harm our business and results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to improve the access to and quality of healthcare, and to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or together, the Affordable Care Act, was passed, which substantially changes the way health care is financed by both governmental and private insurers and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act, among other things, imposes a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, extends the rebate program to individuals enrolled in Medicaid managed care organizations, adds a provision to increase the Medicaid rebate for line extensions or reformulated drugs, establishes annual fees and taxes on manufacturers and importers of certain branded prescription drugs and biologic agents, and promotes a new Medicare Part D coverage gap discount program. The Affordable Care Act also expands eligibility for Medicaid programs and introduced a new Patient Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. There have been judicial and congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future particularly in the light of the pending change in administrations following the 2016 U.S. presidential election.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. For example, on August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2012 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2025 unless additional Congressional action is taken. Additionally, on January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which among other things, further reduced Medicare payments

to certain providers, including physicians, hospitals and cancer treatment centers. In addition, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

We expect that the Affordable Care Act, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms could result in reduced demand for our product candidates or additional pricing pressures, and may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

We may be subject, directly or indirectly, to federal and state healthcare laws and regulations, including fraud and abuse, false claims, physician payment transparency and health information privacy and security laws. If we are unable to comply or have not fully complied with such laws, we could face substantial penalties.

Our operations may be directly or indirectly through our customers subject to various federal and state fraud and abuse laws, including without limitation, the federal Anti-Kickback Statute, the federal False Claims Act and physician sunshine laws and regulations. These laws may impact, among other things, our clinical research, proposed sales, marketing and education programs. In addition, we may be subject to patient data privacy and security regulation by both the federal government and the states in which we conduct our business. The healthcare laws that may affect our ability to operate include but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce, reward, or in return for either the referral of an individual for, or the purchase, recommendation, order or furnishing of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting or causing to be presented claims for payment from Medicare, Medicaid or other government health programs that are false or fraudulent and which may apply to entities that provide coding and billing advice to customers;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, which imposes certain requirements, including mandatory contractual terms, relating to the privacy, security and transmission of individually identifiable health information on health plans, certain healthcare providers, and healthcare clearinghouses, and their business associates;
- the federal legislation commonly referred to as the Physician Payments Sunshine Act under the Affordable Care Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value made by such manufacturers to physicians and teaching hospitals and ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations; and

- analogous state and foreign laws and regulations, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent healthcare reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to commit a violation. Moreover, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources.

Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

The international aspects of our business expose us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

We currently have limited international operations of our own and have a number of international collaborations. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us or our collaboration partners to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations by us or our collaboration partners;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems by our collaboration partners;
- limits in our or our collaboration partners' ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;

- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its books and records provisions or its anti-bribery provisions.

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 harm our business.

Our research, development and manufacturing activities and our third-party suppliers' activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research, development and manufacturing efforts and business operations, and environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by us for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

Risks Related to Ownership of Our Securities

The trading price of our securities is likely to be volatile, and purchasers of our securities could incur substantial losses.

The market price of our securities is likely to be volatile. The stock market in general and the market in which we operate have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their securities at a profit. The market price of our securities could be subject to wide fluctuations in response to a variety of factors, including but not limited to:

- the success of competitive products or technologies;
- adverse results or delays in preclinical or clinical trials;
- any inability to obtain additional funding;
- any delay in filing an IND, BLA or other regulatory submission for any of our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory agency's review of that IND, BLA or other regulatory submission;
- the perception of limited market sizes or pricing for our product candidates;
- failure to successfully develop and commercialize our product candidates;
- post-marketing safety issues relating to our product candidates or biosimilars generally;
- failure to maintain our existing strategic collaborations or enter into new collaborations;
- failure by us or our licensors and strategic collaboration partners to prosecute, maintain or enforce our intellectual property rights;

- changes in laws or regulations applicable to our products;
- any inability to obtain adequate product supply for our product candidates or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products, services or technologies by our competitors, including biosimilars, interchangeable biosimilars, and biobetter versions of the same molecules we are targeting;
- failure to meet or exceed financial projections we may provide to the public;
- failure to meet or exceed the financial projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us, our strategic collaboration partners or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including stockholder litigation and litigation filed by us or filed against us pertaining to patent infringement or other violations of intellectual property rights;
- the outcomes of any citizens petitions filed by parties seeking to restrict or limit the approval of biosimilar products;
- if securities or industry analysts do not publish research or reports about our business or if they issue an adverse or misleading opinion regarding our stock;
- changes in the market valuations of similar companies;
- general economic, industry or market conditions;
- sales of our securities by us or our stockholders in the future;
- trading volume of our securities;
- issuance of patents to third parties that could prevent our ability to commercialize our product candidates;
- reductions in the prices of reference products that could reduce the overall market opportunity for our product candidates intended as biosimilars to such reference products;
- the loss of one or more employees constituting our leadership team;
- changes in biosimilar regulatory requirements that could make it more difficult for us to develop our product candidates; and
- the other factors described in this “Risk Factors” section.

In addition, biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our securities, regardless of our actual operating performance.

Our principal stockholders and management own a significant percentage of our stock and are able to exert significant control over matters subject to stockholder approval, preventing new investors from influencing significant corporate decisions.

As of September 30, 2016, our executive officers, directors and 5% stockholders and their affiliates beneficially owned approximately 47.5% of our outstanding voting stock. The interests of this group of securityholders may not coincide with the interests of other securityholders. These securityholders have the ability to influence us through their ownership positions, which may prevent or discourage unsolicited acquisition proposals or offers for our capital stock that you may believe are in your best interest as one of our securityholders.

Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

Our quarterly operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are out of our control and may be difficult to predict, including but not limited to:

- our ability to successfully develop, market and sell ONS-3010, ONS-1045, ONS-1050 and our other product candidates;
- the cost of clinical development for ONS-3010, ONS-1045 and ONS-1050;
- the success of competitive products or technologies;
- results of clinical trials of our product candidates or those of our competitors;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, manufacture, acquire or in-license additional product candidates;
- 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;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

If our quarterly operating results fall below the expectations of investors or securities analysts, the market price of our securities could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our securities to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

If securities or industry analysts do not publish research, or publish unfavorable research, about our business, the market price of our securities and trading volume could decline.

The trading market for our securities will depend in part on the research and reports that securities or industry analysts publish about us or our business, our market and our competitors. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our securities or change their opinion of our securities, the market price of our securities would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause the market price of our securities or trading volume to decline.

We are an “emerging growth company” and, due to the reduced reporting requirements applicable to emerging growth companies, certain investors may find investing in our securities less attractive.

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden

parachute payments not previously approved. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds $700 million as of March 31 (the end of our second fiscal quarter) of any fiscal year before that time or if we have total annual gross revenue of $1.0 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following September 30 (the last day of our fiscal year) or, if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, we would cease to be an emerging growth company immediately. We cannot predict if investors will find our securities less attractive because we may rely on this exemption. If some investors find our securities less attractive as a result, there may be a less active trading market for our securities and the market price of our securities may be more volatile.

We have and will continue to incur significant costs and demands upon management as a result of complying with the laws and regulations affecting public companies in the United States, which may harm our operating results.

As a public company listed in the United States, we have and will continue to incur significant additional legal, accounting and other expenses. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and NASDAQ, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If, notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us, and our business may be harmed.

Further, failure to comply with these laws, regulations and standards might also make it more difficult for us to obtain certain types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

Due to the speculative nature of warrants, there is no guarantee that it will ever be profitable for holders of the Series A warrants and Series B warrants to exercise such warrants.

The Series A warrants and Series B warrants represent the right to acquire shares of our common stock at a fixed price for a limited period of time. If not exercised prior to their expiration dates, such warrants expire and have no further value. In the event the price of a share of our common stock price does not exceed the exercise price of the warrants, such warrants may not have any value. Moreover, the market value of the warrants is uncertain and there can be no assurance that the market value of the warrants will equal or exceed their initial public offering price. There can be no assurance that the market price of our common stock will ever equal or exceed the exercise price of the warrants, and, consequently, whether it will ever be profitable for holders of the Series A and Series B warrants to exercise such warrants.

Future sales and issuances of our common stock or rights to purchase securities, including pursuant to our equity incentive plans or exercise of warrants, could result in additional dilution of the percentage ownership of our stockholders and could cause the market price of our securities to fall.

We will need additional capital in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to the 2015 Equity Incentive Plan, or the 2015 Plan, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. Under the 2015 Plan, the number of shares of our common stock reserved for issuance as of September 30, 2016 was 1,930,460 shares. The number of shares available for future grant under the 2015 Plan will be increased by (i) the number of shares pursuant to outstanding awards under the 2015 Plan that are forfeited or lapse unexercised and which following the effective date are not issued under the 2015 Plan and (ii) an annual increase on January 1 beginning in 2017 and ending in 2025, equal to 3% of the shares of stock outstanding as of December 31st of the immediately preceding year, or such smaller number of shares as determined by our board of directors. Pursuant to the 2016 Employee Stock Purchase Plan, or the ESPP, which became effective upon the execution of the underwriting agreement related to our initial public offering, upon implementation of an offering under the ESPP, eligible employees will be able to acquire shares of our common stock at a discount to the prevailing market price, and an aggregate of 289,855 shares were available for issuance under the ESPP as of September 30, 2016. The number of shares available for issuance under the ESPP will automatically increase on the first day of each fiscal year beginning in 2016 and ending in 2025, equal to the lesser of (i) 1% of the shares of common stock outstanding on December 31st of the immediately preceding calendar year, (ii) 510,145 shares of common stock, subject to adjustments as provided in the ESPP or (iii) such smaller number of shares as determined by our board of directors. If our board of directors does not elect to reduce the annual increases in the number of shares available for future grant under the 2015 Plan or the ESPP, our stockholders may experience additional dilution, which could cause the market price of our securities to fall.

As of September 30, 2016, we had outstanding warrants to acquire an aggregate of 1,520,268 shares of our common stock, which have an initial exercise price of $0.01 per share, which may increase to $1.00 per share under certain circumstances. Issuance of shares of common stock upon exercise of these warrants may result in additional dilution to investors. We also had outstanding 3,333,333 Series A warrants, which have an exercise price of $6.60 per share and 3,333,333 Series B warrants, which have an exercise price of $8.50 per share, each as of September 30, 2016. We also have outstanding warrants to acquire an aggregate of 1,920,500 shares of our common stock at $3.00 per share, which have a term of five years, which we issued in December 2016. We may issue up to an additional 379,500 of these warrants under the terms of our December 2016 note and warrant purchase agreement.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We may have experienced ownership changes in the past and may experience ownership changes in the future as a result of subsequent shifts in our stock ownership (some of which shifts are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income will be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows.

We do not intend to pay dividends on our capital stock, and as such any returns will be limited to the value of our securities.

We have never declared or paid any cash dividends on our capital stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to securityholders will therefore be limited to the appreciation of their securities. In addition, our senior secured notes issued in December 2016 restrict our ability to pay dividends.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our securityholders or remove our current management.

Our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law contain provisions that may have the effect of delaying or preventing a change in control of us or changes in our management. Our charter documents also contain other provisions that could have an anti-takeover effect, such as:

- establishing a classified board of directors so that not all members of our board of directors are elected at one time;
- permitting the board of directors to establish the number of directors and fill any vacancies and newly created directorships;
- providing that directors may only be removed for cause;
- prohibiting cumulative voting for directors;
- requiring super-majority voting to amend some provisions in our amended and restated certificate of incorporation and amended and restated bylaws;
- authorizing the issuance of "blank check" preferred stock that our board of directors could use to implement a stockholder rights plan;
- eliminating the ability of stockholders to call special meetings of stockholders; and
- prohibiting stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders.

These provisions, alone or together, could delay, deter or prevent hostile takeovers and changes in control or changes in our management.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us.

Any provision of our amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our securityholders to receive a premium for their securities and could also affect the price that some investors are willing to pay for our securities.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. If a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business and financial condition.

If we fail to develop and maintain proper and effective internal controls over financial reporting, the accuracy and timeliness of our financial reporting may be adversely affected.

We will be required, pursuant to Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for our fiscal year ending September 30,

2017. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. Our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting until our first annual report required to be filed with the SEC following the later of the date we are deemed to be an "accelerated filer" or a "large accelerated filer," each as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act, or the date we are no longer an "emerging growth company," as defined in the JOBS Act. We will be required to disclose changes made in our internal control and procedures on a quarterly basis. To comply with the requirements of being a public company, we may need to undertake various actions, such as implementing new internal controls and procedures and hiring accounting or internal audit staff. We are beginning the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404, and we may not be able to complete our evaluation, testing and any required remediation in a timely fashion.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our headquarters are located in Cranbury, New Jersey where we occupy approximately 48,000 square feet of office and laboratory space under a lease that expires in June 2021. Additionally, we entered into a lease for approximately 82,000 square feet of office and laboratory space in Cranbury, New Jersey, with lease payments that commenced in March 2016 and expire in March 2026.

We believe that our existing facilities are adequate for our current needs. When our leases expire, or if we need to hire more employees, we may exercise our renewal option or look for additional or alternate space for our operations and we believe that suitable additional or alternative space will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings

From time to time, we may become involved in litigation relating to claims arising from the ordinary course of business. Our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which would have a material adverse effect on our results of operations, financial condition or cash flows.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

Our units, which comprised one share of our common stock, one-half of a Series A warrant and one-half of a Series B warrant began trading under the symbol "ONSIU" on the NASDAQ Global Market on May 13, 2016 in connection with our initial public offering. Following separation of the units, on June 13, 2016, our shares of common stock and the Series A warrants and Series B warrants began trading under the symbols "ONS," "ONSIW" and "ONSIZ," respectively, and our units were delisted. Prior to our initial public offering, there was no public market for our securities. The high and low closing sales price of our common stock for the period from June 13, 2016 to June 30, 2016 was $4.48 and $3.25, respectively. The high and low closing sales price of our common stock for the period from July 1, 2016 to September 30, 2016 was $5.49 and $3.04, respectively.

On December 28, 2016, the closing sale price of our common stock was $2.34.

Common Stockholders

As of December 28, 2016, there were approximately 97 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock and do not anticipate paying any cash dividends in the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant. Our outstanding senior secured notes issued in December 2016 restrict our ability to pay dividends.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this Item regarding equity compensation plans is incorporated by reference to the information set forth in Item 12 of this Annual Report on Form 10-K.

Use of Proceeds

On May 12, 2016, the Registration Statement on Form S-1 (File No. 333-204091) for our initial public offering of units was declared effective by the SEC, pursuant to which we sold an aggregate 5.8 million units at a public offering price of $6.00 per unit for aggregate gross proceeds of $35.0 million. Jefferies LLC and Barclays Capital Inc. acted as joint book-running managers for the offering, and Cantor Fitzgerald & Co. acted as the lead manager. We received net proceeds from the IPO of approximately $29.2 million, after deducting approximately $5.8 million of underwriting discounts, commissions and offering expenses paid by us. None of these expenses consisted of payments made by us to directors, officers or persons owning 10% or more of our common stock or to their associates, or to our affiliates. There has been no material change in the planned use of proceeds from our initial public offering as described in our prospectus dated May 12, 2016 filed with the SEC on May 13, 2016 pursuant to Rule 424(b)(4).

Recent Sales of Unregistered Equity Securities

None.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during fiscal year ended September 30, 2016.

Item 6. Selected Financial Data

Not applicable.

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

The following discussion should be read in conjunction with the consolidated financial statements and notes thereto included elsewhere in this Annual Report on Form 10-K. This Annual Report on Form 10-K, including the following sections, contains forward-looking statements within the meaning of the federal securities laws. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those expressed or implied by such forward-looking statements. For a detailed discussion of these risks and uncertainties, see the "Risk Factors" section in Item 1A of this Annual Report on Form 10-K. We caution the reader not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Form 10-K. We undertake no obligation to update forward-looking statements, which reflect events or circumstances occurring after the date of this Form 10-K.

Overview

We are a clinical-stage biopharmaceutical company focused on identifying, developing, manufacturing and commercializing complex biosimilar therapeutics. Our current focus is on technically challenging and commercially attractive monoclonal antibodies, or mAbs, in the disease areas of immunology and oncology. A mAb is a type of protein that is produced by a single clone of cells or cell line and made to bind to a specific substance in the body. Our strategy is to cost-effectively develop these biosimilars on an accelerated timeline, which is fundamental to our success and we believe positions us to be a leading biosimilar company. We have leveraged our team's biopharmaceutical expertise to establish fully integrated in-house development and manufacturing capabilities, which we refer to as our BioSymphony Platform. We believe this platform addresses the numerous complex technical and regulatory challenges in developing and commercializing mAb biosimilars and was designed to provide significant pricing flexibility. We have identified eight biosimilar product candidates for further development and have advanced two of these product candidates through Phase 1 clinical trials and into preparations for Phase 3 clinical trials: ONS-3010, a biosimilar to adalimumab (Humira®), and ONS-1045, a biosimilar to bevacizumab (Avastin®).

- **ONS-3010.** We have successfully completed a randomized, double-blind, single-dose and single-center Phase 1 clinical trial comparing ONS-3010 to Humira in three treatment arms. In this trial, ONS-3010 met its primary and secondary endpoints, demonstrating a similar pharmacokinetic (meaning how the body affects the molecule), or PK, profile, as well as an immunogenicity profile equivalent to both U.S.- and E.U.-Humira across all three treatment arms. In addition, ONS-3010 demonstrated a rate of injection site reactions lower than that of Humira. We have received regulatory feedback and agreement on our Phase 3 clinical trial design in the sensitive plaque psoriasis patient population from the U.S. Food and Drug Administration, or FDA, the European Medical Agency, or EMA, and national agencies such as the Medicines and Healthcare Products Regulatory Agency, or MHRA, and the Swedish regulatory authority. We have also completed a site feasibility study to identify global sites (North and South America, Europe, Australia and New Zealand) in preparation for the commencement of our planned Phase 3 clinical trial in 2016. Humira is currently approved in the United States for multiple indications. We initially intend to seek approval of ONS-3010 for the treatment of plaque psoriasis, and will seek to expand such approval to the same indications as Humira as appropriate. We have informed the regulatory authorities of our intent to seek extrapolation to all approved Humira indications, and have also reviewed our Phase 3 interchangeability study design with the FDA.
- **ONS-1045.** We have completed a randomized, double-blind, single-dose and single-center Phase 1 clinical trial. In this trial, ONS-1045 met its primary and secondary endpoints demonstrating a similar PK profile, as well as an immunogenicity profile equivalent to both U.S.- and EU-Avastin. We are preparing ONS-1045 for a global Phase 3 clinical trial to commence upon receipt of additional funding. Avastin is currently approved in the United States for multiple indications. We initially intend to seek approval of ONS-1045 for the treatment of non-squamous non-small cell lung cancer, and will seek to expand such approval to the same indications as Avastin when appropriate. We have informed the regulatory authorities of our intent to seek extrapolation to all approved Avastin indications, and have also discussed our study design with the FDA.

Through September 30, 2016, we have funded substantially all of our operations through the sale and issuance of $139.5 million net proceeds of our common stock, preferred stock and debt. Through

September 30, 2016, we have also received $24.0 million pursuant to our collaboration and licensing agreements. On May 18, 2016 we completed the initial public offering, or IPO, of our securities, through the sale of units. Each unit consisted of one share of common stock, one-half of a Series A warrant and one-half of a Series B warrant. Each whole Series A warrant entitles the holder to purchase one share of common stock at an initial exercise price of $6.60, subject to adjustment. Each whole Series B warrant entitles the holder to purchase one share of common stock at an initial exercise price of $8.50, subject to adjustment. The initial public offering price was $6.00 per unit. We also completed a private placement of 833,332 shares of common stock, 416,666 Series A warrants and 416,666 Series B warrants for aggregate gross proceeds of approximately $5.0 million that closed concurrent with the IPO. The units separated in accordance with their terms, and ceased trading, and on June 13, 2016, each of the component securities underlying the units (common stock, Series A warrants and Series B warrants) began trading on the NASDAQ Global Market. We raised net proceeds of approximately $29.2 million from our IPO and an additional $4.6 million of net proceeds from the concurrent private placement, in each case excluding any proceeds we may receive from the exercise of the Series A and Series B warrants. In addition, in October, November and December 2016 we issued an aggregate of $1.85 million of unsecured promissory notes, which notes were exchanged for new senior secured promissory notes and warrants in December 2016 concurrent with the issuance of $6.5 million aggregate principal amount of new senior secured promissory notes and warrants for cash.

As described in their audit report included elsewhere in this Annual Report on Form 10-K, our auditors have included an explanatory paragraph that states that we have incurred recurring losses and negative cash flows from operations since inception and have an accumulated deficit at September 30, 2016 of $147.4 million and $4.6 million of indebtedness that is due on demand. We will need to raise substantial additional capital to fund our planned future operations, commence Phase 3 clinical trials, receive approval for and commercialize ONS-3010 and ONS-1045 and continue to develop our other pipeline candidates. We plan to finance our future operations with a combination of proceeds from the issuance of equity securities, the issuance of additional debt, potential collaborations and revenues from potential future product sales, if any. There are no assurances that we will be successful in obtaining an adequate level of financing for the development and commercialization of ONS-3010, ONS-1045 or any other current or future biosimilar product candidates. If we are unable to secure adequate additional funding, our business, operating results, financial condition and cash flows may be materially and adversely affected. These matters raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

Our current cash resources of $2.4 million as of September 30, 2016 and the proceeds from our October, November and December 2016 note and warrant issuances are expected to fund our operations through February 2017. To provide additional working capital, we continue to engage in active discussions with global and regional pharmaceutical companies for licensing and/or co-development rights to our late- and early-stage pipeline product candidates. While we expect to finalize one or more of these transactions in early 2017, there is no guarantee that we will be able to do so. If we are not successful in raising additional capital or entering into one or more licensing and/or co-development rights agreements, we will be required to scale back our plans and place certain activities on hold.

We do not have any products approved for sale and we have only generated revenue from our collaboration agreements. We have incurred operating losses and negative operating cash flows since inception and there is no assurance that we will ever achieve profitable operations, and if achieved, that profitable operations will be sustained. Our net loss for the year ended September 30, 2016 was $53.3 million. We also had a net loss of $47.4 million for the year ended September 30, 2015. In addition, development activities, clinical and preclinical testing and commercialization of our product candidates will require significant additional financing.

Collaboration and License Agreements

From time to time, we enter into collaboration and license agreements for the research and development, manufacture and/or commercialization of our biosimilar products and/or biosimilar product candidates. These agreements generally provide for non-refundable upfront license fees, development and commercial performance milestone payments, cost sharing, royalty payments and/or profit sharing.

Selexis SA

In October 2011, we entered into a research license agreement with Selexis SA, or Selexis, pursuant to which we acquired a non-exclusive license to conduct research internally or in collaboration with third parties to develop recombinant proteins from mammalian cells created lines using the Selexis expression technology, or the Selexis Technology. The original research license had a three-year term, but on October 9, 2014, was extended for an additional three-year term through October 9, 2017. We may sublicense our rights with Selexis' prior written consent but are prohibited from making commercial use of the Selexis Technology or the resultant recombinant proteins comprising our biosimilars in humans, or from filing an investigational new drug, absent a commercial license agreement with Selexis covering the particular biosimilar product candidate developed under the research license. In connection with the entry into the research license, we paid Selexis an initial fee and agreed to make additional annual maintenance payments of the same amount for each of the three years that the research license agreement term was extended.

Selexis also granted us a non-transferrable option to obtain a perpetual, non-exclusive, worldwide commercial license under the Selexis Technology to manufacture, or have manufactured, a recombinant protein produced by a cell line developed using the Selexis Technology for clinical testing and commercial sale. We exercised this option in April 2013 and entered into three commercial license agreements with Selexis for our ONS-3010, ONS-1045 and ONS-1050 biosimilar candidates. We paid an upfront licensing fee to Selexis for each commercial license and also agreed to pay a fixed milestone payment for each licensed product. In addition, we are required to pay a single-digit royalty on a final product-by-final product and country-by-country basis, based on worldwide net sales of such final products by us or any of our affiliates or sub-licensees during the royalty term. At any time during the term, we have the right to terminate our royalty payment obligation by providing written notice to Selexis and paying Selexis a royalty termination fee.

IPCA Laboratories Limited — Humira (ONS-3010), Avastin (ONS-1045) and Herceptin (ONS-1050)

In August 2013, we entered into a strategic license agreement with IPCA Laboratories Limited, or IPCA, under which we granted IPCA and its affiliates a license for the research, development, manufacture, use or sale of ONS-3010 and, by amendment in May 2014, ONS-1045. The license is exclusive with respect to India, Sri Lanka and Myanmar, and non-exclusive with respect to Nepal and Bhutan. Under the terms of the August 2013 agreement, we received an upfront payment from IPCA, and are eligible to earn additional regulatory milestone payments for each of ONS-3010 and ONS-1045. In addition, we are eligible to receive royalties at a low teens percentage rate of annual net sales of products by IPCA and its affiliates in the agreed territory.

In January 2014, we entered into an agreement with IPCA to assist IPCA in establishing its research, development and manufacturing capabilities for mAbs and biologics, including, in part, through collaborative development, manufacture and commercialization of ONS-1050 (our Herceptin biosimilar), in the agreed territory (as specified below). The agreed territory for ONS-1050 includes the Republics of India, Sri Lanka, Myanmar, Nepal and Bhutan, while the agreed territory for any product candidates developed independent of our involvement is global without geographical restriction. We also agreed to assist IPCA with its research and development program. Under the terms of the January 2014 agreement, we are eligible to receive development payments and commercialization fees. In addition, we are eligible to receive royalties from IPCA at a mid-single digit rate on annual net sales of ONS-1050 commercialized by IPCA and its affiliates in the agreed territory.

As of September 30, 2016, we have received an aggregate of $5.0 million of payments from IPCA under our various agreements.

Liomont — Humira (ONS-3010) and Avastin (ONS-1045)

In June 2014, we entered into a strategic license agreement with Laboratories Liomont, S.A. de C.V., or Liomont, under which we granted Liomont and its affiliates an exclusive, sublicenseable license in Mexico for the research, development, manufacture, use or sale of the ONS-3010 and ONS-1045 biosimilar product candidates in Mexico. Under the terms of the agreement, we received an upfront payment from Liomont, and we are eligible to earn milestone payments for each of ONS-3010 and ONS-1045. In addition, we are

eligible to receive tiered royalties at upper single-digit to low teens percentage rates of annual net sales of products by Liomont and its affiliates in Mexico. As of September 30, 2016, we have received an aggregate of $3.0 million of upfront and milestone payments from Liomont.

Huahai — Humira (ONS-3010) and Avastin (ONS-1045)

In May 2013, we entered into a series of agreements with Zhejiang Huahai Pharmaceutical Co., Ltd., or Huahai, to form an alliance for the purpose of developing and obtaining regulatory approval for, and commercial launch and marketing of licensed products in an agreed territory, as described below. The agreements include a strategic alliance agreement, which sets out the governance framework for the relationship, along with a joint participation agreement regarding joint development and commercialization of ONS-3010, and a co-development and license agreement for each of ONS-3010 and ONS-1045. As of September 30, 2016, we have received an aggregate of $16.0 million of upfront and milestone payments from Huahai.

As contemplated by the strategic alliance agreement, we entered into a joint participation agreement with Huahai where we agreed to co-fund the development and share the value ownership interest of ONS-3010 in the United States, Canada, European Union, Japan, Australia and New Zealand. Under the agreement as amended, we are responsible for completing a defined "Phase-3 Ready Package" at our expense, for which the portion of the funds received from Huahai to date under this joint participation agreement was used.

In December 2014, we received an option to reacquire all rights to ONS-3010 from Huahai, which would have terminated the joint participation agreement. We had to exercise the option prior to December 23, 2015 and pay Huahai a total of $28.0 million, consisting of an $11.0 million initial payment due within seven days of exercise, and four additional installment payments of $4.25 million payable over the course of the following year. We did not make the $11.0 million initial payment within the time frame required.

In the event Huahai funds its proportionate share of development costs incurred after completion of the "Phase-3 Ready Packages," Huahai would be entitled to retain its 51% value ownership, with us entitled to retain our 49% value ownership, of ONS-3010 in the agreed territories. To maintain its 51% value ownership of ONS-3010 as of September 30, 2016, Huahai is required to make a payment to us of approximately $13.0 million. Similarly, revenues from commercialization of ONS-3010 in the agreed countries (including major markets such as the United States and the European Union, or EU, among others), would also be shared based on such proportional ownership interests. In the event that Huahai does not fund its proportionate share of such development costs, the joint participation agreement provides for a proportionate adjustment to our respective value ownership interests based on our respective investments in such development costs, which would increase our value ownership interest in ONS-3010. Under the joint participation agreement, we could also be required to form a joint venture to further develop and commercialize ONS-3010 with Huahai in the agreed countries, if so requested by Huahai.

In conjunction with the strategic alliance agreement, we also entered into a co-development and license agreement with Huahai, under which we granted Huahai and its affiliates an exclusive license, in the territory (as specified below) for the research, development, manufacture, use or sale of ONS-3010 or ONS-1045 in China, including, the People's Republic of China, Hong Kong, Macau and Taiwan. We will each bear our respective costs under the development plans. Huahai agreed to carry out all clinical, manufacturing and regulatory requirements necessary for approval of the products in the agreed territory. Under the terms of the agreement, we received an upfront payment from Huahai for ONS-3010, and have received regulatory milestone payments for each of ONS-3010 and ONS-1045.

Components of Our Results of Operations

Collaboration Revenue

To date, we have derived revenue only from activities pursuant to our collaboration and licensing agreements. We have not generated any revenue from commercial product sales. For the foreseeable future, we expect all of our revenue, if any, will be generated from our collaboration and licensing agreements. If any of our biosimilar product candidates currently under development are approved for commercial sale, we may generate revenue from product sales, or alternatively, we may choose to select a collaborator to commercialize our product candidates.

The following table sets forth a summary of revenue recognized from our collaboration and licensing agreements for the years ended September 30, 2016 and 2015:

	Year ended September 30,	
	2016	2015
IPCA collaboration	$ 421,732	$1,702,377
Liomont collaboration	1,382,264	341,280
Huahai collaboration	1,175,580	3,175,580
	$2,979,576	$5,219,237

The following table summarizes the milestone payments and recognition of deferred revenues from our collaboration and licensing agreements during the years ended September 30, 2016 and 2015:

	Year ended September 30,	
	2016	2015
Milestone payments	$1,000,000	$2,500,000
Recognition of deferred revenues	1,979,576	1,919,237
Research and development payments	—	800,000
	$2,979,576	$5,219,237

Each of our collaboration and licensing agreements is considered to be a multiple-element arrangement for accounting purposes. We determined that there are two deliverables; specifically, the license to our biosimilar product candidate and the related research and development services that we are obligated to provide. We concluded that these deliverables should be accounted for as a single unit of accounting. We determined that the upfront license payments received should be deferred and recognized as revenue on a straight-line basis through the estimated period of completion of our obligations under the agreement. We recognize revenues from the achievement of milestones if the milestone event is substantive and achievability of the milestone was not reasonably assured at the inception of the agreement.

Research and Development Expenses

Research and development expense consists of expenses incurred in connection with the discovery and development of our biosimilar product candidates. We expense research and development costs as incurred. These expenses include:

- expenses incurred under agreements with contract research organizations, or CROs, as well as investigative sites and consultants that conduct our preclinical studies and clinical trials;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial materials and commercial materials, including manufacturing validation batches;
- outsourced professional scientific development services;
- employee-related expenses, which include salaries, benefits and stock-based compensation;
- payments made under a third-party assignment agreement, under which we acquired intellectual property;
- expenses relating to regulatory activities, including filing fees paid to regulatory agencies;
- laboratory materials and supplies used to support our research activities; and
- allocated expenses, utilities and other facility-related costs.

The successful development of our biosimilar product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of, or when, if ever, material net cash inflows may commence from any of our other biosimilar product candidates. This uncertainty is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of many factors, including:

- the number of clinical sites included in the trials;
- the length of time required to enroll suitable patients
- the number of patients that ultimately participate in the trials;
- the number of doses patients receive;
- the duration of patient follow-up;
- the results of our clinical trials;
- the establishment of commercial manufacturing capabilities;
- the receipt of marketing approvals; and
- the commercialization of product candidates.

Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals. We may never succeed in achieving regulatory approval for any of our biosimilar product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some biosimilar product candidates or focus on others. A change in the outcome of any of these variables with respect to the development of a biosimilar product candidate could mean a significant change in the costs and timing associated with the development of that biosimilar product candidate. For example, if the U.S. Food and Drug Administration, or FDA, or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Biosimilar product commercialization will take several years and millions of dollars in development costs.

Research and development activities are central to our business model. Biosimilar product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase significantly over the next several years as we increase personnel costs, including stock-based compensation, conduct clinical trials and prepare regulatory filings for our biosimilar product candidates.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, administrative, finance and legal functions, including stock-based compensation, travel expenses and recruiting expenses. Other general and administrative expenses include facility related costs, patent filing and prosecution costs and professional fees for business development, legal, auditing and tax services and insurance costs.

We anticipate that our general and administrative expenses will increase as a result of increased payroll, expanded infrastructure and an increase in accounting, consulting, legal and tax-related services associated with maintaining compliance with stock exchange listing and SEC requirements, investor relations costs, and director and officer insurance premiums associated with being a public company. We also anticipate that our general and administrative expenses will increase in support of our clinical trials as we expand and progress our development programs. Additionally, if and when we believe a regulatory approval of a biosimilar product candidate appears likely, we anticipate an increase in payroll and expense as a result of our preparation for commercial operations, particularly as it relates to the sales and marketing of our biosimilar product.

Interest Expense

Interest expense consists of cash paid and non-cash interest expense related to our bank loans, notes with current and former stockholders, equipment loans and capital lease obligations.

Income Taxes

During the year ended September 30, 2015, we sold New Jersey state net operating losses, or NOLs, and research credits of $4.8 million resulting in the recognition of an income tax benefit of $0.7 million. In addition, during the years ended September 30, 2016 and 2015, we incurred $0.1 million and $0.5 million, respectively, of foreign withholding taxes in connection with our collaboration and licensing agreements.

Since inception, we have not recorded any U.S. federal or state income tax benefits (excluding the sale of New Jersey state NOLs and research credits) for the net losses we have incurred in each year or on our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. As of September 30, 2016, we had federal and state NOL carryforwards of $99.8 million and $37.0 million, respectively, which will begin to expire in 2030 and 2036, respectively. As of September 30, 2016, we had federal foreign tax credit carryforwards of $2.3 million available to reduce future tax liabilities, which begin to expire starting in 2023. As of September 30, 2016, we also had federal research and development tax credit carryforwards of $0.8 million which begin to expire in 2032.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its NOLs to offset future taxable income. We have not completed a study to assess whether an ownership change has occurred in the past. Our existing NOLs may be subject to limitations arising from previous ownership changes and our IPO, and our ability to utilize NOLs could be further limited by Section 382 of the Code. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Code. Our NOLs are also subject to international regulations, which could restrict our ability to utilize our NOLs. Furthermore, our ability to utilize NOLs of companies that we may acquire in the future may be subject to limitations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

Results of Operations

Comparison of Years Ended September 30, 2016 and 2015

	Year ended September 30,		
	2016	2015	Change
Collaboration revenues	$ 2,979,576	$ 5,219,237	$(2,239,661)
Operating expenses:			
Research and development	33,101,543	38,876,040	(5,774,497)
General and administrative	21,636,345	12,905,823	8,730,522
	54,737,888	51,781,863	2,956,025
Loss from operations	(51,758,312)	(46,562,626)	(5,195,686)
Interest expense	1,467,950	2,297,339	(829,389)
Loss before income taxes	(53,226,262)	(48,859,965)	(4,366,297)
Income tax expense (benefit)	103,000	(190,111)	293,111
Net loss	$(53,329,262)	$(48,669,854)	$(4,659,408)

Collaboration Revenues

Collaboration revenues decreased $2.2 million for the year ended September 30, 2016 compared to the year ended September 30, 2015 due to a $1.5 million reduction in milestone payments and a $0.8 million reduction in research and development payments received in 2016.

Research and Development Expenses

The following table summarizes our research and development expenses by functional area for the year ended September 30, 2016 and 2015:

	Year ended September 30,	
	2016	2015
Preclinical and clinical development	$14,820,730	$21,469,678
Compensation and related benefits	9,214,216	6,576,810
Stock-based compensation	2,044,379	5,817,830
Other research and development	7,022,218	5,011,722
Total research and development expenses	$33,101,543	$38,876,040

The following table summarizes our research and development expenses by compound for the year ended September 30, 2016 and 2015:

	Year ended September 30,	
	2016	2015
ONS-3010	$10,124,418	$ 7,894,315
ONS-1045	4,088,686	12,763,886
Early-stage compounds	607,626	811,477
Personnel related and stock-based compensation	11,258,595	12,394,640
Other research and development	7,022,218	5,011,722
Total research and development expenses	$33,101,543	$38,876,040

Research and development expenses for the year ended September 30, 2016 decreased by $5.8 million compared to the year ended September 30, 2015, primarily due to a reduction of approximately $8.7 million in expenses related to our ONS-1045 program as we postponed the planned Phase 3 clinical trial until we secure a licensing or co-development partner to share in the costs. This reduction in spending was offset by an increase of approximately $2.2 million in expenses incurred in our ONS-3010 program as we make preparations to begin a global Phase 3 clinical trial in plaque psoriasis patients.

General and Administrative Expenses

The following table summarizes our general and administrative expenses by type for the years ended September 30, 2016 and 2015:

	Year ended September 30,	
	2016	2015
Professional fees	$ 4,549,315	$ 2,724,465
Compensation and related benefits	4,131,014	2,579,810
Stock-based compensation	10,405,700	5,360,027
Facilities, fees and other related costs	2,550,316	2,241,521
Total general and administration expenses	$21,636,345	$12,905,823

General and administrative expenses increased $8.7 million for the year ended September 30, 2016, compared to the year ended September 30, 2015. The increase was primarily attributable to increased stock-based compensation expense of $5.0 million upon meeting the exercisability and vesting conditions of our PSUs and RSUs upon the completion of our IPO, a $1.0 million bonus payment earned by our chief executive officer upon completion of our IPO, as well as increased professional fees related to meeting public company compliance requirements.

Interest Expense

Interest expense decreased by $0.8 million to $1.5 million for the year ended September 30, 2016 as compared to $2.3 million for the year ended September 30, 2015 primarily due to the reductions in outstanding balances under stockholder notes, and other debt obligations over the comparable period.

Liquidity and Capital Resources

We have not generated any revenue from biosimilar product sales. Since inception, we have incurred net losses and negative cash flows from our operations. Through September 30, 2016, we have funded substantially all of our operations through the sale and issuance of $139.5 million net proceeds of our equity securities and borrowings under debt facilities. We have also received an aggregate of $24.0 million pursuant to our collaboration and licensing agreements. In May 2016, we closed the IPO and concurrent private placement raising aggregate net proceeds of approximately $33.8 million, excluding any proceeds we may receive from the exercise of the warrants. In addition, in October, November and December 2016 we issued $1.85 million of unsecured promissory notes, which notes were exchanged for new senior secured promissory notes and warrants to acquire 425,500 shares of our common stock in December 2016 concurrent with the issuance of $6.5 million aggregate principal amount of new senior secured promissory notes and warrants to acquire an aggregate 1,495,000 shares of our common stock for cash. We may issue up to an additional $1.65 million of senior secured notes and warrants to acquire an additional 379,500 shares of our common stock under the same note and warrant purchase agreement. We used $2.4 million of the proceeds to repay senior bank loans. We will require additional capital to fund our operations past February 2017. Alternatively, we will be required to scale back our plans and place certain activities on hold.

As of September 30, 2016, we had an accumulated deficit of $147.4 million and a cash balance of $2.4 million. In addition, we had $4.6 million of indebtedness that is due on demand. These matters raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. We anticipate incurring additional losses until such time, if ever, that we can generate significant sales of our product candidates currently in development. We will need substantial additional financing to fund our operations and to commercially develop our product candidates. Management is currently evaluating various strategic opportunities to obtain the required funding for future operations. These strategies may include, but are not limited to: private placements of equity and/or debt, payments from potential strategic research and development, licensing and/or marketing arrangements with pharmaceutical companies, and public offerings of equity and/or debt securities. Additionally, we continue to engage in active discussions with global and regional pharmaceutical companies for licensing and/or co-development rights to our late- and early-stage pipeline candidates. While we expect to finalize one or more of these transactions in early 2017, there can be no assurance that these future funding efforts will be successful.

Our future operations are highly dependent on a combination of factors, including (i) the timely and successful completion of additional financing discussed above, (ii) our ability to complete revenue-generating partnerships with pharmaceutical companies, (iii) the success of our research and development, (iv) the development of competitive therapies by other biotechnology and pharmaceutical companies, and, ultimately, (v) regulatory approval and market acceptance of our proposed future products.

Cash Flows

The following table summarizes our cash flows for each of the years presented:

	Year ended September 30,	
	2016	2015
Net cash used in operating activities	$(45,482,672)	$(27,476,200)
Net cash used in investing activities	(1,098,180)	(8,804,244)
Net cash provided by financing activities	39,861,764	43,002,106
Net (decrease) increase in cash	$ (6,719,088)	$ 6,721,662

Operating Activities

During the year ended September 30, 2016, we used $45.5 million of cash in operating activities, primarily resulting from our net loss of $53.3 million and the net cash used from changes in our operating assets and liabilities of $7.0 million. These uses of cash in our operating activities were offset by $14.9 million of noncash items such as stock-based compensation and depreciation and amortization expense. The change

in our operating assets and liabilities was primarily due to decreases in accounts payable related to the timing of vendor payments for research and development and professional services in connection with preparations for our IPO in May 2016 and decreases in deferred revenues due to ratable recognition of upfront payments received under our collaboration arrangements. These outflows were offset by increases in our prepaid expenses and other current assets, and increases in accrued expenses, and other liabilities that relate to the timing of vendor payments and the recognition of research and development expenses.

During the year ended September 30, 2015, we used $27.5 million of cash in operating activities, primarily resulting from our net loss of $48.7 million that was offset by $13.0 million of noncash items and $8.2 million in net cash provided by changes in our operating assets and liabilities. The noncash items were primarily comprised of depreciation and amortization of our fixed assets and the re-measurement of our PSU awards. The change in our operating assets and liabilities were primarily due to an $8.8 million increase in accounts payable and accrued expenses, which increased due to the timing in which we paid our research and development vendors. We also received $2.5 million in upfront fees and milestone payments under our collaboration and licensing agreements. These increases were offset by the prepayments of certain expenses and other assets.

Investing Activities

During the years ended September 30, 2016 and 2015, we used cash of $1.1 million and $8.8 million, respectively, in investing activities for the purchase of property and equipment. The purchases of property and equipment during the year ended September 30, 2015 were primarily attributable to the launching of our manufacturing facility, which resulted in significant increases in our laboratory equipment and leasehold improvements.

Financing Activities

During the year ended September 30, 2016, net cash provided by financing activities was $39.9 million, primarily attributable to $33.8 in aggregate net proceeds from our IPO and concurrent private placement in May 2016, $14.8 million in net proceeds from the sale of our common stock and $4.3 million in proceeds from the collection of subscriptions receivable. We also received $0.8 million from Sonnet Biotherapeutics, Inc. in connection with their note receivable. These inflows were offset by $13.5 million in debt payments and $0.4 million upon the deconsolidation of Sonnet Biotherapeutics, Inc. See Note 1 to our audited consolidated financial statements for more information regarding Sonnet Biotherapeutics, Inc.

During the year ended September 30, 2015, net cash provided by financing activities was $43.0 million, primarily attributable to the proceeds received from the issuance of our common stock and debt of $41.2 million, $10.9 million, respectively. These cash inflows were offset by debt payments and the partial repurchase of outstanding shares of Series A redeemable preferred stock of $9.3 million and $0.2 million, respectively.

Funding Requirements

We plan to focus in the near term on the development, regulatory approval and potential commercialization of our biosimilar product candidates. We anticipate we will incur net losses and negative cash flow from operations for the next several years as we complete clinical development and continue research and development. In addition, we plan to continue to invest in discovery efforts to explore additional biosimilar product candidates, potentially build commercial capabilities and expand our corporate infrastructure. We may not be able to complete the development and initiate commercialization of these programs if, among other things, our clinical trials are not successful or if the FDA does not approve our biosimilar products arising out of our current clinical trials when we expect, or at all.

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, clinical costs, external research and development services, laboratory and related supplies, legal and other regulatory expenses, and administrative and overhead costs. Our future funding requirements will be heavily determined by the resources needed to support development of our biosimilar product candidates.

As a publicly traded company we will incur significant legal, accounting and other expenses that we were not required to incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules adopted by the SEC and The NASDAQ Stock Market LLC, requires

public companies to implement specified corporate governance practices that are currently inapplicable to us as a private company. We expect these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

We believe our existing cash as of September 30, 2016 together with the proceeds from our December 2016 note and warrant issuance will provide adequate financial resources to fund our planned operations through February 2017. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We will need to raise substantial additional capital in order to commence any Phase 3 clinical trials of, receive approval for and commercialize ONS-3010 and ONS-1045 and commence clinical trials for any of our other pipeline candidates. We plan to finance our future operations with a combination of proceeds from the issuance of equity securities, the issuance of additional debt, potential strategic collaborations and revenues from potential future product sales, if any. If we raise additional capital through the sale of equity or convertible debt securities, your ownership will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. There are no assurances that we will be successful in obtaining an adequate level of financing for the development and commercialization of ONS-3010, ONS-1045 or any other current or future biosimilar product candidates. If we are unable to secure adequate additional funding, our business, operating results, financial condition and cash flows may be materially and adversely affected.

Because of the numerous risks and uncertainties associated with research, development and commercialization of biosimilar products, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on many factors, including:

- the number and characteristics of the biosimilar product candidates we pursue;
- the scope, progress, results and costs of researching and developing our biosimilar product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our biosimilar product candidates;
- the cost of manufacturing our biosimilar product candidates and any drugs we successfully commercialize;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future biosimilar product candidates, if any.

See “Risk Factors” for additional risks associated with our substantial capital requirements.

Contractual Obligations and Commitments

Our future contractual obligations as of September 30, 2016 were as follows:

	Payments Due by Period				
	Total	Less Than 1 Year	1 – 3 Years	3 – 5 Years	More Than 5 Years
Operating lease commitments[1]	$11,950,610	$1,551,513	$3,488,586	$3,368,521	$3,541,990
Debt obligations[2]	7,493,981	5,198,954	1,065,487	1,066,633	162,907
Capital leases[3]	1,297,985	977,248	320,737	—	—
Total[4]	$20,742,576	$7,727,715	$4,874,810	$4,435,154	$3,704,897

(1) Operating lease obligations reflect our obligation to make payments in connection with the leases for our office, manufacturing and laboratory facilities located in Cranbury, New Jersey.

(2) Debt obligations reflect outstanding principal obligations due to investors on notes payable and institutions and financing organizations for non-lease related equipment.

(3) Capital lease obligations reflect our outstanding principal payment obligations in connection with leased equipment used in our manufacturing facility.

(4) This table does not include (a) any milestone payments that may become payable to third parties under license agreements as the timing and likelihood of such payments are not known with certainty, (b) any royalty payments to third parties as the amounts, timing and likelihood of such payments are not known, and (c) contracts that are entered into in the ordinary course of business that are not material in the aggregate in any period presented above.

Under our license agreement with Selexis, we are obligated to pay milestone payments, as well as a royalty at a single-digit percentage of net sales of any covered product we successfully commercialize.

We also have employment agreements with certain employees, which require the funding of a specific level of payments if certain events, such as a change in control or termination without cause, occur.

In addition, in the course of normal business operations, we have agreements with contract service providers to assist in the performance of our research and development and manufacturing activities. Expenditures to CROs represent a significant cost in clinical development. We can elect to discontinue the work under these agreements at any time. We could also enter into additional collaborative research and licensing, contract research, manufacturing, and supplier agreements in the future, which may require upfront payments and even long-term commitments of cash.

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 in the rules and regulations of the SEC.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reported period. We base our estimates on historical experience, known trends and events and various other factors that we believe to be 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. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions and conditions.

While our significant accounting policies are described in more detail in the notes to our audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

We generate revenue primarily through collaboration and licensing agreements that contain multiple deliverables, generally a license and research and development services. Revenue recognition for arrangements with multiple elements requires the determination of whether an arrangement involving multiple deliverables contains more than one unit of accounting. A delivered item within an arrangement is considered a separate unit of accounting only if both of the following criteria are met:

- the delivered item has value to the customer on a stand-alone basis; and
- if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in our control.

If both of the criteria above are not met, then separate accounting for the individual deliverables is not appropriate. Revenue recognition for arrangements with multiple deliverables constituting a single unit of accounting is recognized generally over the greater of the term of the arrangement or the expected period of performance, either on a straight-line basis or on a modified proportional performance method. We record amounts received prior to satisfying the revenue recognition criteria as deferred revenue on our balance sheet. We classify amounts expected to be recognized as revenue in the next twelve months following the balance sheet date as current liabilities.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify 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 actual costs. The majority of our service providers require advance payments; however, some invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of the estimates with the service providers and makes adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors in connection with preclinical development activities;
- the production of preclinical and clinical trial materials;
- CROs in connection with clinical trials; and
- investigative sites in connection with clinical trials.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions and CROs that conduct and manage preclinical studies and clinical trials 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 expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. 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 the estimate, we adjust the accrual or prepaid 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 may result in reporting amounts that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

Stock-Based Compensation and PSU Obligation

As of September 30, 2015 our outstanding stock-based compensation awards were substantially comprised of PSUs, which were liability classified as the PSUs settled in cash and therefore were subject to remeasurement until the award is settled or extinguished.

In December 2015, we completed a tender-offer to holders of outstanding PSUs to amend the terms of such outstanding awards to provide for settlement in shares of our common stock or cash, at our discretion. As a result of this modification, the PSUs became equity classified. Concurrent with the amendment, several PSU holders cancelled an aggregate of 434,780 PSUs in exchange for 391,303 restricted stock units, or RSUs. During the year ended September 30, 2016, we issued an additional 705,311 RSUs before the cancellation of 2,263 RSUs.

Because the exercisability of the PSUs occurs upon a corporate valuation of $400 million, the fair value of the PSUs were estimated using a Monte Carlo simulation model. The inputs used in preparing the Monte Carlo simulation model include (i) volatility of our common stock, (ii) risk free interest rate, (iii) base price of the PSUs, (iv) fair value of our common stock and enterprise value, and (v) derived service period.

The most significant input affecting the estimated fair value of the PSUs is the fair value of our common stock. As of September 30, 2015, the fair value of our common stock was $25.79 per share, based on contemporaneous, arms-length transactions with new investors purchasing our common stock.

Using the above common stock fair value, the estimated fair value of the PSUs was $22.22 per PSU as of September 30, 2015. Upon the closing of our IPO, the fair value of the PSUs became fixed and is no longer subject to remeasurement.

For the years ended September 30, 2016 and 2015, we had compensation related to our equity and liability awards as follows:

	Year ended September 30,	
	2016	2015
Research and development	$ 2,044,379	$ 5,817,830
General and administrative	10,405,700	5,360,028
	$12,450,079	$11,177,858

	Year ended September 30,	
	2016	2015
Equity-classified compensation	$10,058,217	$ 8,925
Liability-classified compensation	2,391,862	11,168,933
	$12,450,079	$11,177,858

Internal Controls and Procedures

We will be required, pursuant to Section 404(a) of the Sarbanes-Oxley Act, or Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for the year following our first annual report required to be filed with the SEC. This assessment will need to include disclosure of any material weaknesses identified by management over our internal control over financial reporting. However, our independent registered public accounting firm will not be required to report on the effectiveness of our internal control over financial reporting pursuant to Section 404(b) until the later of the year following our first annual report required to be filed with the SEC, or the date we are no longer an “emerging growth company” if we take advantage of the exemptions contained in the Jumpstart Our Business Startups Act of 2012, or JOBS Act.

We have not initiated the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing or 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 controls are designed and operating effectively, which could result in a loss of investor confidence in the accuracy and completeness of our financial reports. This could cause the market price of our securities to decline, and we may be subject to investigation or sanctions by the SEC.

JOBS Act Accounting Election

The JOBS Act permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

Recently Issued and Adopted Accounting Pronouncements

In March 2016, the FASB issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting, which is intended to simplify the accounting and reporting for employee share-based payment transactions*. The pronouncement is effective for interim and annual periods beginning after December 31, 2016 with early adoption permitted. The adoption of this guidance is not expected to have a material impact on our consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases*, (Topic 842). This new ASU represents a wholesale change to lease accounting and introduces a lease model that brings most leases on the balance sheet. It also eliminates the required use of bright-line tests in current U.S. GAAP for determining lease classification. This ASU is effective for annual periods beginning after December 15, 2018 (i.e., calendar periods beginning on January 1, 2019), and interim periods thereafter. Earlier application is permitted for all entities. We are currently evaluating the impact of ASU 2016-02 on our consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. The amendments in this update will explicitly require a company's management to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. The new standard will be effective in the first annual period ending after December 15, 2016. Early application is permitted. We are currently evaluating the potential impact of the adoption of this standard, but we believe its adoption will have no impact on our consolidated results of operations, financial position or cash flows.

In May 2014, the FASB issued ASU, No. 2014-09, *Revenue from Contracts with Customers*. This guidance requires an entity to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This guidance also requires an entity to disclose sufficient information to enable users of financial statements to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. Qualitative and quantitative information is required about:

Contracts with customers — including revenue and impairments recognized, disaggregation of revenue and information about contract balances and performance obligations (including the transaction price allocated to the remaining performance obligations).

Significant judgments and changes in judgments — determining the timing of satisfaction of performance obligations (over time or at a point in time), and determining the transaction price and amounts allocated to performance obligations.

Certain assets — assets recognized from the costs to obtain or fulfill a contract.

In July 2015, the FASB delayed the effective date of this guidance. As a result, this guidance will be effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. Earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. We are currently evaluating the impact that this guidance will have on our consolidated results of operations, financial position and cash flows.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

Item 8. Consolidated Financial Statements and Supplementary Data

ONCOBIOLOGICS, INC.
ANNUAL REPORT ON FORM 10-K

INDEX TO AUDITED CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Oncobiologics, Inc.:

We have audited the accompanying consolidated balance sheets of Oncobiologics, Inc. and subsidiaries (the Company) as of September 30, 2016 and 2015, and the related consolidated statements of operations, redeemable preferred stock, common stock, noncontrolling interests and stockholders' equity (deficit), and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated 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 consolidated financial statements referred to above present fairly, in all material respects, the financial position of Oncobiologics, Inc. and subsidiaries as of September 30, 2016 and 2015, and the results of their operations and their cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has incurred recurring losses and negative cash flows from operations since inception and has an accumulated deficit at September 30, 2016 of $147.4 million and $4.6 million of indebtedness that is due on demand, which raises substantial doubt about its ability to continue as a going concern. Management's plan in regards to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KPMG LLP

Philadelphia, Pennsylvania
December 29, 2016

Oncobiologics, Inc.

Consolidated Balance Sheets

	September 30, 2016	September 30, 2015
Assets		
Current assets:		
Cash	$ 2,351,887	$ 9,070,975
Accounts receivable	—	20,000
Stock subscription receivable	—	4,280,149
Prepaid and other current assets	3,326,607	1,793,109
Total current assets	5,678,494	15,164,233
Property and equipment, net	16,958,553	17,759,938
Restricted cash	216,086	213,663
Deferred offering costs	—	960,563
Other assets	852,801	910,224
Total assets	$ 23,705,934	$ 35,008,621
Liabilities, redeemable preferred stock, common stock, noncontrolling interests and stockholders' equity (deficit)		
Current liabilities:		
Current portion of debt	$ 586,454	$ 742,646
Current portion of capital lease obligations	977,248	862,849
Current portion of stockholder notes	4,612,500	14,214,196
Accounts payable	5,071,520	11,563,055
Accrued expenses	6,121,942	5,924,648
Income taxes payable	1,854,629	1,754,629
Deferred revenue	1,212,561	1,979,576
Total current liabilities	20,436,854	37,041,599
Long-term debt	2,233,803	2,922,764
Capital lease obligations	320,737	1,219,373
Stockholder notes	—	2,000,000
Deferred revenue	5,153,384	6,365,945
Stock-based compensation liability	—	12,726,722
Other liabilities	761,334	284,710
Total liabilities	28,906,112	62,561,113
Commitments (Note 9)		
Redeemable preferred stock, common stock and noncontrolling interests:		
Redeemable preferred stock, no par value:		
Series A – No shares authorized, issued and outstanding at September 30, 2016; 8,000 shares authorized; 3,568 issued and outstanding at September 30, 2015	—	5,072,653
Series B – No shares authorized, issued and outstanding at September 30, 2016; 4,000 shares authorized, issued and outstanding at September 30, 2015;	—	5,118,208
Redeemable common stock – 1,739,130 shares issued and outstanding at September 30, 2015	—	15,426,673
Redeemable noncontrolling interests	—	1,703,777
Total redeemable preferred stock, common stock and noncontrolling interests	—	27,321,311
Stockholders' equity (deficit):		
Series A preferred stock, par value $0.01 per share: 10,000,000 shares authorized, no shares issued and outstanding	—	—
Common stock, par value $0.01 per share; 200,000,000 shares authorized at September 30, 2016; 22,802,778 shares issued and outstanding at September 30, 2016; No shares authorized, issued and outstanding at September 30, 2015	228,028	—
Common stock, no shares authorized issued and outstanding at September 30, 2016; no par value; 100,000,000 shares authorized; 9,436,294 shares issued and outstanding at September 30, 2015	—	39,844,900
Additional paid-in capital	141,965,342	—
Accumulated deficit	(147,393,548)	(94,064,286)
Total Oncobiologics, Inc. stockholders' equity (deficit)	(5,200,178)	(54,219,386)
Noncontrolling interests	—	(654,417)
Total stockholders' equity (deficit)	(5,200,178)	(54,873,803)
Total liabilities, redeemable preferred stock, common stock, noncontrolling interests and stockholders' equity (deficit)	$ 23,705,934	$ 35,008,621

See accompanying notes to consolidated financial statements.

Oncobiologics, Inc.

Consolidated Statements of Operations

	Year Ended September 30,	
	2016	2015
Collaboration revenues	$ 2,979,576	$ 5,219,237
Operating expenses:		
Research and development	33,101,543	38,876,040
General and administrative	21,636,345	12,905,823
	54,737,888	51,781,863
Loss from operations	(51,758,312)	(46,562,626)
Interest expense, net	1,467,950	2,297,339
Loss before income taxes	(53,226,262)	(48,859,965)
Income tax expense (benefit)	103,000	(190,111)
Net loss	(53,329,262)	(48,669,854)
Less: Net loss attributable to noncontrolling interests	—	(1,276,571)
Net loss attributable to Oncobiologics, Inc.	(53,329,262)	(47,393,283)
Accretion of redeemable preferred stock and noncontrolling interests	(2,463,160)	(4,306,488)
Deemed dividends upon the repurchase of Series A redeemable preferred stock and redeemable noncontrolling interests	—	(1,298,631)
Deemed dividend upon issuance of warrants to common stockholders	(7,373,820)	—
Net loss attributable to common stockholders of Oncobiologics, Inc.	$(63,166,242)	$(52,998,402)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (3.67)	$ (5.43)
Weighted average shares outstanding, basic and diluted	17,212,983	9,753,616

See accompanying notes to consolidated financial statements.

Oncobiologics, Inc.

Consolidated Statements of Redeemable Preferred Stock, Common Stock, Noncontrolling Interests and Stockholders' Equity (Deficit)

	Redeemable Preferred Stock, Common Stock and Noncontrolling Interests							Stockholders' Equity (Deficit)							
	Preferred Stock														
	Series A		Series B		Common Stock		Noncontrolling Interests	Series A Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Noncontrolling Interests	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount		Shares	Amount	Shares	Amount				
Balance at October 1, 2014	3,681	$ 4,787,996	4,000	$ 4,589,872	1,739,130	$ 12,225,096	$ 3,101,047	—	$ —	7,670,783	$ —	$ —	$ (45,151,218)	$ —	$(45,151,218)
Distribution of common stock in Sonnet Biotherapeutics, Inc. to stockholders	—	—	—	—	—	—	—	—	—	—	—	—	(221,154)	221,154	—
Contributions to noncontrolling interests	—	—	—	—	—	—	—	—	—	—	—	—	—	401,000	401,000
Repurchase of Series A redeemable preferred stock and deemed dividends	(113)	(142,370)	—	—	—	—	—	—	—	—	—	—	(83,631)	—	(83,631)
Repurchase of redeemable noncontrolling interests and deemed dividends	—	—	—	—	—	—	(1,546,818)	—	—	—	—	—	(1,215,000)	—	(1,215,000)
Forfeitures of restricted stock	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Sale of common stock, net of issuance costs	—	—	—	—	—	—	—	—	—	1,765,511	44,142,463	—	—	—	44,142,463
Accretion of redeemable preferred stock, common stock and noncontrolling interests	—	427,027	—	528,336	—	3,201,577	149,548	—	—	—	(4,306,488)	—	—	—	(4,306,488)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	8,925	—	—	—	8,925
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(47,393,283)	(1,276,571)	(48,669,854)
Balance at September 30, 2015	3,568	5,072,653	4,000	5,118,208	1,739,130	15,426,673	1,703,777	—	—	9,436,294	39,844,900	—	(94,064,286)	(654,417)	(54,873,803)
Deconsolidation of Sonnet Biotherapeutics, Inc.	—	—	—	—	—	—	—	—	—	—	—	—	—	654,417	654,417
Employee tax withholdings related to the vesting of restricted stock	—	—	—	—	—	—	—	—	—	(2,782)	(71,760)	—	—	—	(71,760)
Reincorporation to a Delaware Corporation	(3,568)	(5,072,653)	(4,000)	(5,118,208)	—	—	—	10,193	102	2,193,601	(39,656,869)	49,847,628	—	—	10,190,861
Issuance of common stock upon the dissolution of Parilis	—	—	—	—	—	—	(1,703,777)	1,626	16	226,663	2,267	1,701,494	—	—	1,703,777
Sale of common stock, net of issuance costs	—	—	—	—	—	—	—	—	—	573,388	5,734	16,132,179	—	—	16,137,913
Reclassification of stock-based compensation liability	—	—	—	—	—	—	—	—	—	—	—	15,118,584	—	—	15,118,584
Accretion of redeemable common stock	—	—	—	—	—	2,463,160	—	—	—	—	—	(2,463,160)	—	—	(2,463,160)
Sale of common stock units upon consummation of initial public offering and concurrent private placement, net of issuance costs	—	—	—	—	—	—	—	—	—	6,666,666	66,667	33,717,538	33,784,205	—	33,784,205
Reclassification of redeemable common stock upon consummation of the initial public offering	—	—	—	—	(1,739,130)	(17,889,833)	—	—	—	1,739,130	17,391	17,872,442	—	—	17,889,833
Conversion of Series A preferred stock in connection with the initial public offering	—	—	—	—	—	—	—	(11,819)	(118)	1,969,818	19,698	(19,580)	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	10,058,217	—	—	10,058,217
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(53,329,262)	—	(53,329,262)
Balance at September 30, 2016	—	$ —	—	$ —	—	$ —	$ —	—	$ —	22,802,778	$ 228,028	$141,965,342	$(147,393,548)	$ —	$ (5,200,178)

See accompanying notes to consolidated financial statements.

Oncobiologics, Inc.

Consolidated Statements of Cash Flows

	Year Ended September 30,	
	2016	2015
OPERATING ACTIVITIES		
Net loss	$(53,329,262)	$(48,669,854)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,394,279	1,824,600
Non-cash interest expense	13,465	12,264
Stock-based compensation	12,450,079	11,177,858
Loss on disposal of fixed assets	13,647	—
Changes in operating assets and liabilities:		
Accounts receivable	20,000	(20,000)
Prepaid expenses and other current assets	(1,533,498)	(1,021,852)
Other assets	57,423	(322,729)
Accounts payable	(5,326,374)	6,580,722
Accrued expenses	1,154,712	2,240,800
Income taxes payable	100,000	190,218
Deferred revenue	(1,979,576)	530,763
Other liabilities	482,433	1,010
Net cash used in operating activities	(45,482,672)	(27,476,200)
INVESTING ACTIVITIES		
Purchase of property and equipment	(1,098,180)	(8,804,244)
Net cash used in investing activities	(1,098,180)	(8,804,244)
FINANCING ACTIVITIES		
Repurchase of Series A redeemable preferred stock	—	(226,001)
Proceeds from the sale of common stock, net of offering costs	16,137,913	41,249,998
Proceeds from sale of common stock units in connection with initial public offering and private placement	37,074,996	—
Payment of offering costs and common stock issuance costs	(4,637,647)	—
Proceeds from subscriptions receivable	4,280,149	—
Proceeds from the sale of equity in noncontrolling interest	—	401,000
Proceeds from stockholders notes	—	10,880,252
Payments of capital leases obligations	(884,620)	(686,676)
Proceeds from debt	200,416	—
Repayment of debt	(1,059,034)	(725,598)
Repayment of stockholder notes	(11,601,696)	(7,888,658)
Change in restricted cash	(2,423)	(2,211)
Proceeds from Sonnet Biotherapeutics, Inc.	826,561	—
Deconsolidation of Sonnet Biotherapeutics, Inc.	(401,091)	—
Payment of employee tax withholdings related to the vesting of restricted stock	(71,760)	—
Net cash provided by financing activities	39,861,764	43,002,106
Net (decrease) increase in cash	(6,719,088)	6,721,662
Cash at beginning of year	9,070,975	2,349,313
Cash at end of year	$ 2,351,887	$ 9,070,975
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 1,477,913	$ 1,402,209
Cash paid for income taxes	$ 3,000	$ 2,250
Supplemental schedule of noncash investing activities:		
Purchases of property and equipment in accounts payable and accrued expenses	$ 634,941	$ (2,770,730)
Supplemental schedule of noncash financing activities:		
Accretion of redeemable preferred stock, common stock and noncontrolling interests	$ 2,463,160	$ 4,306,488
Deemed dividend upon repurchase of Series A redeemable preferred stock in excess of carrying value	$ —	$ (1,298,631)
Issuance of subscription receivable upon sale of common stock	$ —	$ (4,280,149)
Issuance of common and Series A preferred stock to redeemable preferred stockholders and noncontrolling interests upon reincorporation	$ 11,894,638	$ —
Reclassification of equity classified stock-based compensation	$ 15,118,584	$ —
Distribution of common stock in Sonnet Biotherapeutics, Inc. to stockholders	$ —	$ (221,154)
Issuance of capital lease obligations in connection with purchase of property and equipment	$ 100,383	$ 2,603,894
Deferred offering costs and common stock issuance costs in accounts payable and accrued expenses	$ 3,144	$ 2,310,961

See accompanying notes to consolidated financial statements.

Oncobiologics, Inc.

Notes to Consolidated Financial Statements

1. Organization and Operations

Description of the Business

Oncobiologics, Inc. ("Oncobiologics" or the "Company") was incorporated in New Jersey on January 5, 2010 and started operations in July 2011. Oncobiologics is a clinical-stage biopharmaceutical company focused on identifying, developing, manufacturing and commercializing complex biosimilar therapeutics in the disease areas of immunology and oncology. The Company has established fully integrated in-house development and manufacturing capabilities that addresses the numerous complex technical and regulatory challenges in developing and commercializing mAb biosimilars. Since inception, the Company has advanced two product candidates into clinical trials: a Phase 3-ready biosimilar to adalimumab (Humira®) and a Phase 3-ready biosimilar to bevacizumab (Avastin®). Additionally, the Company has six preclinical biosimilar product candidates under active development.

In April 2015, the Company spun-off certain assets unrelated to its biosimilar business through a pro rata distribution to its stockholders through a newly-formed subsidiary, Sonnet Biotherapeutics, Inc. ("Sonnet"). Concurrent with the Company's contribution of the assets relating to the innovation business of Sonnet, the Company distributed all of its shares of Sonnet to Oncobiologics' stockholders.

In October 2015, the Company reincorporated in Delaware through the merger with and into Oncobiologics, Inc., a newly formed Delaware corporation, with the Delaware corporation surviving the merger. As a result of the merger, each share of the Company's previously issued and outstanding common stock converted into and became a share of common stock of the Delaware corporation on a 1-for-1 basis, each share of the Company's previously issued and outstanding Series A redeemable preferred stock converted into 289 shares of common stock and approximately 1.4035 shares of Series A preferred stock of the Delaware corporation, and each share of the Company's previously issued and outstanding Series B redeemable preferred stock converted into 289 shares of common stock and approximately 1.2867 shares of Series A preferred stock of the Delaware corporation. The holders of Series A and B also received an aggregate of 10,193 shares of Series A preferred stock of the Delaware corporation. Additionally, effective upon the reincorporation and in connection with the dissolution of the Company's business development subsidiary, Parilis Biopharmaceuticals ("Parilis"), the Company issued 226,663 shares of common stock and 1,626 shares of Series A preferred stock to the holders of outstanding Parilis preferred member units in exchange for all such units.

In May 2016, the Company completed the initial public offering ("IPO") of its securities by offering 5,833,334 units. Each unit consisted of one share of the Company's common stock, one-half of a Series A warrant and one-half of a Series B warrant. Each whole Series A warrant entitles the holder to purchase one share of common stock at an initial exercise price of $6.60, subject to adjustment. Each whole Series B warrant entitles the holder to purchase one share of common stock at an initial exercise price of $8.50, subject to adjustment. The IPO price was $6.00 per unit. In addition, the Company also completed a concurrent private placement of an additional 833,332 shares of its common stock, 416,666 Series A warrants and 416,666 Series B warrants, for gross proceeds of approximately $5.0 million. On May 13, 2016, the units began trading on the NASDAQ Global Market. The units separated in accordance with their terms and ceased trading, and on June 13, 2016, the component securities (common stock, Series A warrants and Series B warrants) began trading on the NASDAQ Global Market. As a result of the IPO and the concurrent private placement, the Company received approximately $33.8 million in net proceeds, after deducting discounts and commissions of approximately $2.9 million and offering expenses of approximately $3.3 million payable by the Company.

On May 18, 2016, the Company filed an amended and restated certificate of incorporation (the "Restated Certificate") with the Secretary of State of the State of Delaware in connection with the closing of its IPO. As set forth in the Restated Certificate, the Company's authorized capital stock now consists of 200,000,000 shares of common stock, par value $0.01 per share, and 10,000,000 shares of preferred stock, par value $0.01 per share.

Oncobiologics, Inc.

Notes to Consolidated Financial Statements

2. Liquidity

The Company has incurred substantial losses and negative cash flows from operations since its inception and has an accumulated deficit of $147.4 million as of September 30, 2016. In addition, the Company has $4.6 million of indebtedness that is due on demand. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

The Company has substantial indebtedness that includes $4.6 million in notes payable to stockholders that are payable on demand. There can be no assurance that note holders will not exercise their right to demand repayment.

The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its products currently in development. The Company closed the IPO of its securities and the concurrent private placement on May 18, 2016 raising aggregate net proceeds of approximately $33.8 million, excluding any proceeds it may receive from the exercise of the Series A warrants and Series B warrants. In October, November and December 2016, the Company raised $8.35 million of cash proceeds from the issuance of notes and warrants, of which $2.4 million was used to repay existing senior secured bank loans (see Note 15). Management believes that the Company's existing cash as of September 30, 2016 and the net proceeds from the issuance of the notes and warrants will be sufficient to fund its operations through February 2017. Substantial additional financing will be needed by the Company to fund its operations and to commercially develop its product candidates. Management is currently evaluating different strategies to obtain the required funding for future operations. These strategies may include, but are not limited to: private placements of equity and/or debt, payments from potential strategic research and development, licensing and/or marketing arrangements with pharmaceutical companies, and public offerings of equity and/or debt securities. There can be no assurance that these future funding efforts will be successful.

The Company's future operations are highly dependent on a combination of factors, including (i) the timely and successful completion of additional financing discussed above; (ii) the Company's ability to complete revenue-generating partnerships with pharmaceutical companies; (iii) the success of its research and development; (iv) the development of competitive therapies by other biotechnology and pharmaceutical companies, and, ultimately; (v) regulatory approval and market acceptance of the Company's proposed future products.

3. Basis of Presentation and Summary of Significant Accounting Policies

Basis of presentation

The accompanying consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

The consolidated financial statements include the accounts of the Company's subsidiaries and affiliates in which the Company held a controlling financial interest as of the financial statement date. As the Company had been the primary funding source for Sonnet, the operations and financial position of Sonnet were included in the consolidated financial statements of the Company through September 30, 2015. Participation of the stockholders in the net assets and losses of Sonnet were reflected in the line items "Noncontrolling interests" in the Company's consolidated balance sheet and "Net loss attributable to the noncontrolling interests" in the Company's consolidated statement of operations.

Prior to its dissolution, Parilis had issued Series A and Series A Hybrid Redeemable Preferred Units ("Preferred Units") to investors other than Oncobiologics. The Preferred Units were redeemable both at the option of the Parilis Preferred holders and upon the occurrence of an event that was not solely within the Company's control. Because redemption of Preferred Units was outside of the Company's control, the noncontrolling interests was presented on the consolidated balance sheet under the caption redeemable noncontrolling interests and was carried at its current redemption value. As of and for the year ended September 30, 2015, the redeemable noncontrolling interests was presented at its carrying amount and adjusted for dividends to and contributions from the noncontrolling interests with an offsetting charge to common stock or, in the absence of common stock, a charge to accumulated deficit.

Use of estimates

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Due to the uncertainty of factors surrounding the estimates or judgments used in the preparation of the consolidated financial statements, actual results may materially vary from these estimates. Estimates and assumptions are periodically reviewed and the effects of revisions are reflected in the consolidated financial statements in the period they are determined to be necessary.

Recapitalization

On April 26, 2016, the Company filed a certificate of amendment to amend its certificate of incorporation effecting a 1-for-3.45 reverse split of the Company's common stock. All references in the consolidated financial statements to the number of shares and per-share amounts of common stock have been retroactively restated to reflect the reverse split.

Restricted cash

As of September 30, 2016 and 2015, the Company had $216,086 and $213,663, respectively, in certificates of deposit related to the requirements of the Company's bank loans.

Fair value of financial instruments

At September 30, 2016 and 2015, the Company's financial instruments included accounts payable, accrued expenses, stockholder notes and debt. The carrying amount of accounts payable and accrued expenses approximates fair value due to the short-term maturities of these instruments. The stockholder notes and debt approximates fair value as the interest rates are reflective of the rate the Company could obtain on debt with similar terms and conditions. As of September 30, 2015, the carrying value of the stock-based compensation liability was the estimated fair value of the liability (See Note 11).

Prepaid expenses and other current assets

As of September 30, 2016 and 2015, the Company had prepaid research and development of $1,979,527 and $355,182, respectively.

Property and equipment

Property and equipment are recorded at cost. Depreciation and amortization is determined using the straight-line method over the estimated useful lives ranging from 3 to 10 years. Leasehold improvements are amortized over the life of the lease or the estimated useful life of the assets, whichever is shorter. Expenditures for maintenance and repairs are expensed as incurred while renewals and betterments are capitalized. When property and equipment is sold or otherwise disposed of, the cost and related accumulated depreciation are eliminated from the accounts and any resulting gain or loss is reflected in operations.

Long-lived assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net cash flows expected to be generated. Impairment charges are recognized at the amount by which the carrying amount of an asset exceeds the fair value of the asset. Assets to be disposed of are reported at the lower of the carrying amount or the fair value less costs to sell. The Company has not recognized any impairment of long-lived assets.

Deferred offering costs

The Company capitalizes costs that are directly associated with in-process equity financings until such financings are consummated at which time such costs are recorded against the gross proceeds of the offering.

Stock-based compensation

The Company measures equity classified stock-based awards granted to employees and directors based on the estimated fair value on the date of grant and recognizes compensation expense of those awards, net of estimated forfeitures, on a straight-line basis over the requisite service period, which is generally the vesting period of the respective award.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option pricing model, which is described more fully in note 11. The fair value of each restricted stock award is measured as the fair value per share of the Company's common stock on the date of grant.

Stock-based awards granted to consultants and non-employees are measured based on the fair value of the award on the date on which the related services are completed. Compensation expense is recognized over the period during which services are rendered by such consultants and non-employees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is remeasured using the then-current fair value of the Company's common stock and updated assumption inputs in the Black-Scholes option-pricing model.

Stock-based awards that are settled in cash are accounted for as liabilities and are remeasured at each reporting period until the obligations are satisfied. Stock-based compensation liabilities are valued through the use of a Monte Carlo simulation model.

Revenue recognition

The Company's revenue is generated primarily through collaboration research and license agreements. The terms of these agreements generally contain multiple deliverables which may include (i) licenses, (ii) research and development activities, clinical manufacturing, and (iii) product supply. The payment terms of these agreements may include nonrefundable upfront fees, payments for research and development activities, payments based upon the achievement of certain milestones, royalty payments based on product sales derived from the collaboration, and payments for supplying product.

The Company considers whether the deliverables under the arrangement represent separate units of accounting. In determining the units of accounting, management evaluates certain criteria, including whether the deliverables have stand-alone value. The consideration received is allocated to the separate units of accounting using the relative selling price method, and the applicable revenue recognition criteria are applied to each of the separate units.

The Company typically receives upfront, nonrefundable payments when licensing its intellectual property. For intellectual property licenses that do not have stand-alone value from the other deliverables to be provided, the upfront fee is deferred and revenue is recognized over the contractual or estimated performance period, which is typically the term of the research and development obligations. The periods

over which revenue is recognized are subject to estimates by management and may change over the course of the research and development agreement. Such a change could have a material impact on the amount of revenue the Company records in future periods. Payments or reimbursements resulting from the Company's research and development efforts are recognized as the services are performed. Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue.

The Company recognizes revenue from milestone payments when: (i) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement, and (ii) the Company does not have ongoing performance obligations related to the achievement of the milestone earned. Milestone payments are considered substantive if all of the following conditions are met: the milestone payment (a) is commensurate with either the Company's performance to achieve the milestone or the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from the Company's performance to achieve the milestone, (b) relates solely to past performance, and (c) is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

Research and development

Research and development costs are expensed as incurred and consist primarily of funds paid to third parties for the provision of services for product candidate development, clinical and preclinical development and related supply and manufacturing costs, and regulatory compliance costs. At the end of the reporting period, the Company compares payments made to third-party service providers to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that the Company estimates has been made as a result of the service provided, the Company may record net prepaid or accrued expense relating to these costs.

Upfront milestone payments made to third parties who perform research and development services on the Company's behalf are expensed as services are rendered. Costs incurred in obtaining technology licenses are charged to research and development expense as acquired in-process research and development if the technology licensed has not reached technological feasibility and has no alternative future use.

Income taxes

The Company accounts for income taxes using the asset and liability method. Under the asset and liability method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is recorded to the extent it is more likely than not that some portion or all of the deferred tax assets will not be realized.

Accretion of redeemable preferred stock, redeemable common stock and redeemable noncontrolling interests

Accretion of redeemable preferred stock included the accretion of dividends and issuance costs of the Company's Series A and Series B redeemable preferred stock and the redeemable common stock. The carrying values of the Series A and Series B redeemable preferred stock, redeemable common stock and redeemable noncontrolling interests were being accreted to their respective redemption values, using the effective interest method, from the date of issuance to the earliest date the holders can demand redemption. Increases to the carrying value of redeemable preferred stock, common stock, and noncontrolling interests are charged to common stock or, in the absence of common stock, charged to accumulated deficit. Upon repurchase of redeemable preferred stock and redeemable noncontrolling interests, the excess consideration paid over the carrying value at the time of repurchase was accounted for as a deemed dividends to the preferred stockholders.

Net loss per share

Basic and diluted net loss per common share is determined by dividing net loss applicable to common stockholders by the weighted-average common shares during the period. For all periods presented, the outstanding shares of Series A and Series B redeemable preferred stock have been excluded from the calculation because their effects would be anti-dilutive. Therefore the weighted-average shares used to calculate both basic and diluted loss per share are the same.

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding as of September 30, 2016 and 2015, as they would be antidilutive:

	September 30,	
	2016	2015
Series A redeemable preferred stock	—	1,034,181
Series B redeemable preferred stock	—	1,159,418
Performance-based stock units	247,309	—
Restricted stock units	1,094,351	—
Convertible stockholder note	—	96,618
Common stock warrants	8,186,934	—

Amounts in the table above reflect the common stock equivalents of the noted instruments.

Recently issued and adopted accounting pronouncements

In August 2014, the FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. The amendments in this update will explicitly require a company's management to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. The new standard will be effective in the first annual period ending after December 15, 2016. Early application is permitted. The Company is currently evaluating the potential impact of the adoption of this standard, but the Company believes its adoption will have no impact on its consolidated results of operations, financial position or cash flows.

In May 2014, the FASB issued ASU, No. 2014-09, *Revenue from Contracts with Customers*. This guidance requires an entity to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This guidance also requires an entity to disclose sufficient information to enable users of financial statements to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. Qualitative and quantitative information is required about:

Contracts with customers — including revenue and impairments recognized, disaggregation of revenue and information about contract balances and performance obligations (including the transaction price allocated to the remaining performance obligations).

Significant judgments and changes in judgments — determining the timing of satisfaction of performance obligations (over time or at a point in time), and determining the transaction price and amounts allocated to performance obligations.

Certain assets — assets recognized from the costs to obtain or fulfill a contract.

In July 2015, the FASB delayed the effective date of this guidance. As a result, this guidance will be effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. Earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. The Company is currently evaluating the impact that this guidance will have on its consolidated results of operations, financial position and cash flows.

In February 2016, the FASB issued ASU 2016-02, *Leases*, (Topic 842). This new ASU represents a wholesale change to lease accounting and introduces a lease model that brings most leases on the balance sheet. It also eliminates the required use of bright-line tests in current U.S. GAAP for determining lease classification. This ASU is effective for annual periods beginning after December 15, 2018 (i.e., calendar periods beginning on January 1, 2019), and interim periods thereafter. Earlier application is permitted for all entities. The Company is currently evaluating the impact of ASU 2016-02 on its consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Improvements to Employee Share-Based Payment Accounting, which is intended to simplify the accounting and reporting for employee share-based payment transactions. The pronouncement is effective for interim and annual periods beginning after December 31, 2016 with early adoption permitted. The adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

4. Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The asset's or liability's fair value measurement level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. Valuation techniques used need to maximize the use of observable inputs and minimize the use of unobservable inputs.

The following table presents the Company's assets and liabilities that are measured at fair value on a recurring basis:

	September 30, 2015		
	(Level 1)	(Level 2)	(Level 3)
Liabilities			
Stock-based compensation liability	$ —	$ —	$ 12,726,722

Oncobiologics, Inc.

Notes to Consolidated Financial Statements

The table presented below is a summary of changes in the fair value of the Company's Level 3 valuation for the stock-based compensation liability for the years ended September 30, 2016 and 2015:

Balance at October 1, 2014	$ 1,557,789
Change in fair value	11,168,933
Balance at September 30, 2015	12,726,722
Change in fair value	2,391,862
Reclassification to stockholders' equity (deficit)	(15,118,584)
Balance at September 30, 2016	$ —

The Company has issued stock-based performance units ("PSUs"), which generally have a ten year life from the date of grant and vest 50% after the third anniversary from issuance and the remaining 50% on the fourth anniversary. In addition, the PSUs are exercisable upon the earlier of (i) a change in control, (ii) consummation of an IPO, or (iii) a corporate valuation in excess of $400 million and at the discretion by the Company's Board of Directors. Upon exercise, the PSU holder received a cash payment for the difference between the current per share value of the Company and the base price of the PSU. Given the cash settlement, the PSUs were liability classified and re-measured at each reporting date with changes in fair value recorded within the Company's consolidated statements of operations. In December 2015, the PSUs were modified to provide for settlement in common stock or cash, at the Company's discretion. As a result of this modification, the carrying value of the PSUs was reclassified to stockholders' equity (deficit).

The PSUs contain a market condition as the exercisability of the awards are based on the Company achieving a market value of $400 million during the relevant performance period. The fair value of the market condition is valued using a Monte Carlo simulation model. The significant assumptions used in preparing the Monte Carlo simulation model include (i) volatility of the Company's common stock, (ii) risk free interest rate, (iii) base price of the PSUs, (iv) fair value of the Company's common stock and enterprise value of the Company, and (v) derived service period.

The fair value of the PSUs of $22.22 per PSU at September 30, 2015 was derived using the following assumptions:

	September 30, 2015
Risk-free interest rate	1.4%
Derived service period	5 years
Expected volatility	60%
Annual dividend yield	0%
Fair value of common stock	$25.79 per share

5. Property and Equipment

Property and equipment, net, consists of:

	September 30,	
	2016	2015
Laboratory equipment	$11,452,858	$10,936,364
Leasehold improvements	10,031,739	9,889,521
Computer software and hardware	421,206	402,075
Construction in progress	1,014,690	175,425
	22,920,493	21,403,385
Less: accumulated depreciation and amortization	(5,961,940)	(3,643,447)
	$16,958,553	$17,759,938

Depreciation and amortization expense for the years ended September 30, 2016 and 2015 was $2,394,279 and $1,824,600, respectively.

At September 30, 2016 and 2015, $3,630,683 and $3,530,301, respectively represents laboratory equipment under capital leases. The term of the leases are between 22 and 36 months and qualify as capital leases. The leases bear interest between 5.0 % and 19.4 %. At September 30, 2016 and 2015, $732,002 and $407,210, respectively, of accumulated depreciation related to this leased equipment has been recognized.

The following is a schedule of future minimum lease payments under capital leases as of September 30, 2016:

2017	$1,093,624
2018	341,740
	1,435,364
Less: amounts representing interest	(137,379)
Less: current portion	(977,248)
Capital lease obligations, excluding current portion	$ 320,737

6. Accrued Expenses

Accrued expenses consists of:

	September 30,	
	2016	2015
Compensation	$3,884,386	$2,321,508
Research and development	1,343,910	951,759
Interest payable	234,754	806,475
Deferred offering costs	26,028	657,892
Professional fees	486,705	594,572
Director fees	73,125	414,421
Other accrued expenses	73,034	178,021
	$6,121,942	$5,924,648

7. Stockholder Notes

	September 30,	
	2016	2015
Series A repurchase notes	$ —	$ 800,534
Parilis Series A repurchase notes	—	2,275,818
Restricted stock repurchase notes	800,000	1,097,750
Common stock repurchase note	2,812,500	2,812,500
Convertible note	—	2,000,000
Working capital notes	1,000,000	7,227,594
	4,612,500	16,214,196
Less: current portion	(4,612,500)	(14,214,196)
	$ —	$ 2,000,000

In June 2014, the Company, upon the repurchase of its Series A redeemable preferred stock, issued $3,364,534 in notes to the investors as settlement of cumulative unpaid dividends. The notes bore interest at 4.0% and were originally due in June 2015. During the year ended September 30, 2015, $64,000 of the notes were offset against advances previously made to the Company's CEO. Additionally, $100,000 of the notes were offset against advances previously made to an investor. The Company made principal payments of $800,534 and $2,050,000 during the years ended September 30, 2016 and 2015, respectively.

In October 2014, the Company, upon the repurchase of 1,215 Parilis Preferred Units, issued $2,761,818 in notes to the investors at a price of $2,000 per unit and $331,818 in cumulative unpaid dividends. During the years ended September 30, 2016 and 2015, the Company made $2,275,818 and $486,000 in principal payments, respectively.

In June 2014, the Company repurchased shares of its restricted stock in exchange for $1,097,750 in notes payable. During the year ended September 30 2016, the Company paid $297,750 of the notes. The notes bear interest at rates ranging from 0% to 4% and are due on demand.

The Company has a $2,812,500 note payable related to the previous repurchase of common stock that does not bear interest and is due on demand.

In October and December 2014, the Company issued convertible promissory notes to a redeemable common stock investor, each in the amount of $2,000,000 and bearing interest at 12%. The December note was paid in full during the year ended September 30, 2015 and the October note was paid in full during the year ended September 30, 2016.

The Company has borrowed from stockholders for working capital purposes. The notes bear interest from 0% to 30% per annum. One of the notes is collateralized by 0.3 million common shares of the Company's founding stockholder and Chief Executive Officer ("CEO"). The notes are due on demand.

During the years ended September 30, 2016 and 2015, the Company recognized interest expense related to the stockholder notes of $589,675 and $1,869,113, respectively.

8. Debt

	September 30,	
	2016	2015
Term loans-Bank	$2,526,502	$3,404,759
Equipment loans	354,979	334,093
Unamortized debt discount	(61,224)	(73,442)
	2,820,257	3,665,410
Less: current portion	(586,454)	(742,646)
Long-term debt	$2,233,803	$2,922,764

The term bank loans bear interest at the prime rate plus 2.75% and are adjusted monthly. The original term of the loans range from 7 to 10 years. Minimum monthly payments of principal and interest under the terms of the loans are $48,048 and are collateralized by equipment, a secured interest in the personal residence of the founding stockholder and CEO, an unconditional personal guarantee by the founding stockholder and CEO and a $200,000 certificate of deposit. In August 2016, the Company paid in full one of the three term loans. The Company maintains a life insurance policy on its founding stockholder and CEO in which the bank is the primary beneficiary. The loans contain certain non-financial covenants.

The equipment loans bear interest at rates ranging from 12% to 16% with the original term of the loans ranging from 1 to 5 years. Minimum monthly payments of principal and interest under the equipment loans are $19,379 and are collateralized by the related equipment purchased and an unconditional personal guarantee by the founding stockholder and CEO.

Interest expense on the above loans for the years ended September 30, 2016 and 2015 was $230,824 and $287,280, respectively.

Future maturities of debt at September 30, 2016 are as follows:

2017	$ 586,454
2018	515,793
2019	549,694
2020	569,142
2021	497,491
Thereafter	162,907
	$2,881,481

9. Commitments

Selexis Commercial License Agreements

In April 2013, the Company entered into commercial license agreements with Selexis for each of the ONS-3010, ONS-1045 and ONS-1050 biosimilar product candidates (which agreements were subsequently amended on May 21, 2014). Under the terms of each commercial license agreement, the Company acquired a non-exclusive worldwide license under the Selexis Technology to use the applicable Selexis expression technology along with the resulting Selexis materials/ cell lines, each developed under the research license, to manufacture and commercialize licensed and final products, with a limited right to sublicense.

The Company paid an upfront licensing fee to Selexis for each commercial license and also agreed to pay a fixed milestone payment for each licensed product. In addition, the Company is required to pay a low single-digit royalty on a final product-by-final product and country-by-country basis, based on worldwide net sales of such final products by the Company or any of the Company's affiliates or sublicensees during the royalty term. The royalty term for each final product in each country is the period commencing from the first commercial sale of the applicable final product in the applicable country and ending on the expiration of the specified patent coverage. At any time during the term, the Company has the right to terminate its royalty payment obligation by providing written notice to Selexis and paying Selexis a royalty termination fee.

Each of the Company's commercial agreements with Selexis will expire upon the expiration of all applicable Selexis patent rights. Either party may terminate the related agreement in the event of an uncured material breach by the other party or in the event the other party becomes subject to specified bankruptcy, winding up or similar circumstances. Either party may also terminate the related agreement under designated circumstances if the Selexis Technology infringes third-party intellectual property rights. In addition, the Company has the right to terminate each of the commercial agreements at any time at its convenience; however, with respect to the agreements relating to ONS-3010 and ONS-1045, this right is subject to the licensee's consent pursuant to a corresponding letter the Company executed in conjunction with the standby agreement entered into between Selexis and Liomont in November 2014.

The standby agreement permits Liomont to assume the license under the applicable commercial agreement for Mexico upon specified triggering events involving our bankruptcy, insolvency or similar circumstances.

Technology License

The Company entered into a technology license agreement that will require milestone payments of $376,000 (based on an exchange rate on September 30, 2016 for converting Swiss Francs to U.S. dollars) to the licensor by the Company upon achievement of certain clinical milestones and pay a single digit royalty on net sales by the Company utilizing such technology. The Company also has the contractual right to buy out the royalty payments at a future date.

Leases

In July 2016, the Company entered into a fifth amendment to its lease agreement for its office and operating space which, as amended, has a term ending in June 2021. Additionally, in August 2015, the Company entered into a lease for approximately 82,000 square feet of office and laboratory space in Cranbury, New Jersey, with lease payments that commenced in March 2016 and expire in March 2026. Rent expense under the leases was $1,619,019 and $720,875, respectively for the years ended September 30, 2016 and 2015, respectively. The Company recognizes rent expense on a straight-line basis over the lease period and has accrued for rent expense incurred but not yet paid. Landlord allowances for tenant improvements are deferred and recognized as a reduction to rent expense on a straight line basis and over the remaining lease term.

Future minimum rental payments under noncancelable operating leases at September 30, 2016 are as follows:

2017	$ 1,551,513
2018	1,735,263
2019	1,753,323
2020	1,771,545
2021	1,596,976
Thereafter	3,541,990
	$11,950,610

Employment Benefit Plan

The Company maintains a defined contribution 401(k) plan in which employees may contribute up to 100% of their salary and bonus, subject to statutory maximum contribution amounts. The Company matches 100% of the first 3% of employee contributions. The Company assumes all administrative costs of the Plan. For the years ended September 30, 2016 and 2015, the expense relating to the matching contribution was $191,097 and $131,385, respectively.

10. Redeemable Preferred Stock, Common Stock, Noncontrolling Interests and Stockholders' Equity (Deficit)

Common stock

During the year ended September 30, 2015, the Company sold 1,765,511 shares of its common stock at $25.79 per share under a mezzanine funding round raising $44,142,463 in net proceeds of which $4,280,149 was received in October 2015.

From October 2015 through January 2016, the Company sold 573,388 shares of its common stock at $29.05 per share raising $16,137,913 in net proceeds. In May 2016, upon consummation of its IPO and private placement, the Company sold 5,833,334 units at $6.00 per unit and completed a concurrent private placement of an additional 833,332 shares of its common stock, 416,666 Series A warrants and 416,666 Series B warrants, at the same price (See Note 1), raising $33,784,205 in aggregate net proceeds. Each unit consisted of one share of the Company's common stock and warrants described below.

Concurrent with the closing of the IPO, 1,739,130 shares of redeemable common stock were reclassified to common stock upon the lapse of a contractual redemption right.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Subject to preferences that may apply to any outstanding preferred stock, holders of common stock are entitled to receive ratably any dividends that the Company's board of directors may declare out of funds legally available for that purpose on a non-cumulative basis. No dividends had been declared through September 30, 2016.

Series A warrants and Series B warrants

Each unit offered in connection with the Company's IPO consisted of one share of the Company's common stock, one-half of a Series A warrant to purchase one share of the Company's common stock and one-half of a Series B warrant to purchase one share of the Company's common stock. The Company also issued Series A warrants and Series B warrants in the concurrent private placement (see Note 1). Each whole Series A warrant and Series B warrant has an exercise price of $6.60 per share and $8.50 per share, respectively, and are exercisable until February 18, 2017 and May 18, 2018, respectively. Neither the Series A warrant holders nor Series B warrant holders has the rights or privileges of holders of common stock or any voting rights until they exercise their warrants and receive common stock.

The exercise price and number of shares issuable upon exercise of the Series A and Series B warrants may be adjusted upon the occurrence of certain events, including but not limited to any stock split, stock dividend, extraordinary dividend, recapitalization, reorganization, merger or consolidation.

As of September 30, 2016, there were 3,333,333 Series A warrants and 3,333,333 Series B warrants outstanding.

Common stock warrants

In May 2016, upon the closing of the IPO, the Company issued warrants to acquire an aggregate of 1,520,268 shares of its common stock to certain of the investors party to that certain investors' rights agreement dated March 10, 2014, as amended, pursuant to the terms of an amendment to such agreement dated April 26, 2016. The warrants issued to these investors are not exercisable until 180 days after May 12, 2016, and have an initial exercise price of $0.01 per share, which may increase to $1.00 per share under certain circumstances, and expire November 18, 2019. The estimated fair value of the warrants issued to these investors was $7,373,820 and reflected as a deemed dividend in the consolidated statement of operations for purposes of computing basic and diluted loss per share.

Deconsolidation of noncontrolling interests

Through September 30, 2015, the Company consolidated the operations of Sonnet because the Company was the primary funding source to Sonnet through September 2015. Effective October 1, 2015, additional capital was contributed to Sonnet by third-party investors triggering a reconsideration event, which resulted in the Company no longer being considered the primary beneficiary and as a result, the Company has deconsolidated Sonnet. Sonnet issued the Company an $826,561 promissory note which reflects the funding the Company provided Sonnet through September 30, 2015. There were no gains or losses recognized upon deconsolidation because no equity interest was owned by the Company. As of September 30, 2016, the balance of the promissory note plus accrued interest was paid in full.

Series A preferred stock

In connection with the closing of the Company's IPO, all outstanding shares of Series A preferred stock converted into 1,969,818 shares of common stock.

11. Stock-Based Compensation

2011 Equity Incentive Plan

The Company's 2011 Equity Compensation Plan (the "2011 Plan") provided for the Company to sell or issue restricted common stock, restricted stock units ("RSUs"), performance-based awards, cash-based awards or to grant stock options for the purchase of common stock to officers, employees, consultants and directors of the Company. The 2011 Plan was administered by the board of directors or, at the discretion of the board of directors, by a committee of the board. The number of shares of common stock reserved for

issuance under the 2011 Plan is 1,159,420. As of September 30, 2016, PSUs representing 247,309 shares of the Company's common stock were outstanding under the 2011 Plan. In light of the December 2015 adoption of the 2015 Equity Incentive Plan, no future awards under the 2011 Plan will be granted.

2015 Equity Incentive Plan

In December 2015, the Company adopted the 2015 Equity Incentive Plan (the "2015 Plan"). The 2015 Plan provides for the grant of stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards and other forms of equity compensation to Company employees, directors and consultants. On July 11, 2016 the maximum number of shares of the 2015 plan increased by 684,083 shares or 3% of the outstanding common stock of the Company. This increase resulted from a provision in the plan that allows an annual increase of shares in the plan. The maximum number of shares of common stock that may be issued under the 2015 Plan is 1,930,460 shares. As of September 30, 2016, RSUs representing 1,094,351 shares of the Company's common stock were outstanding under the 2015 Plan and 836,109 shares remained available for grant under the 2015 Plan.

The Company recorded stock-based compensation expense in the following expense categories of its consolidated statements of operations for the years ended September 30, 2016 and 2015:

	Year ended September 30,	
	2016	2015
Research and development	$ 2,044,379	$ 5,817,830
General and administrative	10,405,700	5,360,028
	$12,450,079	$11,177,858

	Year ended September 30,	
	2016	2015
Equity-classified compensation	$10,058,217	$ 8,925
Liability-classified compensation	2,391,862	11,168,933
	$12,450,079	$11,177,858

Performance-based stock units

The Company has issued PSUs, which generally have a ten year life from the date of grant and vest 50% after the third anniversary from issuance and the remaining 50% on the fourth anniversary. The PSUs are exercisable upon the earlier of (i) a change in control, (ii) consummation of an initial public offering, or (iii) a corporate valuation in excess of $400 million and at the discretion by the Company's board of directors. Upon exercise, the PSU holder receives common stock or cash at the Company's discretion. See note 4 for discussion of fair value of the PSUs.

The following table summarizes the PSU activity for the years ended September 30, 2016 and 2015:

	Number of PSUs	Base Price Per PSU
Balance at October 1, 2014	658,498	$3.45
Granted	39,988	3.45
Forfeitures	(11,473)	3.45
Balance at October 1, 2015	687,013	3.45
Forfeitures	(4,924)	4.85
Exchanged for restricted stock units	(434,780)	3.45
Balance at September 30, 2016	247,309	$6.33

In December 2015, the Company completed a tender-offer to holders of outstanding PSUs to amend the terms of such outstanding awards to increase the base price to an amount equal to the fair market value of a share of the Company's common stock on the date of grant of the PSU, remove the right to be paid dividend equivalents and provide for settlement in shares of the Company's common stock or cash, at the Company's discretion. Upon amending the settlement terms of the PSUs, the Company reclassified the stock-based compensation liability to additional paid-in capital.

Concurrent with the tender-offer, several PSU holders cancelled an aggregate of 434,780 PSUs in exchange for 391,303 RSUs. The Company accounted for the exchange as a modification, and, as a result, recognized $98,172 of additional stock-based compensation during the year ended September 30, 2016 based on the fair value of the RSUs in excess of the fair value of the PSUs exchanged.

The PSU represents an award that is exercisable based upon the achievement of either a performance condition or a market condition. As a result, the Company measures and records compensation cost taking into consideration both conditions: (1) an award that becomes exercisable upon the Company achieving a market value of $400 million and at the discretion by the Company's Board of Directors and (2) an award that is exercisable upon the earlier of a change in control or consummation of an IPO. Through December 2015, the fair value of both the performance and market conditions were remeasured prior to the PSUs being reclassified into equity. However, given the discretionary action required to be taken by the Company's Board of Directors, the fair value of the market condition continued to be remeasured each reporting period as compensation cost was recognized. Because a change of control or an IPO is not deemed probable until such event occurs, no compensation cost related to the performance condition was recognized prior to the consummation of the Company's IPO. Upon the consummation of the IPO in May 2016, the Company recorded compensation expense for the year ended September 30, 2016 based upon the fair value of the performance condition of the PSUs which was established in December 2015 when the PSUs became equity classified.

The fair value of the PSUs of $25.74 per PSU at December 31, 2015 was derived using the following assumptions:

	December 31, 2015
Risk-free interest rate	1.0%
Derived service period	2.3 years
Expected volatility	57.6%
Annual dividend yield	0%
Fair value of common stock	$29.05 per share

As of September 30, 2016, there was $646,531 of unamortized expense that will be recognized over a weighted-average period of 1.71 years.

Restricted stock units

The following table summarizes the activity related to RSUs granted during the year ended September 30, 2016:

	Number of RSUs	Weighted Average Grant Date Fair Value
Balance at October 1, 2015	—	$ —
Granted	705,311	28.31
Forfeitures	(2,263)	13.78
Issued in connection with PSU exchange	391,303	29.05
Balance at September 30, 2016	1,094,351	$28.61

As of September 30, 2016, there were 387,868 RSUs that will vest upon the expiration of the 180-day lock up period following the Company's IPO. The remaining 706,483 RSUs will vest upon the expiration of the 180-day lock up period following the Company's IPO and over the following time-based vesting periods:

- 424,468 RSUs with 50% vesting on each of the first and second anniversaries of the recipient's grant date
- 21,738 RSUs with one-third vesting on each of the first, second, and third anniversaries of the recipient's hire date
- 260,277 RSUs with 50% vesting on each of the third and fourth anniversaries of the recipient's hire date

The expiration of the lock-up period following an IPO or a change in control are performance conditions that are outside the Company's control. Therefore, the Company did not recognize any stock-based compensation until the consummation of the IPO in May 2016. As of September 30, 2016, there was $12,527,573 of unamortized expense that will be recognized over a weighted-average period of 1.53 years.

12. Collaboration Arrangements

Huahai agreement

In May 2013, the Company entered into strategic license and collaboration arrangement with Zhejiang Huahai Pharmaceutical Co., Ltd ("Huahai") under which the Company granted Huahai and its affiliates an exclusive license for the research, development, manufacture, use or sale of ONS-3010 or ONS-1045 in China, including, the People's Republic of China, Hong Kong, Macau and Taiwan. In addition, the Company granted Huahai a right and license under the Selexis Technology agreement to establish a production process for the products in the agreed territory and to market the products in the agreed territory pursuant to the relevant terms and conditions of the Company's commercial license agreement with Selexis.

Under the terms of the arrangement, the Company has received $7,500,000 in upfront payments and non-substantive milestones and received $8,500,000 in substantive milestones. The Company determined that the deliverables under the Huahai arrangement were the exclusive license and the research and development services to be completed by the Company. Since the license did not have standalone value, the upfront and non-substantive milestones payments received have been deferred and are being recognized ratably on a straight line basis through December 2019, the expected date in which the research and development will be completed. Substantive milestones received under the Huahai arrangement are recognized upon achievement.

During each of the years ended September 30, 2016 and 2015, the Company recognized $1,175,580 of deferred revenues. For the year ended September 30, 2015, the Company received and recognized $2,000,000 in substantive milestone payments. As of September 30, 2016 and 2015, deferred revenue included in the Company's consolidated balance sheet related to the Huahai arrangement was $3,752,950 and $4,928,530, respectively.

IPCA License and Collaboration Agreement

In August 2013, the Company entered into a strategic license agreement with IPCA Laboratories Limited and its affiliates ("IPCA") under which the Company granted IPCA a license for the research, development, manufacture, use or sale of the ONS-3010 and, by amendment in May 2014, the ONS-1045 biosimilar product candidates with respect to India, Sri-Lanka, and Myanmar, and non-exclusive with respect to Nepal and Bhutan, or collectively, the agreed territory. In addition, the Company granted IPCA a right and license under the Selexis Technology to enable IPCA to establish an exclusive production process for the

products in its agreed territory and to exclusively market the products in the agreed territory. The Company also agreed not to amend or terminate its rights under its commercial license agreement with Selexis without IPCA's prior written consent.

Pursuant to the agreement, the Company agreed to continue the non-clinical and clinical development of each of ONS-3010 and ONS-1045 and corresponding products around the world and to develop and commercialize such products through Phase 3 clinical trials and regulatory approval in the United States and European Union. These obligations continue until termination of the agreement or the individual development programs or upon final regulatory approval of the last product for such biosimilars in the United States or European Union. The Company agreed to provide IPCA with a pre-IND package as submitted to EMEA and FDA, as well as perform preclinical development and characterization of ONS-3010 and ONS-1045 so as to enable IPCA to file an IND to conduct clinical trials and to perform clinical trials.

Under the terms of the agreement, the Company has received upfront and non-substantive milestone payments of $2,400,000, and received $1,000,000 in regulatory milestone payments. In addition, the Company is eligible to receive royalties at a low double-digit percentage rate of annual net sales of products by IPCA and its affiliates in the agreed territory. For each of ONS-3010 and ONS-1045, IPCA agreed to fund a portion of the global costs associated with the Phase 3 clinical trials.

The Company determined that the deliverables under the IPCA arrangement were the exclusive license and the research and development services to be completed by the Company. Since the license did not have standalone value, the upfront and non-substantive milestones payments received have been deferred and are being recognized ratably on a straight line basis through December 2019, the expected date in which the research and development will be completed. Substantive milestone payments received under the IPCA arrangement are recognized upon achievement. Cost reimbursements from IPCA related to the global costs associated with the Phase 3 clinical trials are recorded as a reduction in research and development expense.

During the years ended September 30, 2016 and 2015, the Company recognized deferred revenues of $421,732 and $402,377, respectively. For the year ended September 30, 2015, the Company received and recognized a $500,000 substantive milestone payment. As of September 30, 2016 and 2015, deferred revenue included in the Company's consolidated balance sheets was $1,370,630 and $1,792,362, respectively.

Strategic Collaboration and Non-Exclusive License Agreement

In January 2014, the Company entered into a strategic collaboration and license agreement with IPCA to assist IPCA in establishing its research, development and manufacturing capabilities for monoclonal antibodies and biologics, including, in part, through collaborative development, manufacture and commercialization of ONS-1050 in the agreed territory (as specified below). Under the agreement, the Company granted IPCA and its affiliates a non-exclusive license in the agreed territory for the research, development, manufacture, use or sale of ONS-1050. The Company also agreed to assist IPCA with its research and development program. The agreed territory for ONS-1050 includes the Republics of India, Sri-Lanka, and Myanmar, Nepal and Bhutan, while the agreed territory for any product candidates developed independent of the Company's involvement is global without geographical restriction. Any further collaboration between for such independently developed product candidates will be the subject of a separate written agreement if required by IPCA.

Under the terms of the agreement, the Company receives development payments and commercialization fees. In addition, the Company is eligible to receive royalties from IPCA at a mid-single digit rate on annual net sales of ONS-1050 commercialized by IPCA and its affiliates in the agreed territory.

The Company accounts for the agreement with IPCA as a research and development services arrangement and recognizes revenue under the proportional performance model. For the years ended September 30, 2016 and 2015, the Company recognized revenue of $0 and $800,000, respectively.

Liomont agreement

In June 2014, the Company entered into a strategic license agreement with Laboratorios Liomont, S.A. ("Liomont"), under which the Company granted Liomont and its affiliates an exclusive, sublicenseable license in Mexico for the research, development, manufacture, use or sale of the ONS-3010 and ONS-1045 biosimilar product candidates in Mexico. In addition, the Company granted Liomont a non-exclusive right and license under the Selexis Technology and related intellectual property to enable Liomont to distribute, market and commercialize the products in Mexico. The Company also agreed not to amend or terminate its rights under the commercial agreement with Selexis without Liomont's prior written consent.

Under the terms of the agreement, the Company has received upfront payments and non-substantive milestone payments of $2,000,000 and received $1,000,000 in regulatory milestone payments. In addition, the Company is eligible to receive up to $2,000,000 in future substantive milestone payments. For each of ONS-3010 and ONS-1045, Liomont agreed to fund a portion of the global costs for Phase 3 clinical trials. The Company is eligible to receive tiered royalties at upper single-digit to low double-digit percentage rates of annual net sales of products by Liomont and its affiliates in Mexico.

The Company determined that the deliverables under the Liomont arrangement were the exclusive license and the research and development services to be completed by the Company. Since the license did not have standalone value, the upfront payments received have been deferred and are being recognized ratably on a straight line basis through December 2019, the expected date in which the research and development will be completed. Cost reimbursements from Liomont related to the global costs associated with the Phase 3 clinical trials are recorded as a reduction in research and development expense.

During the years ended September 30, 2016 and 2015, the Company recognized deferred revenue of $382,264 and $341,280, respectively. As of September 30, 2016 and 2015, deferred revenue included in the Company's consolidated balance sheets was $1,242,365 and $1,624,629.

13. Related-Party Transactions

During the years ended September 30, 2016 and 2015, the following related party transactions occurred other than as disclosed in Note 7 and Note 8:

- During the year ended September 30, 2015, the Company provided $783,707 of non-interest bearing advances to the Company's founding stockholder and CEO, of which $395,257 was repaid. Additionally, the CEO has deferred a portion of his salary, bonus, and related benefits during the year ended September 30, 2015 and applied such deferrals against previous advances. As of September 30, 2015, the Company had accrued compensation payments of $117,506, due to the CEO.

- In March 2015, a director of the Company loaned $1,000,000 to the Company with an interest rate of 24%. The loan was repaid in October 2015 and included $128,219 in accrued interest.

- During the years ended September 30, 2015 and 2014, the Company repurchased 1,250 shares of Series A redeemable preferred stock and satisfied accrued dividends of $326,354 from three directors of the Company in exchange for $650,000 in cash payments and the issuance of $1,850,000 in stockholder notes. The notes bear interest at 4% which are due on demand. Under the terms of the agreement, because the notes were not paid upon maturity, they now bear interest at 6%. Terms of the share repurchase were the same as non-related parties. Refer to notes 7 and 10.

Oncobiologics, Inc.

Notes to Consolidated Financial Statements

14. Income Taxes

Income tax expense (benefit) for the years ended September 30, 2016 and 2015 consists of the following:

	Year Ended September 30,	
	2016	2015
State tax, including sale of New Jersey losses and credits	$ 3,000	$(725,969)
Foreign tax provision	100,000	535,858
	$103,000	$(190,111)

The Company has been eligible to receive cash from the sale of its net operating losses ("NOLs") and R&D tax credits under the State of New Jersey Technology Business Tax Certificate Transfer Program. During the year ended September 30, 2015, the Company received $0.7 million from the sale of New Jersey NOLs. In addition, the Company incurred $0.1 million and $0.5 million of foreign withholding taxes in connection with the Company's collaboration and licensing agreements during the years ended September 30, 2016 and 2015, respectively.

A reconciliation of income tax (expense) benefit at the statutory federal income tax rate and income taxes as reflected in the financial statements is as follows:

	Year Ended September 30,	
	2016	2015
U.S. federal statutory rate	(34.0)%	(34.0)%
State taxes, net of federal benefit	(5.9)	(5.5)
Foreign withholding tax	0.2	1.1
Permanent differences	—	1.8
Foreign tax credits	—	(1.1)
Research and development credit	—	(6.9)
Change in valuation allowance	40.0	44.6
Other	(0.1)	(0.4)
Effective income tax rate	0.2%	(0.4)%

The tax effects of the temporary differences that gave rise to deferred taxes were as follows:

	Year Ended September 30,	
	2016	2015
Deferred tax assets		
Net operating loss carryforwards	$ 36,146,789	$ 20,164,392
Stock compensation	11,249,314	6,317,492
Deferred revenue	2,542,558	3,333,201
Research and development credit carryforward	757,701	5,979,964
Foreign tax credits	2,257,309	2,602,949
Accruals and others	1,287,592	1,072,422
Gross deferred tax assets	54,241,263	39,470,420
Less: valuation allowance	(52,737,104)	(38,694,795)
	1,504,159	775,625
Deferred tax liability:		
Fixed assets	(1,504,159)	(775,625)
Net deferred tax assets	$ —	$ —

As of September 30, 2016, the Company has approximately $99.8 million and $37.0 million of Federal and New Jersey net operating losses that will begin to expire in 2030 and 2036, respectively. As of September 30, 2016, the Company has Federal research and development tax credit carryforwards of $0.8 million available to reduce future tax liabilities which will begin to expire in 2032. As of September 30, 2016, the Company has Federal foreign tax credit carryforwards of $2.3 million available to reduce future tax liabilities which will begin to expire starting in 2023. $1.8 million of the FTC carryforward is included in the balance of unrecognized tax benefits. Realization of the deferred tax asset is contingent on future taxable income and based upon the level of historical losses, management has concluded that the deferred tax asset does not meet the more-likely-than-not threshold for realizability. Accordingly, a full valuation allowance continues to be recorded against the Company's deferred tax assets as of September 30, 2016 and 2015. The valuation allowance increased $14.0 million and $21.3 million during the years ended September 30, 2016 and 2015, respectively.

When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely-than-not be realized. The determination as to whether the tax benefit will more-likely-than-not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. The Company recognizes interest and penalties accrued on any unrecognized tax benefits within the provision for income taxes in its consolidated statements of operations.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	Year Ended September 30,	
	2016	2015
Balance at beginning of year	$1,754,629	$1,564,411
Additions based on tax positions related to the current year	100,000	190,218
Balance at end of year	1,854,629	1,754,629

The Company does not anticipate material change in the unrecognized tax benefits in the next 12 months. These unrecognized tax benefits, if recognized, would affect the annual effective tax rate. The Company's income tax returns for the years from 2011 through 2015 remain open for examination by the Internal Revenue Service as well as various state, local and foreign jurisdictions.

Due to the change in ownership provisions of the Internal Revenue Code, the availability of the Company's net operating loss carryforwards may be subject to annual limitations against taxable income in future periods, which could substantially limit the eventual utilization of such carryforwards. The Company has not analyzed the historical or potential impact of its equity financings on beneficial ownership and therefore no determination has been made whether the net operating loss carry forward is subject to any Internal Revenue Code Section 382 limitation. To the extent there is a limitation, there would be a reduction in the deferred tax assets with an offsetting reduction in the valuation allowance.

15. Subsequent Events

In October, November and December 2016, the Company issued $1.85 million aggregate principal amount of unsecured bridge notes to accredited investors. These unsecured notes bore interest at a rate of 15% per year and had a one-year maturity date from the date of issuance.

On December 22, 2016, the Company entered into a Note and Warrant Purchase Agreement with accredited investors providing for the issuance and sale of up to $10.0 million of senior secured promissory notes (the "Notes"), which bear interest at a rate of 5% per year and mature December 22, 2017 and warrants (the "Warrants") to acquire an aggregate 2.3 million shares of the Company's common stock at an exercise price of $3.00 per share which have a five-year term. The Company closed the initial sale and purchase of the Notes and Warrants on December 22, 2016, issuing $8.35 million aggregate principal amount of Notes and Warrants to acquire 1,920,500 shares of the Company's common stock in exchange

for $6.5 million of cash and an aggregate of $1.85 million of existing unsecured bridge notes issued by the Company in October, November and December 2016. The Company used $2.4 million of the proceeds from the sale of the Notes to pay off its existing senior secured bank loans, and will use the remainder for working capital purposes. The Company may issue up to $1.65 million of additional Notes and Warrants to acquire up to an additional 379,500 shares of the Company's common stock in additional closings over the next 90 days without approval of holders of the Notes. Under the Note and Warrant Purchase Agreement, the Company agreed to customary negative covenants restricting its ability to repay indebtedness to officers, pay dividends to stockholders, repay or incur other indebtedness other than as permitted, grant or suffer to exist a security interest in any of the Company's assets, other than as permitted, or enter into any transactions with affiliates. In addition to the negative covenants in the Note and Warrant Purchase Agreement, the Notes include customary events of default.

In connection with the closing of the initial sale of the Notes and Warrants, the Company entered into a Security Agreement and an Intellectual Property Security Agreement, each dated December 22, 2016, granting the holders of the Notes a security interest in all of its assets.

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

None

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) prior to the filing of this Annual Report on Form 10-K. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer, have concluded that, as of the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures were, in design and operation, effective.

Internal Control over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitation on the Effectiveness of Internal Control.

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurances. In addition, 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. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting.

Item 9B. Other Information

Not applicable.

PART III

Certain information required by PART III is omitted from this Annual Report on From 10-K because the Company will file a Definitive Proxy Statement with the Securities and Exchange Commission within 120 days after the end of our year ended September 30, 2016.

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item is incorporated herein by reference to the Proxy Statement.

Item 11. Executive Compensation

The information required by this item is incorporated herein by reference to the Proxy Statement.

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

The information required by this item is incorporated herein by reference to the Proxy Statement.

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

The information required by this item is incorporated herein by reference to the Proxy Statement.

Item 14. Principal Accounting Fees and Services

The information required by this item is incorporated herein by reference to the Proxy Statement.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) (1) The financial statements required by Item 15(a) are filed in Item 8 of this Annual Report on Form 10-K.

(2) The financial statement schedules required by Item 15(a) are omitted because they are not applicable, not required or the required information is included in the financial statements or notes thereto as filed in Item 8 of this Annual Report on Form 10-K.

(3) We have filed, or incorporated into this report by reference, the exhibits listed on the accompanying Index to Exhibits immediately following the signature page of this Annual Report on Form 10-K.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) the Securities Exchange Act of 1934, the registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: December 29, 2016	By:	/s/ Pankaj Mohan
	Name:	Pankaj Mohan, Ph.D.
	Title:	Chairman, President and Chief Executive Officer (Principal Executive Officer)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

/s/ Pankaj Mohan Pankaj Mohan, Ph.D.	Chairman, President and Chief Executive Officer *(Principal Executive Officer)*	December 29, 2016
/s/ Lawrence A. Kenyon Lawrence A. Kenyon	Chief Financial Officer *(Principal Financial and Accounting Officer)*	December 29, 2016
/s/ Todd C. Brady, M.D., Ph.D. Todd C. Brady, M.D., Ph.D.	Director	December 29, 2016
/s/ Scott Canute Scott Canute	Director	December 29, 2016
/s/ Albert D. Dyrness Albert D. Dyrness	Director	December 29, 2016
/s/ Donald J. Griffith Donald J. Griffith	Director	December 29, 2016
/s/ Kurt J. Hilzinger Kurt J. Hilzinger	Director	December 29, 2016
/s/ Robin Smith Hoke Robin Smith Hoke	Director	December 29, 2016

EXHIBIT INDEX

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of Oncobiologics, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed with the SEC on May 19, 2016).
3.2	Amended and Restated Bylaws of Oncobiologics, Inc. (incorporated by reference to Exhibit 3.2 to the Registrant's current report on Form 8-K filed with the SEC on May 19, 2016).
3.3	Amendment to the Amended and Restated Bylaws of Oncobiologics, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed with the SEC on November 29, 2016).
10.1	Investors' Rights Agreement by and among Oncobiologics, Inc. and certain of its stockholders, dated March 10, 2014, as amended (incorporated by reference to Exhibit 10.1 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on May 11, 2016).
10.2#	2011 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.3#	Form of Amended and Restated Performance Stock Unit Agreement for 2011 Stock Incentive Plan (incorporated by reference to Exhibit 10.29 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on April 27, 2016).
10.4#	2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.5#	Forms of agreements and award grant notices for 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.6#	2016 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.5 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on February 12, 2016).
10.7#	Form of Indemnity Agreement, by and between Oncobiologics, Inc. and each of its directors and executive officers (incorporated by reference to Exhibit 10.12 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.8†	Research License Agreement by and between Oncobiologics, Inc. and Selexis SA, effective as of October 3, 2011, as amended by Amendment No. 1 dated as of October 9, 2014 (incorporated by reference to Exhibit 10.13 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on February 26, 2016).
10.9†	ONS-3010 Commercial License Agreement by and between Oncobiologics, Inc. and Selexis SA effective as of April 11, 2013, as amended effective as of May 21, 2014 (incorporated by reference to Exhibit 10.14 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.10†	ONS-1045 Commercial License Agreement by and between Oncobiologics, Inc. and Selexis SA effective as of April 11, 2013, as amended effective as of May 21, 2014 (incorporated by reference to Exhibit 10.15 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.11†	ONS-1050 Commercial License Agreement by and between Oncobiologics, Inc. and Selexis SA effective as of April 11, 2013, as amended effective as of May 21, 2014 (incorporated by reference to Exhibit 10.16 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).

Exhibit Number	Description
10.12	Joint Participation Agreement by and between Oncobiologics, Inc. and Zhejiang Huahai Pharmaceutical Co., Ltd., effective as of May 6, 2013, as amended by that Amendment No. 1 and Mutual Termination Agreement re: Joint Participation Agreement, dated December 23, 2014 (incorporated by reference to Exhibit 10.17 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.13	Lease Agreement by and between Oncobiologics, Inc. and Cedar Brook 7 Corporate Center, LP, dated as of March 18, 2011 (incorporated by reference to Exhibit 10.18 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.14	First Amendment to Lease Agreement by and between Oncobiologics, Inc. and Cedar Brook 7 Corporate Center, LP, dated as of December 2013 (incorporated by reference to Exhibit 10.19 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.15	Second Amendment to Lease Agreement by and between Oncobiologics, Inc. and Cedar Brook 7 Corporate Center, LP, dated as of July 18, 2014 (incorporated by reference to Exhibit 10.20 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.16	Third Amendment to Lease Agreement by and between Oncobiologics, Inc. and Cedar Brook 7 Corporate Center, LP, dated as of January 16, 2015 (incorporated by reference to Exhibit 10.21 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.17	Fourth Amendment to Lease Agreement by and between Oncobiologics, Inc. and Cedar Brook 7 Corporate Center, LP, dated as of February 9, 2015 (incorporated by reference to Exhibit 10.22 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.18	Fifth Amendment to Lease Agreement by and between Oncobiologics, Inc. and Cedar Brook 7 Corporate Center, LP, dated as of September 26, 2015 (incorporated by reference to Exhibit 10.23 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.19	Lease Agreement by and between Cedar Brook East Corporate Center, LP and Oncobiologics, Inc., dated as of August 31, 2015 (incorporated by reference to Exhibit 10.24 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.20#	Employment Agreement between Oncobiologics, Inc. and Pankaj Mohan, Ph.D., dated February 22, 2016 (incorporated by reference to Exhibit 10.25 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on April 27, 2016).
10.21#	Employment Agreement between Oncobiologics, Inc. and Lawrence A. Kenyon, dated February 18, 2016 (incorporated by reference to Exhibit 10.28 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on April 27, 2016).
10.22#	Employment Agreement between Oncobiologics, Inc. and Kenneth Bahrt, M.D., dated February 22, 2016 (incorporated by reference to Exhibit 10.26 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on April 27, 2016).
10.23#	Employment Agreement between Oncobiologics, Inc. and Elizabeth A. Yamashita, dated February 24, 2016 (incorporated by reference to Exhibit 10.27 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on April 27, 2016).
10.24#	Form of Amended and Restated Performance Stock Unit Agreement for 2011 Stock Incentive Plan (incorporated by reference to Exhibit 10.29 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on April 27, 2016).

Exhibit Number	Description
10.25	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 10.30 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on May 11, 2016).
10.26	Securities Purchase Agreement between Oncobiologics, Inc. and Sabby Healthcare Master Fund Ltd., dated May 11, 2016 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on May 19, 2016).
10.27	Warrant Agreement by and between Oncobiologics, Inc. and American Stock Transfer & Trust Company LLC, as Warrant Agent dated May 18, 2016 (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on June 27, 2016).
10.28	Form of Series A warrant certificate (included in Exhibit 10.27).
10.29	Form of Series B warrant certificate (included in Exhibit 10.27).
10.30	Note and Warrant Purchase Agreement by and between Oncobiologics, Inc. and the Purchasers named therein dated December 22, 2016 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on December 23, 2016).
10.31	Form of Senior Secured Promissory Note (included as Exhibit A to the Note and Warrant Purchase Agreement filed as Exhibit 10.30).
10.32	Form of Warrant (included as Exhibit B to the Note and Warrant Purchase Agreement filed as Exhibit 10.30).
10.33	Security Agreement by and between Oncobiologics, Inc. and the Secured Parties named therein dated December 22, 2016 (incorporated by reference to Exhibit 10.4 to the Registrant's current report on Form 8-K filed with the SEC on December 23, 2016).
10.34	Intellectual Property Security Agreement by and between Oncobiologics, Inc. and the Secured Parties named therein dated December 22, 2016 (incorporated by reference to Exhibit 10.5 to the Registrant's current report on Form 8-K filed with the SEC on December 23, 2016).
23.1	Consent of independent registered public accounting firm.
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1*	Certifications of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been filed separately with the SEC.

* Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

# Indicates management contract or compensatory plan.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors
Oncobiologics, Inc.:

We consent to the incorporation by reference in the Registration Statement (No. 333-211362) on Form S-8 of Oncobiologics, Inc. of our report dated December 29, 2016, with respect to the consolidated balance sheets of Oncobiologics, Inc. as of September 30, 2016 and 2015, and the related consolidated statements of operations, redeemable preferred stock, common stock, noncontrolling interests and stockholders' equity (deficit), and cash flows for the years then ended, which report appears in the September 30, 2016 annual report on Form 10-K of Oncobiologics, Inc.

Our report dated December 29, 2016 contains an explanatory paragraph that states that Oncobiologics, Inc. has incurred recurring losses and negative cash flows from operations since inception and has an accumulated deficit at September 30, 2016 of $147.4 million and $4.6 million of indebtedness that is due on demand, which raises substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KPMG LLP

Philadelphia, Pennsylvania
December 29, 2016

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO
SECTION 13(a) OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Pankaj Mohan, certify that:

1. I have reviewed this Annual Report on Form 10-K of Oncobiologics, Inc. (the "registrant"); and

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: December 29, 2016

/s/ Pankaj Mohan
Pankaj Mohan, Ph.D.
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
SECTION 13(a) OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Lawrence A. Kenyon, certify that:

1. I have reviewed this Annual Report on Form 10-K of Oncobiologics, Inc. (the "registrant"); and

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: December 29, 2016

/s/ Lawrence A. Kenyon
Lawrence A. Kenyon
Chief Financial Officer

Exhibit 32.1

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officers of Oncobiologics, Inc. (the "Registrant") certify that the Annual Report of Oncobiologics, Inc. on Form 10-K for the year ended September 30, 2016 (the " Report ") fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that information contained in the Report fairly presents in all material respects the financial condition and results of operations of the Registrant.

Date: December 29, 2016	By:	/s/ Pankaj Mohan
	Name:	Pankaj Mohan, Ph.D.
	Title:	Chairman, President and Chief Executive Officer (Principal Executive Officer)
Date: December 29, 2016	By:	/s/ Lawrence A. Kenyon
	Name:	Lawrence A. Kenyon
	Title:	Chief Financial Officer

A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350 has been provided to the Registrant and will be retained by the Registrant and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.