As filed with the Securities and Exchange Commission on May 11, 2016.

Registration No. 333-209011

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

AMENDMENT NO. 5 TO FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Oncobiologics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**2836**	**38-3982704**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

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)

Pankaj Mohan, Ph.D.
Chairman, President and Chief Executive Officer
Oncobiologics, Inc.
7 Clarke Drive
Cranbury, New Jersey 08512
(609) 619-3990

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Yvan-Claude Pierre **Daniel I. Goldberg** **Divakar Gupta** **Cooley LLP** **1114 Avenue of the Americas** **New York, New York 10036** **(212) 479-6000**	**Stuart M. Cable** **Edwin M. O'Connor** **Seo Salimi** **Goodwin Procter LLP** **Exchange Place** **53 State Street** **Boston, Massachusetts 02109** **(617) 570-1000**

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☒

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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

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

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price[1]	Amount of registration fee[1]
Units of common stock, $0.01 par value per share, Series A warrants and Series B warrants[2][3]	$ 40,250,005	$ 4,053.18
Common stock, $0.01 par value per share, included in the units[3][4][5]	—	—
Series A warrants included in the units[3][5]	—	—
Common stock, $0.01 par value per share, underlying the Series A warrants included in the units[3][4][6]	$ 22,137,503	$ 2,229.25
Series B warrants included in the units[3][5]	—	—
Common stock, $0.01 par value per share, underlying the Series B warrants included in the units[3][4][7]	$ 28,510,420	$ 2,871.00
Total[8]	$ 90,897,928	$ 9,153.43

(1) Estimated solely for the purpose of computing the amount of registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended, or the Securities Act.

(2) Includes the offering price of units that the underwriters have the option to purchase to cover over-allotments, if any.

(3) Each unit will consist of one share of common stock, one-half of a Series A warrant to purchase one share of common stock and one-half of a Series B warrant to purchase one share of common stock.

(4) Pursuant to Rule 416 of the Securities Act, the securities being registered hereunder include such additional securities as may be issued after the date hereof as a result of share splits, share dividends or similar transactions.

(5) No fee required pursuant to Rule 457(g) under the Securities Act.

(6) We have calculated the proposed maximum aggregate offering price of the common stock underlying the Series A warrants by assuming that such warrants are exercisable to purchase common stock at a price per share equal to $6.60.

(7) We have calculated the proposed maximum aggregate offering price of the common stock underlying the Series B warrants by assuming that such warrants are exercisable to purchase common stock at a price per share equal to $8.50.

(8) The Registrant previously paid a registration fee of $11,580.50 with the initial filing of this registration statement.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any jurisdiction where such offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED MAY 11, 2016

PRELIMINARY PROSPECTUS

5,833,334 Units

This is the initial public offering of securities of Oncobiologics, Inc. We are offering to sell 5,833,334 units, each unit consisting of one share of our 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 our 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 our common stock at an initial exercise price of $8.50, subject to adjustment. We currently expect the initial public offering price to be $6.00 per unit.

Our common stock has been approved for listing on the NASDAQ Global Market under the symbol “ONS.” We have applied for the listing of our units, Series A warrants and Series B warrants on the NASDAQ Global Market under the symbols “ONSIU,” “ONSIW” and “ONSIZ,” respectively.

The Series A warrants, Series B warrants and shares of our common stock will trade together as units only during the first 30 days following the date of this prospectus, and thereafter, the units will automatically separate and the common stock, Series A warrants and Series B warrants will trade separately, unless Jefferies LLC and Barclays Capital Inc., as representatives of the underwriters, determine that an earlier date is acceptable based upon, among other things, its assessment of the relative strengths of the securities markets and small capitalization companies in general, and the trading pattern of, and demand for, our securities in particular.

We are an “emerging growth company” under the federal securities laws and will be subject to reduced public company reporting requirements for this prospectus and future filings.

Investing in our securities involves a high degree of risk. See “Risk Factors” beginning on page 11.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	PER UNIT	TOTAL
Public Offering Price	$	$
Underwriting Discounts and Commissions(1)	$	$
Proceeds to Oncobiologics, Inc. (Before Expenses)	$	$

(1) See “Underwriting” beginning on page 145 for additional disclosure regarding underwriting discounts, commissions and estimated offering expenses.

Certain of our existing and new investors have indicated an interest in purchasing up to an aggregate of approximately $20.0 million of units in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, fewer or no units in this offering to any of these investors, or any of these investors may determine to purchase more, fewer or no units in this offering.

In addition, Sabby Healthcare Master Fund, Ltd., an existing stockholder, has indicated an interest in purchasing $5.0 million of our units at the initial public offering price in a private placement that would close concurrently with this offering. This indication of interest is not a binding agreement or commitment to purchase, and we could determine to sell more, less or no units to this stockholder and this stockholder could determine to purchase more, less or no units in the proposed concurrent private placement. The underwriters will serve as placement agents for such concurrent private placement and receive a placement agent fee equal to a percentage of the total purchase price of the private placement units, which percentage will be equal to the percentage discount the underwriters will receive on units sold in this offering. The closing of this offering is not conditioned upon the closing of such concurrent private placement.

Delivery of the units is expected to be made on or about , 2016. We have granted the underwriters an option for a period of 30 days to purchase an additional 875,000 units. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be $, and the total proceeds to us, before expenses, will be $.

Joint Book-Running Managers

Jefferies **Barclays**

Lead Manager

Cantor Fitzgerald & Co.

Preliminary Prospectus dated , 2016

TABLE OF CONTENTS

We are responsible for the information contained in this prospectus and in any free-writing prospectus we prepare or authorize. We have not authorized anyone to provide you with different information, and we take no responsibility for any other information others may give you. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the cover of this prospectus.

Persons who come into possession of this prospectus and any applicable free writing prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus and any such free writing prospectus applicable to that jurisdiction.

Our name "Oncobiologics," the Oncobiologics logo and other trademarks or service marks of Oncobiologics, Inc. appearing in this prospectus are the property of Oncobiologics, Inc. Other trademarks, service marks or trade names appearing in this prospectus are the property of their respective owners. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

Convenience translations between Swiss Francs, or CHF, and U.S. dollars provided herein are based on the noon buying rate in New York City for cable transfers in foreign currencies as certified for customs purposes by the Federal Reserve Bank of New York on December 31, 2015, or CHF 1.0017 = $1.00. We do not represent that CHF were, could have been, or could be, converted into U.S. dollars at such rate or at any other rate.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary provides an overview of selected information and does not contain all of the information you should consider before investing in our securities. You should read this entire prospectus carefully, especially the section titled "Risk Factors" and our consolidated financial statements and related notes included elsewhere in this prospectus, before making an investment decision. Except as otherwise indicated or unless the context otherwise requires, references to "company," "we," "us," "our" or "Oncobiologics," refer to Oncobiologics, Inc. and its consolidated subsidiary.

Overview

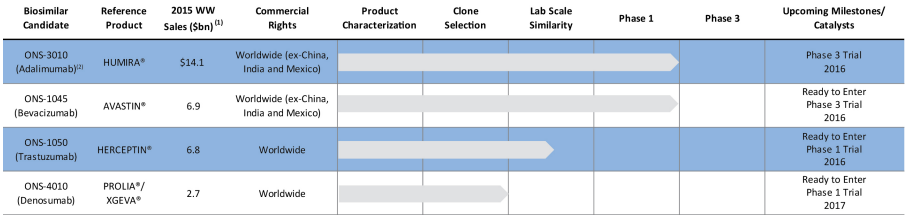
We are a clinical-stage biopharmaceutical company focused on identifying, developing, manufacturing and commercializing complex biosimilar therapeutics. Our current focus is on technically challenging and commercially attractive monoclonal antibodies, or mAbs, in the disease areas of immunology and oncology. 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. Since inception, we have advanced two product candidates into clinical trials: ONS-3010, a Phase 3-ready biosimilar to adalimumab (Humira®), and ONS-1045, a Phase 3-ready biosimilar to bevacizumab (Avastin®). Additionally, we have identified multiple other biosimilar product candidates, including six that are in active preclinical development, one of which is expected to be ready to enter clinical trials in 2016.

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.

Our Pipeline

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 two mAb biosimilars for which we expect to initiate development by the end of 2016. Our current pipeline of mAb biosimilars for which we have completed clone selection is described in the following chart.



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

(2) We currently have an arrangement with Zhejiang Huahai Pharmaceutical Co., Ltd., or 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** is our adalimumab (Humira) biosimilar. Humira is a subcutaneous injectable mAb that binds to tumor necrosis factor-alpha, or TNFα. 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. 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 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 the following indications: rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult crohn's disease, pediatric crohn's disease, ulcerative colitis, plaque psoriasis, and hidradenitis suppurativa. 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 discussed our interchangeability study design with the FDA. We intend to deliver ONS-3010 in the same manner as Humira, via subcutaneous injection.
- **ONS-1045** is our bevacizumab (Avastin) biosimilar. Avastin is a mAb administered by infusion that interferes with tumor growth by binding to vascular endothelial growth factor, or VEGF, a protein that stimulates the formation of new blood vessels. We have completed a randomized, double-blind, single-dose and single-center Phase 1 clinical trial. 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. 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 have completed the next series of our regulatory interactions with the FDA, EMA, MHRA and the Danish Health and Medicines Agency to obtain further guidance on our confirmatory trial design and have gained agreement on the sensitive patient population in non-squamous non-small cell lung cancer. We have also begun preparatory planning with the intention to discuss our Japanese development strategy with Japan's Pharmaceuticals and Medical Devices Agency in 2016 and initiated a site feasibility study (targeting North and South America, Europe and Asia) to ready ONS-1045 for a global Phase 3 clinical trial.
  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 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. We intend to deliver ONS-1045 in the same manner as Avastin, via infusion.
- **ONS-1050** is our trastuzumab (Herceptin) biosimilar. Herceptin is a mAb administered by infusion that binds to human epidermal growth factor receptor 2, or HER2. A clone with a "highly similar" profile to Herceptin has been chosen for further process development. Extensive analytical characterization and *in*

vitro functionality studies comparing ONS-1050 to Herceptin are underway to support the biosimilarity assessment required to be ready to initiate a Phase 1 clinical trial in 2016.
Herceptin currently approved in the United States for the following indications: treatment of HER2-overexpressing breast cancer and treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. We have not yet determined the indication for which we will initially seek approval of ONS-1050, although it will be for one of the indications for which Herceptin is approved. It is our intent to then seek to expand such approval to the same indications as Herceptin via extrapolation. We intend to deliver ONS-1050 in the same manner as Herceptin, via infusion.

- In addition to the product candidates we are currently advancing through clinical development, we are leveraging our BioSymphony Platform to develop additional preclinical product 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.
  - **ONS-4010**, a biosimilar to denosumab (Prolia®/Xgeva®), has cell lines developed with clone selection completed. We have completed preliminary characterization and reverse engineering of the amino acid sequences of the reference product. We plan to complete process development, and be ready to commence our Phase 1 clinical trial, in 2017. Prolia is a subcutaneous injectable that is 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.
  - **ONS-1055**, a biosimilar to cetuximab (Erbitux®), has cell lines developed with clone selection nearing completion. We have completed preliminary characterization and reverse engineering of the amino acid sequences of the reference product. We plan to complete lab scale similarity in 2016. According to recent filings with the Securities and Exchange Commission, 2015 worldwide sales of Erbitux® were approximately $2.0 billion.
  - **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 2016, we anticipate completing clone selection for ONS-3030, and reference product characterization for each of ONS-3035 and ONS-3040.

Our Strategy

Our goal is to utilize the BioSymphony Platform to identify, develop, manufacture and commercialize technically challenging and commercially attractive mAbs 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;*
- *employing our expertise in product development to further expand our pipeline*;
- *cost effectively developing and manufacturing mAb biosimilars in an accelerated timeframe;*
- *continuing to invest in and expand our in-house manufacturing capabilities*; *and*
- *maximizing the value of our pipeline by retaining development and commercialization rights in the United States and continuing to selectively out-license to ex-U.S. markets.*

Our Team

We have assembled a team of industry veterans, with decades of cumulative experience in biologics development and commercialization at such organizations as Bristol-Myers Squibb Company, Genentech, Inc., Hoffman-La Roche, NPS Pharmaceuticals, Inc. and Savient Pharmaceuticals, Inc. Our leadership team has also been instrumental in obtaining global regulatory approval for multiple complex biologics at leading multinational biopharmaceutical companies. Our Chairman, President and Chief Executive Officer, Pankaj Mohan, Ph.D., served as a Senior Manager at Eli Lilly and Company, head of Business Operations and Portfolio Management of Biologics Process and Product Development at Bristol-Myers Squibb Company and Director of Bioprocess Engineering at Genentech, Inc. 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.

Our Culture and Mission

We are focused on identifying, developing and manufacturing complex biosimilar mAb therapeutics in the areas of immunology and oncology. We are dedicated to bringing cost-effective treatment options to patients and their families living with cancer and other serious diseases. The foundation of our BioSymphony Platform is our collaborative culture, which is based on the following core values:

- ***Agility and Speed*** — we are committed to effective execution of the development process with a focus on simplification leading to efficient decision-making.
- ***Technical Excellence*** — our leadership team and team of scientific experts have implemented a state-of-the-art technology platform to enable application of scientific rigor in our development and manufacturing processes.
- ***Industry Experience*** — our team cumulatively has decades of experience in identifying, developing, manufacturing and commercializing complex biologics.

Risks Associated with Our Business

Our business is subject to numerous risks and uncertainties, including those highlighted in the section titled “Risk Factors” immediately following this prospectus summary. These risks include, among others, the following:

- We have a limited operating history, have incurred significant losses since our inception and expect to continue to incur significant losses for the foreseeable future and will need to raise substantial additional funding, even with the net proceeds expected from this offering and the concurrent private placement, if any.
- Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.
- 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.
- 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.
- 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. To our knowledge, there have been only two biosimilar product applications approved by the FDA under the 351(k) pathway to date.
- Clinical development of biosimilars is different and can be more complex than clinical development programs for the reference products.
- We expect to depend on third parties for the commercialization of our biosimilar product candidates in certain major markets for ONS-3010, ONS-1045 and ONS-1050 outside the United States, and their failure to commercialize in those markets could harm our business and operating results. 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 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.
- 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 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.
- 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 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 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.
- 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.
- 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.

If we are unable to adequately address these and other risks we face, our business, financial condition, operating results and prospects may be harmed.

Implications of Being an Emerging Growth Company

As a company with less than $1.0 billion in revenues during our last fiscal year, we are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012, and therefore we intend to take advantage of certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved. We may take advantage of these exemptions for up to five years or until we are no longer an "emerging growth company." We would cease to be an "emerging growth company" if we have more than $1.0 billion in annual revenues, have more than $700 million in market value of our common stock held by non-affiliates as of the last day of our second fiscal quarter or issue more than $1.0 billion of non-convertible debt over a three-year period. We may choose to take advantage of some, but not all, of the available benefits under the JOBS Act. We have taken advantage of some reduced reporting burdens in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

In addition, the JOBS Act provides that an "emerging growth company" can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of delayed adoption of new or revised accounting standards and, therefore, we will be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not "emerging growth companies."

Recent Developments

In January 2016, we issued and sold an aggregate of 87,287 shares of our common stock to five accredited investors at a purchase price of $29.05 per share, for aggregate net proceeds of approximately $2.5 million. All of the investors who purchased shares in this offering became party to the co-sale agreement, as amended, and the investors' rights agreement, as amended.

On April 26, 2016, we entered into an amendment of that certain investors' rights agreement dated March 10, 2014, as amended, and agreed, under certain circumstances, to issue certain of the investors upon the closing of this offering three-year warrants to purchase an aggregate of 1,520,284 shares of our common stock. Such warrants are not exercisable until 180 days after effectiveness of the registration statement for this offering, and have an initial exercise price of $0.01 per share, which may increase to $1.00 per share under certain circumstances.

Concurrent Private Placement

Sabby Healthcare Master Fund, Ltd., or Sabby, an existing stockholder, has indicated an interest in purchasing $5.0 million of our units at the initial public offering price in a private placement that would close concurrently with this offering. This indication of interest is not a binding agreement or commitment to purchase, and we could determine to sell more, less or no units to this stockholder and this stockholder could determine to purchase more, less or no units in the proposed concurrent private placement. The units that may be sold in the proposed concurrent private placement will constitute restricted securities under the Securities Act of 1933, as amended. The underwriters will serve as placement agents for such concurrent private placement and will receive a placement agent fee equal to a percentage of the total purchase price of the private placement units, which percentage will be equal to the percentage discount the underwriters will receive on units sold in this offering. The closing of this offering is not conditioned upon the closing of such concurrent private placement.

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 prospectus and should not be considered to be part of this prospectus.

THE OFFERING

Securities offered by us	5,833,334 units, each consisting 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 our common stock at an initial exercise price of $6.60, subject to adjustment. Each whole Series A warrant will be exercisable 30 days after the date of this prospectus or on such date the underwriters separate the units, whichever date is earlier and will expire at 5:00 p.m. New York City time on February , 2017. Each whole Series B warrant entitles the holder to purchase one share of our common stock at an initial exercise price of $8.50, subject to adjustment. Each whole Series B warrant will be exercisable 30 days after the date of this prospectus or on such date the underwriters separate the units, whichever date is earlier, and will expire at 5:00 p.m. New York City time on May , 2018.
Concurrent private placement	Sabby has indicated an interest in purchasing approximately $5.0 million of our units at a price per unit equal to the initial public offering price (or 833,332 units based on the assumed initial public offering price of $6.00 per unit) in a private placement that would close concurrently with this offering. See "Certain Relationships and Related Party Transactions — Concurrent Private Placement."
Common stock to be outstanding immediately after this offering	21,969,446 shares (including shares included in the units but excluding shares underlying the warrants included in the units and any securities that may be issued in the concurrent private placement, if any).
Over-allotment option	875,000 units
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $29.8 million, or approximately $34.6 million if the underwriters exercise in full their over-allotment option to purchase additional units, at an assumed initial public offering price of $6.00 per unit, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Our estimated net proceeds do not include the exercise of the Series A and Series B warrants included in the units nor any proceeds that we may receive from the concurrent private placement, if any. We intend to use the net proceeds from this offering to: fund our most advanced biosimilar product candidates through or ready them for entry into clinical development; fund our other research and development activities; and the remainder for working capital and general corporate purposes. We may also use a portion of the net proceeds to acquire complementary businesses, products or technologies, although, we have no present commitments or agreements for any specific acquisitions.
Risk factors	You should read the section titled "Risk Factors" together with all the other information included in this prospectus before deciding to invest in our securities.

Trading commencement and separation of common stock, Series A warrants and Series B warrants	The units will begin trading on or promptly after the date of this prospectus. The units will automatically separate and each of the shares of common stock, Series A warrants and Series B warrants underlying the units will begin trading separately no later than the 30th day after the date of this prospectus.
Proposed symbols and listing	Our common stock has been approved for listing on the NASDAQ Global Market under the symbol “ONS.” We have applied for the listing of our units, Series A warrants and Series B warrants on the NASDAQ Global Market under the symbols “ONSIU,” “ONSIW” and “ONSIZ,” respectively.

Certain of our existing and new investors have indicated an interest in purchasing up to an aggregate of approximately $20.0 million of units in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, fewer or no units in this offering to any of these investors, or any of these investors may determine to purchase more, fewer or no units in this offering. Certain of these investors have agreed to a 60-day lock-up agreement with the underwriters in respect of any units they may acquire in this offering.

The number of shares of common stock to be outstanding after this offering is based on 16,136,112 shares of common stock outstanding as of December 31, 2015, and excludes the following:

- 249,510 shares of common stock issuable upon the exercise of PSUs whose terms provide for settlement in shares of common stock or cash at our discretion, with a weighted-average exercise price of $6.35;
- 1,066,193 shares issuable upon vesting of restricted stock unit awards, or RSUs, granted under our 2015 Equity Incentive Plan, or the 2015 Plan;
- 180,184 shares of common stock reserved for future issuance under the 2015 Plan, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan;
- 289,855 shares of common stock reserved for future issuance under our 2016 Employee Stock Purchase Plan, or the ESPP, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan, which will become effective upon the execution of the underwriting agreement related to this offering; and
- 1,520,284 shares of our common stock issuable upon the exercise of warrants to be issued upon the closing of this offering.

Unless otherwise noted, all information in this prospectus reflects a 1-for-3.45 reverse split of our common stock that was effected on April 26, 2016 and assumes:

- the issuance and sale of an aggregate of 87,287 shares of common stock in January 2016;
- the conversion of all outstanding shares of Series A preferred stock (with an aggregate liquidation preference of $11,819,000 and a conversion price equal to the initial public offering price) into 1,969,818 shares of common stock immediately prior to the closing of this offering (assuming an initial public offering price of $6.00 per share of common stock included in the units sold in this offering);
- the reclassification of 1,739,130 shares of redeemable common stock to common stock upon lapse of a contractual redemption right;
- effectiveness of our amended and restated certificate of incorporation, which we will file in connection with the closing of this offering, and our amended and restated bylaws;
- no exercise of any outstanding PSUs or vesting or settlement of RSUs after December 31, 2015;
- no exercise of the underwriters’ over-allotment option to purchase 875,000 units;
- no exercise of the Series A warrants and the Series B warrants included in the units sold in this offering; and
- no sale of securities in the proposed concurrent private placement.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following table summarizes our consolidated financial data. We derived the consolidated statements of operations data for the years ended September 30, 2014 and 2015 from our audited consolidated financial statements included elsewhere in this prospectus. The consolidated statements of operations data for the three months ended December 31, 2014 and 2015 and the consolidated balance sheet data as of December 31, 2015 have been derived from our unaudited interim financial statements included elsewhere in this prospectus and have been prepared on the same basis as the audited financial statements. In the opinion of management, the unaudited data reflects all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the financial information in those statements. Our historical results are not necessarily indicative of the results that may be expected in the future, and our interim period results are not necessarily indicative of results to be expected for a full year or any other interim period. You should read this data together with our consolidated financial statements and related notes thereto, and the sections titled "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus.

	Year Ended September 30,		Three Months Ended December 31,	
	2014	2015	2014	2015
			(Unaudited)	
Consolidated Statements of Operations Data:				
Collaboration revenues	$ 9,050,542	$ 5,219,237	$ 2,934,555	$ 994,894
Operating expenses:				
Research and development	14,124,631	38,876,040	5,840,030	12,733,976
General and administrative	7,318,314	12,905,823	1,237,839	4,674,155
	21,442,945	51,781,863	7,077,869	17,408,131
Loss from operations	(12,392,403)	(46,562,626)	(4,143,314)	(16,413,237)
Interest expense	901,052	2,297,339	357,580	398,975
Loss before income taxes	(13,293,455)	(48,859,965)	(4,500,894)	(16,812,212)
Income tax expense (benefit)	439,018	(190,111)	406,363	52,000
Net loss	(13,732,473)	(48,669,854)	(4,907,257)	(16,864,212)
Less: Net loss attributable to noncontrolling interests	—	(1,276,571)	—	—
Net loss attributable to Oncobiologics, Inc.	(13,732,473)	(47,393,283)	(4,907,257)	(16,864,212)
Accretion of redeemable preferred stock and noncontrolling interests	(3,588,996)	(4,306,488)	(1,071,164)	(939,539)
Deemed dividends upon the repurchase of Series A redeemable preferred stock and redeemable noncontrolling interests	(3,336,855)	(1,298,631)	(1,230,998)	—
Net loss attributable to common stockholders of Oncobiologics, Inc.	$(20,658,324)	$(52,998,402)	$ (7,209,419)	$ (17,803,751)
Per share information:[1]				
Net loss per share of common stock, basic and diluted	$ (2.43)	$ (5.43)	$ (0.77)	$ (1.36)
Weighted-average shares outstanding, basic and diluted	8,509,654	9,753,616	9,377,450	13,061,557
Pro forma net loss per share of common stock – basic and diluted (unaudited)		$ (3.35)		$ (1.12)
Pro forma weighted-average shares outstanding (unaudited)		14,143,696		15,031,375

(1) See Note 3 to our annual and interim consolidated financial statements, respectively, included elsewhere in this prospectus for an explanation of the calculations of our basic and diluted net loss per common share, pro forma net loss per common share and the weighted-average number of shares used in the computation of the per share amounts.

	As of December 31, 2015 (Unaudited)		
	Actual	Pro forma[1]	Pro forma as adjusted[2][3]
Consolidated Balance Sheet Data:			
Cash	$ 5,582,255	$ 10,806,901	$ 40,556,905
Working capital (deficit)	(25,087,988)	(22,562,819)	7,187,185
Total assets	31,322,869	33,797,518	61,572,678
Debt obligations, current and long-term	15,488,800	15,488,800	15,488,800
Redeemable common stock	16,366,212	—	—
Total stockholders' equity (deficit)	(30,914,816)	(12,023,435)	17,726,569

(1) The pro forma column reflects (i) the issuance of 87,287 shares of common stock for aggregate net proceeds of approximately $2.5 million in January 2016, (ii) cash proceeds of approximately $2.7 million received subsequent to December 31, 2015 related to stock issued in December 2015, (iii) the conversion of 11,819 shares of Series A preferred stock into 1,969,818 shares of common stock immediately prior to the closing of this offering (assuming an initial public offering price of $6.00 per share of common stock included in the units sold in this offering) and (iv) the reclassification of 1,739,130 shares of redeemable common stock to common stock upon lapse of a contractual redemption right.

(2) The pro forma as adjusted column further reflects the receipt of $29.8 million in net proceeds from our sale of units in this offering at an assumed initial public offering price of $6.00 per unit, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(3) A $1.00 increase (decrease) in the assumed initial public offering price of $6.00 per unit would increase (decrease) each of cash, working capital, total assets and total stockholders' equity on a pro forma as adjusted basis by approximately $5.4 million, assuming that the number of units offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, an increase (decrease) by 1,000,000 units in the number of units offered by us would increase (decrease) each of cash, working capital, total assets and total stockholders' equity on a pro forma as adjusted basis by approximately $5.6 million, assuming that the assumed initial public offering price remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information discussed above is illustrative only and will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus and any related free writing prospectus, including our consolidated financial statements and the related notes thereto and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our securities. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our securities could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

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 $13.7 million and $47.4 million for the years ended September 30, 2014 and 2015, respectively, and $16.9 million for the three months ended December 31, 2015.

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, 2015 of $94.1 million and $14.2 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.

Even if this offering and the concurrent private placement are successful, we expect that we will need to raise substantial additional funding. 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. Furthermore, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company.

As of December 31, 2015, our cash was $5.6 million. We expect that our existing cash along with the net proceeds from this offering will be sufficient to fund our current operations for the next 12 months. Even if this offering and the concurrent private placement are successful, 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. 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, including purchasers of units in this offering and the concurrent private placement, if any, 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. Although we expect to use the proceeds from this offering to advance development of ONS-3010 through Phase 3 clinical trials, we may require additional funds to do so. Further, even if the concurrent private placement occurs, 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, and we expect to be ready to commence a Phase 1 clinical trial of ONS-1050 in 2016. 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 two 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 two 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 unclear. 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 an adalimumab (Humira) biosimilar, 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 December 31, 2002 in the case of Humira, 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;
- 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), 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 other 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. 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 have 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 have 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 have also entered into a license agreement with Liomont to develop and commercialize ONS-3010 and ONS-1045 in Mexico. Further, we have 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 in certain major markets for ONS-3010, ONS-1045 and ONS-1050 outside the United States, and their failure to commercialize in those markets could harm our business and operating results.

One prong of our strategy is to maximize the value of our pipeline by retaining development and commercialization rights in the United States and continuing to selectively out-license to ex-U.S. markets. Accordingly, we will need to identify third-parties and then negotiate the terms of the development and commercialization agreements for 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. Although we currently have in place licensing agreements for commercialization of ONS-3010 and ONS-1045, these are for smaller 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 new 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 have 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 clinical stage biosimilar product candidates are currently 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 new 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 will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, 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 pricing of this 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 March 31, 2016, we had 89 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 approximately 57% 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 PPACA, 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 PPACA, 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 PPACA 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.

In addition, other legislative changes have been proposed and adopted in the United States since the PPACA 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 2024 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.

We expect that the PPACA, 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.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, 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 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 PPACA, 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 PPACA, 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 PPACA 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, 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 this Offering and Ownership of Our Securities

An active trading market for our securities may not develop or be sustainable, and you may not be able to resell your units.

Prior to this offering, there has not been a public market for our securities. The initial public offering price for the units will be determined by negotiations between us and the representatives of the underwriters and may not be indicative of prices that will prevail in the trading market for the units, or the shares of common stock or warrants included in the units. An active trading market for our securities may not develop, or be sustained, following this offering. If an active market for our securities does not develop, you may not be able to sell your units, or the shares of common stock or warrants included in the units, quickly or at the market price. We cannot predict the prices at which our securities will trade and you may not be able to resell your units, or the shares of common stock or warrants included in the units.

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 or above the initial public offering price. 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 will be able to exert significant control over matters subject to stockholder approval, preventing new investors from influencing significant corporate decisions.

As of March 31, 2016, our executive officers, directors and 5% stockholders and their affiliates beneficially owned approximately 58.8% of our voting stock and, upon closing of this offering, that same group will beneficially own approximately 43.2% of our outstanding voting stock (assuming no exercise of the underwriters’ option to purchase additional shares and excluding units purchased by any such holders in this offering and the concurrent private placement, if any). In addition, such holders may further increase their ownership in our company pursuant to the directed unit program. At our request, the underwriters have reserved 291,666 units, or 5% of the units being offered by this prospectus (excluding the units that may be issued upon the underwriters’ exercise of their over-allotment option to purchase additional units), for sale at the initial public offering price to our employees, executive officers, directors, stockholders and others through a directed unit program. The interests of this group of securityholders may not coincide with the interests of other securityholders. Therefore, even after this offering and the concurrent private placement, if any, these securityholders will 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 will incur 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 will 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.

If you purchase units in this offering, you will incur immediate and substantial dilution in the book value of your units.

Investors purchasing units in this offering will pay a price per unit that substantially exceeds the pro forma book value per share forming part of the unit. As a result, investors purchasing units in this offering will incur immediate dilution of $5.19 per share forming part of the unit, based on an assumed initial public offering price of $6.00 per unit, and our pro forma net tangible book value per share as of December 31, 2015. For information on how the foregoing amounts were calculated, see the section titled “Dilution.”

This dilution is due to the substantially lower price paid by our investors who purchased our securities prior to this offering as compared to the price offered to the public in this offering. As a result of the dilution to investors purchasing units in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation.

Sales of a substantial number of our common stock in the public market could cause the price of our securities to fall.

If our existing stockholders sell or indicate an intention to sell substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale discussed in this prospectus lapse, the market price of our securities could decline. Based upon the number of shares of common stock, on an as-converted basis, outstanding as of December 31, 2015, upon the closing of this offering we will have outstanding a total of 21,969,446 shares of common stock, including 5,833,334 shares of common stock included in the units but excluding the 5,833,334 shares underlying the Series A warrants and Series B warrants included in the units, and assuming no exercise of the underwriters’ option to purchase additional units and excluding any securities that may be issued in the concurrent private placement, if any. Of these shares, as of the date of this prospectus, all of the shares forming part of the unit sold in this offering, including any shares forming part of the unit sold upon exercise of the underwriters’ option to purchase additional units, will be freely tradable, without restriction, in the public market immediately following this offering, except for any shares forming part of the unit purchased by certain of our existing and new investors who have indicated an interest in purchasing up to an aggregate of approximately $20.0 million of units, of which some have entered into a 60-day lock-up agreement with the underwriters or by our affiliates, as defined in Rule 144 under the Securities Act of 1933, as amended, or the Securities Act, in respect of such units if acquired.

The lock-up agreements pertaining to shares of common stock held prior to this offering will expire 180 days from the date of this prospectus. After such lock-up agreements expire, based upon the number of shares of common stock, on an as-converted basis, outstanding as of December 31, 2015, 16,136,112 shares of common stock will be eligible for sale in the public market, of which approximately 9,483,074 shares are held by directors, executive officers and 5% stockholders and their affiliates, and will be subject to the manner of sale, volume limitations and public reporting requirements of Rule 144 under the Securities Act. Jefferies LLC and Barclays Capital Inc. may however, in their sole discretion, permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

After this offering, the holders of approximately 4,078,029 shares of our common stock, or approximately 25.3% of our outstanding common stock as of December 31, 2015, will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up agreements described above. The shares of common stock issuable upon the exercise of warrants to acquire an aggregate of 1,520,284 shares of our common stock to be issued to certain investors upon the closing of this offering will also be entitled to rights with respect to registration under the Securities Act. Registration of any of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a negative impact on the market price of our securities.

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 included in the units offered hereby represent the right to acquire shares of common stock at a fixed price for a limited period of time beginning 30 days after the date of this prospectus or the date on which Jefferies LLC and Barclays Capital Inc., as representatives of the underwriters, separate the units, whichever date is earlier. 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 during the period when the warrants are exercisable, such warrants may not have any value. Moreover, following this offering, 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 included in the units offered hereby to exercise such warrants. See the section titled "Description of Securities — Series A Warrants and Series B Warrants Issued as Part of the Units" for more information regarding the Series A warrants and Series B warrants included in the units.

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 initially reserved for issuance was 1,246,377 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, (ii) 3% of the shares of stock outstanding on the 60th day following the date of the underwriting agreement for this offering and (iii) 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 will become effective upon the execution of the underwriting agreement related to this 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 will initially be available for issuance under the ESPP. 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.

Following the closing of this offering, we could have outstanding warrants to acquire an aggregate of 1,520,284 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 in this offering.

We will have broad discretion in the use of the net proceeds from this offering and may invest or spend the proceeds in ways with which you do not agree and in ways that may not yield a return.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section titled "Use of Proceeds," and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary from their currently intended use. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in investment-grade, interest-bearing securities. These investments may not yield a favorable return to our securityholders.

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 this offering and/or 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.

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 will 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;
- prohibits 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 will provide 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 the first fiscal year beginning after the effective date of this offering. 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future financial condition, business strategy and plans, and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “design,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “positioned,” “potential,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology.

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of known and unknown risks, uncertainties and assumptions, including risks described in the section titled “Risk Factors” and elsewhere in this prospectus, regarding, among other things:

- the timing and the success of the design of the clinical trials and planned clinical trials of ONS-3010, ONS-1045 and ONS-1050;
- whether the results of our clinical trials will be sufficient to support domestic or global regulatory approvals;
- our ability to obtain and maintain regulatory approval of our current and future biosimilar product candidates;
- our expectations regarding the potential market size and the size of the patient populations for our biosimilar product candidates, if approved, for commercial use;
- our ability to fund our working capital requirements;
- the implementation of our business model and strategic plans for our business and biosimilar product candidates;
- the initiation, timing, progress and results of future preclinical studies and clinical trials and our research and development programs;
- developments or disputes concerning our intellectual property or other proprietary rights;
- our ability to maintain and establish collaborations or obtain additional funding;
- the rate and degree of market acceptance of our current and future biosimilar product candidates;
- our expectation that our existing capital resources and the net proceeds from this offering will be sufficient to enable us to complete our planned clinical trial;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to compete in the markets we serve; and
- the factors that may impact our financial results.

These risks are not exhaustive. Other sections of this prospectus may include additional factors that could harm our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus or to conform these statements to actual results or to changes in our expectations.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and achievements may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

MARKET AND INDUSTRY DATA

Unless otherwise indicated, information contained in this prospectus concerning our industry and the market in which we operate, including our general expectations and market position, market opportunity and market size, is based on information from various sources including the independent industry publication set forth below and is subject to a number of assumptions and limitations. Although we are responsible for all of the disclosure contained in this prospectus and we believe the information from the industry publication and other third-party sources included in this prospectus is reliable, such information is inherently imprecise. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled “Risk Factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

USE OF PROCEEDS

We estimate that we will receive net proceeds from the sale of 5,833,334 units that we are selling in this offering of approximately $29.8 million at an assumed initial public offering price of $6.00 per unit, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise in full their over-allotment option to purchase 875,000 additional units, we estimate that our net proceeds will be approximately $34.6 million, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Such amounts do not include $5.0 million in proceeds from the concurrent private placement. Because we have not entered into any definitive agreements with Sabby related to the concurrent private placement, there can be no guarantee that the concurrent private placement will take place or that the terms of the concurrent private placement will be consistent with those assumed in this prospectus. For more information, please see "Certain Relationships and Related Party Transactions — Concurrent Private Placement." The private placement with Sabby is contingent upon, and will occur concurrently with, the closing of this offering, if at all.

A $1.00 increase (decrease) in the assumed initial public offering price of $6.00 per unit would increase (decrease) the net proceeds to us from this offering by approximately $5.4 million, assuming the number of units offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of units we are offering. Similarly, an increase (decrease) of 1,000,000 units in the number of units offered by us would increase (decrease) the net proceeds to us from this offering by approximately $5.6 million, assuming that the assumed initial public offering price remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We do not expect that a change in the initial price to the public or the number of units by these amounts would have a material effect on our uses of the proceeds from this offering, although it may accelerate the time at which we will need to seek additional capital.

We currently intend to use the net proceeds from this offering as follows:

- approximately $20.0 million to advance clinical development of ONS-3010 through Phase 3 clinical trials;
- approximately $5.0 million to fund our other ongoing research and development activities, including advancing development of ONS-1045 to be ready to enter a Phase 3 clinical trial, and advancing development of ONS-1050 and ONS-4010 to be ready to enter Phase 1 clinical trials; and
- the remainder for working capital and general corporate purposes.

However, due to the uncertainties inherent in the product development process, it is difficult to estimate with certainty the exact amounts of the net proceeds from this offering that may be used for the above purposes. Our management will have broad discretion over the use of the net proceeds from this offering. The amounts and timing of our expenditures will depend upon numerous factors including the results of our research and development efforts, the timing and success of preclinical studies and any ongoing clinical trials or clinical trials we may commence in the future, the timing of regulatory submissions and the amount of cash obtained through current and any future collaborations.

We believe opportunities may exist from time to time to expand our current business through acquisitions or in-licenses of complementary companies, medicines or technologies. While we have no current agreements, commitments or understandings for any specific acquisitions or in-licenses at this time, we may use a portion of the net proceeds for these purposes.

Pending the use of the proceeds from this offering as described above, we intend to invest the net proceeds in interest-bearing investment-grade securities or government securities.

DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock, and we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors subject to applicable laws, and will depend upon, among other factors, our results of operations, financial condition, contractual restrictions and capital requirements. Our future ability to pay cash dividends on our stock may also be limited by the terms of any future debt, issuances of preferred securities or terms of future credit facilities.

CAPITALIZATION

The following table sets forth our cash and capitalization as of December 31, 2015 on:

- an actual basis;
- a pro forma basis to give effect to (i) the issuance of 87,287 shares of common stock for aggregate net proceeds of approximately $2.5 million in January 2016, (ii) cash proceeds of approximately $2.7 million received subsequent to December 31, 2015 related to stock issued in December 2015, (iii) the conversion of 11,819 shares of Series A preferred stock into 1,969,818 shares of common stock immediately prior to the closing of this offering (assuming an initial public offering price of $6.00 per share of common stock included in the units sold in this offering) and (iv) the reclassification of 1,739,130 shares of redeemable common stock to common stock upon lapse of a contractual redemption right; and
- a pro forma as adjusted basis, to give further effect to (i) the sale of 5,833,334 units in this offering at an assumed initial public offering price of $6.00 per unit, after deducting estimated underwriting discounts and commissions, and estimated offering expenses payable by us and (ii) the filing of our amended and restated certificate of incorporation.

Actual data as of December 31, 2015 in the table below is derived from our unaudited consolidated financial statements. The pro forma data included in the table below is also unaudited. You should read this table together with the section titled "Selected Consolidated Financial Data," our consolidated financial statements and the related notes thereto appearing elsewhere in this prospectus and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this prospectus.

	As of December 31, 2015 (Unaudited)		
	Actual	Pro forma	Pro forma as adjusted[1]
Cash	$ 5,582,255	$ 10,806,901	$ 40,556,905
Debt obligations, current and long term	15,488,800	15,488,800	15,488,800
Redeemable common stock	16,366,212	—	—
Stockholders' equity (deficit):			
Series A preferred stock, par value $0.01 per share: 10,000,000 shares authorized, 11,819 shares issued and outstanding actual; no shares issued and outstanding pro forma and pro forma as adjusted	118	—	—
Common stock, par value $0.01 per share; 100,000,000 shares authorized, 12,339,877 shares issued and outstanding actual; 16,136,112 issued and outstanding pro forma; and 21,969,446 shares issued and outstanding pro forma as adjusted	123,399	161,361	219,694
Additional paid-in capital	79,890,165	98,743,702	128,435,373
Accumulated deficit	(110,928,498)	(110,928,498)	(110,928,498)
Total stockholders' equity (deficit)	(30,914,816)	(12,023,435)	17,726,569
Total capitalization	$ 940,196	$ 3,465,365	$ 33,215,369

(1) A $1.00 increase (decrease) in the assumed initial public offering price of $6.00 per unit, would increase (decrease) each of cash, additional paid-in capital, total stockholders' equity and total capitalization by approximately $5.4 million, assuming that the number of units offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, an increase (decrease) of 1,000,000 units in the number of units offered by us would increase (decrease) cash, additional paid-in capital, total stockholders' equity and total capitalization by approximately $5.6 million, assuming an initial public offering price of $6.00 per unit, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information discussed above is illustrative only and will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.

The number of shares of common stock in the table above excludes the following:

- 249,510 shares of common stock issuable upon the exercise of PSUs whose terms provide for settlement in shares of common stock or cash at our discretion, with a weighted-average exercise price of $6.35;
- 1,066,193 shares issuable upon vesting of restricted stock unit awards, or RSUs, granted under the 2015 Plan;
- 180,184 shares of common stock reserved for future issuance under the 2015 Plan, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan;
- 289,855 shares of common stock reserved for future issuance under the ESPP, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan, which will become effective upon the execution of the underwriting agreement related to this offering; and
- 1,520,284 shares of our common stock issuable upon the exercise of warrants to be issued upon the closing of this offering.

DILUTION

If you invest in our units, your interest will be diluted to the extent of the difference between the initial public offering price per unit assuming no value is attributable to the Series A warrants and Series B warrants included in the units sold in this offering, and the pro forma as adjusted net tangible book value per share of our common stock included in the units sold in this offering, immediately after the closing of this offering. Such calculation does not reflect any dilution associated with the sale and exercise of the Series A warrants or Series B warrants issued as part of the units, which would cause the actual dilution to our public securityholders to be higher, particularly where a cashless exercise is utilized. Such calculation also does not reflect the sale of $5.0 million of units to Sabby at a price per unit equal to the initial public offering price (or 833,332 units based on the assumed initial public offering price of $6.00 per unit) in the concurrent private placement, if any.

As of December 31, 2015, we had a historical net tangible book value (deficit) of $(30.9) million, or $(2.51) per share of common stock. Our historical net tangible book value (deficit) represents total tangible assets less our total liabilities. Historical net tangible book value per share is our historical net tangible book value (deficit) divided by the number of shares of common stock outstanding as of December 31, 2015.

Our pro forma net tangible book value (deficit) was $(12.0) million, or $(0.75) per share. Pro forma net tangible book value (deficit) per share represents our total tangible assets less our total liabilities, divided by the number of outstanding shares of common stock, after giving effect to (i) the issuance of 87,287 shares of common stock for aggregate net proceeds of approximately $2.5 million in January 2016, (ii) cash proceeds of approximately $2.7 million received subsequent to December 31, 2015 related to stock issued in December 2015, (iii) the conversion of 11,819 shares of Series A preferred stock into 1,969,818 shares of common stock immediately prior to the closing of this offering (assuming an initial public offering price of $6.00 per share of common stock included in the units sold in this offering) and (iv) the reclassification of 1,739,130 shares of redeemable common stock to common stock upon lapse of a contractual redemption right.

After giving further effect to the sale of 5,833,334 units in this offering at an assumed initial public offering price of $6.00 per unit, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value (deficit) as of December 31, 2015 would have been approximately $17.7 million, or $0.81 per share of common stock included in the units sold in this offering. This represents an immediate increase in pro forma as adjusted net tangible book value (deficit) of $1.56 per share to our existing stockholders and an immediate dilution of $5.19 per share to new investors purchasing units in this offering.

The following table illustrates this dilution on a per share basis to new investors, assuming no value is attributed to the Series A warrants and the Series B warrants issued as part of each unit:

Assumed initial public offering price per share		$ 6.00
Historical net tangible book value (deficit) per share at December 31, 2015	$ (2.51)	
Increase per share attributable to pro forma adjustments	1.76	
Pro forma net tangible book value (deficit) per share at December 31, 2015	(0.75)	
Increase in pro forma net tangible book value (deficit) per share attributable to this offering	1.56	
Pro forma as adjusted net tangible book value per share after this offering		0.81
Dilution in net tangible book value per share to new investors in this offering		$ 5.19

A $1.00 increase (decrease) in the assumed initial public offering price of $6.00 per unit would increase (decrease) our pro forma as adjusted net tangible book value per share after this offering by $0.24 per share and the dilution to new investors by $0.76 per share, assuming the number of units offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1,000,000 units in the number of units offered by us would increase (decrease) the pro forma as adjusted net tangible book value by $0.20 per share and the dilution to new investors by $0.20 per share, assuming the assumed initial public offering price remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise in full their over-allotment option to purchase 875,000 additional units from us, the pro forma as adjusted net tangible book value per share after giving effect to this offering would be $0.99 per share, representing an immediate increase to existing stockholders of $1.74 per share and immediate dilution to investors in this offering of $5.01 per share.

The following table summarizes, as of December 31, 2015, on a pro forma as adjusted basis described above:

- the total number of shares of common stock purchased from us by our existing stockholders and by new investors purchasing units that include shares of common stock in this offering;
- the total consideration paid to us by our existing stockholders and by new investors purchasing units that include shares of common stock in this offering, assuming an initial public offering price of $6.00 per unit, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us in connection with this offering; and
- the average price per share paid by existing stockholders and by new investors purchasing units that include shares of common stock in this offering.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing Stockholders	16,136,112	73%	$ 81,394,129	70%	$5.04
New Investors[1]	5,833,334	27	35,000,004	30	$6.00
Total	21,969,446	100%	$116,394,133	100%	$5.30

(1) Includes shares included in the units sold in this offering.

The total number of shares of common stock reflected in the discussion and tables above is based on (i) 12,339,877 shares of common stock outstanding as of December 31, 2015 on an actual basis, (ii) the issuance of 87,287 shares of common stock for aggregate net proceeds of approximately $2.5 million in January 2016, (iii) cash proceeds of approximately $2.7 million received subsequent to December 31, 2015 related to stock issued in December 2015, (iv) the conversion of 11,819 shares of Series A preferred stock into 1,969,818 shares of common stock immediately prior to the closing of this offering (assuming an initial public offering price of $6.00 per share of common stock included in the units sold in this offering) and (v) the reclassification of 1,739,130 shares of redeemable common stock to common stock upon lapse of a contractual redemption right, and excludes the following outstanding as of December 31, 2015:

- 249,510 shares of common stock issuable upon the exercise of PSUs whose terms provide for settlement in shares of common stock or cash at our discretion, with a weighted-average exercise price of $6.35;
- 1,066,193 shares issuable upon vesting of restricted stock unit awards, or RSUs, granted under the 2015 Plan;
- 180,184 shares of common stock reserved for future issuance under the 2015 Plan, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan;
- 289,855 shares of common stock reserved for future issuance under the ESPP, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan, which will become effective upon the execution of the underwriting agreement related to this offering; and
- 1,520,284 shares of our common stock issuable upon the exercise of warrants to be issued upon the closing of this offering.

A $1.00 increase (decrease) in the assumed initial public offering price of $6.00 per unit would increase (decrease) total consideration paid by new investors by approximately $5.8 million and increase (decrease) the total consideration paid to us by new investors by approximately 3%, assuming the number of units offered by us, as set forth on the cover page of this prospectus, remains the same, and before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

SELECTED CONSOLIDATED FINANCIAL DATA

You should read the following selected consolidated financial data together with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included in this prospectus. The selected consolidated financial data included in this section are not intended to replace the consolidated financial statements and related notes included elsewhere in this prospectus.

The consolidated statements of operations data for the years ended September 30, 2014 and 2015 and the consolidated balance sheet data as of September 30, 2014 and 2015 are derived from our audited consolidated financial statements included elsewhere in this prospectus. The consolidated statements of operations data for the three months ended December 31, 2014 and 2015 and the consolidated balance sheet data as of December 31, 2015 have been derived from our unaudited interim financial statements included elsewhere in this prospectus and have been prepared on the same basis as the audited financial statements. In the opinion of management, the unaudited data reflects all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the financial information in those statements. Our historical results are not necessarily indicative of the results to be expected in the future, and our interim period results are not necessarily indicative of results to be expected for a full year or any other interim period.

	Year Ended September 30,		Three Months Ended December 31,	
	2014	2015	2014	2015
			(Unaudited)	
Consolidated Statements of Operations Data:				
Collaboration revenues	$ 9,050,542	$ 5,219,237	$ 2,934,555	$ 994,894
Operating expenses:				
Research and development	14,124,631	38,876,040	5,840,030	12,733,976
General and administrative	7,318,314	12,905,823	1,237,839	4,674,155
	21,442,945	51,781,863	7,077,869	17,408,131
Loss from operations	(12,392,403)	(46,562,626)	(4,143,314)	(16,413,237)
Interest expense	901,052	2,297,339	357,580	398,975
Loss before income taxes	(13,293,455)	(48,859,965)	(4,500,894)	(16,812,212)
Income tax expense (benefit)	439,018	(190,111)	406,363	52,000
Net loss	(13,732,473)	(48,669,854)	(4,907,257)	(16,864,212)
Less: Net loss attributable to noncontrolling interests	—	(1,276,571)	—	—
Net loss attributable to Oncobiologics, Inc.	(13,732,473)	(47,393,283)	(4,907,257)	(16,864,212)
Accretion of redeemable preferred stock and noncontrolling interests	(3,588,996)	(4,306,488)	(1,071,164)	(939,539)
Deemed dividends upon the repurchase of Series A redeemable preferred stock and redeemable noncontrolling interests	(3,336,855)	(1,298,631)	(1,230,998)	—
Net loss attributable to common stockholders of Oncobiologics, Inc.	$(20,658,324)	$(52,998,402)	$ (7,209,419)	$ (17,803,751)
Per share information:[1]				
Net loss per share of common stock, basic and diluted	$ (2,43)	$ (5.43)	$ (0.77)	$ (1.36)
Weighted-average shares outstanding, basic and diluted	8,509,654	9,753,616	9,377,450	13,061,557
Pro forma net loss per share of common stock – basic and diluted (unaudited)		$ (3.35)		$ (1.12)
Pro forma weighted-average shares outstanding (unaudited)		14,143,696		15,031,375

(1) See Note 3 to our annual and interim consolidated financial statements, included elsewhere in this prospectus for an explanation of

the calculations of our basic and diluted net loss per common share, pro forma net loss per common share and the weighted-average number of shares used in the computation of the per share amounts.

	As of September 30,		As of December 31, 2015
	2014	2015	(Unaudited)
Consolidated Balance Sheet Data:			
Cash	$ 2,349,313	$ 9,070,975	$ 5,582,255
Working capital (deficit)	(17,063,539)	(21,877,366)	(25,087,988)
Total assets	11,603,707	35,008,621	31,322,869
Debt obligations, current and long-term	15,168,532	21,961,828	15,488,800
Redeemable preferred stock, common stock and noncontrolling interests	24,704,011	27,321,311	16,366,212
Total stockholders' equity (deficit)	(45,151,218)	(54,873,803)	(30,914,816)

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes thereto included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this prospectus, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

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. Since inception, we have advanced two product candidates into clinical trials: ONS-3010, a Phase 3-ready biosimilar to adalimumab (Humira®), and ONS-1045, a Phase 3-ready biosimilar to bevacizumab (Avastin®). Additionally, we have identified multiple other biosimilar product candidates, including six that are in pre-clinical development, one of which is expected to be ready to enter clinical trials in 2016.

Through December 31, 2015, we have funded substantially all of our operations through the sale and issuance of approximately $103.5 million of our common stock, preferred stock and debt. Through December 31, 2015, we have also received $23.5 million pursuant to our collaboration and licensing agreements.

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, 2015 of $94.1 million and $14.2 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 be necessary if we are unable to continue as a going concern.

We will need to raise substantial additional financing in the future to fund our operations. We believe our existing cash together with the proceeds from this offering, will provide adequate financial resources to fund our planned operations through at least the next 12 months. We will need to raise substantial additional capital or enter into strategic collaboration arrangements in order to commercialize ONS-3010, commence any Phase 3 clinical trials of 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 strategic 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 commercialization of ONS-3010, or the development or commercialization of 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.

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 losses were $13.7 million and $47.4 million for the years ended September 30, 2014 and 2015, respectively, and $16.9 million for the three months ended December 31, 2015. In addition, development activities, clinical and preclinical testing and commercialization of our product candidates will require significant additional financing.

Reincorporation in Delaware

In October 2015, we reincorporated in Delaware by merging 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 our 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 issued and outstanding share of our 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 issued and outstanding share of 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. Additionally, in October 2015, effective upon our reincorporation and in connection with the dissolution of our business development subsidiary, Parilis Biopharmaceuticals, LLC, or Parilis, we issued 226,663 shares of common stock and 1,626 shares of Series A preferred stock to the holders of outstanding units in Parilis in exchange for all such units.

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. For additional information relating to our agreements, see “Business — Collaboration and License Agreements.”

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 sublicensees 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 December 31, 2015, 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 December 31, 2015, we have received an aggregate of $2.5 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 December 31, 2015, 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. Similarly, revenues from 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. 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, 2014 and 2015 and for the three months ended December 31, 2014 and 2015:

	Year ended September 30,		Three months ended December 31,	
	2014	2015	2014	2015
IPCA Collaboration	$1,439,472	$1,702,377	$ 586,078	$ 105,433
Liomont Collaboration	34,091	341,280	54,582	595,566
Huahai Collaboration	7,576,979	3,175,580	2,293,895	293,895
	$9,050,542	$5,219,237	$ 2,934,555	$ 994,894

The following table summarizes the milestone payments and recognition of deferred revenues from our collaboration and licensing agreements during the years ended September 30, 2014 and 2015 and for the three months ended December 31, 2014 and 2015:

	Year ended September 30,		Three months ended December 31,	
	2014	2015	2014	2015
Milestone payments	$7,000,000	$2,500,000	$ 2,500,000	$ 500,000
Recognition of deferred revenues	1,300,542	1,919,237	434,555	494,894
Research and development payments	750,000	800,000	—	—
	$9,050,542	$5,219,237	$ 2,934,555	$ 994,894

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 for 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 higher consulting, legal and tax-related services associated with maintaining compliance with stock exchange listing and Securities and Exchange Commission, or SEC, requirements, accounting and 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 years ended September 30, 2014 and 2015, we sold New Jersey state net operating losses, or NOLs, and research credits of $9.9 million and NOLs of $4.8 million, respectively, resulting in the recognition of income tax benefits of $0.8 million and $0.7 million, respectively. In addition during the years ended September 30, 2014 and 2015, and for the three months ended December 31, 2014 and 2015, we incurred $1.3 million, $0.5 million, $0.4 million and $0.1 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, 2015, we had federal and state NOL carryforwards of $52.9 million and $36.9 million, respectively, that will begin to expire in 2030 and 2032, respectively. As of September 30, 2015, we had federal foreign tax credit carryforwards of $2.6 million available to reduce future tax liabilities, which begin to expire at various dates starting in 2023. As of September 30, 2015, we also had federal and state research and development tax credit carryforwards of $4.2 million and $1.7 million, respectively, which begin to expire in 2021.

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 if we undergo an ownership change in connection with or after this offering, 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 Three Months Ended December 31, 2014 and 2015

The following table summarizes our results of operations for the three months ended December 31, 2014 and 2015:

	Three Months Ended December 31,		
	2014	2015	Change
	(Unaudited)		
Collaboration revenues	$ 2,934,555	$ 994,894	$ (1,939,661)
Operating expenses:			
Research and development	5,840,030	12,733,976	6,893,946
General and administrative	1,237,839	4,674,155	3,436,316
	7,077,869	17,408,131	10,330,262
Loss from operations	(4,143,314)	(16,413,237)	(12,269,923)
Interest expense	357,580	398,975	41,395
Loss before income taxes	(4,500,894)	(16,812,212)	(12,311,318)
Income tax expense	406,363	52,000	(354,363)
Net loss	$ (4,907,257)	$ (16,864,212)	$(11,956,955)

Collaboration Revenues

Our collaboration revenues decreased $1.9 million, to $1.0 million, for the three months ended December 31, 2015, as compared to $2.9 million for the three months ended December 31, 2014. The change is primarily attributable to the $2.0 million decrease in milestone payments offset by a $60,000 increase in the amortization of deferred revenue.

Research and Development Expenses

We do not currently utilize a formal time allocation system to capture expenses on a project-by-project basis because we are organized and record expense by functional department and our employees may allocate time to more than one development project. Accordingly, we do not allocate expenses to individual projects or product candidates, although we do allocate some portion of our research and development expenses by functional area and by compound, as shown below.

The following table summarizes our research and development expenses by functional area for the three months ended December 31, 2014 and 2015 and for the period from January 5, 2010 (inception) through December 31, 2015:

	Three months ended December 31,		Period from January 5, 2010 (inception) through December 31, 2015
	2014	2015	
	(Unaudited)		
Preclinical and clinical development	$3,524,528	$ 7,007,033	$ 40,174,156
Compensation and related benefits	2,193,204	3,815,357	27,366,937
Stock-based compensation	84,275	1,356,408	7,907,386
Regulatory filings and other	38,023	555,178	2,765,050
Total research and development expenses	$5,840,030	$ 12,733,976	$ 78,213,529

The following table summarizes our research and development expenses by compound for the three months ended December 31, 2014 and 2015 and for the period from January 5, 2010 (inception) through December 31, 2015:

	Three months ended December 31,		Period from January 5, 2010 (inception) through December 31, 2015
	2014	2015	
	(Unaudited)		
ONS-3010	$1,547,912	$ 4,208,306	$ 19,405,507
ONS-1045	1,718,730	2,740,735	17,652,009
Other research and development	295,909	613,169	5,881,689
Personnel related and stock-based compensation	2,277,479	5,171,766	35,274,324
Total research and development expenses	$5,840,030	$ 12,733,976	$ 78,213,529

Research and development expenses were $5.8 million for the year three months ended December 31, 2014, compared to $12.7 million for the three months ended December 31, 2015. Our preclinical and clinical development costs increased $3.5 million, which was primarily attributable to the timing of our Phase 1 clinical trials of ONS-3010 and ONS-1045, preparation for our planned Phase 3 clinical trials of ONS-3010 and ONS-1045, and related internal manufacturing and testing costs, respectively. We had an increase in compensation costs of $1.6 million due to increased headcount as we launched our in-house manufacturing facility in 2015. We also had a $0.5 million increase in research and development expense primarily due to government filing fees for our product candidates. In addition, we had an increase in stock-based compensation of $1.3 million upon the re-measurement of our Performance Stock Units, or PSUs.

General and Administrative Expenses

General and administrative expenses were $1.2 million for the three months ended December 31, 2014, compared to $4.7 million for the three months ended December 31, 2015. The increase of $3.5 million was primarily attributable to an increase of $1.6 million in professional service fees as we initiated our compliance efforts in anticipation of becoming a publicly traded company; a $0.4 million increase in compensation expenses as we increased our headcount; a $0.2 million increase in our facility costs and related rent as we expanded the space in which we lease our offices; and a $1.1 million increase in stock-based compensation upon the re-measurement of our PSUs.

Interest Expense

Interest expense remained consistent at $0.4 million during each of the three months ended December 31, 2014 and 2015 primarily due to the increase in capital lease obligations offset by reductions in stockholder notes and other debt obligations.

Comparison of Years Ended September 30, 2014 and 2015

The following table summarizes our results of operations for the years ended September 30, 2014 and 2015:

	Year Ended September 30,		
	2014	2015	Change
Collaboration revenues	$ 9,050,542	$ 5,219,237	$ (3,831,305)
Operating expenses:			
Research and development	14,124,631	38,876,040	24,751,409
General and administrative	7,318,314	12,905,823	5,587,509
	21,442,945	51,781,863	30,338,918
Loss from operations	(12,392,403)	(46,562,626)	(34,170,223)
Interest expense	901,052	2,297,339	1,396,287
Loss before income taxes	(13,293,455)	(48,859,965)	(35,566,510)
Income tax expense (benefit)	439,018	(190,111)	(629,129)
Net loss	$ (13,732,473)	$ (48,669,854)	$ (34,937,381)

Collaboration Revenues

Our collaboration revenues decreased $3.8 million, to $5.2 million, for the year ended September 30, 2015, as compared to the year ended September 30, 2014. The change is primarily attributable to the $4.5 million decrease in milestone payments offset by a $0.6 million increase in the amortization of deferred revenue.

Research and Development Expenses

The following table summarizes our research and development expenses by functional area for the years ended September 30, 2014 and 2015 and for the period from January 5, 2010 (date of inception) through September 30, 2015:

	Year ended September 30,		Period from January 5, 2010 (inception) through September 30, 2015
	2014	2015	
Preclinical and clinical development	$ 6,715,346	$ 21,714,405	$ 33,167,123
Compensation and related benefits	6,424,884	10,202,065	23,477,173
Stock-based compensation	671,745	5,817,830	6,625,385
Regulatory filings and other	312,656	1,141,740	2,209,872
Total research and development expenses	$ 14,124,631	$ 38,876,040	$ 65,479,553

The following table summarizes our research and development expenses by compound for the years ended September 30, 2014 and 2015 and for the period from January 5, 2010 (date of inception) through September 30, 2015:

	Year ended September 30,		Period from January 5, 2010 (inception) through September 30, 2015
	2014	2015	
ONS-3010	$ 4,641,138	$ 6,942,002	$ 15,197,201
ONS-1045	1,819,446	12,763,886	14,911,274
Other research and development	567,418	3,150,257	5,268,520
Personnel related and stock-based compensation	7,096,629	16,019,895	30,102,558
Total research and development expenses	$ 14,124,631	$ 38,876,040	$ 65,479,553

Research and development expenses were $14.1 million for the year ended September 30, 2014, compared to $38.9 million for the year ended September 30, 2015. Our preclinical and clinical development costs increased $15.0 million, which was primarily attributable to the timing of our Phase 1 clinical trials of ONS-3010 and ONS-1045, our Phase 3 clinical trials of ONS-3010, and related internal manufacturing and testing costs, respectively. We had an increase in

compensation costs of $3.8 million due to increased headcount as we launched our in-house manufacturing facility in 2015. We also had a $0.8 million increase in research and development expense primarily due to government filing fees for our product candidates. In addition we had an increase in stock-based compensation of $5.1 million upon the re-measurement of our PSUs.

General and Administrative Expenses

General and administrative expenses were $7.3 million for the year ended September 30, 2014, compared to $12.9 million for the year ended September 30, 2015. The increase of $5.6 million was primarily attributable to an increase of $2.1 million in professional service fees as we initiated our compliance efforts in anticipation of becoming a publicly traded company; a $1.1 million increase in compensation expenses as we increased our headcount; a $0.1 million increase in our facility costs and related rent as we expanded the space in which we lease our offices; and a $2.1 million increase in stock-based compensation upon the re-measurement of our PSUs.

Interest Expense

Interest expense was $0.9 million for the year ended September 30, 2014, compared to $2.3 million for the year ended September 30, 2015. The increase of $1.4 million was primarily attributable to the $10.9 million in additional borrowings during 2015.

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 December 31, 2015, we have funded substantially all of our operations through the sale and issuance of $103.5 million net proceeds of our common stock, and sales of our preferred stock and borrowings under debt facilities. Through December 31, 2015, we have also received an aggregate of $23.5 million pursuant to our collaboration and licensing agreements. As of December 31, 2015, we had an accumulated deficit of $110.9 million and had a cash balance of $5.6 million. In addition, we had $10.1 million of indebtedness that is due on demand.

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, 2015 of $94.1 million and $14.2 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 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.

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 periods presented:

	Year Ended September 30,		Three months ended December 31,	
	2014	2015	2014	2015
			(Unaudited)	
Net cash used in operating activities	$ (7,020,469)	$(27,476,200)	$ (3,666,423)	$ (12,012,281)
Net cash used in investing activities	(2,366,772)	(8,804,244)	(527,877)	(364,242)
Net cash provided by financing activities	11,474,146	43,002,106	3,670,527	8,887,803
Net increase (decrease) in cash	$ 2,086,905	$ 6,721,662	$ (523,773)	$ (3,488,720)

Operating Activities.

During the three months ended December 31, 2014, we used $3.7 million in operating activities, primarily resulting from our net loss of $4.9 million that was offset by $0.4 million of noncash items and $0.8 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, stock-based compensation, and the re-measurement of our PSU awards. The change in our operating assets and liabilities were primarily due to increases in deferred revenue upon receipt of upfront payments under our collaboration and licensing arrangements, and increases in accounts payable and accrued expenses related to our Phase 1 clinical trials and the timing of our vendor payments. These inflows were offset primarily from an increase in accounts receivable from our collaboration agreements.

During the three months ended December 31, 2015, we used $12.0 million in operating activities, primarily resulting from our net loss of $16.9 million that was offset by $3.1 million of noncash items. The change in our operating assets and liabilities were primarily due to increases in accounts payable and accrued expenses related to our Phase 3 clinical trials and the timing of our vendor payments. These inflows were offset by increases in prepaid expenses related to the timing in which we recognize research and development expenses, and the amortization of deferred revenues.

During the year ended September 30, 2014, we used $7.0 million of cash in operating activities, primarily resulting from our net loss of $13.7 million that was offset by $4.8 million of noncash items and $1.9 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, stock-based compensation, and the re-measurement of our PSU awards. The change in our operating assets and liabilities were primarily due to receipt of upfront payments under our collaboration and licensing agreements and prepayments to certain vendors. We also had increases in accrued expenses related to accrued compensation, research and development, and professional fees and our income taxes payable in connection with foreign tax withholdings.

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 three months ended December 31, 2014 and 2015 and the years ended September 30, 2014 and 2015, we used cash of $0.5 million, $0.4 million, $2.4 million and $8.8 million, respectively, in investing activities for the purchase of property and equipment. The increase in purchases of property and equipment during the year ended September 30, 2015 was 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 three months ended December 31, 2014, net cash provided by financing activities was $3.7 million, primarily attributable to $4.0 million in net proceeds from the issuance of stockholder notes offset by $0.3 million in debt payments.

During the three months ended December 31, 2015, net cash provided by financing activities was $8.9 million, primarily attributable to $11.3 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 $0.2 million from Sonnet in connection with their note receivable. These inflows were offset by $6.5 million in debt payments and $0.4 million upon the deconsolidation of Sonnet.

During the year ended September 30, 2014, net cash provided by financing activities was $11.5 million, primarily attributable to the proceeds received from the issuance of our redeemable common stock, Series B redeemable preferred stock, common stock and debt of $10.9 million, $0.3 million, $0.1 million and $8.5 million, respectively. These cash inflows were offset by debt payments and the June 2014 buyback of our Series A redeemable preferred stock of $4.1 million and $4.1 million, respectively.

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.

Following this offering, we will be a publicly traded company and 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 together with the proceeds from this offering, will provide adequate financial resources to fund our planned operations through at least the next 12 months. 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 receive approval for and commercialize ONS-3010, commence any Phase 3 clinical trials of 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

The following table summarizes our contractual obligations at September 30, 2015 and the effect such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments Due by Period				
	Total	Less Than 1 Year	1 – 3 Years	3 – 5 Years	More Than 5 Years
Operating lease commitments[1][5]	$ 5,027,353	$ 888,710	$ 1,731,526	$ 1,763,368	$ 643,749
Debt obligations[2]	19,953,048	14,956,842	3,355,273	1,032,926	608,007
Capital leases[3]	2,082,222	862,849	1,219,373	—	—
Total[4]	$ 27,062,623	$ 16,708,401	$ 6,306,172	$ 2,796,294	$ 1,251,756

(1) Operating lease obligations reflect our obligation to make payments in connection with the lease for our office and manufacturing facility 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.

(5) We entered into an operating lease for a facility located in Cranbury, New Jersey with a 10-year term, which commenced on March 1, 2016. Not included in the table are the future minimum lease payments of $7,247,800.

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.

Quantitative and Qualitative Disclosures about Market Risks

We are exposed to market risks in the ordinary course of our business. As of December 31, 2015, we had $5.6 million of cash, and we had $15.5 million of debt obligations. Our cash is deposited in accounts at two financial institutions, and amounts may exceed federally insured limits. We do not believe we are exposed to significant credit risk due to the financial strength of the depository institutions in which the cash is held. As a result, a change in market interest rates would not have a material impact on our financial position or results of operations.

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 prospectus, 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, 2014 and 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 are equity classified as of December 31, 2015. Concurrent with the amendment, several PSU holders cancelled an aggregate of 434,780 PSUs in exchange for 391,304 restricted stock units, or RSUs. During the three months ended December 31, 2015, we issued an additional 674,905 RSUs.

Because the exercisability of the PSUs occurs upon a corporate valuation of $400 million, the fair value of the PSUs are 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 and December 2015, the fair value of our common stock was $25.79 and $29.05 per share, respectively, and based on contemporaneous, arms-length transactions with new investors purchasing our common stock.

As of September 30, 2014, we were required to estimate the fair value of our common stock underlying our PSU awards. We have engaged an independent third-party valuation firm to assist management in estimating the fair value of our common stock. We estimated the fair value of our common stock using methodologies, approaches and assumptions consistent with the AICPA Practice Guide. In addition, management considered various objective and subjective factors, along with input from the independent third-party valuation firm, to estimate the fair value of our common stock. As of September 30, 2014, the estimated fair value of our common stock was $7.62 per share.

We believe that the receipt of the results from our Phase 1 clinical trial of ONS-3010 in early 2015, and the continued advancement of our other biosimilar product candidate development programs were the main drivers behind the increase in our price per share from September 30, 2014 to September 30, 2015.

Using the above common stock fair values, the estimated fair value of the PSUs was $3.45, $22.22 and $25.70 per PSU as of September 30, 2014 and 2015 and December 31, 2015, respectively. The increase in the fair value of the PSUs is driven by the increase in the fair value of our common stock and related increase in the enterprise value of our company. The grant-date fair value of the RSUs equals the fair value of our common stock of $29.05 per share.

For the years ended September 30, 2014 and 2015 and for the three months ended December 31, 2014 and 2015, we had compensation related to our equity and liability awards as follows:

	Year ended September 30,		Three months ended December 31,	
	2014	2015	2014	2015
Research and development	$ 671,745	$ 5,817,830	$ 84,275	$ 1,356,408
General and administrative	3,286,735	5,360,028	61,399	1,133,626
	$3,958,480	$11,177,858	$ 145,674	$ 2,490,034

	Year ended September 30,		Three months ended December 31,	
	2014	2015	2014	2015
Equity-classified compensation	$2,764,878	$ 8,925	$ 2,231	$ 98,172
Liability-classified compensation	1,193,602	11,168,933	143,443	2,391,862
	$3,958,480	$11,177,858	$ 145,674	$ 2,490,034

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 April 2015, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Updates, or ASU, 2015-03, *Interest — Imputation of Interest* (Subtopic 835-30). The update requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction from the debt liability rather than as an asset. The guidance is effective for fiscal years beginning after December 15, 2015. We early adopted this guidance for all periods presented.

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.

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 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. Since inception, we have advanced two product candidates into clinical trials: ONS-3010, a Phase 3-ready biosimilar to adalimumab (Humira®), and ONS-1045, a Phase 3-ready biosimilar to bevacizumab (Avastin®). Additionally, we have identified multiple other biosimilar product candidates, including six that are in active preclinical development, one of which is expected to be ready to enter clinical trials in 2016.

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 a 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, 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 rate of injection site reactions lower than that of Humira. We have initiated Phase 3 preparatory activities for ONS-3010 and expect to commence enrollment in 2016 upon receipt of the necessary regulatory authorizations. 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 advancing development of ONS-1045 to be Phase-3 ready in 2016.

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. We expect to be ready to commence Phase 1 clinical trials of ONS-1050 in 2016 and ONS-4010 in 2017, pending successful completion of comparative analytical and *in vitro* functional studies and receipt of necessary regulatory authorizations. 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.

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.

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:

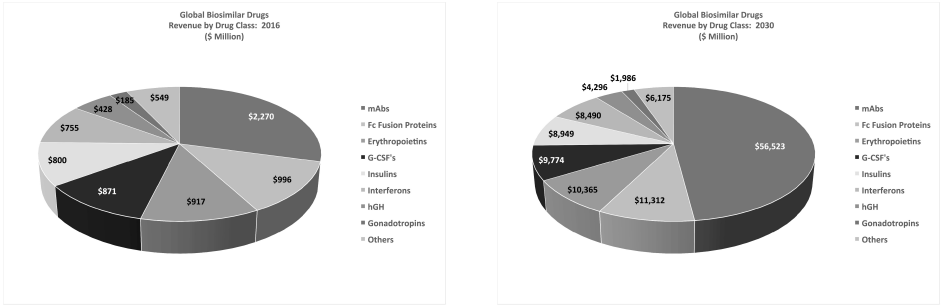
- ***Rapidly advancing our lead product candidates through late-stage clinical development and continuing to advance our preclinical pipeline.*** ONS-3010 and ONS-1045 are our most advanced clinical-stage product candidates. In the first quarter of 2015, ONS-3010 met its primary and secondary study endpoints in a Phase 1 clinical trial and we are preparing to commence enrollment in a confirmatory Phase 3 clinical trial in 2016. 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 ONS-1045 to be Phase-3 ready in 2016. 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 be ready to commence Phase 1 clinical trials in 2016 and 2017, respectively, pending successful completion of comparative analytical and *in vitro* functional studies.
- ***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 by retaining development and commercialization rights in the United States and continuing to selectively out-license to ex-U.S. markets.*** The United States is the largest potential biosimilar market in the world. We currently intend to retain U.S.-rights to select product candidates while entering into additional strategic collaborations and partnerships with biotechnology and pharmaceutical companies in other regions. We believe this strategy will maximize the 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, 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%.

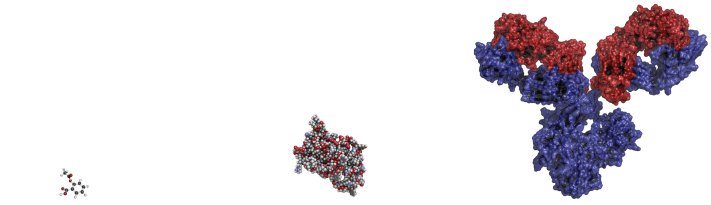


"The Biosimilar Drugs Market: Opportunities, Challenges, Strategies & Forecasts"; SNS Research Ltd.

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.

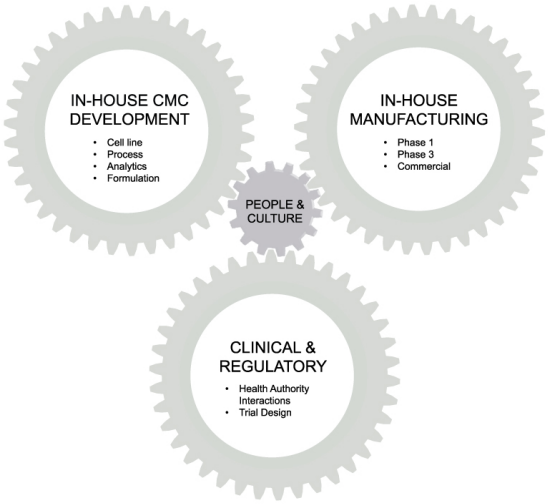
Regulatory hurdles associated with biosimilar development include:

- 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 figure below.



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 are expanding our development capacity by an additional 82,000 square feet in our current industrial complex. We intend to build-out additional state-of-the-art development infrastructure, which we will occupy in phases as needed. We also plan 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, which eliminates the need for rigorous cleaning and sterilization procedures, and related operational requirements necessary for manufacture in traditional stainless-steel based facilities, including the use of the largest single-use bioreactor available. 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 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 also retained a regional expert regulatory consultant in Japan, and may do so for other countries as well, 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 have recently completed discussions with the FDA on seeking both biosimilarity and interchangeability designation for ONS-3010, our Humira biosimilar. 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, 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 and Genentech, Inc. 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 two mAb biosimilars for which we expect to initiate development by the end of 2016. 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.

Biosimilar Candidate	Reference Product	2015 WW Sales ($bn) [1]	Commercial Rights	Product Characterization	Clone Selection	Lab Scale Similarity	Phase 1	Phase 3	Upcoming Milestones/ Catalysts
ONS-3010 (Adalimumab)[2]	HUMIRA®	$14.1	Worldwide (ex-China, India and Mexico)						Phase 3 Trial 2016
ONS-1045 (Bevacizumab)	AVASTIN®	6.9	Worldwide (ex-China, India and Mexico)						Ready to Enter Phase 3 Trial 2016
ONS-1050 (Trastuzumab)	HERCEPTIN®	6.8	Worldwide						Ready to Enter Phase 1 Trial 2016
ONS-4010 (Denosumab)	PROLIA®/ XGEVA®	2.7	Worldwide						Ready to Enter Phase 1 Trial 2017

(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

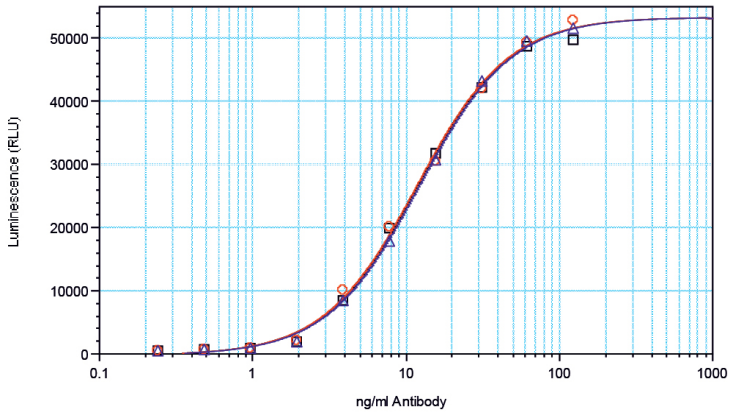
Worldwide sales of Humira were $14.1 billion in 2015, with approximately $8.4 billion in the United States and projected to grow to $18.0 billion worldwide by 2020, and is one of the world's best selling drugs. Humira has been approved by the FDA and the EMA for the treatment of nine and 12 indications, 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, and hidradenitis suppurativa. 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. We have discussed our approach 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 in place prior to the Phase 1 clinical trial and this same formulation will 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).



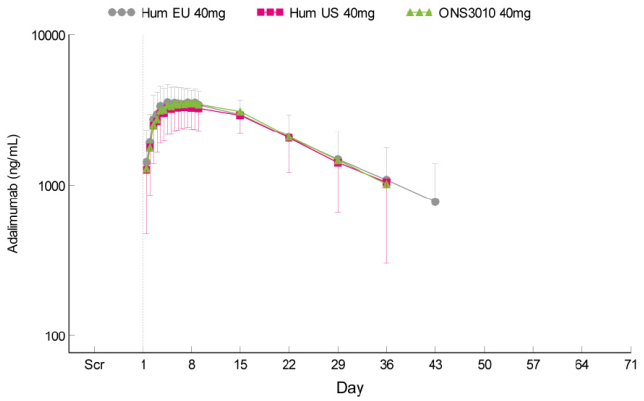
Using our commercial scale process at our manufacturing facility, we are manufacturing sufficient supply of ONS-3010 for Phase 3 clinical testing. We have contracted with a large U.S.-based pharmaceutical fill-finish facility to package ONS-3010 into a single-use, pre-filled syringe. We have also selected 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

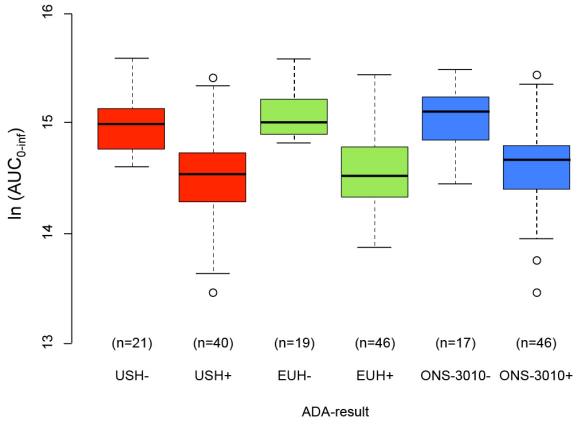
under the auspices of the Stichting Beoordeling Ethiek Biomedisch Onderzoek. In this trial, ONS-3010 met its primary and secondary endpoints, demonstrating a similar PK profile, as well as an immunogenicity profile equivalent to both U.S.- and E.U.-Humira across all three treatment arms. ONS-3010 was 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 ($AUC_{0-\infty}$)



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 in 2016.

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

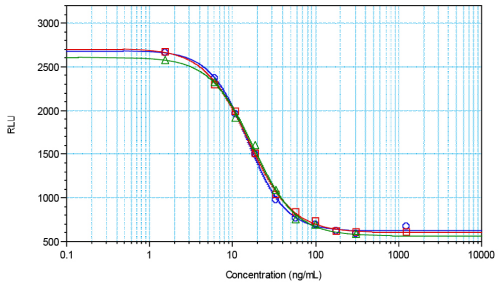
Worldwide sales of Avastin were approximately $7.0 billion in 2014 and 2015. Furthermore, worldwide sales of Avastin are projected to grow to $7.4 billion by end of 2019. Avastin has been approved by the FDA and the EMA for the treatment of seven and eight indications, respectively. Avastin is currently 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 of ONS-1045 across all of these 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)

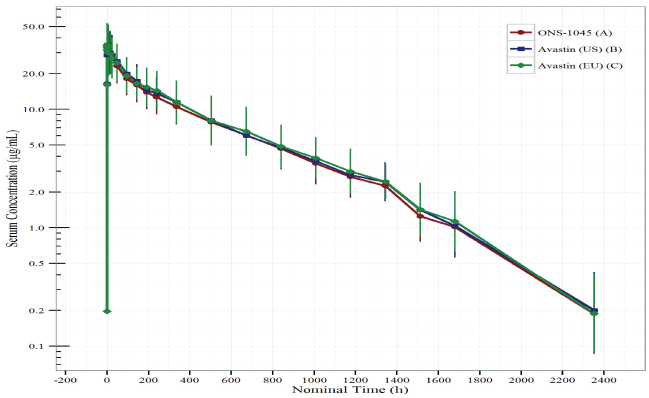


In preparation for producing Phase 3 clinical supplies, we are manufacturing ONS-1045 using our commercial scale process at our manufacturing facility. These batches will be filled into vials at a contracted U.S.-based commercial fill-finish facility.

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 ($AUC_{0-\infty}$)



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 in 2016.

We have initiated a site feasibility study (targeting North and South America, Europe and Asia) in order to advance ONS-1045 to be Phase-3 ready in 2016.

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.

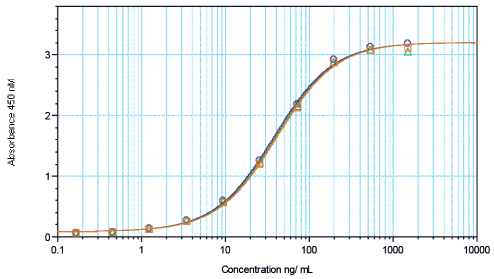
Market Opportunity

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 of these 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 is planned to be completed in the first half of 2016. 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 be completed in 2016 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 during 2016.

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 and be ready to commence our Phase 1 clinical trial for ONS-4010 in 2017. We plan to complete lab scale similarity of ONS-1055 in 2016. According to recent filings with the Securities and Exchange Commission, 2015 worldwide sales of Erbitux® were approximately $2.0 billion.

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. We anticipate completing clone selection in 2016 for ONS-3030, and reference product characterization in 2016 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 effecting selective licensing opportunities to fund the development of our assets. We currently intend to retain U.S. rights to select product candidates while entering into additional strategic collaborations and partnerships with biotechnology and pharmaceutical companies in 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 $23.5 million in payments to us as of December 31, 2015, 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 retain U.S. marketing and commercialization rights to our product candidates and actively pursue licensing

partnerships for the EU. 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 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 $23.5 million in payments as of December 31, 2015.

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, 2015, 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, 2015, 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 $23.5 million in payments as of December 31, 2015 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. 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 December 31, 2015, we have received an aggregate of $5.0 million of payments from IPCA under our various agreements, an aggregate of $2.5 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, as well as those with biosimilar products, such as AbbVie Inc. (the holder of rights to Humira), Genentech Inc. (the holder of rights to the Avastin), Pfizer (pipeline, which includes five biosimilar candidates), Amgen (pipeline, which includes six biosimilar candidates), Sandoz (as a biosimilar company with the only currently FDA-approved biosimilar product), Bioepis and Merck & Co., Inc., or Merck (through their collaboration to develop and commercialize biosimilar candidates), Coherus (pipeline, which includes two Phase 3 biosimilar candidates), Bioepis (pipeline, which includes six biosimilar candidates) and Celltrion (pipeline, which includes two 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 February 8, 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. Accordingly, we anticipate that our PCT application will be nationalized in April 2016. We have not yet determined the countries in which we will pursue national patent protection. 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, 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 may also be 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 2016 is to review 85% 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 is comparable 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 2016, the FDA has committed to reviewing 85% 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, 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, product approval may require, as a condition of approval, post-approval testing and surveillance to monitor the product's safety or efficacy. 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, if our product candidates are approved and we begin commercialization, we will be subject to additional 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, 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. We continue to evaluate the effect that the Affordable Care Act has on our business. 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, such as Canada, Japan, China, Brazil, Mexico and Korea, also have 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. 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 March 31, 2016, we had 89 full-time employees, 47 of whom were primarily engaged in research and development activities and 19 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 have entered into a lease for approximately 82,000 square feet of occupiable office and laboratory space in Cranbury, New Jersey, with lease payments that commenced in March 2016 and expire in March 2026.

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.

MANAGEMENT

Executive Officers and Directors

The following table sets forth information regarding our executive officers and directors as of March 31, 2016:

Name	Age	Position(s)
Executive Officers		
Pankaj Mohan, Ph.D.	52	Chairman, President and Chief Executive Officer
Kenneth M. Bahrt, M.D.	63	Chief Medical Officer
Kogan Bao, Ph.D.	47	Vice President, Analytical Sciences
Scott A. Gangloff	42	Senior Vice President, Development & Manufacturing
Lawrence A. Kenyon	50	Chief Financial Officer and Secretary
Stephen J. McAndrew, Ph.D.	62	Senior Vice President, Business Strategy & Development
Elizabeth A. Yamashita	55	Vice President, Regulatory Affairs
Non-Employee Directors		
Todd C. Brady, M.D., Ph.D.[(1)(3)]	44	Director
Scott Canute[(2)]	55	Director
Albert D. Dyrness[(2)(3)]	53	Director
Donald J. Griffith	67	Director
Kurt J. Hilzinger[(1)(2)]	55	Director
Robin Smith Hoke[(1)(3)]	53	Director

(1) Member of the Audit Committee

(2) Member of the Compensation Committee

(3) Member of the Nominating and Corporate Governance Committee

Executive Officers

Pankaj Mohan, Ph.D. Dr. Mohan has served as our Chairman, President and Chief Executive Officer since January 2011. Prior to founding our company, from May 2008 to December 2010, Dr. Mohan served as head of Business Operations and Portfolio Management of Biologics Process and Product Development at Bristol-Myers Squibb Company, a biopharmaceutical company. From June 2006 to May 2008, Dr. Mohan served as a Director of Bioprocess Engineering at Genentech, Inc., a biotechnology company. Prior to that, from May 1996 to May 2006, Dr. Mohan served as a senior manager at Eli Lilly and Company, a pharmaceutical company. From May 1993 to April 1996, Dr. Mohan served as Assistant Professor (Lecturer/Fellow) at the Advanced Centre for Biochemical Engineering, University College London, London, United Kingdom. From August 1987 to December 1989, Dr. Mohan served as a Scientific Officer for the Department of Atomic Energy for the Government of India. Dr. Mohan has served as a member of the board of directors of Sonnet Biotherapeutics, Inc., a privately held biopharmaceutical company, since its inception in April 2015. Dr. Mohan received a Ph.D. in Biochemical Engineering from the School of Chemical Engineering, University of Birmingham, Birmingham, United Kingdom, a Masters in Financial Management from Middlesex University Business School, London, United Kingdom, an Executive Management Program (AMP) from Fuqua School of Business at Duke University and a Bachelor of Chemical Engineering from the Indian Institute of Technology in Roorkee, India.

We believe Dr. Mohan's experience on our board of directors and as our Chairman, President and Chief Executive Officer, as well as his experience in the biopharmaceutical industry, qualifies him to serve on our board of directors.

Kenneth M. Bahrt, M.D. Dr. Bahrt has served as our Chief Medical Officer since June 2015. Prior to joining us, from February 2014 to May 2015, Dr. Bahrt served as the Vice President of U.S. Medical Affairs at NPS Pharmaceuticals, Inc., a biopharmaceutical company. From August 2011 to January 2014, Dr. Bahrt served as Senior Vice President and Chief Medical Officer at Savient Pharmaceuticals, Inc., a biopharmaceutical company. Prior to that, from September 2009 to August 2011, Dr. Bahrt served as the Therapeutic Head of Immunology Medical Affairs at Genentech, Inc. From July 2007 to September 2009, Dr. Bahrt served as the Global Medical Director for Immunology at Hoffman-La Roche, a Swiss healthcare company. Prior to this, Dr. Bahrt held positions of increasing responsibility at Bristol Myers Squibb, Pfizer, and

Daiichi. Prior to joining the pharmaceutical industry, Dr. Bahrt was in clinical practice. Dr. Bahrt is a board-certified Internist and Rheumatologist and a Fellow of the American College of Rheumatology. Dr. Bahrt received an M.D. from Hahnemann University and a Bachelor's degree in Biology from Muhlenberg College.

Kogan Bao, Ph.D. Dr. Bao has served as our Vice President of Analytical Sciences since January 2016. Prior to joining us, Dr. Bao served as Analytical Similarity Leader at Amgen, Inc. from October 2013 to January 2016 with responsibility for the overall analytical strategy and plan for drug development of several biosimilar assets as well as serving as the primary author for regulatory submissions. From December 2003 to June 2013, Dr. Bao served in roles of increasing responsibility at Allergan, Inc., establishing the pre-formulation and biophysical characterization groups to support early- and late-stage development of biologics as well as providing support for commercial products. Prior to that, Dr. Bao served as a post-doctoral fellow at Stanford University in the Department of Biochemistry from 2002 to 2003. Dr. Bao received a Ph.D. in Biochemistry and Biophysics from Oregon State University and an A.B. from the University of California, Berkeley.

Scott A. Gangloff. Mr. Gangloff has served as our Senior Vice President, Development & Manufacturing since January 2015. Prior to that, Mr. Gangloff served as our Vice President of Process Development and Manufacturing from January 2013 to January 2015 and as our Executive Director of Process Development and Manufacturing from May 2011 to January 2013. Prior to joining us, Mr. Gangloff held various process engineering and manufacturing roles at Bristol-Myers Squibb Company, serving as Associate Director, Process Scale-up from January 2006 to May 2011 with oversight of clinical manufacturing, Manager of Biologics Scale-Up Facility from June 2004 to January 2006, and roles of increasing responsibility in cell culture development and process engineering from July 1998 to June 2004. From January 1996 to July 1998, Mr. Gangloff served as Process Engineer at Jacobs Engineering Group Inc., a technical professional services firm. Mr. Gangloff received a Masters of Engineering in Chemical Engineering from Lehigh University and a Bachelor of Chemical Engineering from Villanova University.

Lawrence A. Kenyon. Mr. Kenyon has served as our Chief Financial Officer and Secretary since September 2015. Prior to that, from February 2014 to September 2015, Mr. Kenyon served as the Chief Financial Officer of Arno Therapeutics, Inc., a biopharmaceutical company focused on the development of therapeutics for cancer and other life threatening diseases, and also as Chief Operating Officer from July 2014 to September 2015. From December 2011 to March 2013, Mr. Kenyon served as the Interim President & Chief Executive Officer, Chief Financial Officer and Secretary of Tamir Biotechnology, Inc., a publicly held biopharmaceutical company engaged in the development of oncology and anti-infective therapeutics. Prior to that, from December 2008 to July 2010, Mr. Kenyon was the Executive Vice President, Finance and, commencing in March 2009, the Chief Financial Officer of, Par Pharmaceutical Companies, Inc., a publicly held generic and branded specialty pharmaceutical company, or Par. Prior to joining Par, Mr. Kenyon was the Chief Financial Officer and Secretary of Alfacell Corporation, or Alfacell, from January 2007 through February 2009 and also served at various times during this period as Alfacell's Executive Vice President, Chief Operating Officer and President, and was a member of Alfacell's board of directors from November 2007 to April 2009. Prior to joining Alfacell, Mr. Kenyon served as the Executive Vice President, Chief Financial Officer and Corporate Secretary at NeoPharm, Inc., a publicly traded biopharmaceutical company, from 2000 to 2006. Mr. Kenyon received a B.A. in Accounting from the University of Wisconsin-Whitewater and is a Certified Public Accountant in Illinois.

Stephen J. McAndrew, Ph.D. Dr. McAndrew served initially as our Vice President of Business Development from February 2012 through March 2014, and as our Senior Vice President, Business Strategy & Development since March 2014. Prior to joining us, from March 2011 to February 2012, Dr. McAndrew served as the President of SJM BioPharm Consulting, a biopharmaceutical consulting company. From December 2009 to March 2011, Dr. McAndrew served as Vice President of Scientific Commercial Development at Taconic Biosciences, Inc., a contract research and biotechnology company, and from August 2007 to December 2009, Dr. McAndrew served as Vice President of Business Development at Caliper Life Sciences, Inc., a biotechnology company. Prior to that, from January 2004 to August 2007, Dr. McAndrew served as Vice President of Business Development at Xenogen Biosciences Corporation, a provider of *in vivo* drug discovery services. From January 2001 to December 2003, Dr. McAndrew served as Vice President of Pharmaceutical Business Development at Lexicon Pharmaceuticals, Inc., a biopharmaceutical drug-development company. Prior to that, from March 1993 to December 2001, Dr. McAndrew served in various positions of increasing responsibility at Bristol-Myers Squibb Company, including as Director of Biotechnology Licensing. Dr. McAndrew received a Ph.D. in Cellular and Molecular Biology from Ohio University, an M.S. in Molecular Genetics from the State University of New York at Albany and a B.S. from the State University of New York at Oswego.

Elizabeth A. Yamashita. Ms. Yamashita has served as our Vice President of Regulatory Affairs since July 2015 and, prior to that, our Vice President of Regulatory and Clinical Affairs since April 2014. Prior to joining us, from October 2012 to January 2014, Ms. Yamashita served as Group Vice President of Regulatory Affairs at Savient Pharmaceuticals, Inc., a

biopharmaceutical company, and also as Vice President, CMC Regulatory from June 2011 to October 2012. From May 2006 to June 2011, Ms. Yamashita served as Principal Fellow, CMC Regulatory Strategy and Vice President Regulatory CMC & Operations at ImClone Systems Inc., a biopharmaceutical company. Prior to that, Ms. Yamashita was employed by Bristol-Myers Squibb Company for 24 years and from 2000 to 2006, Ms. Yamashita served as the Group Director of Global Regulatory Sciences, CMC. Ms. Yamashita received a Regulatory Affairs Certification from the Regulatory Affairs Professional Society and a B.S. in Chemistry from the University of Rochester.

Non-Employee Directors

Todd C. Brady, M.D., Ph.D. Dr. Brady has served as a member of our board of directors since September 2014. Since January 2012, Dr. Brady also has served as Chief Executive Officer and President of Aldeyra Therapeutics, Inc., a biotechnology company, and has served as a member of its board of directors since September 2005. Dr. Brady further has served as a member of the board of directors of Evoke Pharma, Inc., a biotechnology company, since June 2007, of Novadigm Therapeutics, Inc., a biotechnology company, since December 2007 and of Cantex Pharmaceuticals, Inc., a biotechnology company, since August 2006. From 2004 to 2013, Dr. Brady served as an entrepreneur-in-residence and principal at Domain Associates, a healthcare venture capital firm. Dr. Brady received an M.D. from Duke University Medical School, a Ph.D. from Duke University Graduate School and an A.B. from Dartmouth College.

We believe Dr. Brady's experience as a Chief Executive Officer in a biotechnology company and as a director of publicly traded biotechnology companies, as well as his experience as a venture capital investor in the industry, qualifies him to serve on our board of directors.

Scott Canute. Mr. Canute has served as a member of our board of directors since October 2011. Mr. Canute also has served as a member of the technical advisory board of Moderna Therapeutics, Inc., a physical therapy company, since October 2012, and further has served as a member of the board of directors of Proteon Therapeutics, Inc., a biopharmaceutical company, since July 2015 and Flexion Therapeutics, Inc., a pharmaceutical company, since March 2015. In addition, Mr. Canute formerly served as a member of the board of directors of Inspiration Biopharmaceuticals, Inc., a biopharmaceutical company, from September 2012 to September 2013 and AlloCure Inc., a biotechnology company, from October 2012 to October 2014. From March 2010 to July 2011, Mr. Canute served as the President of Global Manufacturing and Corporate Operations of Genzyme Corporation, a biotechnology company. Prior to that, from 1982 to 2007, Mr. Canute served in various management positions at Eli Lilly and Company, including as the President of Global Manufacturing Operations from 2004 to 2007, Vice President of Global Manufacturing from 2001 to 2004, Vice President of Global Pharmaceutical Manufacturing from 1999 to 2001 and General Manager of European Manufacturing Operations from 1998 to 1999. Mr. Canute received an M.B.A. from Harvard Business School and a B.S. in Chemical Engineering from the University of Michigan.

We believe Mr. Canute's experience in the biopharmaceutical industry, as well as his experience as a member on the boards of director of multiple companies in the industry, qualifies him to serve on our board of directors.

Albert D. Dyrness. Mr. Dyrness has served as a member of our board of directors since December 2015. Mr. Dyrness co-founded ADVENT Engineering Services, Inc., a privately held engineering consulting firm, in 1988, and since that time, he has served in several roles, most recently as the Principal and Managing Director of the Life Sciences Division since 1995. Mr. Dryness is a recognized industry leader in bio-process engineering, with expertise in upstream, downstream and fill-finish processes, member of the American Society of Mechanical Engineers Bioprocess Equipment Standard, or ASME BPE, and has served as the Vice Chairperson for the ASME BPE System Design subcommittee since 2013. Mr. Dyrness is also an Industrial Advisory Board Member of the University of the Pacific's Bioengineering program. Mr. Dyrness received an M.S. in Mechanical Engineering from Massachusetts Institute of Technology and holds professional engineering licenses in the State of California for both Chemical Engineering and Mechanical Engineering.

We believe Mr. Dyrness' experience in the design, start-up and qualification of systems, and equipment used for producing and developing biologics and pharmaceutics, as well as in the life sciences sector, qualifies him to serve on our board of directors.

Donald J. Griffith. Mr. Griffith has served as a member of our board of directors since August 2011. Mr. Griffith served as our Chief Financial Officer and Secretary from May 2011 through September 2015. Mr. Griffith currently serves as Chairman, President, Chief Executive Officer and Treasurer of Sonnet Biotherapeutics, Inc. and also serves as a member of its board of directors. From May 1991 to May 2011, Mr. Griffith served as a partner at Stolz & Griffith, LLC, a New Jersey accounting firm. Prior to that, Mr. Griffith was employed in the accounting group at Exxon Mobil Corporation. Mr. Griffith is an active member of the New Jersey Society of CPAs and the American Institute of CPAs. Mr. Griffith received an M.B.A. from Fairleigh Dickenson University and a B.B.A. in Business Administration from the City College of New York.

We believe Mr. Griffith's experience on our board of directors, as well as his extensive financial and accounting experience, qualifies him to serve on our board of directors.

Kurt J. Hilzinger. Mr. Hilzinger has served as a member of our board of directors since December 2015. Since 2007, Mr. Hilzinger has served as a partner at Court Square Capital Partners L.P., an independent private equity firm, where he is responsible for investing in the healthcare sector. Since July 2003, Mr. Hilzinger also has served in various capacities as a member of the board of directors at Humana, Inc., a managed care company, including serving as Lead Director from August 2010 to January 2014, and as Chairman since January 2014. In addition, Mr. Hilzinger also has served several roles at AmerisourceBergen Corporation, a healthcare company, including as a member of the board of directors from March 2004 to November 2007, as the President and Chief Operating Officer from October 2002 to November 2007 and as the Executive Vice President and Chief Operating Officer from August 2001 to October 2002. Mr. Hilzinger also serves on the Visiting Committee at the Ross School of Business at the University of Michigan. Mr. Hilzinger received a B.B.A. in Accounting from the University of Michigan and is a Certified Public Accountant in Michigan.

We believe Mr. Hilzinger's experience and financial expertise in the healthcare sector qualifies him to serve on our board of directors.

Robin Smith Hoke. Ms. Hoke has served as a member of our board of directors since December 2015. Since July 2012, Ms. Hoke has been acting as a consultant providing pharmaceutical and healthcare advisory services to multi-national, mid-tier and emerging companies and private equity firms. Previously, Ms. Hoke served in various roles at Ricerca Biosciences, LLC, a preclinical contract research organization, including as a member of the board of directors from February 2013 to December 2015, as well as the Chair of the board of directors and the Interim Chief Executive Officer from August 2013 to February 2014. Prior to that, Ms. Hoke served as the President for GeneralMedix Pharmaceuticals, Inc., a privately held specialty injectable company, from July 2007 to June 2012. Ms. Hoke also served as the Senior Vice President, Global Business Development and Strategic Initiatives, Generic Pharmaceuticals, at Cardinal Health, Inc., a healthcare company, from 2005 to 2007, and served as General Counsel from 2001 to 2005. Previously, Ms. Hoke was in-house counsel at Abbott Laboratories, a healthcare company, and a business partner at the law firm of Kegler, Brown, Hill & Ritter Co., LP. Ms. Hoke received a B.S. from Michigan State University and a J.D. from Thomas M. Cooley Law School.

We believe Ms. Hoke's healthcare and pharmaceutical experience qualifies her to serve on our board of directors.

Family Relationships

There are no family relationships among our directors and executive officers.

Board Composition

Our board of directors will consist of seven members upon the closing of this offering. In accordance with our amended and restated certificate of incorporation to be filed in connection with this offering, immediately prior to this offering, our board of directors will be divided into three classes. At each annual general meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- The Class I directors will be Albert D. Dyrness, Kurt J. Hilzinger and Robin Smith Hoke, and their terms will expire at the annual meeting of stockholders to be held in 2017;
- The Class II directors will be Todd C. Brady, M.D., Ph.D. and Donald J. Griffith, and their terms will expire at the annual meeting of stockholders to be held in 2018; and
- The Class III directors will be Scott Canute and Pankaj Mohan, Ph.D., and their terms will expire at the annual meeting of stockholders to be held in 2019.

We expect that any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Director Independence

Under the listing requirements and rules of the NASDAQ Global Market, or NASDAQ, independent directors must comprise a majority of our board of directors as a listed company within one year of the closing of this offering.

Our board of directors has undertaken a review of its composition, the composition of its committees and the independence of each director. Based upon information requested from and provided by each director concerning his/her background,

employment and affiliations, including family relationships, our board of directors has determined that Todd C. Brady, M.D., Ph.D., Scott Canute, Albert D. Dyrness, Kurt J. Hilzinger and Robin Smith Hoke do not have any relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the applicable rules and regulations of the SEC and the listing requirements and rules of the NASDAQ. In making this determination, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director.

Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, as well as other committees, which currently include a finance committee, culture committee and a science and technology committee. Our board of directors may establish other committees to facilitate the management of our business. The composition and functions of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors.

Audit Committee

Our audit committee consists of Todd C. Brady, M.D., Ph.D., Kurt J. Hilzinger and Robin Smith Hoke. Our board of directors has determined that Todd C. Brady, M.D., Ph.D., Kurt J. Hilzinger and Robin Smith Hoke are independent under the NASDAQ listing standards and Rule 10A-3(b)(1) of the Exchange Act. The chair of our audit committee is Kurt J. Hilzinger. Our board of directors has determined that Kurt J. Hilzinger is an "audit committee financial expert" within the meaning of SEC regulations. Our board of directors has also determined that each member of our audit committee can read and understand fundamental financial statements in accordance with applicable requirements. In arriving at these determinations, the board of directors has examined each audit committee member's scope of experience and the nature of their employment in the corporate finance sector.

The primary purpose of the audit committee is to discharge the responsibilities of our board of directors with respect to our accounting, financial and other reporting and internal control practices and to oversee our independent registered accounting firm. Specific responsibilities of our audit committee include:

- selecting a qualified firm to serve as the independent registered public accounting firm to audit our consolidated financial statements;
- helping to ensure the independence and performance of the independent registered public accounting firm;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, our interim and year-end operating results;
- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing our policies on risk assessment and risk management;
- reviewing related party transactions;
- obtaining and reviewing a report by the independent registered public accounting firm at least annually, that describes our internal quality-control procedures, any material issues with such procedures, and any steps taken to deal with such issues when required by applicable law; and
- approving (or, as permitted, pre-approving) all audit and all permissible non-audit services, other than de minimis non-audit services, to be performed by the independent registered public accounting firm.

Compensation Committee

Our compensation committee consists of Scott Canute, Albert D. Dyrness and Kurt J. Hilzinger. Our board of directors has determined that Scott Canute, Albert D. Dyrness and Kurt J. Hilzinger are independent under the NASDAQ listing standards, are "non-employee directors" as defined in Rule 16b-3 promulgated under the Exchange Act and are "outside directors" as that term is defined in Section 162(m) of the Internal Revenue Code of 1986, as amended, or Section 162(m). The chair of our compensation committee is Scott Canute.

The primary purpose of our compensation committee is to discharge the responsibilities of our board of directors to oversee our compensation policies, plans and programs and to review and determine the compensation to be paid to our executive officers, directors and other senior management, as appropriate. Specific responsibilities of our compensation committee include:

- reviewing and approving, or recommending that our board of directors approve, the compensation of our executive officers;
- reviewing and recommending to our board of directors the compensation of our directors;
- reviewing and approving, or recommending that our board of directors approve, the terms of compensatory arrangements with our executive officers;
- administering our stock and equity incentive plans;
- selecting independent compensation consultants and assessing whether there are any conflicts of interest with any of the committees compensation advisers;
- reviewing and approving, or recommending that our board of directors approve, incentive compensation and equity plans, severance agreements, change in control protections and any other compensatory arrangements for our executive officers and other senior management, as appropriate; and
- reviewing and establishing general policies relating to compensation and benefits of our employees and reviewing our overall compensation philosophy.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Todd C. Brady, M.D., Ph.D., Albert D. Dyrness and Robin Smith Hoke. The chair of our nominating and corporate governance committee is Robin Smith Hoke. Each member of the nominating and corporate governance committee is independent within the meaning of applicable listing standards, is a non-employee director and is free from any relationship that would interfere with the exercise of his or her independent judgment, as determined by the board of directors in accordance with the applicable NASDAQ listing standards.

Specific responsibilities of our nominating and corporate governance committee include:

- identifying, evaluating and selecting, or recommending that our board of directors approve, nominees for election to our board of directors;
- evaluating the performance of our board of directors and of individual directors;
- considering and making recommendations to our board of directors regarding the composition of the committees of the board of directors;
- reviewing developments in corporate governance practices;
- evaluating the adequacy of our corporate governance practices and reporting;
- reviewing management succession plans;
- developing and making recommendations to our board of directors regarding corporate governance guidelines and matters; and
- overseeing an annual evaluation of the board of directors' performance.

As noted above, our board may from time to time establish other committees for the benefit of the company. Currently, our board has established a culture committee, a finance committee and a science and technology committee. We believe these committees, which may have members from both our board of directors and management, will foster an exchange of ideas and create a culture of collaboration that leverages the skills of our directors, management and employees.

Compensation Committee Interlocks and Insider Participation

None of the members of the compensation committee is currently, or has been at any time, one of our officers or employees. None of our executive officers currently serves, or has served during the last year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee other than Dr. Mohan, who currently serves on the board of directors of Sonnet Biotherapeutics, Inc., or Sonnet, for which Mr. Griffith, another member of our board of directors, also serves as chairman, president, chief executive officer and treasurer. For more information regarding Sonnet, please see "Certain Relationships and Related Party Transactions — Sonnet Biotherapeutics, Inc."

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that applies to all of our employees and officers (including our principal executive officer, principal financial officer and principal accounting officer or controller), or persons performing similar functions and agents and representatives, including directors and consultants. The full text of our code of business

conduct and ethics will be posted on our website at www.oncobiologics.com. We intend to disclose future amendments to certain provisions of our code of business conduct and ethics, or waivers of such provisions applicable to any principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, and our directors, on our website identified above.

Non-Employee Director Compensation

We have entered into director engagement letters with two of our non-employee directors, Dr. Brady and Mr. Canute. Pursuant to Dr. Brady's director engagement letter, he is eligible to receive a fee of $100,000 per year for his service paid in cash and a grant of PSUs with respect to 57,971 shares of our common stock. The PSUs have not been granted to Dr. Brady. Pursuant to Mr. Canute's director engagement letter, he is eligible to receive a fee of $100,000 per year for his service paid in cash. Mr. Canute also received a grant of 115,942 shares of restricted stock on December 19, 2011, which were subject to a four year vesting schedule and he is eligible to receive equity awards as determined by the board of directors in its sole discretion. In June 2014, we conducted a buyback of certain of our outstanding securities (see "Certain Relationships and Related Party Transactions — June 2014 Buyback"). Specifically, we offered restricted stockholders approximately $1.73 per share to forfeit their restricted shares payable in the form of a 0% promissory note due December 31, 2015, as amended. In connection therewith, Mr. Canute received a 0% promissory note with an aggregate principal amount of $200,000 due December 31, 2015, as amended, in exchange for his 115,942 shares of restricted stock. All outstanding amounts have been paid in full. Although we do not have a written policy, we generally reimburse our directors for their reasonable out-of-pocket expenses incurred in attending board of directors meetings and with respect to our business.

The following table sets forth information concerning the compensation earned for service on our board of directors by our directors during the year ended September 30, 2015. Mr. Griffith, our former Chief Financial Officer and Secretary is also a director, but he did not receive any additional compensation for service as a director during the year ended September 30, 2015. Dr. Mohan, our President and Chief Executive Officer, is also Chairman of our board but he does not receive any additional compensation for service as a director. Dr. Mohan's compensation as an executive officer is set forth below under "Executive Compensation — Summary Compensation Table."

Name	Fees Earned or Paid in Cash[1] ($)	Total ($)
Todd C. Brady, M.D., Ph.D.	100,000	100,000
Scott Canute	100,000	100,000

(1) Represents the annual cash fees per terms of director engagement letters.

Non-Employee Director Compensation Policy

We have adopted a non-employee director compensation policy pursuant to which our non-employee directors will be eligible to receive compensation for service on our board of directors and committees of our board of directors, which takes effect in connection with this offering.

Equity Compensation

Initial Grant

Each new non-employee director who joins our board of directors will be granted a non-statutory stock option to purchase 7,246 shares of common stock under the 2015 Plan, vesting annually over three years from the grant date, subject to continued service as a director through the applicable vesting date.

Annual Grant

On the date of each annual meeting of our stockholders, each current non-employee director will be granted an annual non-statutory stock option to purchase 4,348 shares of common stock under the 2015 Plan, vesting on the first anniversary of the grant date, subject to continued service as a director though the applicable vesting date. The exercise price per share of each stock option granted under the non-employee director compensation policy will be the fair market value of a share of our common stock, as determined in accordance with the 2015 Plan, on the date of the option grant. Each stock option will have a term of ten years from the date of grant, subject to earlier termination in connection with a termination of the non-employee director's continuous service with us.

Cash Compensation

Each non-employee director will receive an annual cash retainer of $35,000 for serving on our board of directors. The chairperson of our board of directors will receive an additional annual cash retainer of $30,000.

The chairperson and members of the three principal standing committees of our board of directors will be entitled to the following annual cash retainers:

Board Committee	Chairperson Fee	Member Fee
Audit Committee	$ 15,000	$ 7,500
Compensation Committee	10,000	5,000
Nominating and Corporate Governance Committee	8,000	4,000

All annual cash compensation amounts will be payable in equal quarterly installments in arrears, on the last day of each fiscal quarter for which the service occurred, pro-rated based on the days served in the applicable fiscal quarter.

EXECUTIVE COMPENSATION

Our named executive officers for the year ended September 30, 2015, which consist of our principal executive officer and our two other most highly compensated executive officers, are:

- Pankaj Mohan, Ph.D., our Chairman, President and Chief Executive Officer;
- Kenneth M. Bahrt, M.D., our Chief Medical Officer; and
- Elizabeth A. Yamashita, our Vice President, Regulatory Affairs.

Summary Compensation Table

The following table provides information regarding the compensation earned by our named executive officers for the year ended September 30, 2015.

Name and Principal Position	Year	Salary ($)	Bonus ($)[1]	Equity Plan Awards ($)[2]	All Other Compensation ($)[3]	Total ($)
Pankaj Mohan, Ph.D. *Chairman, President and Chief Executive Officer*	2015	290,004		—	29,839	319,843
Kenneth M. Bahrt, M.D.[4] *Chief Medical Officer*	2015	65,542		644,000	6,881	716,423
Elizabeth A. Yamashita *Vice President, Regulatory Affairs*	2015	235,746		—	15,809	251,555

(1) Discretionary bonus amounts for fiscal year ended September 30, 2015 have not yet been determined. Bonus amounts potentially payable are discussed below under "— Narrative to Summary Compensation Table — Annual Base Salary and Bonus."

(2) In accordance with SEC rules, this column reflects the aggregate grant date fair value of the performance stock unit, or PSU, awards granted during fiscal year 2015 computed in accordance with Financial Accounting Standard Board Accounting Standards Codification Topic 718, or ASC 718, for stock-based compensation transactions. The PSU awards are a form of stock appreciation right that originally were settled in cash. Assumptions used in the calculation of these amounts are included in Note 4 to our consolidated financial statements appearing elsewhere in this prospectus. These amounts do not reflect the actual economic value that would be realized by the named executive officer upon the exercise of the PSUs. Effective December 31, 2015, Dr. Bahrt's and Ms. Yamashita's PSUs were cancelled, and they each received a grant of restricted stock units issued under the 2015 Plan.

(3) Amounts in this column reflect the payment of term life and disability insurance premiums, along with 401(k) matching contributions. All of these benefits are provided to the named executive officers on the same terms as provided to all of our regular full-time employees. For more information regarding these benefits, see below under "— Perquisites, Health, Welfare and Retirement Benefits." We also reimbursed Dr. Mohan for cell phone expenses. Dr. Mohan is also entitled to a car allowance of up to $8,400 pursuant to his employment letter, however, such amounts were not paid nor accrued in the year ended September 30, 2015.

(4) Dr. Bahrt joined our company in June 2015.

Narrative to Summary Compensation Table

We review compensation annually for all employees, including our named executive officers. In setting executive base salaries and bonuses and granting equity incentive awards, we consider compensation for comparable positions in the market, the historical compensation levels of our executives, individual performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders and a long-term commitment to our company.

The independent members of our board of directors have historically determined our executive officers' compensation, and typically review and discuss management's proposed compensation with the chief executive officer for all executives other than the chief executive officer. Based on those discussions and its discretion, the independent members of the board of directors then recommend, and the full board then approves, the compensation for each executive officer.

Annual Base Salary and Bonus

The compensation of our named executive officers is generally determined and approved at the beginning of each calendar year or, if later, in connection with the commencement of employment of the executive. The base salaries are reviewed periodically by our board of directors.

We seek to motivate and reward our executives for achievements relative to our corporate goals and expectations for each fiscal year. From time to time our board of directors or compensation committee may approve discretionary bonuses for our named executive officers based on individual performance, company performance or as otherwise determined appropriate.

Long-Term Incentives

Our equity-based incentive awards are designed to align our interests and the interests of our stockholders with those of our employees and consultants, including our named executive officers.

Our 2011 Stock Incentive Plan, or our 2011 Plan, authorizes us to make grants to eligible recipients of non-qualified stock options, incentive stock options, restricted stock awards, restricted stock unit awards and equity or cash-based performance awards. All of our awards outstanding under this plan are in the form of PSUs. We initially granted restricted stock and stock options under the 2011 Plan to employees, subject to time-based vesting restrictions. We converted to using PSUs subject to both time-based and performance-based vesting as the primary incentive for long-term compensation to our named executive officers because they are able to profit from performance stock units only if our stock price increases and the performance conditions are achieved. PSUs are a form of stock appreciation right, generally subject to a four year time-based vesting schedule with 50% vesting on each of the third and fourth anniversaries of the recipient's hire date, and grant the award recipient the right to receive, upon exercise, a cash amount equal to the difference between the fair market value of a share of our common stock and the exercise price of the PSU, less applicable withholding taxes. PSUs may only be exercised during their 10-year term on or following the achievement of time-based vesting and specified performance conditions, including the occurrence of a change in control, the closing of this offering, or, subject to the discretion of our board of directors, our achieving an enterprise value of at least $400 million. In addition, PSUs may be subject to additional acceleration of time-based vesting restrictions upon certain termination and change in control events. In November 2015, we commenced a tender-offer to all the holders of our outstanding PSUs except PSUs held by our officers and one director to amend the terms of such outstanding awards to increase the exercise price to an amount equal to the fair market value of a share of our 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 our common stock or cash, at our discretion. We closed the tender-offer on December 21, 2015. Effective December 31, 2015, Dr. Bahrt's and Ms. Yamashita's PSUs were cancelled, and Dr. Mohan, Dr. Bahrt and Ms. Yamashita each received a grant of restricted stock units, or RSUs, issued under the 2015 Plan. All of the RSUs are subject to performance-based vesting such that the RSUs will vest upon the first to occur of a change in control of the company and the date that is six months following the effective date of the registration statement of which this prospectus forms a part, in each case subject to the recipient's continued service with us through such event. In addition, certain of the RSUs are subject to additional time-based vesting restrictions that will be satisfied if the executive remains in continuous service with us through certain dates as follows: (i) 50% of the RSUs granted to Dr. Mohan will satisfy the time-based vesting restrictions on each of the first and second anniversaries of the grant date and (ii) 50% of the RSUs granted to Dr. Bahrt and Ms. Yamashita will satisfy the time-based vesting restrictions on each of the third and fourth anniversaries of their original hire dates.

We may grant equity awards at such times as our board of directors determines appropriate. Our executives generally are awarded an initial grant in connection with their commencement of employment. Additional grants may occur periodically in order to specifically incentivize executives with respect to achieving certain corporate goals or to reward executives for exceptional performance.

Agreements with our Named Executive Officers

Below are written descriptions of our employment agreement with Dr. Mohan and offer letter agreements with our other named executive officers.

Dr. Mohan. We entered into an employment agreement with Dr. Mohan for full-time services in January 2011 setting forth the terms of his employment as Chief Executive Officer. Pursuant to the agreement, Dr. Mohan was entitled to an initial annual base salary of $230,000 upon his commencement of full time services with us and an increased annual base salary of $290,000 after the initiation of revenue, an annual discretionary bonus equal to the greater of 8% of EBITDA during a fiscal year or 33% of the total incentive pay pool allocated to company employees and directors with respect to a fiscal year, and reimbursement for an automobile down payment, allowance and expenses. We also pay all premiums associated with Dr. Mohan's health insurance. Dr. Mohan is currently employed by and performing services for us on a full-time basis. The term of Dr. Mohan's employment agreement will continue until the earlier of a sale of the company, the company's initial public offering of stock, or another similar liquidity event with respect to the company. Dr. Mohan's employment agreement provides that we may terminate Dr. Mohan's employment with us and the term of the agreement at any time (i) with cause, (ii) without cause on thirty (30) days written notice, or (iii) due to Dr. Mohan's disability upon written notice to Dr. Mohan. Dr. Mohan may terminate his employment with us and the term of the employment agreement at any time (i) with good reason upon written notice, or (ii) without good reason upon thirty (30) days written notice. Dr. Mohan's employment with us and his employment agreement will automatically terminate upon his death or the end of the term of

the agreement. Dr. Mohan is additionally entitled to certain severance and change in control benefits pursuant to his agreement, the terms of which are described below under "— Potential Payments upon Termination or Change of Control."

On February 22, 2016, we entered into a new employment agreement with Dr. Mohan that takes effect in connection with this offering. Under Dr. Mohan's new employment agreement, Dr. Mohan is entitled to an initial annual base salary of $490,000, is eligible to receive an annual performance bonus of up to 50% of his annual base salary as determined by our board of directors, and is also eligible for reimbursement for an automobile down payment and expenses. Dr. Mohan is also entitled to a one-time lump sum performance bonus of $990,000 contingent upon the closing of this offering. Dr. Mohan is currently employed by and performing services for us on a full-time basis. His employment agreement does not have a specified term and his employment may be terminated by us or by Dr. Mohan at any time, with or without cause. Dr. Mohan is also entitled to certain severance and change in control benefits pursuant to his employment agreement, the terms of which are described below under "— Potential Payments upon Termination or Change of Control."

Dr. Bahrt. We entered into an employment offer letter agreement with Dr. Bahrt for full-time services in June 2015 setting forth the terms of his employment. Pursuant to the agreement, Dr. Bahrt was entitled to an initial annual base salary of $250,000, a target annual discretionary bonus equal to $100,000 and the grant of 28,985 PSUs that vest over a four year period subject to Dr. Bahrt's continued service with us. Dr. Bahrt is currently employed by and performing services for us on a full-time basis. Dr. Bahrt is employed by us on an at-will basis. His employment offer letter agreement does not have a specified term and his employment may be terminated by us or Dr. Bahrt at any time, with or without cause. Dr. Bahrt is not entitled to any additional compensation or benefits under his employment offer letter agreement upon termination of his employment or a change of control. Dr. Bahrt's PSUs were cancelled in December 2015, and he was awarded a grant of RSUs pursuant to the terms of the 2015 Plan.

On February 22, 2016, we entered into a new employment agreement with Dr. Bahrt that takes effect in connection with this offering. Under Dr. Bahrt's new employment agreement, Dr. Bahrt is entitled to an initial annual base salary of $400,000 and is eligible to receive an annual performance bonus of up to 40% of his base salary as determined by our board of directors. Dr. Bahrt is currently employed by and performing services for us on a full-time basis. His employment agreement does not have a specified term and his employment may be terminated by us or by Dr. Bahrt at any time, with or without cause. Dr. Bahrt is additionally entitled to certain severance and change in control benefits pursuant to his employment agreement, the terms of which are described below under "— Potential Payments upon Termination or Change of Control."

Ms. Yamashita. We entered into an employment offer letter agreement with Ms. Yamashita for full-time services in March 2014 setting forth the terms of her employment. Pursuant to the agreement, Ms. Yamashita was entitled to an initial annual base salary of $230,000, which was increased to $235,000 in August 2015, a target annual discretionary bonus equal to 50% of her annual base salary in the event that sufficient revenue was generated and the grant of 43,478 PSUs that vest over a four year period subject to Ms. Yamashita's continued service with us. Ms. Yamashita is currently employed by and performing services for us on a full-time basis. Ms. Yamashita is employed by us on an at-will basis. Her employment offer letter agreement does not have a specified term and her employment may be terminated by us or Ms. Yamashita at any time, with or without cause. Ms. Yamashita is not entitled to any additional compensation or benefits under her employment offer letter agreement upon termination of her employment or a change of control. Ms. Yamashita's PSUs were cancelled in December 2015, and she was awarded a grant of RSUs pursuant to the terms of the 2015 Plan.

On February 24, 2016, we entered into a new employment agreement with Ms. Yamashita that takes effect in connection with this offering. Under Ms. Yamashita's new employment agreement, Ms. Yamashita is entitled to an initial annual base salary of $255,000 and is eligible to receive an annual performance bonus of up to 40% of her annual base salary as determined by our board of directors. Ms. Yamashita is currently employed by and performing services for us on a full-time basis. Her employment agreement does not have a specified term and her employment may be terminated by us or by Ms. Yamashita at any time, with or without cause. Ms. Yamashita is also entitled to certain severance and change in control benefits pursuant to her employment agreement, the terms of which are described below under "— Potential Payments upon Termination or Change of Control."

Potential Payments upon Termination or Change of Control

Regardless of the manner in which a named executive officer's service terminates, the named executive officer is entitled to receive amounts earned during his or her term of service, including salary and unused vacation pay.

Dr. Mohan. Pursuant to Dr. Mohan's employment agreement that takes effect in connection with this offering, if he is terminated without cause or if he resigns for good reason, subject to his execution of a separation agreement with an effective release of claims in favor of us and continued compliance with certain restrictive covenants set forth in such

employment agreement and a proprietary information, inventions, non-solicitation and non-competition agreement, or PIIA, he is entitled to continued payment of his base salary for 12 months following the termination, 100% of his target bonus for the calendar year of termination paid in a lump sum, employee benefit coverage for up to 12 months, full vesting of 50% of his then unvested equity awards, and reimbursement of expenses owed to him through the date of his termination.

Pursuant to the employment agreement, if Dr. Mohan's employment is terminated by us or any successor entity (provided such successor entity either assumes Dr. Mohan's equity awards or substitutes similar equity awards) without cause or if he resigns for good reason within two months prior to or within 12 months following a change in control (as defined in the 2015 Plan), subject to his execution of a separation agreement with an effective release of claims in favor of us and continued compliance with certain restrictive covenants set forth in such employment agreement and the PIIA, he is entitled to continued payment of his base salary for 18 months, 150% of his annual target bonus for the calendar year of termination paid in a lump sum, employee benefit coverage for up to 18 months, and reimbursement of expenses owed to him through the date of his termination. Additionally, 100% of his then unvested equity awards shall become fully vested.

Dr. Bahrt. Pursuant to Dr. Bahrt's employment agreement that takes effect in connection with this offering, if he is terminated without cause or if he resigns for good reason, subject to his execution of a separation agreement with an effective release of claims in favor of us and continued compliance with certain restrictive covenants set forth in such employment agreement and the PIIA, he is entitled to continued payment of his base salary for 12 months following the termination, employee benefit coverage for up to 12 months, full vesting of 50% of his then unvested equity awards, and reimbursement of expenses owed to him through the date of his termination.

Pursuant to the employment agreement, if Dr. Bahrt's employment is terminated by us or any successor entity (provided such successor entity either assumes Dr. Bahrt's equity awards or substitutes similar equity awards) without cause or if he resigns for good reason within two months prior to or within 12 months following a change in control (as defined in the 2015 Plan), subject to his execution of a separation agreement with an effective release of claims in favor of us and continued compliance with certain restrictive covenants set forth in such employment agreement and the PIIA, he is entitled to continued payment of his base salary for 12 months, 100% of his annual target bonus for the calendar year of termination paid in a lump sum, employee benefit coverage for up to 12 months, and reimbursement of expenses owed to him through the date of his termination. Additionally, 100% of his then unvested equity awards shall become fully vested.

Ms. Yamashita. Pursuant to Ms. Yamashita's employment agreement that takes effect in connection with this offering, if she is terminated without cause or if she resigns for good reason, subject to her execution of a separation agreement with an effective release of claims in favor of us and continued compliance with certain restrictive covenants set forth in such employment agreement and the PIIA, she is entitled to continued payment of her base salary for six months following the termination, employee benefit coverage for up to six months, full vesting of 50% of her then unvested equity awards, and reimbursement of expenses owed to her through the date of her termination.

Pursuant to the employment agreement, if Ms. Yamashita's employment is terminated by us or any successor entity (provided such successor entity either assumes Ms. Yamashita's equity awards or substitutes similar equity awards) without cause or if she resigns for good reason within two months prior to or within 12 months following a change in control (as defined in the 2015 Plan), subject to her execution of a separation agreement with an effective release of claims in favor of us and continued compliance with certain restrictive covenants set forth in such employment agreement and the PIIA, she is entitled to continued payment of her base salary for six months, 50% of her annual target bonus for the calendar year of termination paid in a lump sum, employee benefit coverage for up to six months, and reimbursement of expenses owed to her through the date of her termination. Additionally, 100% of her then unvested equity awards shall become fully vested.

For purposes of Dr. Mohan's, Dr. Bahrt's and Ms. Yamashita's employment agreements that take effect in connection with this offering:

- "cause" generally means, (i) a material breach of any covenant or condition under the employment agreement or any other agreement between us and the named executive; (ii) any act constituting dishonesty, fraud, immoral or disreputable conduct; (iii) any conduct which constitutes a felony under applicable law; (iv) material violation of any of our policies or any act of misconduct; (v) refusal to follow or implement a clear and reasonable directive from us; (vi) negligence or incompetence in the performance of the named executive's duties or failure to perform such duties in a manner satisfactory to us after the expiration of 10 days without cure after written notice of such failure; or (vii) breach of fiduciary duty.
- "good reason" means the occurrence, without the named executive's consent, of any of the following events: (i) a material reduction in the named executive's base salary under the employment agreement of at least 25%; (ii) a material breach of the employment agreement by us; (iii) a material reduction in the named executive's duties,

authority and responsibilities relative to his or her duties, authority, and responsibilities in effect immediately prior to such reduction; or (iv) the relocation of the named executive's principal place of employment in a manner that lengthens his or her one-way commute distance by 50 or more miles from his or her then-current principal place of employment immediately prior to such relocation; *provided, however,* that none of the events described in this sentence will constitute good reason unless and until (x) the named executive first notifies us in writing describing in reasonable detail the condition(s) that constitutes good reason within 30 days of its occurrence, (y) we fail to cure the condition(s) within 30 days after our receipt of written notice, and (z) the named executive voluntarily terminates his or her employment within 30 days after the end of 30-day cure period.

Outstanding Equity Awards at Fiscal Year-End.

The following table sets forth certain information regarding equity awards granted to our named executive officers that remain outstanding as of September 30, 2015.

		Equity Awards[1]			
	Grant Date	Number of Securities Underlying Unexercised PSUs Exercisable (#)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned PSUs (#)	Exercise Price ($)	Expiration Date
Pankaj Mohan, Ph.D.	—	—	—	—	—
Kenneth M. Bahrt, M.D.	6/22/2015	28,985[2]	—	3.45	6/22/2025
Elizabeth A. Yamashita	6/30/2015	48,695[3]	—	3.45	6/30/2024

(1) All of the outstanding equity awards as of September 30, 2015 are PSUs that were granted under and subject to the terms of the 2011 Stock Incentive Plan, described below under "— Equity Benefit Plans." None of our named executive officers held any other stock awards at the end of 2015. Except as otherwise indicated, each PSU award is subject to performance-based and time-based vesting, subject to the executive's continuous service with us through the time-based vesting dates and the potential vesting acceleration of the time-based vesting conditions upon a change in control and certain terminations of employment, as described above under "— Narrative to Summary Compensation Table" and below under "Equity Benefit Plans — 2011 Stock Incentive Plan." Effective December 31, 2015, all such outstanding PSUs were cancelled, and our named executive officers received grants of RSUs issued under the 2015 Plan.

(2) As of September 30, 2015, these PSUs were subject to both time-based and performance-based vesting conditions: the time-based vesting restrictions will lapse with respect to 50% of the PSUs on June 22, 2018 and 50% of the PSUs on June 22, 2019, subject to Dr. Bahrt's continuous service with us through such date. In addition, 100% of the PSUs may not be exercised unless and until there is a change in control, an initial public offering of our stock or our achieving an enterprise value of at least $400 million, subject to the discretion of the board of directors, within the term of the PSU. Effective December 31, 2015, Dr. Bahrt's PSUs were cancelled and forfeited, and he received a grant of RSUs issued under the 2015 Plan, subject to both performance and time-based vesting. The RSUs will satisfy the performance-based vesting restrictions upon the first to occur of a change in control of the company and the date that is six months following the effective date of the registration statement of which this prospectus forms a part, in each case subject to Dr. Bahrt's continued service with us through such event. Of these RSUs, 50% will satisfy the time-based vesting restrictions on each of June 22, 2018 and 2019, subject to Dr. Bahrt's continuous service with us through such dates; provided that 100% will satisfy the time-based vesting restrictions upon the occurrence of a change in control, subject to Dr. Bahrt's continuous service with us through such date.

(3) As of September 30, 2015, these PSUs were subject to both time-based and performance-based vesting conditions: the time-based vesting restrictions will lapse with respect to 50% of the PSUs on April 7, 2017 and 50% of the PSUs on April 7, 2018, subject to Ms. Yamashita's continuous service with us through such date. In addition, 100% of the PSUs may not be exercised unless and until there is a change in control, an initial public offering of our stock or our achieving an enterprise value of at least $400 million, subject to the discretion of the board of directors, within the term of the PSU. Effective December 31, 2015, Ms. Yamashita's PSUs were cancelled and forfeited, and she received a grant of RSUs issued under the 2015 Plan, subject to both performance and time-based vesting. The RSUs will satisfy the performance-based vesting restrictions upon the first to occur of a change in control of the company and the date that is six months following the effective date of the registration statement of which this prospectus forms a part, in each case subject to Ms. Yamashita's continued service with us through such event. Of these RSUs, 50% will satisfy the time-based vesting restrictions on each of April 7, 2017 and 2018, subject to Ms. Yamashita's continued service with us through such dates; provided that 100% will satisfy the time-based vesting restrictions upon the occurrence of a change in control, subject to Ms. Yamashita's continuous service with us through such date.

Option Exercises and Stock Vested

Our named executive officers did not exercise any stock option or PSUs during the fiscal year ended September 30, 2015.

Option Repricings, Modifications and Cancellations

We did not engage in any repricings or other modifications or cancellations to any of our named executive officers' outstanding equity awards during the year ended September 30, 2015. In November, 2015, we commenced a tender-offer to all the holders of our outstanding PSUs except our officers and one director to amend the terms of such outstanding awards to increase the exercise price to an amount equal to the fair market value of a share of our 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 our common stock or cash, at our discretion. We closed the tender-offer on December 21, 2015. Effective December 31, 2015, Dr. Bahrt's and Ms. Yamashita's PSUs were cancelled and forfeited, and they each received a grant of restricted stock units issued under the 2015 Plan subject to the vesting conditions described above under "— Outstanding Equity Awards at Fiscal Year-end."

Perquisites, Health, Welfare and Retirement Benefits

Our named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, group life, disability and accidental death and dismemberment insurance plans, in each case on the same basis as all of our other employees, subject to the terms and eligibility requirements of those plans. We pay a portion of the health insurance premiums for all of our employees. We also provide a 401(k) plan to our employees, including our employee named executive officers, as discussed in the section below titled "— 401(k) Plan."

We generally do not provide perquisites or personal benefits to our named executive officers, but we do provide an automobile allowance and reimbursement of cell phone expenses for Dr. Mohan. In addition, we pay the premiums for term life insurance and disability insurance for all of our employees, including our employee named executive officers. Our board of directors may elect to adopt qualified or non-qualified benefit plans in the future if it determines that doing so is in our best interests.

401(k) Plan

We maintain a defined contribution employee retirement plan, or 401(k) plan, for our employees. Our named executive officers are eligible to participate in the 401(k) plan on the same basis as our other employees. The 401(k) plan is intended to qualify as a tax-qualified plan under Section 401(k) of the Internal Revenue Code. The 401(k) plan provides that each participant may contribute up to the lesser of 100% of his or her compensation or the statutory limit, which is $18,000 for calendar year 2015. Participants that are 50 years or older can also make "catch-up" contributions, which in calendar year 2015 may be up to an additional $5,500 above the statutory limit. We currently make matching contributions up to 3% of base salary into the 401(k) plan on behalf of participants. Participant contributions are held and invested, pursuant to the participant's instructions, by the plan's trustee.

Pension Benefits

Our named executive officers did not participate in, or otherwise receive any benefits under, any defined benefit pension or retirement plan sponsored by us during 2015.

Nonqualified Deferred Compensation

None of our named executive officers participate in or have account balances in nonqualified defined contribution plans or other nonqualified deferred compensation plans maintained by us. Our board of directors may elect to provide our officers and other employees with non-qualified defined contribution or other nonqualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

Equity Benefit Plans

2015 Equity Incentive Plan

On December 4, 2015 our board of directors adopted, and on December 7, 2015, our stockholders approved, our 2015 Equity Incentive Plan, or the 2015 Plan. The 2015 Plan provides for the grant of statutory stock options within the meaning of Section 422 of the Internal Revenue Code, or the ISOs, to our employees and for the grant of nonstatutory stock options, or NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards and other forms of equity compensation to our employees, including officers, directors and consultants. The 2015 Plan also provides for the grant of performance cash awards to our employees, consultants and directors.

Authorized Shares. The maximum number of shares of our common stock that may be issued under the 2015 Plan is 1,246,377 shares. The number of shares of our common stock reserved for issuance under the 2015 Plan will automatically increase on the date that is sixty (60) calendar days following the date of the underwriting agreement for this offering, by an amount of shares of our common stock equal to 3% of the total number of shares of our common stock outstanding on such sixtieth (60th) day. In addition, the number of shares of our common stock reserved for issuance under the 2015 Plan will automatically increase on January 1 of each year, beginning January 1, 2017 and continuing through and including January 1, 2025, by an amount equal to 3% of the total number of shares of our capital stock outstanding on December 31st of the preceding calendar year; or a lesser number of shares determined by our board of directors. The maximum number of shares of our common stock that may be issued upon the exercise of ISOs under the 2015 Plan is 4,927,536. As of December 31, 2015, RSUs representing 1,066,193 shares of our common stock were outstanding under the 2015 Plan and 180,184 shares remained available for grant under the 2015 Plan. No awards have been granted under the 2015 Plan other than RSUs.

Shares issued under the 2015 Plan may be authorized but unissued or reacquired shares of our common stock. Shares subject to stock awards granted under the 2015 Plan that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, will not reduce the number of shares available for issuance under the 2015 Plan. Additionally, shares issued pursuant to stock awards under the 2015 Plan that we repurchase or that are forfeited, as well as shares used to pay the exercise price of a stock award or to satisfy the tax withholding obligations related to a stock award, become available for future grant under the 2015 Plan.

Plan Administration. Our board of directors, or a duly authorized committee of our board of directors, administers the 2015 Plan. Our board of directors has delegated its authority to administer the 2015 Plan to our compensation committee. Our board of directors may also delegate to one or more of our officers the authority to (1) designate employees (other than officers) to receive specified stock awards and (2) determine the number of shares subject to such stock awards. Under the 2015 Plan, the board of directors has the authority to determine the terms of awards, including recipients, the exercise, purchase or strike price of stock awards, if any, the number of shares subject to each stock award, the fair market value of a share of our common stock, the vesting schedule applicable to the awards, together with any vesting acceleration, the form of consideration, if any, payable upon exercise or settlement of the award and the terms of the award agreements.

Our plan administrator may also modify outstanding awards under the 2015 Plan with the consent of any adversely affected participant. Our plan administrator has the authority to reprice any outstanding option or stock appreciation right, cancel any outstanding stock award in exchange for new stock awards, cash or other consideration or take any other action that is treated as a repricing under generally accepted accounting principles.

Stock Options. ISOs and NSOs are granted pursuant to stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for stock options, within the terms and conditions of the 2015 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2015 Plan vest at the rate specified by the plan administrator.

The plan administrator determines the term of stock options granted under the 2015 Plan, up to a maximum of 10 years. Unless the terms of an option holder's stock option agreement provide otherwise, if an option holder's service relationship with us, or any of our affiliates, ceases for any reason other than disability, death or cause, the option holder may generally exercise any vested options for a period of three months following the option holder's cessation of service. The option term may be extended in the event that exercise of the option or sale of the underlying shares following such a termination of service is prohibited by applicable securities laws or by our insider trading policy. If an option holder's service relationship with us or any of our affiliates ceases due to disability or death, or an option holder dies within a certain period following cessation of service, the option holder or a beneficiary may generally exercise any vested options for a period of 12 months in the event of disability and 18 months in the event of death. Options generally terminate immediately upon the termination of the individual for cause. In no event may an option be exercised beyond the expiration of its term.

The plan administrator will determine acceptable consideration for the purchase of common stock issued upon the exercise of a stock option, which may include the following methods: (1) cash, check, bank draft or money order; (2) a broker-assisted cashless exercise procedure; (3) the tender of shares of our common stock previously owned by the option holder; (4) if the option is a nonstatutory stock option, by a net exercise arrangement; and (5) other legal consideration set forth in the applicable award agreement.

In general, options are not transferable except by will, the laws of descent and distribution, or as otherwise provided by the plan administrator under the 2015 Plan. An option holder may designate a beneficiary, however, who may exercise the option following the option holder's death.

Tax Limitations on Incentive Stock Options. The aggregate fair market value, determined at the time of grant, of our common stock with respect to incentive stock options that are exercisable for the first time by an option holder during any calendar year under all of our stock plans may not exceed $100,000. Options or portions thereof that exceed such limit will generally be treated as nonstatutory stock options. No incentive stock option may be granted to any person who, at the time of grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant and (2) the term of the incentive stock option does not exceed five years from the date of grant.

Restricted Stock Unit Awards. RSUs are granted pursuant to RSU award agreements adopted by the plan administrator. RSU awards may be granted in consideration for any form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator or in any other form of consideration set forth in the RSU award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a RSU award. Except as otherwise provided in the applicable award agreement, RSUs that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

Restricted Stock Awards. Restricted stock awards are granted pursuant to restricted stock award agreements adopted by the plan administrator. A restricted stock award may be awarded in consideration for cash, check, bank draft or money order, past services to us or any other form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. The plan administrator determines the terms and conditions of restricted stock awards, including vesting and forfeiture terms. Common stock acquired under a restricted stock award may, but need not, be subject to a share repurchase option in our favor in accordance with a vesting schedule to be determined by the plan administrator. Rights to acquire shares under a restricted stock award may be transferred only upon such terms and conditions as set by the plan administrator. Except as otherwise provided in the applicable award agreement, restricted stock awards that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

Stock Appreciation Rights. Stock appreciation rights are granted pursuant to stock appreciation grant agreements adopted by the plan administrator. The plan administrator determines the purchase price or strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Upon the exercise of a stock appreciation right, we will pay the participant an amount equal to the product of (1) the excess, if any, of the per share fair market value of our common stock on the date of exercise over the purchase price or strike price and (2) the number of shares of common stock with respect to which the stock appreciation right is exercised. This amount may be paid in shares of our common stock, in cash, in any combination of cash and shares of our common stock or in any other form of consideration, as determined by the plan administrator and set forth in the award agreement. A stock appreciation right granted under the 2015 Plan vests at the rate specified in the stock appreciation right agreement as determined by the plan administrator.

The plan administrator determines the term of stock appreciation rights granted under the 2015 Plan, which may be up to a maximum of 10 years. Unless the terms of a participant's stock appreciation right agreement provides otherwise, if a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. The term of the stock appreciation right may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws or by our insider trading policy. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant (or, if applicable, a beneficiary) may generally exercise any vested stock appreciation right for a period of 12 months (in the case of disability) or 18 months (in the case of death). Stock appreciation rights generally terminate immediately upon the occurrence of the event giving rise to the termination of the individual for cause. In no event may a stock appreciation right be exercised beyond the expiration of its term.

Section 162(m) limits. Certain limits apply when we make awards under the 2015 Plan that are intended to comply with Section 162(m) of the Code. These limitations are intended to give us the flexibility to grant compensation that will not be subject to the $1,000,000 annual limitation on the income tax deductibility imposed by Section 162(m) of the Code. In the case of stock options, stock appreciation rights and other stock awards whose value is determined by reference to an increase over an exercise price or strike price of at least 100% of the fair market value of our common stock on the date of grant, such awards will not cover more than 434,783 shares of our common stock in any calendar year. Additionally, no participant may be granted in a calendar year a performance stock award covering more than 434,783 shares of our common stock or a performance cash award having a maximum value in excess of $1,500,000 under the 2015 Plan.

Performance Awards. The 2015 Plan permits the grant of performance-based stock and cash awards that may qualify as performance-based compensation that is not subject to the $1,000,000 limitation on the income tax deductibility imposed by Section 162(m) of the Code. Our compensation committee may structure awards so that the stock or cash will be issued or paid only following the achievement of certain pre-established performance goals during a designated performance period.

Our compensation committee may establish performance goals by selecting from one or more of the following performance criteria: (1) earnings (including earnings per share and net earnings); (2) earnings before interest, taxes and depreciation; (3) earnings before interest, taxes, depreciation and amortization; (4) earnings before interest, taxes, depreciation, amortization and legal settlements; (5) earnings before interest, taxes, depreciation, amortization, legal settlements and other income (expense); (6) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense) and stock-based compensation; (7) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense), stock-based compensation and changes in deferred revenue; (8) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense), stock-based compensation, other non-cash expenses and changes in deferred revenue; (9) total stockholder return; (10) return on equity or average stockholder's equity; (11) return on assets, investment, or capital employed; (12) stock price; (13) margin (including gross margin); (14) income (before or after taxes); (15) operating income; (16) operating income after taxes; (17) pre-tax profit; (18) operating cash flow; (19) sales or revenue targets; (20) increases in revenue or product revenue; (21) expenses and cost reduction goals; (22) improvement in or attainment of working capital levels; (23) economic value added (or an equivalent metric); (24) market share; (25) cash flow; (26) cash flow per share; (27) cash balance; (28) cash burn; (29) cash collections; (30) share price performance; (31) debt reduction; (32) implementation or completion of projects or processes (including, without limitation, clinical trial initiation, clinical trial enrollment and dates, clinical trial results, regulatory filing submissions, regulatory filing acceptances, regulatory or advisory committee interactions, regulatory approvals, new and supplemental indications for existing products, and product supply); (33) stockholders' equity; (34) capital expenditures; (35) debt levels; (36) operating profit or net operating profit; (37) workforce diversity; (38) growth of net income or operating income; (39) billings; (40) bookings; (41) employee retention; (42) initiation of phases of clinical trials and/or studies by specific dates; (43) acquisition of new customers, including institutional accounts; (44) customer retention and/or repeat order rate; (45) number of institutional customer accounts (46) budget management; (47) improvements in sample and test processing times; (48) regulatory milestones; (49) progress of internal research or clinical programs; (50) progress of partnered programs; (51) partner satisfaction; (52) milestones related to samples received and/or tests run; (53) expansion of sales in additional geographies or markets; (54) research progress, including the development of programs; (55) submission to, or approval by, a regulatory body (including, but not limited to the U.S. Food and Drug Administration) of an applicable filing or a product; (56) timely completion of clinical trials; (57) milestones related to samples received and/or tests or panels run; (58) expansion of sales in additional geographies or markets; (59) research progress, including the development of programs; (60) patient samples processed and billed; (61) sample processing operating metrics (including, without limitation, failure rate maximums and reduction of repeat rates); (62) strategic partnerships or transactions (including in-licensing and out-licensing of intellectual property; and (63) and to the extent that an award is not intended to comply with Section 162(m) of the Code, other measures of performance selected by the board.

Our compensation committee may establish performance goals on a company-wide basis, with respect to one or more business units, divisions, affiliates or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless otherwise specified by our board of directors (i) in the award agreement at the time the award is granted or (ii) in such other document setting forth the performance goals at the time the performance goals are established, our compensation committee will appropriately make adjustments in the method of calculating the attainment of the performance goals as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of any items of an unusual nature or of infrequency of occurrence as determined under generally accepted accounting principles; (6) to exclude the dilutive effects of acquisitions or joint ventures; (7) to assume that any business divested by us achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (8) to exclude the effect of any change in the outstanding shares of our common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change or any distributions to common stockholders other than regular cash dividends; (9) to exclude the effects of stock-based compensation and the award of bonuses under our bonus plans; (10) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; (11) to exclude the goodwill and intangible asset impairment charges that are

required to be recorded under generally accepted accounting principles; (12) to exclude the effect of any other unusual, non-recurring gain or loss or other extraordinary item; and (13) to exclude the effects of the timing of acceptance for review and/or approval of submission to the FDA or any other regulatory body. In addition, to the extent set forth in an award agreement, our compensation committee retains the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of the goals. The performance goals may differ from participant to participant and from award to award.

Other Stock Awards. The plan administrator may grant other awards based in whole or in part by reference to our common stock. The plan administrator will set the number of shares under the stock award and all other terms and conditions of such awards.

Changes to Capital Structure. In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split or recapitalization, appropriate adjustments will be made to (1) the class and maximum number of shares reserved for issuance under the 2015 Plan, (2) the class and maximum number of shares by which the share reserve may increase automatically each year, (3) the class and maximum number of shares that may be issued upon the exercise of incentive stock options, (4) the class and maximum number of shares subject to stock awards that can be granted in a calendar year (as established under the 2015 Plan pursuant to Section 162(m) of the Code) and (5) the class and number of shares and exercise price, strike price or purchase price, if applicable, of all outstanding stock awards.

Corporate Transactions. In the event of certain specified significant corporate transactions, the plan administrator has the discretion to take any of the following actions with respect to stock awards:

- arrange for the assumption, continuation or substitution of a stock award by a surviving or acquiring entity or parent company;
- arrange for the assignment of any reacquisition or repurchase rights held by us to the surviving or acquiring entity or parent company;
- accelerate the vesting of the stock award and provide for its termination prior to the effective time of the corporate transaction;
- arrange for the lapse of any reacquisition or repurchase right held by us;
- cancel or arrange for the cancellation of the stock award in exchange for such cash consideration, if any, as our board of directors may deem appropriate; or
- make a payment equal to the excess of (1) the value of the property the participant would have received upon exercise of the stock award over (2) the exercise price otherwise payable in connection with the stock award.

Our plan administrator is not obligated to treat all stock awards, even those that are of the same type, in the same manner.

Under the 2015 Plan, a corporate transaction is generally the consummation of (1) a sale or other disposition of all or substantially all of our consolidated assets, (2) a sale or other disposition of at least 50% of our outstanding securities, (3) a merger, consolidation or similar transaction following which we are not the surviving corporation or (4) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

Change in Control. The plan administrator may provide, in an individual award agreement or in any other written agreement between a participant and us that the stock award will be subject to additional acceleration of vesting and exercisability in the event of a change in control. For example, certain of our employees may receive an award agreement that provides for vesting acceleration upon a change in control or upon the individual's termination without cause or resignation for good reason (including a material reduction in the individual's base salary, duties, responsibilities or authority, or a material relocation of the individual's principal place of employment with us) in connection with a change in control. Under the 2015 Plan, a change in control is generally (i) the acquisition by a person or entity of more than 50% of our combined voting power other than by merger, consolidation or similar transaction; (ii) a consummated merger, consolidation or similar transaction immediately after which our stockholders cease to own more than 50% of the combined voting power of the surviving entity; or (iii) a consummated sale, lease or exclusive license or other disposition of all or substantially of our consolidated assets. The RSU award agreements for the named executive officers holding RSUs provide for full vesting of the time-based vesting restrictions upon the occurrence of a change in control subject to their continuous service with us through such event.

Transferability. A participant may not transfer stock awards under the 2015 Plan other than by will, the laws of descent and distribution or as otherwise provided under the 2015 Plan.

Plan Amendment or Termination. Our board of directors has the authority to amend, suspend or terminate the 2015 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. No incentive stock options may be granted after the tenth anniversary of the date our board of directors adopted the 2015 Plan. No stock awards may be granted under the 2015 Plan while it is suspended or after it is terminated.

2011 Stock Incentive Plan

In October 2011, our board of directors adopted, and in December 2011 our stockholders approved, our 2011 Stock Incentive Plan, or the 2011 Plan. The 2011 Plan provides for the grant of ISOs to our employees, and for the grant of NSOs, restricted stock, restricted stock units and performance stock and cash awards to our officers, directors, employees and consultants.

Authorized Shares. We have reserved an aggregate of 1,159,420 shares of our common stock for issuance under the 2011 Plan. As of December 31, 2015, PSUs representing 249,510 shares of our common stock were outstanding under the 2011 Plan at a weighted average base price of $6.35 per share. Effective as of the effective date of the 2015 Plan, no further awards may be granted under our 2011 Plan, but all outstanding stock awards will continue to be governed by their existing terms.

Administration. Our board of directors, or a committee thereof appointed by our board of directors, administers our 2011 Plan and the awards granted under it. Our board of directors delegated its authority to administer our 2011 Plan to our Chief Executive Officer with respect to awards granted to any employee or service provider other than the chief executive officer.

Corporate Transactions. Our 2011 Plan provides that the administrator may provide that, in the event of a change in control transaction, options outstanding as of the date of the change in control that are not fully vested will become fully vested and exercisable, and the administrator has discretion to provide, with respect to any outstanding award under the 2011 Plan, that the securities of another entity be substituted for the common stock subject to the award and to make equitable adjustments to the award in the administrator's discretion. In addition, our form of award agreement for PSU grants provides that PSUs are subject to time-based vesting and that PSUs will become exercisable upon the occurrence of a change in control, an initial public offering of our stock or our achieving an enterprise value of at least $400 million. In addition, the PSU award agreement provides that the time-based vesting restrictions will accelerate and the PSUs will become fully vested if the recipient's employment is terminated other than for cause as a result of a change in control and, if the recipient's employment terminates due to death, disability or retirement, then the PSUs will fully vest on the earlier of the one-year anniversary of termination or the expiration of the remaining time-based vesting period.

For these purposes, a change in control means (i) any corporation, person or other entity, other than us, one of our majority-owned subsidiaries or an employee benefit plan sponsored by us, becomes the beneficial owner of stock representing more than 50% of the combined voting power of our then outstanding securities, (ii) our stockholders approving a definitive agreement to merge or consolidate the company with or into another corporation other than a majority-owned subsidiary, or to sell or otherwise dispose of all or substantially all of our assets and the persons who were members of our Board prior to such approval do not represent a majority of the directors of the surviving, resulting or acquiring entity or its parent, (iii) our stockholders approve a plan of liquidation of the company, or (iv) within any 24 consecutive month period, persons who were members of our board of directors immediately prior to the 24 month period, together with persons who were first elected as directors during the 24 month period by or upon the recommendation of persons who were members of our board of directors immediately prior to the 24 month period and who constituted a majority of our board of directors at the time of such election, cease to constitute a majority of our board of directors.

Plan Amendment and Termination. Our board of directors may at any time amend, alter or discontinue our 2011 Plan. However, our board of directors must obtain approval of our stockholders for any amendment requiring such approval under federal tax or federal securities laws. In addition, our board of directors may not materially impair the rights of a holder of any award previously granted under our 2011 Plan without the consent of the holder of such award, except any amendment to avoid an expense charge to us or an affiliate, to comply with applicable law or to permit us or an affiliate a deduction under applicable law. Our 2011 Plan will terminate in August 2022 or, if earlier, a date determined by our board of directors.

2016 Employee Stock Purchase Plan

In January 2016, our board of directors adopted, and our stockholders approved, our 2016 Employee Stock Purchase Plan, or the ESPP. The ESPP will become effective immediately upon the execution and delivery of the underwriting agreement related to this offering but we have no current plans to grant purchase rights under the ESPP. The purpose of the ESPP is

to secure the services of new employees, to retain the services of existing employees and to provide incentives for such individuals to exert maximum efforts toward our success and that of our affiliates. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code.

Share Reserve. Following this offering, the ESPP authorizes the issuance of 289,855 shares of our common stock pursuant to purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance will automatically increase on January 1st of each calendar year, from January 2017 (assuming the ESPP becomes effective in 2016) through January 1, 2026, by the lesser of (1) 1% of the total number of shares of our common stock outstanding on December 31st of the preceding calendar year and (2) 510,145 shares; *provided*, that prior to the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (1) and (2). As of the date hereof, no shares of our common stock have been purchased under the ESPP.

Administration. Our board of directors has delegated its concurrent authority to administer the ESPP to our compensation committee. The ESPP is implemented through a series of offerings under which eligible employees are granted purchase rights to purchase shares of our common stock on specified dates during such offerings. Under the ESPP, we may specify offerings with durations of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. An offering under the ESPP may be terminated under certain circumstances.

Payroll Deductions. Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, up to 15% of their earnings (as defined in the ESPP) for the purchase of our common stock under the ESPP. Unless otherwise determined by our board of directors, common stock will be purchased for the accounts of employees participating in the ESPP at a price per share equal to the lower of (a) 85% of the fair market value of a share of our common stock on the first date of an offering or (b) 85% of the fair market value of a share of our common stock on the date of purchase.

Limitations. Employees may have to satisfy one or more of the following service requirements before participating in the ESPP, as determined by our board of directors, including: (1) being customarily employed for more than 20 hours per week; (2) being customarily employed for more than five months per calendar year; or (3) continuous employment with us or one of our affiliates for a period of time (not to exceed two years). No employee may purchase shares under the ESPP at a rate in excess of $25,000 worth of our common stock based on the fair market value per share of our common stock at the beginning of an offering for each year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under the ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value pursuant to Section 424(d) of the Code.

Changes to Capital Structure. In the event that there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or similar transaction, the board of directors will make appropriate adjustments to (1) the number of shares reserved under the ESPP, (2) the maximum number of shares by which the share reserve may increase automatically each year and (3) the number of shares and purchase price of all outstanding purchase rights.

Corporate Transactions. In the event of certain significant corporate transactions, including: (1) a sale of all or substantially all of our assets, (2) the sale or disposition of 50% of our outstanding securities, (3) the consummation of a merger or consolidation where we do not survive the transactions and (4) the consummation of a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction, any then-outstanding rights to purchase our stock under the ESPP may be assumed, continued or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our common stock within 10 business days s prior to such corporate transaction, and such purchase rights will terminate immediately.

ESPP Amendments, Termination. Our board of directors has the authority to amend or terminate our ESPP, provided that except in certain circumstances such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

Limitations on Liability and Indemnification Matters

Upon the closing of this offering, our certificate of incorporation will contain provisions that limit the liability of our current and former directors for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit. Such limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation and our amended and restated bylaws will provide that we are required to indemnify our directors, officers, employees and other agents to the fullest extent permitted by Delaware law. Our amended and restated bylaws will also provide that, upon satisfaction of certain conditions, we shall advance expenses incurred by a director in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws will also provide our board of directors with discretion to indemnify our officers and employees when determined appropriate by the board. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by the board of directors. With certain exceptions, these agreements provide for indemnification for related expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these certificate of incorporation and bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

At present, there is no pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought and we are not aware of any threatened litigation that may result in claims for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for directors, executive officers or persons controlling us, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Rule 10b5-1 Sales Plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and executive officers also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information subject to compliance with the terms of our insider trading policy. Prior to 180 days after the date of this offering (subject to early termination), the sale of any shares under such plan would be subject to the lock-up agreement that the director or officer has entered into with the underwriters.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a summary of transactions since October 1, 2012 to which we have been a party, in which the amount involved exceeded or will exceed $120,000 and in which any of our directors, executive officers or holders of more than 5% of our capital stock, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest other than compensation and other arrangements that are described in the section titled “Executive Compensation.”

We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, in arm’s-length transactions.

Financings

Common Stock

Founders

In December 2012, Dr. Mohan, our Chairman, President and Chief Executive Officer, and his wife, Swati Mohan, a holder of more than 5% of our capital stock at such time, agreed to cancel an aggregate of 666,666 shares of our then issued and outstanding common stock held by them in exchange for nominal consideration.

In December 2012, we then issued 666,666 shares of our common stock to a third party associated with India Infrastructure Private Limited, or IIPL, for services provided.

Strides Pharma, Inc.

In March 2014, we issued and sold to Strides Pharma, Inc., or Strides, 1,159,420 shares of our common stock at a purchase price of $6.04 per share, or $7,000,000. Following this investment, Strides became a beneficial owner of more than 5% of our outstanding capital stock. In June 2014, we issued and sold to Strides an additional 579,710 shares of our common stock at a purchase price of $6.90 per share, or $4,000,000. In connection with such issuances, we entered into an investors’ rights agreement and a co-sale agreement with Strides. Upon the closing of this offering, certain provisions of the investors’ rights agreement will terminate and the continuing provisions are described below. The co-sale agreement will automatically terminate effective upon the completion of this offering. In connection with the Strides investment, we were required to repurchase outstanding capital stock in order to reduce our fully diluted common stock to 11,594,203 shares after giving effect to its investment in our common stock. We refer to this repurchase as a “buyback.”

In October 2014, we issued a 12% $2,000,000 convertible promissory note to Strides, with a stated maturity date of December 31, 2016. The note is convertible at any time into shares of our common stock at a conversion price of $20.70 per share. In October 2015, we repaid $1,000,000 of the principal amount, and Strides has elected to receive payment in cash for the remainder rather than any equity conversion.

In December 2014, we issued a 12% $2,000,000 convertible promissory note to Strides, which matured on March 31, 2015. This note was convertible at any time into shares of our common stock at a conversion price equal to 50% of the fair market value of our common stock on the conversion date. We repaid this note in full at maturity and it is no longer outstanding.

Mezzanine Financings

In June, July and September 2015, we issued and sold an aggregate of 1,765,511 shares of our common stock to nine institutional investors at a purchase price of $25.79 per share, for aggregate gross proceeds of $45,530,484. These investors became party to the Strides investors’ rights agreement, as amended, and the co-sale agreement, as amended.

In December 2015 and January 2016, we issued and sold an aggregate of 573,388 shares of our common stock to 19 accredited investors at a purchase price of $29.05 per share, for aggregate net proceeds of approximately $16.6 million. These investors became party to the Strides investors’ rights agreement, as amended, and the co-sale agreement, as amended.

The foregoing mezzanine financings include the issuance and sale to Proximare Lifesciences Fund LLC, a New Jersey single purpose fund, of an aggregate of 197,003 shares of our common stock at a purchase price of $25.79 per share, for aggregate gross proceeds of approximately $5.1 million, and the issuance and sale to Proximare Lifesciences Fund 2 LLC, a New Jersey single purpose fund, an aggregate of 172,121 shares of our common stock at a purchase price of $29.05 per share, for aggregate gross proceeds of approximately $5.0 million. Three of our directors, Messrs. Canute and Hilzinger and

Ms. Hoke, have invested an aggregate of $2.0 million in our company through investments in these funds. Upon completion of this offering and pursuant to the documents governing such funds, these directors are expected to receive shares of our common stock pro rata to their investments in such funds upon distribution of all of the shares of our common stock held by such funds as follows: Mr. Canute, 57,408 shares; Mr. Hilzinger, 18,517 shares; Ms. Hoke, 1,938 shares.

Series A Redeemable Preferred Stock

From March 2011 to May 2013, we issued and sold an aggregate of 6,995 shares of Series A redeemable preferred stock at $1,000 per share. Certain of our directors and executive officers, including some of their immediate family members, participated in these offerings as described below.

In October 2012, Mr. Canute, a member of our board of directors, purchased 100 additional shares of our Series A redeemable preferred stock for an aggregate purchase price of $100,000, bringing his aggregate investment to 1,150 shares.

In May 2013, Dr. Brady, a member of our board of directors, purchased 100 shares of our Series A redeemable preferred stock for an aggregate purchase price of $100,000.

In October 2015, upon our reincorporation in Delaware, each outstanding share of our Series A redeemable preferred stock held by holders that did not elect to participate in the June 2014 buyback described below, converted into and became approximately 289 shares of common stock and approximately 1.4035 shares of Series A preferred stock. Accordingly, the following related parties received such shares upon conversion of the following amounts of our Series A redeemable preferred stock held by them:

Related Party	# of Shares of Series A Redeemable Preferred Stock Converted	# of Shares of Common Stock Received Upon Conversion	# of Shares of DE Series A Preferred Stock Received Upon Conversion
Mr. Canute	250 shares	72,463 shares	351 shares
Dr. Brady	100 shares	28,985 shares	141 shares
Dr. Mohan's immediate family	150 shares	43,478 shares	212 shares
Mr. Gangloff's immediate family	55 shares	15,942 shares	79 shares
Mr. Griffith's immediate family	35 shares	10,144 shares	50 shares

June 2014 Buyback

In June 2014, as required by the Strides investment in our common stock described above under "— Common Stock — Strides Pharma, Inc." we undertook a buyback of our then outstanding Series A redeemable preferred stock, common stock and restricted stock awards to reduce our fully diluted common stock to 11,594,203 shares after giving effect to Strides' investment in our common stock. No related parties participated in the buyback of common stock.

Series A Redeemable Preferred

In the June 2014 buyback, we offered Series A redeemable preferred stockholders $2,000 per share, payable in cash as payment for their shares of Series A redeemable preferred stock, and a 4% promissory note due September 1, 2015, as payment for accrued but unpaid dividends on such shares (increasing to 6% if unpaid at maturity). However, certain holders elected to receive a 4% promissory note for payment for some of their shares in lieu of the $2,000 per share cash payment. These holders included Dr. Mohan, a member of our board of directors, for 50 of his repurchased shares, Mr. Canute, a member of our board of directors, for 188 of his repurchased shares, and Mr. Griffith, a member of our board of directors, for 43 of his repurchased shares.

In the June 2014 buyback, we acquired an aggregate of 3,314 shares of our Series A redeemable preferred stock, which included the following shares repurchased from related parties:

Related Party	# of Series A Redeemable Preferred Stock Repurchased	Cash Received	Principal Amount of 4% Promissory Notes Received
Dr. Mohan	175	$ —	$ 423,003
Mr. Canute	900	$ 500,000	$ 1,511,384
Mr. Griffith and his immediate family	165	$ 130,000	$ 247,068
Mr. Gangloff's immediate family	45	$ 90,000	$ 12,580
Mr. Dyrness' affiliate	100	$ 200,000	$ 35,107

In November 2014, we bought back an additional 25 shares of Series A redeemable preferred stock from Dr. Mohan for $50,000 in cash. Dr. Mohan did not receive an additional 4% note for the accrued dividend on such shares as such amounts were reflected in the note received in June 2014.

Restricted Stock

In the June 2014 buyback, we offered holders of restricted stock $1.73 per share to forfeit their shares of restricted stock payable in the form of a 0% promissory note due December 31, 2015, as amended. In connection therewith, Mr. Canute received a 0% promissory note with an aggregate principal amount of $200,000 due December 31, 2015, as amended, in exchange for 115,942 shares of restricted stock. All outstanding amounts have been paid in full.

Loans and Guarantees

In March 2015, Mr. Canute, a member of our board of directors, extended a short-term loan to our company of $1,000,000. Accordingly, we issued a promissory note to Mr. Canute for the principal amount of $1,000,000, which note bore stated interest at a rate of 2% per month, with a stated maturity date of June 20, 2015. This note was repaid in full in October 2015 and is no longer outstanding.

Our Chairman, President and Chief Executive Officer, Dr. Mohan, personally guaranteed our outstanding bank loans, as well as one of our equipment financing leases. In addition, since founding our company, Dr. Mohan has regularly extended short-term interest-free loans to our company, and deferred payment of his compensation (both salary and bonuses) in order to address our liquidity needs. As of September 30, 2014 and September 30, 2015, amounts owed to Dr. Mohan amounted to $200,315 and $117,506, respectively. We did not accrue any interest on amounts owed to Dr. Mohan with respect to the loans and all outstanding amounts have been repaid in full.

Employment and Other Compensation Arrangements, Equity Plan Awards

We have entered into employment agreements with certain of our executive officers in connection with their employment. For more information regarding the executives' existing offer letters, see the section titled "Executive Compensation — Employment Agreements."

We also have established certain equity plans, pursuant to which we grant equity awards to our employees and directors. For more information regarding these plans, see the section titled "Executive Compensation — Equity Benefit Plans."

Performance Stock Units

We previously granted our employees, including our executive officers, options to purchase shares of our common stock or restricted stock under our 2011 Plan. In June 2014, we converted most of these outstanding equity awards into an aggregate of 711,430 performance stock units, or PSUs. The PSUs as issued are subject to time-based vesting, with 50% of the award vesting three-years after the original grant date, and the remaining 50% vesting four-years after the grant date and were to be settled in cash. The PSUs may only be exercised during their 10-year term on or following the achievement of specified performance conditions, including the occurrence of a change in control, the closing of this offering, or, subject to the discretion of our board of directors, our achieving an enterprise value of at least $400 million. In addition, PSUs may be subject to additional acceleration of time-based vesting restrictions upon certain termination and change in control events. The following related parties received PSUs in such conversion as follows:

Related Party	Restricted Stock	PSUs
Mr. Gangloff	115,942	129,855
Mr. Griffith	144,927	162,318
Dr. McAndrew	57,971	64,927
Ms. Yamashita	43,478	48,695

On June 22, 2015, in connection with his employment with us, we granted Dr. Bahrt, our Chief Medical Officer, 28,985 PSUs on the terms noted above.

In December 2015, Messrs. Bahrt, Gangloff, Griffith and McAndrew, and Ms. Yamashita forfeited their PSUs and were granted restricted stock units, or RSUs, under our 2015 Plan. The RSUs granted to Mr. Gangloff and Mr. Griffith are subject to performance-based vesting restrictions and will satisfy such conditions upon the first to occur of a change in control of the company and the date that is six months following the effective date of the registration statement of which this prospectus forms a part, in each case subject to the recipient's continued service with us through such event. The RSUs granted to Dr. Bahrt, Dr. McAndrew and Ms. Yamashita are subject to the same performance-based vesting restrictions but are also subject to additional time-based vesting restrictions, with 50% of their RSUs satisfying the time-based vesting restrictions on each of the third and fourth anniversaries of their original hire dates, subject to their continuous service with us through the applicable dates. The time-based vesting restrictions will be satisfied upon a change in control of the company, provided the executive remains in continuous service with us through such date.

Parilis Biopharmaceuticals, LLC

In December 2012, our former subsidiary, Parilis Biopharmaceuticals, LLC, or Parilis, of which we were the sole member, issued 100 of its Series A Units to Dr. Brady, who became a director of our company in September 2014, at a purchase price of $1,000 per share, or an aggregate of $100,000 (bringing his total investment in Parilis to 200 Series A Units).

In September 2015, we terminated the license and business development agreements with Parilis, and reached agreement with the remaining holders of outstanding Series A and Series A Hybrid Units of Parilis to exchange their securities for securities in our company. These holders included Dr. Brady. Accordingly, in September 2015, we entered into an exchange and release agreement pursuant to which they received an aggregate of 226,663 shares of our common stock and an aggregate of 1,626 shares of our Series A preferred stock effective upon our reincorporation in Delaware in October 2015. Accordingly, in October 2015, Dr. Brady received an aggregate of 28,985 shares of our common stock and 257 shares of our Series A preferred stock in exchange for his 200 Series A Units of Parilis.

Sonnet Biotherapeutics, Inc.

In April 2015, we spun-off certain assets unrelated to our biosimilar business through a pro rata distribution to our stockholders. Accordingly, we entered into a contribution agreement with a newly-formed entity, Sonnet Biotherapeutics, Inc., or Sonnet, pursuant to which we contributed certain assets relating to our innovation business to Sonnet in exchange for these assets. We then immediately distributed all the issued and outstanding shares of Sonnet common stock to our stockholders on a pro rata basis, which stockholders included our executive officers, directors and holders of more than 5% of our outstanding capital stock. Accordingly, immediately following the distribution, the stockholders of Sonnet were identical to our stockholders as of April 6, 2015.

We continued to provide funding and certain services and assistance to Sonnet for a transition period that ran from the spin-off date through September 2015, including the transfer of nine of our employees who had been involved in Sonnet's business to Sonnet. In October 2015, Sonnet issued us a promissory note for the principal amount of $826,561, which reflects the funding we have provided them through September 30, 2015. This note bears interest at the annual rate of 3%, and matures September 30, 2016, although Sonnet may prepay at any time. Sonnet paid 10% of the outstanding balance upon execution of the note in October 2015. As of December 31, 2015, the balance was $639,173.

Dr. Mohan and Mr. Griffith are members of the board of directors of Sonnet. In addition, Mr. Griffith is the President, Chief Executive Officer and Chief Financial Officer of Sonnet.

Concurrent Private Placement

Sabby, an existing stockholder, has indicated an interest in purchasing approximately $5.0 million of our units at the initial public offering price (or 833,332 units based on the assumed initial public offering price of $6.00 per unit) in a proposed private placement that would close concurrently with this offering. This indication of interest is not a binding agreement or

commitment to purchase, and we could determine to sell more, less or no units to this stockholder and this stockholder could determine to purchase more, less or no units in the proposed concurrent private placement. The units that may be sold in the proposed concurrent private placement would not be registered under the Securities Act. We will pay the underwriters as placement agents in the proposed concurrent private placement an aggregate cash fee equal to 7.0% of the gross sales price of the units sold in the concurrent private placement. The closing of this offering is not conditioned upon the closing of such concurrent private placement although the concurrent private placement is expected to be contingent upon, and will occur concurrently with, the closing of this offering. As of March 31, 2016, Sabby beneficially owned approximately 2.4% of our common stock (based upon 16,136,112 shares of common stock outstanding, which (i) includes 14,079,007 shares of common stock outstanding as of December 31, 2015, which includes redeemable common stock, (ii) includes 87,287 shares of common stock issued in January 2016, and (iii) gives effect to the conversion of all outstanding shares of Series A redeemable preferred stock (with an aggregate liquidation preference of $11,819,000 and a conversion price equal to the initial public offering price) into 1,969,818 shares of common stock immediately prior to the closing of this offering (assuming an initial public offering price of $6.00 per share of common stock included in the units sold in this offering)). Immediately following this offering and the concurrent private placement, based on the assumed amounts in this prospectus, Sabby would beneficially own approximately 8.7% of our common stock. The sale of units to Sabby in the concurrent private placement will not be registered in this offering.

Investors' Rights Agreement

In connection with our common stock financings, we entered into an investors' rights agreement containing registration rights, among other things, with certain holders of our common stock. On April 26, 2016, we amended the investors' rights agreement and agreed, under certain circumstances, to issue certain of the investors upon the closing of this offering three-year warrants to purchase an aggregate of 1,520,284 shares of our common stock. The terms of such warrants are more fully described in "Description of Securities — Warrants." As a party to the investors' rights agreement, Sabby would also have registration rights with respect to the shares included in the units, as well as the shares issuable upon exercise of the warrants included in the units that Sabby has indicated an interest in acquiring in the concurrent private placement. The registration rights granted under the investors' rights agreement will terminate upon the closing of a qualified liquidation event and at such time as a particular stockholder is able to sell all of its shares pursuant to Rule 144 of the Securities Act. The registration rights are more fully described in "Description of Securities — Registration Rights."

Directed Unit Program

At our request, the underwriters have reserved 291,666 units, or 5% of the units being offered by this prospectus (excluding the units that may be issued upon the underwriters' exercise of their over-allotment option to purchase additional units), for sale at the initial public offering price to our employees, executive officers, directors, stockholders and business associates, as well as to persons related to the company and our affiliates and their friends and family through a directed unit program. The number of units available for sale to the general public in the public offering will be reduced by the number of units these individuals purchase. Any reserved units that are not so purchased will be offered by the underwriters to the general public on the same basis as the other units offered hereby. Directors and officers who purchase these units will be subject to a 180-day lock-up period with respect to these units. We have agreed to indemnify the underwriter conducting the directed unit program against certain liabilities and expenses, including liabilities under the Securities Act, in connection with the directed unit program.

Indemnification Agreements

Our amended and restated certificate of incorporation will contain provisions limiting the liability of directors, and our amended and restated bylaws will provide that we will indemnify each of our directors to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws will also provide our board of directors with discretion to indemnify our officers and employees when determined appropriate by the board. In addition, we have entered into an indemnification agreement with each of our directors and executive officers that requires us to indemnify our directors and executive officers. For more information regarding these agreements, see the section titled "Executive Compensation — Limitations on Liability and Indemnification Matters."

Related-Party Transaction Policy

We intend to adopt a formal written policy that our executive officers, directors, holders of more than 5% of any class of our voting securities, and any member of the immediate family of and any entity affiliated with any of the foregoing persons, are not permitted to enter into a related-party transaction with us without the prior consent of our audit committee, or other

independent members of our board of directors in the event it is inappropriate for our audit committee to review such transaction due to a conflict of interest. Any request for us to enter into a transaction with an executive officer, director, principal stockholder or any of their immediate family members or affiliates, in which the amount involved exceeds $120,000 must first be presented to our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our audit committee will consider the relevant facts and circumstances available and deemed relevant to our audit committee, including, but not limited to, whether the transaction will be on terms no less favorable than terms generally available to an unaffiliated third-party under the same or similar circumstances and the extent of the related-party's interest in the transaction.

All of the transactions described in this section were entered into prior to the adoption of this policy.

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information relating to the beneficial ownership of our common stock as of March 31, 2016, by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our outstanding shares of common stock;
- each of our directors;
- each of our named executive officers; and
- all of our directors and executive officers as a group.

The percentage of shares beneficially owned before the offering shown in the table is based upon 16,136,112 shares of common stock outstanding, which includes (i) 14,079,007 shares of common stock outstanding as of December 31, 2015, which includes redeemable common stock, (ii) 87,287 shares of common stock issued in January 2016, and (iii) gives effect to the conversion of all outstanding shares of Series A redeemable preferred stock (with an aggregate liquidation preference of $11,819,000 and a conversion price equal to the initial public offering price) into 1,969,818 shares of common stock immediately prior to the closing of this offering (assuming an initial public offering price of $6.00 per share of common stock included in the units sold in this offering). The table does not give effect to any units that may be acquired pursuant to the directed unit program or any shares issuable upon the exercise of the Series A warrants or the Series B warrants included in the units sold in this offering or any units that may be sold in the concurrent private placement, if any. The information relating to the number and percentage of shares beneficially owned after the offering assumes the sale by us of 5,833,334 units in this offering. The percentage ownership information assumes no exercise of the underwriters' over-allotment option to purchase additional units and does not include the common stock issuable upon the exercise of the Series A warrants or the Series B warrants included in the units to be sold in the offering or any units that may be sold in the concurrent private placement, if any.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes any shares over which a person exercises sole or shared voting or investment power. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown beneficially owned by them, subject to applicable community property laws. Shares of common stock issuable upon vesting of outstanding equity awards that are exercisable or subject to vesting within 60 days after March 31, 2016 are deemed beneficially owned and such shares are used in computing the percentage ownership of the person holding the awards, but are not deemed outstanding for the purpose of computing the percentage ownership of any other person. The information contained in the following table is not necessarily indicative of beneficial ownership for any other purpose, and the inclusion of any shares in the table does not constitute an admission of beneficial ownership of those shares.

As otherwise noted below, the address for persons listed in the table is c/o Oncobiologics, Inc., 7 Clarke Drive, Cranbury, New Jersey 08512.

		Percentage of Shares Beneficially Owned	
Name of Beneficial Owner	**Number**	**Before Offering**	**After Offering**
Five Percent Stockholders (other than directors and officers):			
Strides Pharma (UK) Limited[1]	1,739,130	10.8%	7.9%
Named Executive Officers and Directors:			
Pankaj Mohan, Ph.D., *Chairman, President and Chief Executive Officer*[2]	7,488,678	46.4%	34.1%
Kenneth M. Bahrt, M.D., *Chief Medical Officer*[3]	—	—	—
Elizabeth A. Yamashita, *Vice President, Regulatory Affairs*[4]	—	—	—
Todd C. Brady, M.D., Ph.D., *Director*[5]	124,273	*	*
Scott Canute, *Director*[6]	130,963	*	*
Albert D. Dyrness, *Director*[7]	—	—	—
Donald J. Griffith, *Director*[8]	—	—	—
Kurt J. Hilzinger, *Director*[9]	—	—	—
Robin Smith Hoke, *Director*[10]	—	—	—
All executive officers and directors as a group (13 persons)	7,743,914	48.0%	35.3%

* Represents beneficial ownership of less than one percent (1%) of the outstanding common stock.

(1) The address for Strides Pharma (UK) Limited is Unit 4, Metro Centre, Tolpits Lane, Watford, Hertfordshire, WD189SS, United Kingdom. Strides Pharma (UK) Limited is a wholly-owned step-down subsidiary of Strides Shasun Limited, a public company listed in India. Strides Pharma (UK) Limited acquired the shares of Oncobiologics from Strides Pharma Inc., another wholly-owned subsidiary of Strides Shasun Limited in October 2015. Strides Pharma (UK) Limited has only voting and investment power over these shares and these decisions are made by its board of directors and not any particular individual. Strides Shasun Limited provides guidance to Strides Pharma (UK) Limited as and when sought.

(2) Includes 30,572 shares held directly by Dr. Mohan's child, 492,753 shares held directly by Dr. Mohan's spouse and 86,956 shares held in a family trust for which Dr. Mohan's spouse serves as trustee. Includes 17,666 shares of common stock issuable upon conversion of 106 shares of Series A preferred stock held by Dr. Mohan's child with a liquidation preference of $1,000 per share (assuming an initial public offering price of $6.00 per unit). Does not include 405,797 restricted stock unit awards, or RSUs, held by Dr. Mohan.

(3) Does not include 28,985 RSUs held by Dr. Bahrt.

(4) Does not include 43,478 RSUs held by Ms. Yamashita.

(5) Includes 66,333 shares of common stock issuable upon conversion of 398 shares of Series A preferred stock held by Dr. Brady with a liquidation preference of $1,000 per share (assuming an initial public offering price of $6.00 per unit). Does not include 57,971 RSUs held by Dr. Brady.

(6) Includes 58,500 shares of common stock issuable upon conversion of 351 shares of Series A preferred stock held by Mr. Canute with a liquidation preference of $1,000 per share (assuming an initial public offering price of $6.00 per unit). Does not include (x) 57,971 RSUs held by Mr. Canute nor (y) 57,406 shares held in a special purpose fund, Proximare Lifesciences Fund LLC, over which he does not have voting or investment control.

(7) Does not include 7,246 RSUs held by Mr. Dyrness.

(8) Does not include 144,927 RSUs held by Mr. Griffith.

(9) Does not include (x) 7,246 RSUs held by Mr. Hilzinger nor (y) 18,517 shares held in special purpose funds, Proximare Lifesciences Fund LLC and Proximare Lifesciences Fund 2 LLC, over which he does not have voting or investment control.

(10) Does not include (x) 7,246 RSUs held by Ms. Hoke nor (y) 1,938 shares held in a special purpose fund, Proximare Lifesciences Fund LLC, over which she does not have voting or investment control.

DESCRIPTION OF SECURITIES

Upon the closing of this offering and the filing of our amended and restated certificate of incorporation, our authorized capital stock will consist 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. The following is a summary of the rights of our common and preferred stock and some of the provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which will each become effective upon the closing of this offering, the investors' rights agreement and relevant provisions of Delaware General Corporation Law. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description you should refer to our amended and restated certificate of incorporation, amended and restated bylaws and investors' rights agreement, copies of which have been filed as exhibits to the registration statement of which this prospectus is a part, as well as the relevant provisions of Delaware General Corporation Law.

Units

Each unit offered consists of one share of our common stock, one-half of a Series A warrant to purchase one share of our common stock and one-half of a Series B warrant to purchase one share of our common stock. We anticipate that the units will begin trading on or promptly after the date of this prospectus. The units will automatically separate 30 days after the date of this prospectus, and the shares of common stock, Series A warrants and Series B warrants underlying the units will begin trading separately, unless Jefferies LLC and Barclays Capital Inc., as representatives of the underwriters, determine that an earlier date is acceptable (based upon, among other things, their assessment of the relative strengths of the securities markets and small capitalization companies in general, and the trading pattern of, and demand for, our securities in particular). If Jefferies LLC and Barclays Capital Inc. permit separate trading of the common stock, Series A warrants and Series B warrants prior to June , 2016, we will issue a press release and file a Current Report on Form 8-K with the Securities and Exchange Commission announcing when such separate trading will begin.

Common Stock

As of December 31, 2015, there were 14,079,007 shares of common stock outstanding, which includes redeemable common stock. After giving effect to (i) the issuance of an aggregate of 87,287 shares of our common stock in January 2016 and (ii) the conversion of all outstanding shares of Series A preferred stock (with an aggregate liquidation preference of $11,819,000 and a conversion price equal to the initial public offering price) into 1,969,818 shares of common stock immediately prior to the closing of this offering (assuming an initial public offering price of $6.00 per share of common stock included in the units sold in this offering), there would have been 16,136,112 shares of common stock outstanding on that date held by 94 stockholders of record.

Voting Rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders. The affirmative vote of holders of 66⅔% of the voting power of all of the then-outstanding shares of capital stock, voting as a single class, will be required to amend certain provisions of our amended and restated certificate of incorporation, including provisions relating to amending our amended and restated bylaws, the classified board, the size of our board, removal of directors, director liability, vacancies on our board, special meetings, stockholder notices, actions by written consent and exclusive jurisdiction.

Dividends

Subject to preferences that may apply to any outstanding preferred stock, holders of our common stock are entitled to receive ratably any dividends that our board of directors may declare out of funds legally available for that purpose on a non-cumulative basis.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preference of any outstanding preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate in the future.

Series A Warrants and Series B Warrants Issued as Part of the Units

Each whole Series A warrant entitles the holder to purchase one share of our common stock at an initial exercise price of $6.60, or 110% of the initial public offering price per unit, subject to adjustment. Each whole Series A warrant will be exercisable 30 days after the date of this prospectus, or the date on which Jefferies LLC and Barclays Capital Inc., as representatives of the underwriters, separate the units, whichever date is earlier and will expire at 5:00 p.m. New York City time on February , 2017. Series A warrants will not be rounded up to the next whole Series A warrant and only whole Series A warrants will be exercisable for a full share of our common stock.

Each whole Series B warrant entitles the holder to purchase one share of our common stock at an initial exercise price of $8.50, or 142% of the initial public offering price per unit, subject to adjustment. Each whole Series B warrant will be exercisable 30 days after the date of this prospectus, or the date on which Jefferies LLC and Barclays Capital Inc., as representatives of the underwriters, separate the units, whichever date is earlier and will expire at 5:00 p.m. New York City time on May , 2018. Series B warrants will not be rounded up to the next whole Series B warrant and only whole Series B warrants will be exercisable for a full share of our common stock.

The Series A warrants and Series B warrants will be issued in registered form, in each case pursuant to a warrant agreement between American Stock Transfer & Trust Company, LLC, as warrant agent, and us.

We have applied to list the Series A warrants and the Series B warrants on the NASDAQ Global Market under the symbol “ONSIW” and “ONSIZ,” respectively.

The exercise price and number of shares issuable upon exercise of the Series A warrants 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. However, neither the Series A warrants nor Series B warrants will be adjusted for issuances of common stock or securities convertible or exercisable into common stock at a price below the then current exercise price of such warrant.

If, at any time a Series A warrant or Series B warrant is outstanding, we consummate any fundamental transaction, as described in such warrants and generally including any consolidation or merger with or into another corporation, the consummation of a transaction whereby another entity acquires more than 50% of our outstanding common stock, or the sale or other disposition of all or substantially all of our assets, or other transaction in which our common stock are converted into or exchanged for other securities or other consideration, the holder of any such warrants will thereafter receive upon exercise of such warrants, the securities or other consideration to which a holder of the number of common stock then deliverable upon the exercise or conversion of such Series A warrants or Series B warrants would have been entitled upon such consolidation or merger or other transaction.

The number of shares of our common stock that may be acquired by any holder upon any exercise of the Series A warrants or Series B warrants, as the case may be, will be limited to the extent necessary to insure that, following such exercise (or other issuance), the total number of common stock then beneficially owned by such holder and its affiliates and any other persons whose beneficial ownership of common stock would be aggregated with the holder’s for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended, does not exceed 9.99% of the total number of issued and outstanding shares of our common stock (including for such purpose the common stock issuable upon such exercise), which we refer to as the beneficial ownership limitation; provided, however, that if a holder and/or its affiliates already own 9.99% on the date of this offering then the beneficial ownership limitation will not apply to such holder. A holder may elect to increase or decrease this beneficial ownership limitation from 9.99% to any other percentage of the total number of issued and outstanding shares of our common stock (including for such purpose the common stock issuable upon such exercise) upon providing us with not less than 61 days’ prior written notice, and any such increase will apply only to such holder.

The Series A warrants and Series B warrants may be exercised, at the option of each holder, in whole or in part, upon surrender of the warrant certificate on or prior to the expiration date at the offices of the warrant agent, with the exercise form on the reverse side of the warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price for the number of common stock purchased upon such exercise, by certified check payable to us or by wire transfer of immediately available funds to an account designated by us. Subject to applicable laws, the Series A warrants and Series B warrants may be transferred at the option of the holders upon surrender of the warrants to us together with the appropriate instruments of transfer.

Neither the Series A warrant holders nor Series B warrant holders will have the rights or privileges of holders of common stock and any voting rights until they exercise their warrants and receive common stock. After the issuance of common stock upon exercise of such warrants, each holder will be entitled to one vote for each common stock held of record on all

matters to be voted on by stockholders. If we fail to issue a holder of our Series A warrants or Series B warrants, within three business days after receipt of an applicable exercise notice, a certificate for the number of shares of our common stock to which such holder is entitled, then such holder can rescind the applicable exercise of such Series A warrant or Series B warrant. If we are otherwise unable to issue and deliver the number of shares of our common stock that a holder is entitled to under the Series A warrant or Series B warrant, as applicable, we have no obligation to pay such holder any cash or other consideration to settle such Series A warrant or Series B warrant, as applicable.

Under the terms of the warrant agreement, we have agreed to use our reasonable best efforts to maintain the effectiveness of the registration statement and current prospectus relating to common stock issuable upon exercise of the warrants at any time that the Series A warrants or Series B warrants are exercisable. During any period that we fail to have maintained an effective registration statement covering the common stock underlying such warrants, the holder may exercise such warrants on a cashless basis.

Preferred Stock

Immediately prior to the closing of this offering, all outstanding shares of our preferred stock will convert into shares of common stock. Upon the closing of this offering and the filing of our amended and restated certificate of incorporation, our board of directors will have the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the number, rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences and sinking fund terms, and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control or other corporate action. We have no current plan to issue any shares of preferred stock.

Common Stock Equivalents

As of the closing of this offering, we will have RSUs outstanding for an aggregate of 1,096,460 shares of our common stock and warrants to acquire an aggregate of 1,520,284 shares of our common stock at an exercise price of $0.01 per share, and the Series A warrants and Series B warrants to acquire an aggregate of 5,833,334 shares of our common stock being issued as part of the units offered hereby.

Warrants

Pursuant to the investors' rights agreement, we have agreed, under certain circumstances, to issue warrants to acquire an aggregate of 1,520,284 shares of our common stock upon the closing of this offering. The warrants have a term of three-years, an initial exercise price of $0.01 per share and are not exercisable until 180 days after effectiveness of the registration statement for this offering. If on the date such warrants become exercisable, the market value of the common stock owned by the investors equals or exceeds the purchase price of those shares acquired by the investor at the time they became a party to the investors' rights agreement, then the exercise price will increase to $1.00 per share.

Stockholder Registration Rights

After the closing of this offering, certain holders of shares of our common stock, including certain holders of 5% of our capital stock, entities in which certain of our directors have invested and Sabby, which has indicated an interest in purchasing $5.0 million of our units at the initial public offering price in the concurrent private placement, will be entitled to certain rights with respect to registration of such shares under the Securities Act including any shares issued upon exercise of warrants held by them. These shares are referred to as registrable securities. The holders of these registrable securities possess registration rights pursuant to the terms of the investors' rights agreement and are described in additional detail below.

The registration of shares of our common stock pursuant to the exercise of the registration rights described below would enable the holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective. We will pay the registration expenses, other than underwriting discounts, selling commissions and stock transfer taxes, of the shares registered pursuant to the demand, piggyback and Form S-3 registrations described below.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions, to limit the number of shares the holders may include. The demand, piggyback and Form S-3 registration rights described below will expire three years after the effective date of the registration statement, of which this prospectus forms a part, or with respect to any particular holder, at such time that such holder can sell its shares under Rule 144 of the Securities Act during any three-month period.

Demand Registration Rights

The holders of the registrable securities will be entitled to certain demand registration rights. At any time beginning 180 days following the closing of this offering, the holders of the registrable securities then outstanding may make a written request that we register all or a portion of their shares, subject to certain specified exceptions. Such request for registration must cover securities the aggregate offering price of which, before payment of underwriting discounts, commissions and other expenses related to such registration, would exceed $5,000,000.

Piggyback Registration Rights

In connection with this offering, the holders of registrable securities were entitled to, and the necessary percentage of holders waived, their rights to notice of this offering and to include their shares of registrable securities in this offering. If we propose to register for offer and sale any of our securities under the Securities Act in another offering, either for our own account or for the account of other security holders, the holders of these shares will be entitled to certain "piggyback" registration rights allowing them to include their shares in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act, including a registration statement on Form S-3 as discussed below, other than with respect to a demand registration or a registration statement on Forms S-4 or S-8 or related to stock issued upon conversion of debt securities, the holders of these shares are entitled to notice of the registration and have the right, subject to limitations that the underwriters may impose on the number of shares included in the registration, to include their shares in the registration.

Form S-3 Registration Rights

The holders of the registrable securities will be entitled to certain Form S-3 registration rights. Any holder of these shares can make a request that we register for offer and sale their shares on Form S-3 if we are qualified to file a registration statement on Form S-3, subject to certain specified exceptions. Such request for registration on Form S-3 must cover securities the aggregate offering price of which, before payment of the underwriting discounts and commissions, equals or exceeds $1,000,000. We will not be required to effect more than two registrations on Form S-3 within any 12-month period.

Anti-Takeover Provisions of Delaware Law and Our Charter Documents

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (1) by persons who are directors and also officers and (2) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; and
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66⅔% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a "business combination" to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder;
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation; and
- in general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

The statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Among other things, our amended and restated certificate of incorporation and amended and restated bylaws will:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in control;
- provide that the authorized number of directors may be changed only by resolution of our board of directors;
- provide that our board of directors will be classified into three classes of directors;
- provide that, subject to the rights of any series of preferred stock to elect directors, directors may only be removed for cause, which removal may be effected, subject to any limitation imposed by law, by the holders of at least a majority of the voting power of all of our then-outstanding shares of the capital stock entitled to vote generally at an election of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent or electronic transmission;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;
- provide that special meetings of our stockholders may be called only by the chairman of our board of directors, our chief executive officer or president or by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- not provide for cumulative voting rights, therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose.

The amendment of any of these provisions would require approval by the holders of at least 66⅔% of the voting power of all of our then-outstanding common stock entitled to vote generally in the election of directors, voting together as a single class.

The combination of these provisions will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Because our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the

benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Choice of Forum

Our amended and restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware will be 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 certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with one or more actions or proceedings described above, a court could find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable.

Listing

Our common stock has been approved for listing on the NASDAQ Global Market under the symbol "ONS." We have applied for the listing of our units, Series A warrants and Series B warrants on the NASDAQ Global Market under the symbols "ONSIU," "ONSIW" and "ONSIZ," respectively.

Transfer Agent, Registrar and Warrant Agent

The transfer agent and registrar for our common stock and the warrant agent for the Series A warrants and Series B warrants included in the units offered hereby is American Stock Transfer & Trust Company, LLC. Its address is 6201 15th Avenue, Brooklyn, New York 11219.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our securities, and a liquid trading market for our securities may not develop or be sustained after this offering. Future sales of our securities, including shares issued upon the exercise of outstanding warrants or vesting of restricted stock unit awards, or RSUs, in the public market after the completion of this offering and the concurrent private placement, if any, or the perception that those sales may occur, could adversely affect the prevailing market price for our securities from time to time or impair our ability to raise equity capital in the future. As described below, only a limited number of shares of our common stock will be available for sale in the public market for a period of several months after the completion of this offering due to contractual and legal restrictions on resale described below. Future sales of our securities in the public market either before (to the extent permitted) or after restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price of our securities at such time and our ability to raise equity capital at a time and price we deem appropriate.

Sale of Restricted Shares

Based on the number of shares of our common stock outstanding as of December 31, 2015 and after taking into account the issuance of an aggregate of 87,287 shares of our common stock in January 2016, upon the closing of this offering and assuming (1) the conversion of all 11,819 outstanding shares of our preferred stock into 1,969,818 shares of common stock immediately prior to the closing of this offering, assuming an initial public offering price of $6.00 per share of common stock included in the units sold in this offering, and (2) no exercise of the underwriters' option to purchase 875,000 units to cover over-allotments or the sale of any units in the concurrent private placement, we will have outstanding an aggregate of 21,969,446 shares of common stock. All of the 5,833,334 shares of common stock included in the units to be sold in this offering will be freely tradable in the public market without restriction or further registration under the Securities Act, except for any shares included in the units sold in this offering to certain of our existing and new investors who have entered into a 60-day lock-up agreement with the underwriters in respect of such shares, shares held by any of our "affiliates" as such term is defined in Rule 144 of the Securities Act, or subject to lock-up agreements, including units purchased in connection with the directed unit program. All remaining shares of common stock held by existing stockholders immediately prior to the consummation of this offering, including shares issued upon vesting of RSUs, will be "restricted securities" as such term is defined in Rule 144. These restricted securities were issued and sold by us in private transactions and are eligible for public sale only if registered under the Securities Act or if they qualify for an exemption from registration under the Securities Act, including the exemptions provided by Rule 144 or Rule 701, which rules are summarized below.

Based on the number of shares of our common stock outstanding as of December 31, 2015, in connection with this offering, the shares of our common stock (excluding the shares included in the units sold in this offering and except as indicated above) that will generally become available for sale in the public market are as follows:

Approximate Number of Shares	First Date Available for Sale into Public Market
16,136,112 shares	181 days after the date of this prospectus, subject in some cases to applicable volume, manner of sale and other limitations under Rule 144 and Rule 701.

We may issue securities from time to time as consideration for future acquisitions, investments or other corporate purposes. In the event that any such acquisition, investment or other transaction is significant, the number of securities that we may issue may in turn be significant. We may also grant registration rights covering those securities issued in connection with any such acquisition and investment.

In addition, the shares of common stock reserved for future issuance under our 2011 Plan, 2015 Plan and ESPP will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements, a registration statement under the Securities Act or an exemption from registration, including Rule 144 and Rule 701.

Lock-Up Agreements

In connection with this offering, we, our directors, our executive officers and holders of substantially all of our other outstanding shares of common stock or securities convertible into or exchangeable for shares of our common stock outstanding immediately prior to the closing of this offering, have agreed, subject to certain exceptions, with the underwriters not to directly or indirectly offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of or hedge any shares of our common stock or any options to purchase shares of our common stock, or any securities convertible into or exchangeable for shares of common stock during the period from the date of the

lock-up agreement continuing through the date 180 days after the date of this prospectus, except with the prior written consent of Jefferies LLC and Barclays Capital Inc. and certain other exceptions. Additionally, certain of our existing and new investors have indicated an interest in purchasing up to an aggregate of approximately $20.0 million of units in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, fewer or no units in this offering to any of these investors, or any of these investors may determine to purchase more, fewer or no units in this offering. Certain of these investors have agreed to a 60-day lock-up agreement with the underwriters in respect of any units they may acquire in this offering. Subject to certain exceptions, these investors will not, directly or indirectly, offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale, or otherwise dispose or hedge any shares of our common stock, any options to purchase shares of our common stock, or any securities convertible into, or exchangeable for shares of common stock for a period of 60 days after the date of this prospectus, except with the prior written consent of Jefferies LLC and Barclays Capital Inc. and certain other exceptions.

In addition to the restrictions contained in the lock-up agreements described above, we have entered into agreements with certain securityholders, including the investors' rights agreement and our standard form of option agreement, that contain market stand-off provisions imposing restrictions on the ability of such securityholders to offer, sell or transfer our equity securities for a period of 180 days following the date of this prospectus.

Prior to the completion of the offering, certain of our employees, including our executive officers, and/or directors may enter into written trading plans that are intended to comply with Rule 10b5-1 under the Exchange Act. Sales under these trading plans would not be permitted until the expiration of the lock-up agreements relating to the offering described above.

Following the lock-up periods set forth in the agreements described above, and assuming that the representatives of the underwriters do not release any parties from these agreements and that there is no extension of the lock-up period, all of the shares of our common stock that are restricted securities or are held by our affiliates as of the date of this prospectus will be eligible for sale in the public market in compliance with Rule 144 under the Securities Act.

Additionally, participants in the directed unit program and any directors or officers and their affiliates that purchase common stock from the underwriters in the offering have agreed with the underwriters that, for a period of 180 days following the date of this prospectus, subject to certain exceptions, they will not, directly or indirectly, offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale, or otherwise dispose of or hedge any shares of common stock.

Rule 144

In general, persons who have beneficially owned restricted shares of our common stock for at least six months, and any affiliate of the company who owns either restricted or unrestricted shares of our common stock, are entitled to sell their securities without registration with the SEC under an exemption from registration provided by Rule 144 under the Securities Act.

In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, and we are current in our Exchange Act reporting at the time of sale, a person (or persons whose shares are required to be aggregated) who is not deemed to have been one of our "affiliates" for purposes of Rule 144 at any time during the 90 days preceding a sale and who has beneficially owned restricted securities within the meaning of Rule 144 for at least six months, including the holding period of any prior owner other than one of our "affiliates," is entitled to sell those shares in the public market (subject to the lock-up agreement referred to above, if applicable) without complying with the manner of sale, volume limitations or notice provisions of Rule 144, but subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than "affiliates," then such person is entitled to sell such shares in the public market without complying with any of the requirements of Rule 144 (subject to the lock-up agreement referred to above, if applicable). In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, our "affiliates," as defined in Rule 144, who have beneficially owned the shares proposed to be sold for at least six months, are entitled to sell in the public market, upon expiration of any applicable lock-up agreements and within any three-month period, a number of those shares of our common stock that does not exceed the greater of:

- 1% of the number of common shares then outstanding, which will equal approximately shares of common stock immediately after the closing of this offering and the concurrent private placement, if any (calculated as of December 31, 2015 on the basis of the assumptions described above and assuming no exercise of the underwriter's option to purchase additional shares and no exercise of outstanding options); or

- the average weekly trading volume of our securities on the NASDAQ Global Market, or NASDAQ, during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Such sales under Rule 144 by our “affiliates” or persons selling shares on behalf of our “affiliates” are also subject to certain manner of sale provisions, notice requirements and to the availability of current public information about us. Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted securities have entered into lock-up agreements as referenced above and their restricted securities will become eligible for sale (subject to the above limitations under Rule 144) upon the expiration of the restrictions set forth in those agreements.

Rule 701

In general, under Rule 701 as currently in effect, any of our employees, directors, officers, consultants or advisors who acquired common stock from us in connection with a written compensatory stock or option plan or other written agreement in compliance with Rule 701 under the Securities Act before the effective date of the registration statement of which this prospectus is a part (to the extent such common stock is not subject to a lock-up agreement) and who are not our “affiliates” as defined in Rule 144 during the immediately preceding 90 days, is entitled to rely on Rule 701 to resell such shares beginning 90 days after the date of this prospectus in reliance on Rule 144, but without complying with the notice, manner of sale, public information requirements or volume limitation provisions of Rule 144. Persons who are our “affiliates” may resell those shares beginning 90 days after the date of this prospectus without compliance with Rule 144’s minimum holding period requirements (subject to the terms of the lock-up agreement referred to below, if applicable).

Registration Rights

Based on the number of shares outstanding as of December 31, 2015 and after taking into account the issuance of an aggregate of (x) 87,287 shares of our common stock in January 2016 and (y) the conversion of all 11,819 outstanding shares of Series A preferred stock into 1,969,818 shares of common stock immediately prior to the closing of this offering (assuming an initial public offering price of $6.00 per share of common stock included in the units sold in this offering), after the consummation of this offering but excluding any units that may be sold in the concurrent private placement, the holders of approximately 4,078,029 shares of our common stock, or their transferees, will, subject to any lock-up agreements they have entered into, be entitled to certain rights with respect to the registration of the offer and sale of those shares under the Securities Act. The holders of shares of common stock issuable upon the exercise of warrants to acquire an aggregate of 1,520,284 shares of our common stock to be issued to certain investors upon the closing of this offering will also be entitled to rights with respect to registration under the Securities Act. For a description of these registration rights, please see the section titled “Description of Securities — Stockholder Registration Rights.” If the offer and sale of these shares are registered, they will be freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. As a party to the investors’ rights agreement, Sabby would also have registration rights with respect to the shares included in the units, as well as the shares issuable upon exercise of the warrants included in the units that Sabby has indicated an interest in acquiring in the concurrent private placement.

MATERIAL U.S. FEDERAL INCOME AND ESTATE TAX CONSIDERATIONS

The following is a general discussion of the material U.S. federal income and estate tax consequences of the acquisition, ownership and disposition of units by "U.S. Holders" and "Non-U.S. Holders" (each as defined below). This discussion is for general information purposes only and does not consider all aspects of U.S. federal income taxation that may be relevant to particular holders in light of their individual circumstances or to certain types of holders subject to special tax rules, including partnerships or other pass-through entities for U.S. federal income tax purposes, banks, financial institutions or other financial services entities, foreign governments or governmental entities, brokers or dealers in securities or currencies, insurance companies, tax-exempt organizations, pension plans, real estate investment trusts, controlled foreign corporations, passive foreign investment companies, corporations that accumulate earnings to avoid U.S. federal income tax, persons who use or are required to use mark-to-market accounting, persons that hold units as part of a "straddle," a "hedge," a "conversion transaction," "synthetic security," integrated investment or other risk reduction strategy, certain former citizens or permanent residents of the United States, persons who hold or receive units pursuant to the exercise of an employee stock option or otherwise as compensation, or investors in pass-through entities (or entities that are treated as disregarded entities for U.S. federal income tax purposes). In addition, this discussion does not address, except to the extent discussed below, the effects of any applicable gift or estate tax, and this discussion does not address the potential application of alternative minimum tax, or any tax considerations that may apply to holders of units under state, local or non-U.S. tax laws and any other U.S. federal tax laws.

This discussion is based on the Internal Revenue Code of 1986, as amended, or the Code, and applicable Treasury Regulations, rulings, administrative pronouncements and judicial decisions that are issued and available as of the date of this registration statement, all of which are subject to change or differing interpretations at any time with possible retroactive effect. We have not sought, and will not seek, any ruling from the Internal Revenue Service, or the IRS, with respect to the tax consequences discussed herein, and there can be no assurance that the IRS will not take a position contrary to the tax consequences discussed below or that any position taken by the IRS would not be sustained. This discussion is limited to a holder who will hold units as capital assets within the meaning of the Code (generally, property held for investment). For purposes of this discussion, the term "U.S. Holder" means a beneficial owner of units that is:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity treated as a corporation) created or organized in the United States or under the laws of the United States or of any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust if (1) a court within the United States can exercise primary supervision over the trust's administration and one or more U.S. persons have the authority to control all of the trust's substantial decisions or (2) the trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person.

A Non-U.S. Holder is a beneficial owner that is not a partnership (or entity or arrangement treated as a partnership for U.S. federal income tax purposes) and is not a U.S. Holder. If a partnership (or entity or arrangement treated as a partnership for U.S. federal income tax purposes) is a beneficial owner of units, the tax treatment of such partnership and a partner in such partnership generally will depend upon the status of the partner and the activities of the partnership. If you are a partner of a partnership holding our shares, you should consult your tax advisor regarding the tax consequences of the purchase, ownership and disposition of units.

THIS SUMMARY IS NOT INTENDED TO BE TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING AND DISPOSING OF OUR UNITS, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR FOREIGN TAX LAWS AND ANY OTHER U.S. FEDERAL TAX LAWS.

Tax Classification of a Unit

There is no authority directly addressing the treatment, for U.S. federal income tax purposes, of securities with terms substantially the same as the units, and, therefore, such treatment is not entirely clear. We intend to treat each unit for U.S. federal income tax purposes as a unit consisting of one share of common stock, one-half of a Series A warrant and one-half of a Series B warrant. Pursuant to this treatment, each holder of a unit must allocate the purchase price paid by such holder for such unit between the ordinary share and the warrants based on their respective relative fair market values. In addition, pursuant to this treatment, a holder's initial tax basis in the ordinary share and the warrants included in each unit should equal the portion of the purchase price of the unit allocated thereto.

Our view of the characterization of the units described above and a holder's purchase price allocation are not, however, binding on the IRS or the courts. Because there are no authorities that directly address instruments that are similar to the

units, no assurance can be given that the IRS or the courts will agree with the characterization described above or the discussion below. Accordingly, prospective investors are urged to consult their own tax advisors regarding the U.S. federal tax consequences of an investment in a unit (including alternative characterizations of a unit) and with respect to any tax consequences arising under the laws of any state, local or non-United States taxing jurisdiction. Unless otherwise stated, the following discussions are based on the assumption that the characterization of the units and the allocation described above are accepted for U.S. federal income tax purposes.

U.S. Holders

Exercise or Lapse of Warrants

Except with respect to any cash paid in connection with the exercise of a warrant, a U.S. Holder will not recognize taxable income, gain or loss upon the exercise of a warrant. Such U.S. Holder's adjusted tax basis in our common stock received by such holder generally will be an amount equal to the sum of the U.S. Holder's initial investment in the warrant (i.e., the portion of the U.S. Holder's purchase price for a unit that is allocated to the warrant, as described above under "— Tax Classification of a Unit") and the exercise price (i.e., the exercise price for each one-half of a Series A warrant and the exercise price for each one-half of a Series B warrant). The holding period for our common stock received pursuant to the exercise of a warrant will begin on the date following the date of exercise and will not include the period during which the U.S. Holder held the warrant.

If a warrant is allowed to lapse unexercised, a U.S. Holder will recognize a capital loss in an amount equal to its tax basis in the warrant. Such loss will be long-term capital loss if the warrant has been held for more than one year as of the date the warrant lapsed. The deductibility of capital losses is subject to limitations.

If we were to make a distribution in cash or other property with respect to our common stock after the issuance of the warrants, then we may, in certain circumstances, make a corresponding distribution to a warrant holder at the time when such warrants are exercised. While the U.S. federal income tax treatment of such payment is unclear and other tax treatments are possible, we intend to treat any such payment as a distribution with respect to our common stock at the time when it is paid. See "Distributions on Our Common Stock" below.

Distributions on Our Common Stock

In general, distributions, if any, paid on our common stock to a U.S. Holder will constitute dividends for U.S. federal income tax purposes to the extent paid from current and accumulated earnings and profits, as determined for U.S. federal income tax purposes. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and will first reduce a U.S. Holder's adjusted tax basis in our common stock, but not below zero. Any excess will be treated as capital gain from the sale of our common stock in the manner described under "Disposition of Our Common Stock" below. Dividends received by certain non-corporate U.S. Holders (including individuals) may be eligible for taxation at preferential rates provided certain holding period and other requirements are satisfied. Distributions received by corporate U.S. Holders of our common stock constituting dividends for U.S. federal income tax purposes generally will be eligible for the dividends-received deduction so long as certain holding period and other requirements are satisfied. No assurance can be given that we will have sufficient earnings and profits to cause dividends to be eligible for a dividends received deduction.

Gain on Sale, Exchange or Other Disposition of Our Common Stock and Warrants

Upon the sale, certain qualifying redemptions, or other taxable disposition of shares of our common stock, or a sale or other taxable disposition of the warrants, a U.S. Holder generally will recognize capital gain or loss equal to the difference, if any, between (i) the amount of cash and the fair market value of any property received upon such taxable disposition and (ii) the U.S. Holder's adjusted tax basis in the shares of our common stock or warrants sold or otherwise disposed of. Such capital gain or loss will be long-term capital gain or loss if a U.S. Holder's holding period in the shares of common stock or warrants, as applicable, is more than one year at the time of the taxable disposition. Long-term capital gains recognized by certain non-corporate U.S. Holders (including individuals) may be eligible for taxation at preferential rates. Deductions for capital losses are subject to limitations under the Code.

Additional Tax on Passive Income

Individuals, estates and certain trusts whose income exceeds certain thresholds will be required to pay a 3.8% Medicare surtax on "net investment income" including, among other things, dividends and net gain from disposition of property (other than property held in certain trades or businesses). U.S. Holders should consult their own tax advisors regarding the effect, if any, of this tax on their ownership and disposition of shares of our common stock and warrants.

Information Reporting and Backup Withholding

Unless U.S. Holders are exempt recipients, such as corporations, information reporting and backup withholding may apply with respect to payments of dividends (including constructive distributions) on our common stock and to certain payments of proceeds on the sale or other disposition of our common stock and warrants if U.S. Holders fail to supply accurate taxpayer identification numbers or otherwise fail to comply with applicable U.S. information reporting or certification requirements. The current backup withholding rate is 28%.

Non-U.S. Holders

Exercise or Lapse of Warrants

Except with respect to any cash received upon exercise of a warrant, a Non-U.S. Holder will generally not be required to recognize taxable income gain or loss upon the exercise of a warrant. Such Non-U.S. Holder's adjusted tax basis in our common stock received by such holder generally will be an amount equal to the sum of the Non-U.S. Holder's initial investment in the warrant (i.e., the portion of the Non-U.S. Holder's purchase price for a unit that is allocated to the warrant, as described above under "— Tax Classification of a Unit") and the exercise price (i.e., the exercise price for each one-half of a Series A warrant and the exercise price for each one-half of a Series B warrant). The holding period for our common stock received pursuant to the exercise of a warrant will begin on the date following the date of exercise and will not include the period during which the Non-U.S. Holder held the warrant.

If a warrant is allowed to lapse unexercised, a Non-U.S. Holder will recognize a capital loss in an amount equal to its tax basis in the warrant. Such loss will be long-term capital loss if the warrant has been held for more than one year as of the date the warrant lapsed. The deductibility of capital losses is subject to limitations.

If we were to make a distribution in cash or other property with respect to our common stock after the issuance of the warrants, then we may, in certain circumstances, make a corresponding distribution to a warrant holder at the time when such warrants are exercised. While the U.S. federal income tax treatment of such payment is unclear and other tax treatments are possible, we intend to treat any such payment as a distribution with respect to our common stock at the time when it is paid. See "Distributions on Our Common Stock" below.

Distributions on Our Common Stock

In general, subject to the discussion below under the headings "Information Reporting and Backup Withholding" and "Foreign Accounts," distributions, if any, paid on our common stock to a Non-U.S. Holder (to the extent paid out of our current or accumulated earnings and profits, as determined under U.S. federal income tax principles) will constitute dividends and be subject to U.S. withholding tax at a rate equal to 30% of the gross amount of the dividend, or a lower rate prescribed by an applicable income tax treaty, unless the dividends are effectively connected with a trade or business carried on by the Non-U.S. Holder within the United States. The portion of any distribution that exceeds our current and accumulated earnings and profits will be treated first as reducing the Non-U.S. Holder's basis in its shares of common stock, but not below zero, and to the extent it exceeds the Non-U.S. Holder's basis, as gain from the sale or exchange of our common stock (see "Gain on Sale, Exchange or Other Taxable Disposition of Common Stock" below).

A Non-U.S. Holder who claims the benefit of an applicable income tax treaty generally will be required to satisfy certain certification and other requirements prior to the distribution date. Such Non-U.S. Holders must generally provide us or our paying agent with a properly executed IRS Form W-8BEN or IRS Form W-8BEN-E (or other appropriate form) claiming an exemption from or reduction in withholding under an applicable income tax treaty. Such certificate must be provided before the payment of dividends and must be updated periodically. If tax is withheld in an amount in excess of the amount applicable under an income tax treaty, a refund of the excess amount may generally be obtained by a Non-U.S. Holder by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under an applicable income tax treaty.

Dividends that are effectively connected with a Non-U.S. Holder's conduct of a U.S. trade or business generally will not be subject to the 30% U.S. withholding tax if the Non-U.S. Holder files the required forms, including IRS Form W-8ECI, with us or our paying agent. Instead, such a Non-U.S. Holder generally will be subject to U.S. federal income tax on those dividends on a net income basis at regular graduated rates in the same manner as if the Non-U.S. Holder were a resident of the United States (except to the extent provided in an applicable income tax treaty, which may require that such dividends be attributable to a U.S. permanent establishment or fixed base in order to be subject to tax as described herein). A corporate Non-U.S. Holder that receives effectively connected dividends may be subject to an additional branch profits tax at a rate of 30% (or such lower rate as may be prescribed by an applicable income tax treaty) on its effectively connected earnings and profits, as adjusted under the Code.

Gain on Sale, Exchange or Other Disposition of Our Common Stock and Warrants

In general, subject to the discussion below under the headings “Information Reporting and Backup Withholding” and “Foreign Accounts,” a non-U.S. holder will not be subject to U.S. federal income tax or withholding tax on any gain realized upon such holder’s sale, exchange or other disposition of shares of our common stock or warrants unless:

(1) the gain is effectively connected with a trade or business carried on by the Non-U.S. Holder within the United States (and, if required by an applicable income tax treaty, attributable to a U.S. permanent establishment or fixed base of the Non-U.S. Holder);

(2) the Non-U.S. Holder is an individual who is present in the United States for 183 days or more in the taxable year of disposition and certain other conditions are met; or

(3) we are or have been a “United States real property holding corporation” for U.S. federal income tax purposes at any time during the shorter of the five year period ending on the date of disposition or the period that the Non-U.S. Holder held the common stock or warrants, and, in the case where shares of our common stock are regularly traded on an established securities market, the Non-U.S. Holder owns, or is treated as owning, more than 5% of our common stock at any time during the foregoing period (including for this purpose any interest in us which is convertible into our common stock, which may include warrants).

Net gain realized by a Non-U.S. Holder that is described in clause (1) above generally will be subject to the regular graduated U.S. federal income tax rates in the same manner as if the Non-U.S. Holder were a resident of the United States. Any gains of a corporate Non-U.S. Holder described in clause (1) above may also be subject to an additional “branch profits tax” at a 30% rate (or such lower rate as may be specified by an applicable income tax treaty) on its effectively connected earnings and profits, as adjusted under the Code.

Gain realized by an individual Non-U.S. Holder described in clause (2) above will be subject to a flat 30% tax, which gain may be offset by U.S. source capital losses, even though the individual is not considered a resident of the United States.

For purposes of clause (3) above, a corporation generally is a United States real property holding corporation, or USRPHC, if the fair market value of its United States real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. We believe that we are not, and we do not anticipate that we will become, a USRPHC. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we became a USRPHC, a Non-U.S. Holder would not be subject to U.S. federal income tax on a sale, exchange or other taxable disposition of our common stock by reason of our status as an USRPHC so long as our common stock is regularly traded on an established securities market (within the meaning of the applicable regulations) and such Non-U.S. Holder does not own and is not deemed to own (directly, indirectly or constructively) more than 5% of our outstanding common stock at any time during the shorter of the five year period ending on the date of disposition and such holder’s holding period. However, no assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above. Prospective investors are encouraged to consult their own tax advisors regarding the possible consequences to them if we are, or were to become, a USRPHC.

Information Reporting and Backup Withholding

Generally, we must report annually to the IRS and to each Non-U.S. Holder the amount of dividends paid, the name and address of the recipient, and the amount, if any, of tax withheld. These information reporting requirements apply even if withholding was not required because the dividends were effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States or withholding was reduced by an applicable income tax treaty. Under applicable income tax treaties or other agreements, the IRS may make its reports available to the tax authorities in the Non-U.S. Holder’s country of residence or country in which the Non-U.S. Holder was established.

Dividends paid to a Non-U.S. Holder that is not an exempt recipient generally will be subject to backup withholding, currently at a rate of 28%, unless the Non-U.S. Holder certifies to the payor as to its foreign status, which certification may generally be made on an applicable IRS Form W-8.

Proceeds from the sale or other disposition of common stock or warrants by a Non-U.S. Holder effected by or through a U.S. office of a broker will generally be subject to information reporting and backup withholding, currently at a rate of 28%, unless the Non-U.S. Holder certifies to the withholding agent under penalties of perjury as to, among other things, its name, address and status as a Non-U.S. Holder or otherwise establishes an exemption. Payment of disposition proceeds

effected outside the United States by or through a non-U.S. office of a non-U.S. broker generally will not be subject to information reporting or backup withholding if the payment is not received in the United States. Information reporting, but generally not backup withholding, will apply to such a payment if the broker has certain connections with the United States unless the broker has documentary evidence in its records that the beneficial owner thereof is a Non-U.S. Holder and specified conditions are met or an exemption is otherwise established.

Backup withholding is not an additional tax. Any amount withheld under the backup withholding rules from a payment to a Non-U.S. Holder that results in an overpayment of taxes generally will be refunded, or credited against the holder's U.S. federal income tax liability, if any, provided that the required information is timely furnished to the IRS.

Foreign Accounts

A U.S. federal withholding tax of 30% may apply to dividends on, and the gross proceeds of, a disposition of our common stock (or a disposition of warrants) paid to a "foreign financial institution" (as specially defined under applicable rules) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding certain U.S. account holders of such institution (which includes certain equity holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or otherwise qualifies for an exemption from these rules. This U.S. federal withholding tax of 30% will also apply to payments of dividends on, and the gross proceeds of, a disposition of our common stock (or a disposition of warrants) paid to a non-financial foreign entity (as specifically defined by applicable rules), unless such entity either certifies it does not have any substantial direct or indirect U.S. owners or provides the withholding agent with a certification identifying substantial direct and indirect U.S. owners of the entity or otherwise qualifies for an exemption from these rules. The withholding tax described above will not apply if the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from the rules. Under certain circumstances, a Non-U.S. Holder might be eligible for refunds or credits of such taxes. The United States has entered into agreements with certain countries that modify these general rules for entities resident in those countries. Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of these rules on their investment in our common stock.

The withholding provisions described above currently apply to payments of dividends on our common stock and will apply to payments of gross proceeds from a sale or other disposition of our common stock by a foreign financial institution on or after January 1, 2019.

U.S. Federal Estate Tax

An individual who at the time of death is not a citizen or resident of the United States and who is treated as the owner of, or has made certain lifetime transfers of, an interest in our common stock will be required to include the value thereof in his or her taxable estate for U.S. federal estate tax purposes, and may be subject to U.S. federal estate tax unless an applicable estate tax treaty provides otherwise. The test for whether an individual is a resident of the United States for U.S. federal estate tax purposes differs from the test used for U.S. federal income tax purposes. Some individuals, therefore, may be "Non-U.S. Holders" for U.S. federal income tax purposes, but not for U.S. federal estate tax purposes, and vice versa.

UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, dated , 2016, between us, Jefferies LLC and Barclays Capital Inc., as the representatives of the underwriters named below, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the respective number of units shown opposite its name below:

Underwriter	Number of Units
Jefferies LLC	
Barclays Capital Inc.	
Cantor Fitzgerald & Co.	
Total	5,833,334

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the units if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that, following the pricing of this offering, they currently intend to make a market in our securities as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the units, that you will be able to sell any of the common stock or warrants held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the units subject to their acceptance of the units from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commission and Expenses

The underwriters have advised us that they propose to offer the units to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers, which may include the underwriters, at that price less a concession not in excess of $ per unit. The underwriters may allow, and certain dealers may reallow, a discount from the concession not in excess of $ per unit to certain brokers and dealers. Certain of the underwriters may sell shares through one or more of their affiliates as selling agents. After the offering, the initial public offering price, concession and reallowance to dealers may be reduced by the representatives. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional units.

		Total	
	Per Unit	Without Option to Purchase Additional Units	With Option to Purchase Additional Units
Public offering price	$	$	$
Underwriting discounts and commissions paid by us	$	$	$
Proceeds to us, before expenses	$	$	$

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately $2.8 million. We have also agreed to reimburse the underwriters for

certain expenses, including an amount not to exceed $35,000 in connection with the clearance of this offering with the Financial Industry Regulatory Authority, as set forth in the underwriting agreement.

Determination of Offering Price

Prior to this offering, there has not been a public market for our units, common stock or warrants. Consequently, the initial public offering price for our units will be determined by negotiations between us and the representatives. Among the factors to be considered in these negotiations will be prevailing market conditions, our financial information, market valuations of other companies that we and the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

We offer no assurances that the initial public offering price will correspond to the price at which the units, common stock or warrants will trade in the public market subsequent to the offering or that an active trading market for the common stock will develop and continue after the offering.

Listing

Our common stock has been approved for listing on the NASDAQ Global Market under the symbol “ONS.” We have applied for the listing of our units, Series A warrants and Series B warrants on the NASDAQ Global Market under the symbols “ONSIU,” “ONSIW” and “ONSIZ,” respectively.

Stamp Taxes

If you purchase units offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus.

Option to Purchase Additional Units

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate 875,000 units from us at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional shares proportionate to that underwriter’s initial purchase commitment as indicated in the table above. This option may be exercised only if the underwriters sell more units than the total number set forth on the cover page of this prospectus.

Directed Unit Program

At our request, the underwriters have reserved 291,666 units, or 5% of the units being offered by this prospectus (excluding the units that may be issued upon the underwriters’ exercise of their over-allotment option to purchase additional units) for sale at the initial public offering price, to employees, executive officers, directors, stockholders, business associates, persons related to the company and our affiliates and their friends and family through a directed unit program. The number of units available for sale to the general public in the public offering will be reduced by the number of units these individuals purchase. Any reserved units that are not so purchased will be offered by the underwriters to the general public on the same basis as the other units offered hereby. Each person buying units through the directed unit program will be subject to the same 180-day lock-up period described above. We have agreed to indemnify the underwriter conducting the directed unit program against certain liabilities and expenses, including liabilities under the Securities Act, in connection with the directed unit program.

No Sales of Similar Securities

We, our officers, directors and holders of all or substantially all our outstanding capital stock have agreed, subject to specified exceptions, not to directly or indirectly, offer, sell, contract to sell, pledge or otherwise dispose of, (or enter into any transaction which is designed to, or might reasonably be expected to, result in the disposition (whether by actual disposition or effective economic disposition due to cash settlement or otherwise) by such shareholder or any affiliate of such shareholder or any person in privity with such shareholder or any affiliate of such shareholder), directly or indirectly, including the filing (or participation in the filing) of a registration statement with the Securities and Exchange Commission, or the SEC, in respect of, or establish or increase a put equivalent position or liquidate or decrease a call equivalent position within the meaning of Section 16 of the Securities Exchange Act of 1934, as amended, and the rules and regulations of the SEC promulgated thereunder with respect to, any shares of capital stock of the Company or any securities

convertible into, or exercisable or exchangeable for such capital stock, or publicly announce an intention to effect any such transaction, for a period from the date hereof until 180 days after the date of the underwriting agreement. Additionally, certain of our existing and new investors have indicated an interest in purchasing up to an aggregate of approximately $20.0 million of units in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, fewer or no units in this offering to any of these investors, or any of these investors may determine to purchase more, fewer or no units in this offering. Any units purchased by certain of these investors in this offering will be subject to a 60-day lock-up agreement with the underwriters. These lock-up agreements are described in the section titled “Shares Eligible for Future Sale.”

Jefferies LLC and Barclays Capital Inc. may, in their discretion and at any time or from time to time before the termination of the 60-day or 180-day periods, as applicable, release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our stockholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up periods.

Stabilization

The underwriters have advised us that they, pursuant to Regulation M under the Securities Exchange Act of 1934, as amended, certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the units at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either “covered” short sales or “naked” short sales.

“Covered” short sales are sales made in an amount not greater than the underwriters’ option to purchase additional units in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional units or purchasing units in the open market. In determining the source of units to close out the covered short position, the underwriters will consider, among other things, the price of units available for purchase in the open market as compared to the price at which they may purchase units through the option to purchase additional units.

“Naked” short sales are sales in excess of the option to purchase additional units. The underwriters must close out any naked short position by purchasing units in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the units in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of units on behalf of the underwriters for the purpose of fixing or maintaining the price of the units. A syndicate covering transaction is the bid for or the purchase of units on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriter’s purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our units or preventing or retarding a decline in the market price of our units. As a result, the price of our units may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the unit originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we, nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our units. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

Electronic Distribution

A prospectus in electronic format may be made available by e-mail or on the websites or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of units for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters’ websites and any information contained in any other website maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

Other Activities and Relationships

The underwriters and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment

research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and certain of their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the underwriters or their respective affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their respective affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the units offered hereby. Any such short positions could adversely affect future trading prices of the units offered hereby. The underwriters and certain of their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Selling Restrictions

Australia

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia:

You confirm and warrant that you are either:

- a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
- a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the Company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;
- a person associated with the Company under Section 708(12) of the Corporations Act; or
- a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the securities issued to you pursuant to this prospectus for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

Canada

The offering of our units in Canada is being made on a private placement basis in reliance on exemptions from the prospectus requirements under the securities laws of each applicable Canadian province and territory where the units may be offered and sold, and therein may only be made with investors that are purchasing as principal and that qualify as both an accredited investor, as such term is defined in National Instrument 45-106 Prospectus and Registration Exemptions and as a permitted client, as such term is defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligation. Any offer and sale of our units in any province or territory of Canada may only be made through a dealer that is properly registered under the securities legislation of the applicable province or territory wherein our units are offered and/or sold or, alternatively, by a dealer that qualifies under and is relying upon an exemption from the registration requirements therein.

Any resale of our units by an investor resident in Canada must be made in accordance with applicable Canadian securities laws, which may require resales to be made in accordance with prospectus and registration requirements, statutory exemptions from the prospectus and registration requirements or under a discretionary exemption from the prospectus and registration requirements granted by the applicable Canadian securities regulatory authority. These resale restrictions may under certain circumstances apply to resales of our units outside of Canada.

Upon receipt of this document, each Canadian investor hereby confirms that it has expressly requested that all documents evidencing or relating in any way to the sale of the securities described herein (including for greater certainty any purchase

confirmation or any notice) be drawn up in the English language only. *Par la réception de ce document, chaque investisseur canadien confirme par les présentes qu'il a expressément exigé que tous les documents faisant foi ou se rapportant de quelque manière que ce soit à la vente des valeurs mobilières décrites aux présentes (incluant, pour plus de certitude, toute confirmation d'achat ou tout avis) soient rédigés en anglais seulement.*

European Economic Area

In relation to each member state of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State"), an offer to the public of any units which are the subject of the offering contemplated by this prospectus may not be made in that Relevant Member State except that an offer to the public in that Relevant Member State of any units may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- to any legal entity which is a "qualified investor" as defined in the Prospectus Directive;
- to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the underwriters or the underwriters nominated by us for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of units shall require us or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer units to the public" in relation to the units in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the units to be offered so as to enable an investor to decide to purchase or subscribe to the units, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

Hong Kong

No securities have been offered or sold, and no securities may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong ("SFO") and any rules made under that Ordinance; or in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong ("CO") or which do not constitute an offer or invitation to the public for the purpose of the CO or the SFO. No document, invitation or advertisement relating to the securities has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the acquisition of the securities, to confirm that he is aware of the restriction on offers of the securities described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended), or FIEL, and the Initial Purchaser will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

Singapore

This prospectus has not been and will not be lodged or registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the units may not be circulated or distributed, nor may the units be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA"), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the units is subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor, securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the units pursuant to an offer made under Section 275 of the SFA except:
- to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- where no consideration is or will be given for the transfer;
- where the transfer is by operation of law;
- as specified in Section 276(7) of the SFA; or
- as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, the Company or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes ("CISA"). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

United Kingdom

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "Order") and/or (ii) high net worth entities falling within Article 49(2)(a) to (d) of the Order and other persons to whom it may lawfully be communicated (each such person being referred to as a "relevant person").

This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

LEGAL MATTERS

The validity of the issuance of our securities offered in this prospectus will be passed upon for us by Cooley LLP, New York, New York. Certain legal matters in connection with this offering will be passed upon for the underwriters by Goodwin Procter LLP, New York, New York.

EXPERTS

The consolidated financial statements of Oncobiologics, Inc. as of September 30, 2014 and 2015 and for the years then ended have been included in this prospectus in reliance upon the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing. The audit report covering the September 30, 2015 consolidated financial statements contains an explanatory paragraph that states that the Company has incurred recurring losses and negative cash flows from operations since inception and has an accumulated deficit at September 30, 2015 of $94.1 million and $14.2 million of indebtedness that is due on demand, which raises substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the securities being offered by this prospectus. This prospectus does not contain all of the information in the registration statement and its exhibits. For further information about us and the securities offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at http://www.sec.gov. You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street, NE, Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, NE, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

Upon the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and web site of the SEC referred to above. We also maintain a website at www.oncobiologics.com, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained on, or that can be accessed through, our website is not a part of this prospectus. Investors should not rely on any such information in deciding whether to purchase our securities. We have included our website address in this prospectus solely as an inactive textual reference.

ONCOBIOLOGICS, INC.

INDEX TO 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, 2014 and 2015, and the related consolidated statements of operations, redeemable preferred stock, common stock, noncontrolling interests and stockholders' equity (deficit), and cash flows for years then ended. The 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, 2014 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, 2015 of $94.1 million and $14.2 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

November 16, 2015, except as to
the recapitalization described
in Note 3, which is as of
April 26, 2016

Oncobiologics, Inc.
Consolidated Balance Sheets

	September 30, 2014	September 30, 2015
Assets		
Current assets:		
Cash	$ 2,349,313	$ 9,070,975
Accounts receivable	—	20,000
Stock subscription receivable	—	4,280,149
Prepaid and other current assets	797,279	1,793,109
Total current assets	3,146,592	15,164,233
Property and equipment, net	8,009,564	17,759,938
Restricted cash	211,452	213,663
Deferred offering costs	—	960,563
Other assets	236,099	910,224
Total assets	$ 11,603,707	$ 35,008,621
Liabilities, redeemable preferred stock, common stock, noncontrolling interests and stockholders' equity (deficit)		
Current liabilities:		
Current portion of debt	$ 725,706	$ 742,646
Current portion of capital lease obligations	132,090	862,849
Current portion of stockholder notes	10,624,784	14,214,196
Accounts payable	3,101,445	11,563,055
Accrued expenses	2,560,279	5,924,648
Income taxes payable	1,564,411	1,754,629
Deferred revenue	1,501,416	1,979,576
Total current liabilities	20,210,131	37,041,599
Long-term debt	3,653,038	2,922,764
Capital lease obligations	32,914	1,219,373
Stockholder notes	—	2,000,000
Deferred revenue	6,313,342	6,365,945
Stock-based compensation liability	1,557,789	12,726,722
Other liabilities	283,700	284,710
Total liabilities	32,050,914	62,561,113
Commitments (Note 9)		
Redeemable preferred stock, common stock and noncontrolling interests:		
Redeemable preferred stock, no par value:		
Series A – 8,000 shares authorized; 3,681 and 3,568 shares issued and outstanding at September 30, 2014 and 2015, respectively; (liquidation preference of $5,072,653 at September 30, 2015)	4,787,996	5,072,653
Series B – 4,000 shares authorized; 4,000 shares issued and outstanding; (liquidation preference of $5,118,208 at September 30, 2015)	4,589,872	5,118,208
Redeemable common stock – 1,739,130 shares issued and outstanding	12,225,096	15,426,673
Redeemable noncontrolling interests	3,101,047	1,703,777
Total redeemable preferred stock, common stock and noncontrolling interests	24,704,011	27,321,311
Stockholders' equity (deficit):		
Common stock, no par value; 100,000,000 shares authorized; 7,670,783 and 9,436,294 shares issued and outstanding at September 30, 2014 and 2015, respectively; actual	—	39,844,900
Additional paid-in capital	—	—
Accumulated deficit	(45,151,218)	(94,064,286)
Total Oncobiologics, Inc. stockholders' equity (deficit)	(45,151,218)	(54,219,386)
Noncontrolling interests	—	(654,417)
Total stockholders' equity (deficit)	(45,151,218)	(54,873,803)
Total liabilities, redeemable preferred stock, common stock, noncontrolling interests and stockholders' equity (deficit)	$ 11,603,707	$ 35,008,621

See accompanying notes to consolidated financial statements

Oncobiologics, Inc.
Consolidated Statements of Operations

	Year Ended September 30,	
	2014	2015
Collaboration revenues	$ 9,050,542	$ 5,219,237
Operating expenses:		
Research and development	14,124,631	38,876,040
General and administrative	7,318,314	12,905,823
	21,442,945	51,781,863
Loss from operations	(12,392,403)	(46,562,626)
Interest expense	901,052	2,297,339
Loss before income taxes	(13,293,455)	(48,859,965)
Income tax expense (benefit)	439,018	(190,111)
Net loss	(13,732,473)	(48,669,854)
Less: Net loss attributable to noncontrolling interests	—	(1,276,571)
Net loss attributable to Oncobiologics, Inc.	(13,732,473)	(47,393,283)
Accretion of redeemable preferred stock and noncontrolling interests	(3,588,996)	(4,306,488)
Deemed dividends upon the repurchase of Series A redeemable preferred stock and redeemable noncontrolling interests	(3,336,855)	(1,298,631)
Net loss attributable to common stockholders of Oncobiologics, Inc.	$ (20,658,324)	$ (52,998,402)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (2.43)	$ (5.43)
Weighted-average shares outstanding, basic and diluted	8,509,654	9,753,616
Pro forma net loss per share of common stock – basic and diluted (unaudited)		$ (3.35)
Pro forma weighted average shares outstanding (unaudited)		14,143,696

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	Common Stock		Accumulated Deficit	Noncontrolling Interests	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount		Shares	Amount			
Balance at October 1, 2013	6,995	$ 8,226,922	3,600	$ 3,067,039	—	$ —	$ 2,829,733	9,665,786	$ —	$ (22,608,182)	$ —	$ (22,608,182)
Sale of redeemable common stock, net of issuance costs	—	—	—	—	1,739,130	10,895,000	—	—	—	—	—	—
Sale of Series B redeemable preferred stock and common stock, net of issuance costs	—	—	400	252,000	—	—	—	115,942	148,000	—	—	148,000
Issuance of restricted stock	—	—	—	—	—	—	—	90,869	—	—	—	—
Repurchase of restricted stock in exchange for notes payable	—	—	—	—	—	—	—	(636,376)	(148,000)	(949,750)	—	(1,097,750)
Exchange of restricted stock for performance-based stock units	—	—	—	—	—	—	—	(602,463)	—	—	—	—
Reclassification of equity classified stock-based compensation	—	—	—	—	—	—	—	—	—	(364,187)	—	(364,187)
Employee tax withholdings related to the vesting of restricted stock	—	—	—	—	—	—	—	(2,831)	—	(23,153)	—	(23,153)
Repurchase of common stock	—	—	—	—	—	—	—	(960,144)	—	(3,312,500)	—	(3,312,500)
Repurchase of Series A redeemable preferred stock and deemed dividends	(3,314)	(4,155,679)	—	—	—	—	—	—	—	(3,336,855)	—	(3,336,855)
Stock-based compensation expense	—	—	—	—	—	—	—	—	2,764,878	—	—	2,764,878
Accretion of redeemable preferred stock, common stock and noncontrolling interests	—	716,753	—	1,270,833	—	1,330,096	271,314	—	(2,764,878)	(824,118)	—	(3,588,996)
Net loss	—	—	—	—	—	—	—	—	—	(13,732,473)	—	(13,732,473)
Balance at September 30, 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)

See accompanying notes to consolidated financial statements

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

	Redeemable Preferred Stock, Common Stock and Noncontrolling Interests							Stockholders' Equity (Deficit)				
	Preferred Stock											
	Series A		Series B		Common Stock		Noncontrolling Interests	Common Stock		Accumulated Deficit	Noncontrolling Interests	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount		Shares	Amount			
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)

See accompanying notes to consolidated financial statements

Oncobiologics, Inc.
Consolidated Statements of Cash Flows

	Year Ended September 30,	
	2014	2015
Operating activities:		
Net loss	$ (13,732,473)	$ (48,669,854)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	878,477	1,824,600
Non-cash interest expense	12,264	12,264
Stock-based compensation	3,958,480	11,177,858
Changes in operating assets and liabilities:		
Accounts receivable	—	(20,000)
Prepaid expenses and other current assets	(719,302)	(1,021,852)
Other assets	(84,330)	(322,729)
Accounts payable	(96,403)	6,580,722
Accrued expenses	598,266	2,240,800
Income taxes payable	1,084,921	190,218
Deferred revenue	949,458	530,763
Other liabilities	130,173	1,010
Net cash used in operating activities	(7,020,469)	(27,476,200)
Investing activities:		
Purchase of property and equipment	(2,366,772)	(8,804,244)
Net cash used in investing activities	(2,366,772)	(8,804,244)
Financing activities:		
Proceeds from the sale of Series B redeemable preferred stock	252,000	—
Repurchase of Series A redeemable preferred stock	(4,128,000)	(226,001)
Proceeds from the sale of redeemable common stock	10,895,000	—
Proceeds from the sale of common stock	148,000	41,249,998
Proceeds from the sale of equity in noncontrolling interest	—	401,000
Payments of capital leases obligations	(193,973)	(686,676)
Proceeds from debt	2,460,434	—
Repayment of debt	(753,531)	(725,598)
Proceeds from stockholder notes	6,000,000	10,880,252
Repayment of stockholder notes	(3,125,000)	(7,888,658)
Change in restricted cash	(3,383)	(2,211)
Payment of employee tax witholdings related to the vesting of restricted stock	(23,153)	—
Payment of financing costs	(54,248)	—
Net cash provided by financing activities	11,474,146	43,002,106
Net increase in cash	2,086,905	6,721,662
Cash at beginning of year	262,408	2,349,313
Cash at end of year	$ 2,349,313	$ 9,070,975
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 817,965	$ 1,402,209
Cash paid for taxes	$ 1,750	$ 2,250
Supplemental schedule of noncash investing activities:		
Purchases of property and equipment in accounts payable and accrued expenses	$ (215,907)	$ (2,770,730)
Supplemental schedule of noncash financing activities:		
Accretion of redeemable preferred stock	$ 3,588,996	$ 4,306,488
Deemed dividend upon repurchase of Series A redeemable preferred stock in excess of carrying value	$ (3,336,855)	$ (1,298,631)
Reclassification of equity classified stock-based compensation	$ (364,187)	$ —
Issuance of notes upon repurchase of restricted stock and common stock	$ 4,410,250	$ —
Issuance of subscription receivable upon sale of common stock	$ —	$ (4,280,149)
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	$ 215,908	$ 2,603,894
Deferred offering costs and common stock issuance costs in accounts payable and accrued expenses	$ —	$ 2,310,961

See accompanying notes to consolidated financial statements

Oncobiologics, Inc.
Notes to Consolidated Financial Statements

1. Organization and Description of 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, two of which are expected to enter clinical trials in 2016.

During 2011, the Company formed Parilis Biopharmaceuticals, LLC ("Parilis"), a New Jersey Limited Liability Company to which the Company owns 100% of Parilis's common member units. The Company entered into a licensing arrangement whereby Parilis was issued an exclusive right to commercialize the Company's Humira biosimilar product.

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 Oncobiologic's 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 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 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 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. Additionally, effective upon the reincorporation and in connection with the dissolution of 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.

2. Liquidity

The Company has incurred substantial losses and negative cash flows from operations since its inception and has an accumulated deficit of $94.1 million and $14.2 million of indebtedness that is due on demand, each as of September 30, 2015. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying 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 $14.2 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. 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.

Oncobiologics, Inc.
Notes to Consolidated Financial Statements

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 holds a controlling financial interest as of the financial statement date. As the Company has been the primary funding source for Sonnet since its distribution to the Company's stockholders, the operations and financial position of Sonnet are included in the consolidated financial statements of the Company. Participation of the stockholders in the net assets and losses of Sonnet are reflected in the line items "Noncontrolling interests" in the Company's consolidated balance sheets and "Net loss attributable to the noncontrolling interests" in the Company's consolidated statements of operations. Noncontrolling interests adjusts the Company's consolidated results of operations to exclude all of the losses of Sonnet as Oncobiologics has no direct equity ownership in Sonnet. Changes in underlying net book value of Sonnet due to equity issuances are reflected as equity transaction in the Company's consolidated statements of stockholders' equity (deficit).

Parilis previously issued Series A and Series A Hybrid Redeemable Preferred Units ("Preferred Units") to investors other than Oncobiologics. Prior to October 2015, 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 is presented on the consolidated balance sheets under the caption redeemable noncontrolling interests and carried at its current redemption value. As of and for the years ended September 30, 2014 and 2015, the redeemable noncontrolling interests is 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, 2014 and 2015, the Company had $211,452 and $213,663, respectively, in certificates of deposit with a maturity date of August 2017 and are related to the requirements of the Company's bank loan.

Fair Value of financial instrument

At September 30, 2014 and 2015, the Company's financial instruments included accounts payable, accrued expenses, stockholder notes, debt and stock-based compensation liability. 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. The carrying value of the stock-based compensation liability is the estimated fair value of the liability (note 11).

Oncobiologics, Inc.
Notes to Consolidated Financial Statements

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 or disposition 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, (iii) clinical manufacturing, and (iv) 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 includes 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 are 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 is 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.

Oncobiologics, Inc.
Notes to Consolidated Financial Statements

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding as of September 30, 2014 and 2015, as they would be antidilutive:

	September 30,	
	2014	2015
Series A redeemable preferred stock	1,066,956	1,034,181
Series B redeemable preferred stock	1,159,418	1,159,418
Unvested shares of restricted common stock	32,463	—
Convertible stockholder note	—	96,618

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

The unaudited pro forma net loss per common share is computed using the weighted-average number of common shares outstanding and assumes the issuance of 1,034,181, 1,159,418 and 226,663 shares of common stock issued to Series A and Series B redeemable preferred stockholders and Parilis Preferred Unit holders, respectively, in connection with the reincorporation of the Company in October 2015. The pro forma weighted-average shares outstanding also assumes the reincorporation and the issuance of 1,969,818 shares of common stock upon settlement of the Series A liquidation value of $11,819,000, assuming the initial public offering price of $6.00 per share of common stock included in the units sold in this offering. The pro forma weighted-average shares outstanding of 14,143,696 was used to compute the pro forma net loss per common share.

The following table summarizes the calculation of unaudited pro forma basic and diluted net loss per common share:

Numerator:	
Net loss applicable to common stockholders of Oncobiologics, Inc.	$ (52,998,402)
Effect of pro forma adjustments:	
Accretion of redeemable preferred stock and noncontrolling interests	4,306,488
Deemed dividends	1,298,631
Pro forma net loss attributable to common stockholders of Oncobiologics, Inc.	$ (47,393,283)
Denominator:	
Weighted-average common shares outstanding	9,753,616
Effect of pro forma adjustments:	
Exchange of Series A and Series B redeemable preferred stock	2,193,599
Exchange of Parilis Preferred Units	226,663
Conversion of Series A Preferred Stock liquidation value	1,969,818
Shares used in computing unaudited pro forma weighted-average basic and diluted common shares outstanding	14,143,696
Unaudited pro forma basic and diluted net loss per common share	$ (3.35)

Recent accounting pronouncements

In April 2015, the Financial Accounting Standards Board (‘‘FASB’’) issued Accounting Standards Updates (‘‘ASU’’) 2015-03, *Interest — Imputation of Interest* (Subtopic 835-30). The update requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction from the debt liability rather than as an asset. The guidance is effective for fiscal years beginning after December 15, 2015. The Company early adopted this guidance for all periods presented.

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 believes its adoption will have no impact on its consolidated results of operations, financial position and 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.

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, 2014		
	(Level 1)	(Level 2)	(Level 3)
Liabilities			
Stock-based compensation liability	$ —	$ —	$ 1,557,789

Oncobiologics, Inc.
Notes to Consolidated Financial Statements

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

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, 2014 and 2015:

Balance at October 1, 2013	$ —
Issued	364,187
Change in fair value	1,193,602
Balance at September 30, 2014	1,557,789
Change in fair value	11,168,933
Balance at September 30, 2015	$ 12,726,722

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 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 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 are liability classified and re-measured at each reporting date with changes in fair value recorded within the Company's consolidated statements of operations.

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 $3.45 and $22.22 per PSU at September 30, 2014 and 2015, respectively, was derived using the following assumptions:

	September 30,	
	2014	2015
Risk-free interest rate	1.8%	1.4%
Derived service period	5 years	5 years
Expected volatility	60%	60%
Annual dividend yield	0%	0%
Fair value of common stock	$7.62 per share	$25.79 per share

Oncobiologics, Inc.
Notes to Consolidated Financial Statements

5. Property and Equipment

Property and equipment, net, consists of:

	September 30,	
	2014	2015
Laboratory equipment	$ 6,847,970	$ 10,936,364
Leasehold improvements	2,756,291	9,889,521
Computer software and hardware	224,150	402,075
Construction in process	—	175,425
	9,828,411	21,403,385
Less: accumulated depreciation and amortization	(1,818,847)	(3,643,447)
	$ 8,009,564	$ 17,759,938

Depreciation and amortization expense for the years ended September 30, 2014 and 2015 was $878,477 and $1,824,600, respectively.

At September 30, 2014 and 2015, $926,231 and $3,530,301, respectively, represents laboratory equipment under capital leases. The term of the leases are between 11 and 36 months and qualify as capital leases. The leases bear interest between 8.6% and 21.4%. At September 30, 2014 and 2015, $206,663 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, 2015:

2016	$ 1,087,192
2017	1,053,748
2018	295,010
	2,435,950
Less: amounts representing interest	(353,728)
Less: current portion	(862,849)
Capital lease obligations, excluding current portion	$ 1,219,373

6. Accrued Expenses

Accrued expenses consists of:

	September 30,	
	2014	2015
Compensation	$ 1,907,684	$ 2,321,508
Research and development	170,513	951,759
Interest payable	106,940	806,475
Deferred offering costs	—	657,892
Professional fees	131,668	594,572
Director fees	239,420	414,421
Other accrued expenses	4,054	178,021
	$ 2,560,279	$ 5,924,648

Oncobiologics, Inc.
Notes to Consolidated Financial Statements

7. Stockholder Notes

	September 30,	
	2014	2015
Series A repurchase notes	$ 3,014,534	$ 800,534
Parilis Series A repurchase notes	—	2,275,818
Restricted stock repurchase notes	1,097,750	1,097,750
Common stock repurchase note	2,812,500	2,812,500
Convertible note	—	2,000,000
Working capital notes	3,700,000	7,227,594
	10,624,784	16,214,196
Less current portion	(10,624,784)	(14,214,196)
Stockholder notes, excluding current portion	$ —	$ 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 bear interest at 4.0% and were originally due in June 2015. Pursuant to the terms of the notes, the interest rate increased to 6% as a result of nonpayment and are due on demand. During the years ended September 30, 2014, and 2015, $350,000 and $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 $2,050,000 during the year ended September 30, 2015.

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 year ended September 30, 2015, the Company made $486,000 in principal payments. The notes bear interest at 4.0% and, as of September 30, 2015, are due upon demand.

In June 2014, the Company repurchased shares of its restricted stock in exchange for $1,097,750 in notes payable. The notes bear interest at rates ranging from 0%-4% and are due on demand as of September 30, 2015.

In June 2014, the Company repurchased 960,144 shares of its common stock in exchange for a $3,312,500 note payable. The note does not bear interest and is due on demand. During the year ended September 30, 2014, the Company made $500,000 in principal payments.

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. The October note matures in December 2016 and is convertible at any time into shares of the Company's common stock at a conversion price of $20.70 per share. Upon issuance, the Company determined there was no beneficial conversion feature as the conversion price exceeded the estimated fair value of the underlying common stock to be issued upon conversion.

During the years ended September 30, 2014 and 2015, the Company borrowed $6,000,000 and $6,880,252, respectively, from stockholders for working capital purposes. During the years ended September 30, 2014 and 2015, the Company made principal payments of $2,625,000 and $3,352,658, respectively. The notes bear interest from 0% to 24% per annum with a weighted-average interest rate of 14.5%. Certain notes are secured by future revenue streams from existing licensing agreements. In addition, 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 as of September 30, 2015.

During the years ended September 30, 2014 and 2015, the Company recognized interest expense related to the stockholder notes of $541,914 and $1,869,113, respectively.

Oncobiologics, Inc.
Notes to Consolidated Financial Statements

8. Debt

	September 30,	
	2014	2015
Term loans-Bank	$ 3,935,574	$ 3,404,759
Equipment loans	528,876	334,093
Unamortized debt discount	(85,706)	(73,442)
	4,378,744	3,665,410
Less current portion	725,706	742,646
Long-term debt, excluding current portion	$ 3,653,038	$ 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 – 10 years. Minimum monthly payments of principal and interest under the terms of the loans are $62,654 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. 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 11%-18% with the original term of the loans ranging from 1-5 years. Minimum monthly payments of principal and interest under the equipment loans are $26,539 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, 2014 and 2015 was $276,496 and $287,280, respectively.

Future maturities of debt at September 30, 2015 are as follows:

2016	$ 742,646
2017	717,794
2018	637,479
2019	509,864
2020	523,062
Thereafter	608,007
	$ 3,738,852

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 which will require milestone payments of $375,000 (based on an exchange rate on September 30, 2015 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 May 2012, the Company entered into a lease agreement for its office and operating space which, as amended, has a term ending in June 2021. Rent expense under the leases was $581,464 and $720,875 for the years ended September 30, 2014 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. As part of the most recent amendment to the lease agreement in May 2014, the Company increased the amount of space to be leased and, accordingly, agreed to new monthly lease terms for the additional space.

Future minimum rental payments under noncancelable operating leases at September 30, 2015 are as follows:

2016	$ 888,710
2017	865,763
2018	865,763
2019	876,323
2020	887,045
Thereafter	643,749
	$ 5,027,353

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, 2014 and 2015, the expense relating to the matching contribution was $83,969 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.

Oncobiologics, Inc.
Notes to Consolidated Financial Statements

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any, subject to the preferential dividend rights of the Series A and Series B redeemable preferred stock (collectively, the "Redeemable Preferred Stock"). The Company may not pay dividends to common stockholders until all dividends accrued or declared but unpaid on the Redeemable Preferred Stock have been paid in full. No dividends had been declared through September 30, 2015.

Redeemable common stock

During the year ended September 30, 2014, the Company sold 1,159,420 and 579,710 shares of its common stock to an investor at $6.04 and $6.90 per share, respectively, and net of $105,000 in issuance costs. Pursuant to the terms of the purchase agreement, in the event that the Company sells its common stock any time prior to the Company engaging in a Qualified IPO or Qualified Liquidation Event, as defined, at a price below $6.04 per share and $6.90 per share for 1,159,420 and 579,710 shares sold, respectively, the investors are entitled to receive additional shares of common stock. In addition, if the Company fails to engage in a Qualified IPO or Qualified Liquidation Event prior to March 10, 2017, the investor shall have the right to require the Company to redeem any or all of the investor's common stock at a redemption price equal to $12.08 per share for 1,159,420 of its shares and $13.80 per share for 579,710 of its shares.

The Redeemable Common Stock is classified outside of stockholders' equity (deficit) because of the redemption right held by the investors.

Redeemable preferred stock

The Company has Redeemable Preferred Stock which is classified outside of stockholders' deficit because the shares contain redemption features that are not solely within the control of the Company.

Through December 2013, the Company sold 6,995 shares of Series A Participating Preferred Stock (Series A) and 3,600 shares of Series B Participating Preferred Stock (Series B). During the year ended September 30, 2014, the Company sold an additional 400 shares of Series B. In connection with the sale of Series B, the Company issued 1,119,565 shares of common stock. In addition to the rights and preferences described below for the Series A and Series B, the investors also received the right to receive an additional 289 shares of common stock for each share of Redeemable Preferred Stock upon redemption.

The total purchase of $10,995,000 was allocated on a relative fair value basis between redeemable preferred stock and the equity instruments resulting in $5,920,000 and $2,280,000 allocated to the initial carrying value of the Series A and Series B, respectively, with the balance allocated to common stock. Subsequently, the carrying value of the Series A and Series B are accreted up to their redemption value using the effective interest method.

Dividends

The holders of the Redeemable Preferred Stock are entitled to receive cumulative dividends at an annual rate of $100 per share. In the event the Company cannot satisfy its redemption obligation to the holders, the annual dividend will increase to $120 per share. Dividends accrue whether or not earned or declared, irrespective of the availability of profits. Dividends on redeemable preferred stock are payable upon redemption or upon liquidation.

Liquidation preference

In the event of a liquidation, dissolution or winding up of the Company, either voluntary or involuntary, or in the event of a Deemed Liquidation Event, as defined, holders of Series A are entitled to receive, in preference to all other stockholders, an amount equal to the Original Issue Price, as defined in the Certificate of Designation for the Series A, plus any unpaid accrued dividends. If upon the occurrence of such event, the assets and funds thus distributed among the holders of the Series A shall be insufficient to pay such holders, then the entire assets and funds of the Company legally available for distribution shall be distributed ratably among the holders of the Series A in proportion to the respective amount of such stock owned by each such holder. After payments have been made in full to the holders of Series A, then, to the extent available, holders of the Series B are entitled to participate in the distribution of the remaining assets, pro rata based on the number of shares by each holder.

Redemption

The holders of redeemable preferred stock have a right to require the Company to redeem all outstanding shares at a redemption price equal to the Original Issue Price plus unpaid accrued dividends. In addition, the holders of Redeemable Preferred Stock will receive 289 shares of common stock for each share of Redeemable Preferred Stock redeemed.

Voting rights

The holders of the Redeemable Preferred Stock have no voting rights outside of matters directly related to each series of Redeemable Preferred Stock. In addition, the holders of the Redeemable Preferred Stock, as a class, may elect 1 board member to represent its interest, respectively.

Repurchase transactions

In June 2014, the Company entered into a series of equity transactions in which it (1) repurchased 3,314 shares of the Series A, (2) repurchased 960,144 shares of common stock, and (3) settled accrued dividends on the Series A of $864,534.

The Series A repurchase price was $2,000 per share for a total of $6,628,000 of which $4,128,000 was paid in cash with the balance of $2,500,000 through the issuance of notes payable. The Company also issued $864,534 of notes payable for the accrued dividends. The Company recorded a deemed dividend of $3,336,855, which represents the total consideration paid of $7,492,534 in excess of carrying value of the Series A of $4,155,679.

In June 2014, the Company repurchased 960,144 shares of common stock and issued notes payable at a repurchase price of $3.45 per share.

In 2015, the Company purchased an additional 113 shares of Series A and cumulative dividends of $29,370 for $2,000 per share upon which the Company recorded a deemed dividend of $83,631, which represents the total consideration paid of $226,000 in excess of carrying value of the Series A of $142,370.

From October through December 2014, the Company repurchased 1,215 Parilis Preferred Units. The repurchase price was $2,000 per share plus unpaid dividends of $331,818 for a total of $2,761,818. The Company recorded a deemed dividend of $1,215,000, which represents the total consideration paid in excess of the carrying value of the redeemable noncontrolling interest of $1,546,818. Upon repurchase, the Company issued notes to the investors.

11. Stock-Based Compensation

The Company's 2011 Equity Compensation Plan (the "2011 Plan") provides for the Company to sell or issue restricted common stock, restricted stock units, performance-based awards, cash-based awards or to grant stock options for the purchase of common stock. The 2011 Plan is 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, which may be granted to officers, employees, consultants and directors of the Company.

As required by the 2011 Plan, the exercise price for stock options granted is not to be less than the fair value of common shares as determined by the Company as of the date of grant. The term of stock options may not be greater than ten years. Generally, stock options granted under the 2011 Plan vest 50% on the third anniversary from the grant date and 50% on the fourth anniversary. In the event of change in control, any outstanding option shall become fully vested and exercisable.

For restricted stock awards granted to employees, the fair value of the award is the current fair value of the Company's common stock on the grant date, while for non-employees, the fair value of the award is re-measured each reporting period using the then-current fair value of the Company's common stock until performance is complete. The restricted stock awards vest 50% on the third anniversary from the grant date and 50% on the fourth anniversary. In the event of change in control, any outstanding unvested share shall become fully vested.

Oncobiologics, Inc.
Notes to Consolidated Financial Statements

The Company recorded stock-based compensation expense in the following expense categories of its statements of operations for the years ended September 30, 2014 and 2015:

	September 30,	
	2014	2015
Research and development	$ 671,745	$ 5,817,830
General and administrative	3,286,735	5,360,028
	$ 3,958,480	$ 11,177,858

	September 30,	
	2014	2015
Equity-classified compensation	$ 2,764,878	$ 8,925
Liability-classified compensation	1,193,602	11,168,933
	$ 3,958,480	$ 11,177,858

In June 2014, the Company entered into agreements with certain employees and non-employees to exchange 31,304 stock options and 602,464 restricted stock awards for 711,430 PSUs. In addition, the Company repurchased 636,376 restricted stock awards in exchange for $1,097,750 of notes payable. Upon issuing the notes payable, the Company recognized the unamortized balance of stock-based compensation expense of $1,730,791.

The repurchase of restricted stock in exchange for notes payable was accounted for as a settlement which effectively accelerated vesting of any unvested awards, requiring the immediate recognition of any unrecognized compensation cost. The Company recorded incremental stock-based compensation expense of $792,601 to reflect this settlement. The exchange of restricted stock and stock options for PSUs was considered a modification with a change in classification from an equity classified award to a liability classified award due to the cash settlement feature of the PSUs. The liability related to the PSUs is re-measured at each reporting period until the PSUs are exercised or expire. Upon recording the initial stock-based compensation liability, the Company increased accumulated deficit $364,187, which represents the cumulative stock-based compensation expense recognized to date for the stock options and restricted stock exchanged into PSUs.

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 a cash payment for the difference between the current per share fair value of the Company's common stock and the base price of the PSU, which is $3.45 per PSU. Given the cash settlement, the PSUs are liability classified and re-measured at each reporting date with changes in fair value recorded within the Company's consolidated statements of operations. See note 4 for discussion of fair value of the PSUs.

The following table summarizes the PSU activity for the years ended September 30, 2014 and 2015:

Balance at October 1, 2013	—
Issued in exchange for restricted shares and stock options	711,430
Additional issuances	16,864
Forfeitures	(69,796)
Balance at September 30, 2014	658,498
Grants	39,988
Forfeitures	(11,473)
Balance at September 30, 2015	687,013

Restricted stock

The following table summarizes the activity related to restricted stock grants to employees and non-employees for the years ended September 30, 2014 and 2015:

	Employees	Non Employees	Weighted Average Grant Date Fair Value
Balance at October 1, 2013	657,681	555,217	$ 1.04
Granted	90,869	—	5.55
Vested	(29,565)	(2,898)	0.69
Exchange for PSUs	(573,478)	(28,986)	1.38
Repurchased for stockholder notes	(115,942)	(520,435)	1.35
Balance at September 30, 2014	29,565	2,898	0.69
Vested	(29,565)	(2,898)	0.69
Balance at September 30, 2015	—	—	$ —

At September 30, 2015, there was no unrecognized compensation cost related to non-vested restricted stock.

Of the 32,463 shares of restricted stock that vested during the year ended September 30, 2014, 2,831 shares were withheld by the Company for income tax withholdings. No shares were withheld by the Company for taxes on the restricted stock that vested during the year ended September 30, 2015.

Stock options

The Company has not granted stock options since December 2011 and there is no unrecognized compensation expense as of September 30, 2015.

The fair value of stock options granted was estimated using the Black-Scholes option pricing model. As a private company, the expected volatility is based on the historical volatility of a publicly traded set of peer companies. The expected term of the Company's stock options is determined utilizing the "simplified" method. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award.

The following table summarizes stock option activity for the year ended September 30, 2014:

	Number of Options	Weighted Average Exercise Price Per Share
Balance at October 1, 2013	31,304	$ 3.45
Exchange for PSUs	(31,304)	3.45
Balance at September 30, 2014	—	$ —

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 the years ended September 30, 2014 and 2015, the Company recognized $1,076,979 and $1,175,580, respectively, of deferred revenues. For the years ended September 30, 2014 and 2015, the Company received and recognized $6,500,000 and $2,000,000 in substantive milestone payments, respectively. As of September 30, 2014 and 2015, deferred revenue included in the Company's consolidated balance sheet related to the Huahai arrangement was $6,104,110 and $4,928,530, respectively.

IPCA agreements

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 recognized when payments are received and recorded as a reduction in research and development expense.

During the years ended September 30, 2014 and 2015, the Company recognized deferred revenues of $189,472 and $402,377, respectively. For each of the years ended September 30, 2014 and 2015, the Company received and recognized a $500,000 substantive milestone payment. As of September 30, 2014 and 2015, deferred revenue included in the Company's consolidated balance sheets was $994,739 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, 2014 and 2015, the Company recognized revenue of $750,000 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 $1,500,000 of upfront payments and $500,000 in non-substantive milestone payments and is eligible to receive up to $3,500,000 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 recognized when payments are received and recorded as a reduction in research and development expense.

During the years ended September 30, 2014 and 2015, the Company recognized deferred revenue of $34,091 and $341,280, respectively. As of September 30, 2014 and 2015, deferred revenue included in the Company's consolidated balance sheets was $715,909 and $1,624,629, respectively.

13. Related Party Transactions

During the years ended September 30, 2014 and 2015, the following related party transactions occurred:

- During the years ended September 30, 2014 and 2015, the Company provided $666,110 and $783,707 of non-interest bearing advances to the Company's founding stockholder and CEO, of which $550,000 and $395,257 was repaid, respectively. Additionally, the CEO has deferred a portion of his salary, bonus, and related benefits during the years ended September 30, 2014 and 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.
- In June 2014, the Company repurchased 115,942 shares of restricted stock from a director of the Company in exchange for $200,000 stockholder note at a zero interest rate due September 1, 2015. Terms of the grant and repurchase were the same as non-related parties. Refer to notes 7 and 10.

- During the years ended September 30, 2014 and 2015, 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 as of September 30, 2015. 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.

14. Income Taxes

Income tax expense (benefit) for the years ended September 30, 2014 and 2015 consists of the following:

	Year Ended September 30,	
	2014	2015
State tax, including sale of New Jersey losses and credits	$ (833,403)	(725,969)
Foreign tax provision	1,272,421	535,858
	$ 439,018	$ (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 years ended September 30, 2014 and 2015, the Company received $835,153 and $728,218, respectively, from the sale of New Jersey NOLs. In addition, the Company incurred $1.3 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, 2014 and 2015, respectively.

A reconciliation of income tax expense (benefit) at the statutory U.S. federal income tax rate and the Company’s effective tax rate is as follows:

	Year Ended September 30,	
	2014	2015
U.S. federal statutory rate	(34.0)%	(34.0)%
State taxes, net of federal benefit	(5.1)	(5.5)
Foreign withholding tax	9.6	1.1
Permanent differences	2.7	1.8
Foreign tax credits	(9.6)	(1.1)
Research and development credit	(11.7)	(6.9)
Change in valuation allowance	51.1	44.6
Other	0.3	(0.4)
Effective income tax rate	3.3%	(0.4)%

Oncobiologics, Inc.
Notes to Consolidated Financial Statements

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

	Year Ended September 30,	
	2014	2015
Current and long term deferred tax assets:		
Net operating loss carryforwards	$ 7,340,745	$ 20,164,392
Stock compensation	1,853,056	6,317,492
Deferred revenue	3,121,214	3,333,201
Research and development credit carryforward	2,680,441	5,979,964
Foreign tax credits	2,067,091	2,602,949
Accruals and others	1,040,117	1,072,422
Gross deferred tax assets	(18,102,664)	(39,470,420)
Less valuation allowance	(17,400,409)	(38,694,795)
	702,255	775,625
Deferred tax liability:		
Fixed assets	(702,255)	(775,625)
Net deferred tax assets	$ —	$ —

As of September 30, 2015, the Company has approximately $52.9 million and $36.9 million of Federal and New Jersey net operating losses that will begin to expire in 2030 and 2032, respectively. As of September 30, 2015, the Company also had federal and state research and development tax credit carryforwards of $4.2 million and $1.7 million, respectively, which begin to expire in 2021. As of September 30, 2015, the Company had Federal foreign tax credit carryforwards of $2.6 million available to reduce future tax liabilities, which will begin to expire at various dates 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, 2014 and 2015.

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. As of September 30, 2014 and 2015, the Company does not have any significant uncertain tax positions. The Company's income tax returns for the years from 2011 through 2014 remain open for examination by the Internal Revenue Service as well as various states and municipalities.

The Company does not recognize tax benefits that are not more-likely-than-not to be supported based upon the technical merits of the tax position taken. A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	Year Ended September 30,	
	2014	2015
Balance at beginning of year	$ 479,490	$ 1,564,411
Additions based on tax positions related to the current year	1,084,921	190,218
Balance at end of year	$ 1,564,411	$ 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.

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

The Company has evaluated subsequent events from the balance sheet date through the date at which the consolidated financial statements were available to be issued, and determined there are no other items requiring disclosure.

Oncobiologics, Inc.
Consolidated Balance Sheets
(unaudited)

	September 30, 2015	December 31, 2015	Pro Forma December 31, 2015
Assets			
Current assets:			
Cash	$ 9,070,975	$ 5,582,255	$ 10,806,901
Accounts receivable	20,000	103,090	103,090
Stock subscription receivable	4,280,149	2,749,997	—
Related party receivable	—	639,173	639,173
Prepaid and other current assets	1,793,109	1,651,036	1,651,036
Total current assets	15,164,233	10,725,551	13,200,200
Property and equipment, net	17,759,938	17,504,020	17,504,020
Restricted cash	213,663	213,663	213,663
Deferred offering costs	960,563	1,974,844	1,974,844
Other assets	910,224	904,791	904,791
Total assets	$ 35,008,621	$ 31,322,869	$ 33,797,518
Liabilities, redeemable preferred stock, common stock, noncontrolling interests and stockholders' equity (deficit)			
Current liabilities:			
Current portion of debt	$ 742,646	$ 751,190	$ 751,190
Current portion of capital lease obligations	862,849	864,902	864,902
Current portion of stockholder notes	14,214,196	10,140,813	10,140,813
Accounts payable	11,563,055	11,667,512	11,616,992
Accrued expenses	5,924,648	8,604,917	8,604,917
Income taxes payable	1,754,629	1,804,629	1,804,629
Deferred revenue	1,979,576	1,979,576	1,979,576
Total current liabilities	37,041,599	35,813,539	35,763,019
Long-term debt	2,922,764	2,737,227	2,737,227
Capital lease obligations	1,219,373	994,668	994,668
Stockholder notes	2,000,000	—	—
Deferred revenue	6,365,945	5,871,051	5,871,051
Stock-based compensation liability	12,726,722	—	—
Other liabilities	284,710	454,988	454,988
Total liabilities	62,561,113	45,871,473	45,820,953
Redeemable preferred stock, common stock and noncontrolling interests:			
Redeemable preferred stock, no par value:			
Series A – 8,000 shares authorized; 3,568 issued and outstanding at September 30, 2015; No shares authorized, issued or outstanding at December 31, 2015	5,072,653	—	—
Series B – 4,000 shares authorized, issued and outstanding at September 30, 2015; No shares authorized, issued or outstanding at December 31, 2015	5,118,208	—	—
Redeemable common stock – 1,739,130 shares issued and outstanding at September 30, 2015 and December 31, 2015 actual	15,426,673	16,366,212	—
Redeemable noncontrolling interests	1,703,777	—	—
Total redeemable preferred stock, common stock and noncontrolling interests	27,321,311	16,366,212	—
Stockholders' equity (deficit):			
Series A preferred stock, par value $0.01 per share: 10,0000,000 shares authorized, 11,819 shares issued and outstanding at December 31, 2015 (liquidation prefence of $11,819,000 at December 31, 2015)	—	118	—
Common stock, par value $0.01 per share; 100,000,000 shares authorized at December 31, 2015; 12,339,877 shares issued and outstanding at December 31, 2015 actual and 16,136,112 shares issued and outstanding pro forma	—	123,399	161,361
Common stock, no par value; 100,000,000 shares authorized at September 30, 2015; 9,436,294 shares issued and outstanding at September 30, 2015; no shares authorized issued or outstanding at December 31, 2015	39,844,900	—	—
Additional paid-in capital	—	79,890,165	98,743,702
Accumulated deficit	(94,064,286)	(110,928,498)	(110,928,498)
Total Oncobiologics, Inc. stockholders' equity (deficit)	(54,219,386)	(30,914,816)	(12,023,435)
Non controlling interests	(654,417)	—	—
Total stockholders' equity (deficit)	(54,873,803)	(30,914,816)	(12,023,435)
Total liabilities, redeemable preferred stock, common stock, noncontrolling interests and stockholders' equity (deficit)	$ 35,008,621	$ 31,322,869	$ 33,797,518

See accompanying notes to unaudited interim consolidated financial statements

Oncobiologics, Inc.
Consolidated Statements of Operations
(unaudited)

	Three Months Ended December 31,	
	2014	2015
Collaboration revenues	$ 2,934,555	$ 994,894
Operating expenses:		
Research and development	5,840,030	12,733,976
General and administrative	1,237,839	4,674,155
	7,077,869	17,408,131
Loss from operations	(4,143,314)	(16,413,237)
Interest expense	357,580	398,975
Loss before income taxes	(4,500,894)	(16,812,212)
Income tax expense	406,363	52,000
Net loss	(4,907,257)	(16,864,212)
Accretion of redeemable preferred stock and noncontrolling interests	(1,071,164)	(939,539)
Deemed dividends upon the repurchase of Series A redeemable preferred stock and redeemable noncontrolling interests	(1,230,998)	—
Net loss attributable to common stockholders of Oncobiologics, Inc.	$ (7,209,419)	$ (17,803,751)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.77)	$ (1.36)
Weighted-average shares outstanding, basic and diluted	9,377,450	13,061,557
Pro forma net loss per share of common stock – basic and diluted		$ (1.12)
Pro forma weighted-average shares outstanding		15,031,375

See accompanying notes to unaudited interim consolidated financial statements

Oncobiologics, Inc.
Consolidated Statements of Redeemable Preferred Stock, Common Stock, Noncontrolling Interests and Stockholders' Equity (Deficit)
For the Three Months Ended December 31, 2015
(unaudited)

	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, 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 witholdings 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 preferred and 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	—	—	—	—	—	—	—	—	—	486,101	4,861	14,063,826	—	—	14,068,687
Reclassification of stock-based compensation liability	—	—	—	—	—	—	—	—	—	—	—	15,118,584	—	—	15,118,584
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	98,172	—	—	98,172
Accretion of redeemable common stock	—	—	—	—	—	939,539	—	—	—	—	—	(939,539)	—	—	(939,539)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(16,864,212)	—	(16,864,212)
Balance at December 31, 2015	—	$ —	—	$ —	1,739,130	$16,366,212	$ —	11,819	$ 118	12,339,877	$ 123,399	$79,890,165	$(110,928,498)	$ —	$ (30,914,816)

See accompanying notes to unaudited interim consolidated financial statements

Oncobiologics, Inc.
Consolidated Statements of Cash Flows
(unaudited)

	Three Months Ended December 31,	
	2014	2015
Operating activities:		
Net loss	$ (4,907,257)	$ (16,864,212)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	222,075	593,977
Non-cash interest expense	2,117	3,065
Stock-based compensation	145,674	2,490,034
Changes in operating assets and liabilities:		
Accounts receivable	(2,501,360)	(83,090)
Prepaid expenses and other current assets	(702,599)	142,073
Other assets	—	5,433
Accounts payable	1,594,145	(233,942)
Accrued expenses	239,224	2,203,188
Income taxes payable	226,113	50,000
Deferred revenue	2,015,445	(494,894)
Other liabilities	—	176,087
Net cash used in operating activities	(3,666,423)	(12,012,281)
Investing activities:		
Purchase of property and equipment	(527,877)	(364,242)
Net cash used in investing activities	(527,877)	(364,242)
Financing activities:		
Repurchase of Series A redeemable preferred stock	(50,001)	—
Proceeds from the sale of common stock	—	11,318,690
Proceeds from subscriptions receivable	—	4,280,149
Proceeds from future stock issuance	—	50,520
Payments of capital leases obligations	(88,984)	(222,652)
Repayment of debt	(189,938)	(180,058)
Proceeds from stockholder notes	4,000,000	—
Repayment of stockholder notes	—	(6,073,383)
Change in restricted cash	(550)	—
Proceeds from related party receivable	—	187,388
Deconsolidation of Sonnet Biotherapeutics, Inc.	—	(401,091)
Payment of employee tax witholdings related to the vesting of restricted stock	—	(71,760)
Net cash provided by financing activities	3,670,527	8,887,803
Net decrease in cash	(523,773)	(3,488,720)
Cash at beginning of period	2,349,313	9,070,975
Cash at end of period	$ 1,825,540	$ 5,582,255
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 265,078	$ 496,296
Cash paid for taxes	$ 250	$ 2,000
Supplemental schedule of noncash investing activities:		
Purchases of property and equipment in accounts payable and accrued expenses	$ (402,050)	$ (200,780)
Supplemental schedule of noncash financing activities:		
Accretion of redeemable preferred stock, common stock and noncontrolling interests	$ 1,071,164	$ 939,539
Deemed dividend upon repurchase of Series A redeemable preferred stock in excess of carrying value	$ 1,230,998	$ —
Issuance of common stock 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)
Issuance of capital lease obligations in connection with purchase of property and equipment	$ 523,293	$ —
Issuance of notes payable upon repurchase of redeemable noncontrolling interests	$ 2,761,818	$ —
Issuance of subscription receivable upon sale of common stock	$ —	$ (2,749,997)
Deferred offering costs and common stock issuance costs in accounts payable and accrued expenses	$ —	$ (1,014,281)

See accompanying notes to unaudited interim consolidated financial statements

Oncobiologics, Inc.
Notes to Unaudited Interim Consolidated Financial Statements

1. Organization and Description of 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, two of which are expected to enter clinical trials in 2016.

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 preferred stock 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.

2. Liquidity

The Company has incurred substantial losses and negative cash flows from operations since its inception and has an accumulated deficit of $94.1 million and $110.9 million as of September 30, 2015 and December 31, 2015, respectively. In addition, the Company has $14.2 million and $10.1 million of indebtedness that is due on demand as of September 30, 2015 and December 31, 2015, respectively. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying unaudited interim consolidated financial statements have been prepared on a going concern basis, which contemplate the realization of assets and satisfaction of liabilities in the normal course of business. The unaudited interim 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 $10.1 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. 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.

3. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited interim consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("GAAP") for interim financial information. 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").

Oncobiologics, Inc.
Notes to Unaudited Interim Consolidated Financial Statements

In the opinion of management, the accompanying consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company's financial position as of December 31, 2015 and its results of operations and cash flows for the three months ended December 31, 2014 and 2015. Operating results for the three months ended December 31, 2015 are not necessarily indicative of the results that may be expected for the year ending September 30, 2016. The interim financial statements, presented herein, do not contain the required disclosures under GAAP for annual financial statements. The accompanying unaudited interim financial statements should be read in conjunction with the annual audited financial statements and related notes as of and for the year ended September 30, 2015.

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.

Unaudited pro forma balance sheet

The unaudited pro forma consolidated balance sheet as of December 31, 2015 assumes the following:

- The issuance of 87,287 shares of common stock in January 2016 for a purchase price of $29.05 per share for approximately $2.5 million net proceeds.
- Cash proceeds of approximately $2.7 million received subsequent to December 31, 2015 related to stock issued in December 2015.
- The conversion of 11,819 shares of Series A preferred stock into 1,969,818 shares of common stock.
- The reclassification of 1,739,130 shares of redeemable common stock upon lapse of a contractual redemption right.

Use of estimates

The preparation of the unaudited interim 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 unaudited interim 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 unaudited interim consolidated financial statements in the period they are determined to be necessary.

Income taxes

For the three months ended December 31, 2014 and 2015, the Company recorded tax expense of $406,363 and $52,000, respectively, which is attributable to the foreign withholding taxes in connection with the Company's collaboration and licensing agreements.

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 outstanding during the period. For all periods presented, the outstanding shares of 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.

Oncobiologics, Inc.
Notes to Unaudited Interim Consolidated Financial Statements

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding as of December 31, 2014 and 2015, as they would be antidilutive:

	December 31,	
	2014	2015
Series A redeemable preferred stock	1,059,710	—
Series B redeemable preferred stock	1,159,418	—
Series A preferred stock	—	1,969,818
Performance share units	—	249,510
Restricted stock units	—	1,066,193
Unvested shares of restricted common stock	32,463	—
Convertible stockholder note	96,618	96,618

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

The unaudited pro forma net loss per common share is computed using the weighted-average number of common shares outstanding and assumes the issuance of 1,969,818 shares of common stock upon settlement of the Series A liquidation value of $11,819,000 assuming the initial public offering price of $6.00 per share of common stock included in the units sold in this offering. The pro forma weighted-average shares outstanding of 15,031,375 was used to compute the pro forma net loss per common share.

The following table summarizes the calculation of unaudited pro forma basic and diluted net loss per common share:

Numerator:	
Net loss applicable to common stockholders of Oncobiologics, Inc.	$ (17,803,751)
Effect of pro forma adjustments:	
Accretion of redeemable common stock	939,539
Pro forma net loss attributable to common stockholders of Oncobiologics, Inc.	$ (16,864,212)
Denominator:	
Weighted-average common shares outstanding	13,061,557
Conversion of Series A preferred stock liquidation value	1,969,818
Shares used in computing unaudited pro forma weighted-average basic and diluted common shares outstanding	15,031,375
Unaudited pro forma basic and diluted net loss per common share	$ (1.12)

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.

Oncobiologics, Inc.
Notes to Unaudited Interim Consolidated Financial Statements

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

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 three months ended December 31, 2015:

Balance at October 1, 2015	$ 12,726,722
Change in fair value	2,391,862
Reclassification to stockholders' equity	(15,118,584)
Balance at December 31, 2015	$ —

As of December 31, 2015, the Company has no assets or liabilities that were measured at fair value.

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 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 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 and $25.70 per PSU at September 30, 2015 and December 31, 2015, respectively, was derived using the following assumptions:

	September 30, 2015	December 31, 2015
Risk-free interest rate	1.4%	1.2%
Derived service period	5 years	3 years
Expected volatility	60%	55%
Annual dividend yield	0%	0%
Fair value of common stock	$25.79 per share	$29.05 per share

Oncobiologics, Inc.
Notes to Unaudited Interim Consolidated Financial Statements

5. Property and Equipment

Property and equipment, net, consists of:

	September 30, 2015	December 31, 2015
Laboratory equipment	$ 10,936,364	$ 10,841,019
Leasehold improvements	9,889,521	9,927,614
Computer software and hardware	402,075	419,684
Construction in process	175,425	484,985
	21,403,385	21,673,302
Less: accumulated depreciation and amortization	(3,643,447)	(4,169,282)
	$ 17,759,938	$ 17,504,020

Depreciation and amortization expense for the three months ended December 31, 2014 and 2015 was $222,075 and $593,977, respectively.

At September 30, 2015 and December 31, 2015, $3,530,301 represents laboratory equipment under capital leases. The term of the leases are between 11 and 36 months and qualify as capital leases. The leases bear interest between 8.6% and 21.4%. At September 30, 2015 and December 31, 2015, $407,210 and $538,308, respectively, of accumulated depreciation related to this leased equipment has been recognized.

6. Accrued Expenses

Accrued expenses consists of:

	September 30, 2015	December 31, 2015
Compensation	$ 2,321,508	$ 2,535,850
Research and development	951,759	2,342,960
Interest payable	806,475	671,532
Deferred offering costs	657,892	1,434,973
Professional fees	594,572	938,426
Director fees	414,421	464,422
Other accrued expenses	178,021	216,754
	$ 5,924,648	$ 8,604,917

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

Common stock

During the three months ended December 31, 2015, the Company sold 486,101 shares of its common stock at $29.05 per share raising $14,068,687 in net proceeds, of which $2,749,997 was received in January 2016.

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders. 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 December 31, 2015.

Oncobiologics, Inc.
Notes to Unaudited Interim Consolidated Financial Statements

Series A preferred stock

In the event of a liquidation, dissolution or winding up of the Company, either voluntary or involuntary, or in the event of a Deemed Liquidation Event, as defined, holders of Series A preferred stock ("Series A") are entitled to receive, in preference to all other stockholders, an amount equal to the original issue price, as defined in the Articles of Incorporation for the Series A, plus any unpaid accrued dividends. If upon the occurrence of such event, the assets and funds thus distributed among the holders of the Series A shall be insufficient to pay such holders, then the entire assets and funds of the Company legally available for distribution shall be distributed ratably among the holders of the Series A in proportion to the respective amount of such stock owned by each such holder.

The Company may redeem the Series A, in whole at any time and from time to time in part, at the option of the Company, for cash, at a redemption price equal to the Original Issuance Price plus any unpaid accrued dividends. The holders of the Series A have no voting rights outside of matters directly related to Series A preferred stock. Immediately prior to the closing of an initial public offering, any outstanding shares of Series A will automatically convert into shares of common stock at a conversion price equal to the initial public offering price per share and divided by the liquidation values of the Series A.

Deconsolidation of noncontrolling interests

Through September 30, 2015, the Company consolidated the operations of Sonnet Biotherapeutics, Inc. ("Sonnet"), which was spun-off to the Company's stockholders in April 2015, since 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 a $826,561 promissory note which reflects the funding the Company provided Sonnet through September 30, 2015. The note bears interest at 3.0% and matures September 30, 2016. There were no gains or losses recognized upon deconsolidation since no equity interest was owned by the Company.

8. Stock-Based Compensation

2011 Equity Incentive Plan

The Company's 2011 Equity Compensation Plan (the "2011 Plan") provides 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. The 2011 Plan is 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, which may be granted to officers, employees, consultants and directors of the Company. As of December 31, 2015, performance-based stock units ("PSUs") representing 249,510 shares of the Company's common stock were outstanding under the 2011 Plan. Upon the adoption of the 2015 Equity Incentive Plan, no future awards under the 2011 Plan will be issued.

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 employees, directors and consultants. The maximum number of shares of common stock that may be issued under the 2015 Plan is 1,246,377 shares. As of December 31, 2015, RSUs representing 1,066,193 shares of the Company's common stock were outstanding under the 2015 Plan and 180,184 shares remained available for grant under the 2015 Plan.

Oncobiologics, Inc.
Notes to Unaudited Interim Consolidated Financial Statements

The Company recorded stock-based compensation expense in the following expense categories of its statements of operations for the three months ended December 31, 2014 and 2015:

	December 31,	
	2014	2015
Research and development	$ 84,275	$ 1,356,408
General and administrative	61,399	1,133,626
	$ 145,674	$ 2,490,034

	December 31,	
	2014	2015
Equity-classified compensation	$ 2,231	$ 98,172
Liability-classified compensation	143,443	2,391,862
	$ 145,674	$ 2,490,034

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 three months ended December 31, 2015:

	Number of PSUs	Base Price Per PSU
Balance at October 1, 2015	687,013	$ 3.45
Forfeitures	(2,723)	3.45
Exchanged for restricted stock units	(434,780)	3.45
Balance at December 31, 2015	249,510	$ 6.35

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 restricted stock units ("RSUs"). The Company accounted for the exchange as a modification, and, as a result, recognized $98,172 of additional stock-based compensation during the three months ended December 31, 2015 based on the fair value of the RSUs in excess of the fair value of the PSUs exchanged.

As of December 31, 2015, there was $1,100,000 of unamortized expense that will be recognized in future periods.

Oncobiologics, Inc.
Notes to Unaudited Interim Consolidated Financial Statements

Restricted stock units

The following table summarizes the activity related to RSUs granted during the three months ended December 31, 2015:

	Number of RSUs	Grant Date Fair Value
Balance at October 1, 2015	—	$ —
Granted	674,890	29.05
Issued in connection with PSU exchange	391,303	29.05
Balance at December 31, 2015	1,066,193	$ 29.05

As of December 31, 2015, there were 388,022 RSUs that will vest upon the closing of the Company's IPO or a change in control. The remaining 678,171 RSUs will vest upon an IPO or change in control and over the following time-based vesting periods:

- 525,999 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
- 130,434 RSUs with 50% vesting on each of the third and fourth anniversaries of the recipient's hire date

The closing of an IPO or a change in control are performance conditions that are outside the Company's control. Therefore, the Company will not recognize any stock-based compensation for the RSUs until the performance conditions have been achieved. As of December 31, 2015, there was $21,100,000 of unamortized expense.

5,833,334 Units

PRELIMINARY PROSPECTUS

Jefferies **Barclays**

Cantor Fitzgerald & Co.

, 2016

Until , 2016 (25 days after the date of this prospectus), all dealers that buy, sell or trade our securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to their unsold allotments or subscriptions.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the costs and expenses, other than the underwriting discounts and commissions, payable by the registrant in connection with the sale of our securities being registered. All amounts are estimates except for the Securities and Exchange Commission, or SEC, registration fee, the Financial Industry Regulatory Authority, or FINRA, filing fee and the NASDAQ Global Market, or NASDAQ, listing fee.

Item	Amount to be paid
SEC registration fee	$ 9,153
FINRA filing fee	14,135
NASDAQ listing fee	125,000
Printing and engraving expenses	65,000
Legal fees and expenses	1,700,000
Accounting fees and expenses	800,000
Transfer agent fees and expenses	4,000
Miscellaneous expenses	82,712
Total	$ 2,800,000

Item 14. Indemnification of Directors and Officers.

As permitted by Section 102 of the Delaware General Corporation Law, we have adopted provisions in our amended and restated certificate of incorporation and amended and restated bylaws that limit or eliminate the personal liability of our directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, directors exercise an informed business judgment based on all material information reasonably available to them. Consequently, a director will not be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any act related to unlawful stock repurchases, redemptions or other distributions or payment of dividends; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not affect the availability of equitable remedies such as injunctive relief or rescission. Our amended and restated certificate of incorporation also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws provide that:

- we may indemnify our directors, officers and employees to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions;
- we may advance expenses to our directors, officers and employees in connection with a legal proceeding to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions; and
- the rights provided in our bylaws are not exclusive.

Our certificate of incorporation, attached as Exhibit 3.1, and our bylaws, attached as Exhibit 3.3, and the amended and restated certificate of incorporation and bylaws that will be in effect upon completion of this offering and which are filed as Exhibits 3.4 and 3.5, provide for the indemnification provisions described above and elsewhere herein. We have entered into separate indemnification agreements with our directors and officers that may be broader than the specific indemnification provisions contained in the Delaware General Corporation Law. These indemnification agreements generally require us, among other things, to indemnify our officers and directors against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct. These indemnification agreements also generally require us to advance any expenses incurred by the directors or officers as a result of any

proceeding against them as to which they could be indemnified. In addition, we have purchased a policy of directors' and officers' liability insurance that insures our directors and officers against the cost of defense, settlement or payment of a judgment in some circumstances. These indemnification provisions and the indemnification agreements may be sufficiently broad to permit indemnification of our officers and directors for liabilities, including reimbursement of expenses incurred, arising under the Securities Act of 1933, as amended, or the Securities Act.

We have entered into indemnification agreement with our directors and executive officers, in addition to the indemnification provided for in our amended and restated certificate of incorporation and amended and restated bylaws, and intend to enter into indemnification agreements with any new directors and executive officers in the future.

We have purchased and currently intend to maintain insurance on behalf of each and every person who is or was a director or officer of our company against any loss arising from any claim asserted against him or her and incurred by him or her in any such capacity, subject to certain exclusions.

The form of Underwriting Agreement, attached as Exhibit 1.1 hereto, provides for indemnification by the underwriters of us and our officers who sign this Registration Statement and directors for specified liabilities, including matters arising under the Securities Act.

Item 15. Recent Sales of Unregistered Securities.

The following list sets forth information as to all securities we have sold since the preceding three years up to the date of this document, which were not registered under the Securities Act.

(a) In 2013, we issued a total of 1,700 shares of our Series B redeemable preferred stock to one institutional investor and two individual investors for a purchase price of $1,000 per share, or $1,700,000 in the aggregate. Each share of Series B redeemable preferred stock converted into shares of our common stock and Series A preferred stock in October 2015 in connection with our reincorporation in Delaware.

(b) From March 2013 to May 2013, we issued a total of 605 shares of our Series A redeemable preferred stock to five individual investors for a purchase price of $1,000 per share, or $605,000 in the aggregate. Each share of Series A redeemable preferred stock converted into shares of our common stock and Series A preferred stock in October 2015 in connection with our reincorporation in Delaware.

(c) Between July 2013 and November 2013, we issued 159,420 shares of common stock to two individuals for services provided in connection with sales of redeemable preferred stock. All of these shares of common stock converted into shares of our common stock in October 2015 in connection with our reincorporation in Delaware.

(d) In March 2014 we sold an aggregate of 1,159,420 shares of our common stock to an institutional investor at a purchase price of $6.04 per share, or $7,000,000. In June 2014, we sold an additional 579,710 shares of our common stock to this investor at a purchase price of $6.90 per share, or $4,000,000. All of these shares of common stock converted into shares of our common stock in October 2015 in connection with our reincorporation in Delaware.

(e) From June 2014 through November 13, 2015, we issued 711,430 performance stock units, or PSUs, in exchange for shares of restricted stock and stock options granted prior to June 2014, and approximately 56,869 additional PSUs during the years ended September 30, 2014 and 2015, all of which were granted under our 2011 Equity Incentive Plan. Of the shares of restricted stock included in the exchange, 96,666 shares of restricted stock were granted subsequent to November 2012.

(f) In June, July and September 2015, we sold an aggregate of 1,765,511 shares of our common stock to nine institutional investors for a purchase price of $25.79 per share or approximately $45.5 million in the aggregate. Citigroup Global Markets, Inc. and Jefferies LLC, each a registered broker-dealer and member of Financial Industry Regulation Authority, Inc., served as placement agents in this offering. The placement agents earned an aggregate of $1.4 million in commissions with respect to this offering.

(g) In October 2015, in connection with our reincorporation in Delaware, we issued 2,193,601 shares of our common stock and 10,193 shares of our Series A preferred stock in exchange for all then outstanding shares of common stock, Series A redeemable preferred stock and Series B redeemable preferred stock.

(h) In October 2015, we issued 226,663 shares of our common stock and 1,626 shares of our Series A preferred stock in exchange for all outstanding Series A and Series A Hybrid Units of our former subsidiary Parilis Biopharmaceuticals LLC.

(i) In December 2015, we issued 1,066,193 restricted stock unit awards under our 2015 Equity Incentive Plan.

(j) In December 2015 and January 2016, we sold an aggregate of 573,388 shares of our common stock to 19 accredited investors for a purchase price of $29.05 per share or approximately $16.6 million in the aggregate. Jefferies LLC, Arclight Advisors LLC and Alere Financial Partners (a division of Cova Capital Partners, LLC), each a registered broker-dealer and member of Financial Industry Regulation Authority, Inc., served as placement agents in this offering. The placement agents earned an aggregate of approximately $62,500 in commissions with respect to this offering.

(k) In April 2016, we issued 30,421 restricted stock unit awards under our 2015 Equity Incentive Plan.

(l) In April 2016, we entered into an amendment of that certain investors' rights agreement dated March 10, 2014, as amended, and agreed, under certain circumstances, to issue certain of the accredited investors upon the closing of this offering three-year warrants to purchase an aggregate of 1,520,284 shares of our common stock.

We claimed exemption from registration under the Securities Act for the sale and issuance of securities in the transactions described in paragraphs (a)-(d), (f)-(h), (j) and (l) by virtue of Section 3(a)(9), 4(a)(2) and/or Regulation D promulgated thereunder as transactions not involving any public offering. All of the purchasers of unregistered securities for which we relied on Section 4(a)(2) and/or Regulation D represented that they were accredited investors as defined under the Securities Act. We claimed such exemption on the basis that (a) the purchasers in each case represented that they intended to acquire the securities for investment only and not with a view to the distribution thereof and that they either received adequate information about the registrant or had access, through employment or other relationships, to such information and (b) appropriate legends were affixed to the stock certificates issued in such transactions.

We claimed exemption from registration under the Securities Act for the sales and issuances of securities in the transactions described in paragraphs (e), (i) and (k) above under Section 4(a)(2) of the Securities Act in that such sales and issuances did not involve a public offering or under Rule 701 promulgated under the Securities Act, in that they were offered and sold either pursuant to written compensatory plans or pursuant to a written contract relating to compensation, as provided by Rule 701.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits. See the Exhibit Index attached to this Registration Statement, which is incorporated by reference herein.

(b) Financial Statement Schedules. Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings.

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) to include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be

reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424 (§230.424 of this chapter);

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(5) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.

(6) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this Amendment No. 5 to the Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in Cranbury, New Jersey, on May 11, 2016.

ONCOBIOLOGICS, INC.

By: /s/ Pankaj Mohan
Pankaj Mohan, Ph.D.
Chairman, President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this Amendment No. 5 to the Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Pankaj Mohan Pankaj Mohan, Ph.D.	Chairman, President and Chief Executive Officer *(Principal Executive Officer)*	May 11, 2016
/s/ Lawrence A. Kenyon Lawrence A. Kenyon	Chief Financial Officer *(Principal Accounting and Financial Officer)*	May 11, 2016
* Todd C. Brady, M.D., Ph.D.	Director	May 11, 2016
* Scott Canute	Director	May 11, 2016
* Albert D. Dyrness	Director	May 11, 2016
* Donald J. Griffith	Director	May 11, 2016
* Kurt J. Hilzinger	Director	May 11, 2016
* Robin Smith Hoke	Director	May 11, 2016

*By: /s/ Pankaj Mohan
Pankaj Mohan, Ph.D.
Attorney-in-fact

EXHIBIT INDEX

Exhibit Number	Description
1.1	Form of Underwriting Agreement.
3.1*	Certificate of Incorporation of Oncobiologics, Inc., as presently in effect.
3.2*	Certificate of Amendment of Certificate of Incorporation, dated April 26, 2016.
3.3*	Bylaws of Oncobiologics, Inc., as presently in effect.
3.4*	Form of Amended and Restated Certificate of Incorporation of Oncobiologics, Inc., to be in effect upon the closing of this offering.
3.5*	Form of Amended and Restated Bylaws of Oncobiologics, Inc., to be in effect upon the closing of this offering.
4.1	Form of Unit Certificate.
4.2	Form of Series A warrant Certificate (included in Exhibit 4.4).
4.3	Form of Series B warrant Certificate (included in Exhibit 4.4).
4.4	Form of Warrant Agreement between Oncobiologics, Inc. and American Stock Transfer & Trust Company LLC, as Warrant Agent.
5.1	Opinion of Cooley LLP.
10.1	Investors' Rights Agreement by and among Oncobiologics, Inc. and certain of its stockholders, dated March 10, 2014, as amended.
10.2*	2011 Stock Incentive Plan.
10.3*	2015 Equity Incentive Plan.
10.4*	Forms of agreements and award grant notices for 2015 Equity Incentive Plan.
10.5*	2016 Employee Stock Purchase Plan.
10.6*	Employment Agreement between Oncobiologics, Inc. and Pankaj Mohan, Ph.D., dated January 1, 2011.
10.7*	Offer Letter between Oncobiologics, Inc. and Lawrence A. Kenyon, dated September 3, 2015.
10.8*	Offer Letter between Oncobiologics, Inc. and Elizabeth A. Yamashita, dated March 27, 2014.
10.9*	Offer Letter between Oncobiologics, Inc. and Kenneth Bahrt, M.D., dated June 14, 2015.
10.10*	Letter between Oncobiologics, Inc. and Todd Brady, dated September 12, 2014.
10.11*	Letter between Oncobiologics, Inc. and Scott Canute, dated October 10, 2011.
10.12*	Form of Indemnity Agreement, by and between Oncobiologics, Inc. and each of its directors and executive officers.
10.13†*	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.
10.14†*	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.
10.15†*	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.
10.16†*	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.
10.17*	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.
10.18*	Lease Agreement by and between Oncobiologics, Inc. and Cedar Brook 7 Corporate Center, LP, dated as of March 18, 2011.
10.19*	First Amendment to Lease Agreement by and between Oncobiologics, Inc. and Cedar Brook 7 Corporate Center, LP, dated as of December 2013.
10.20*	Second Amendment to Lease Agreement by and between Oncobiologics, Inc. and Cedar Brook 7 Corporate Center, LP, dated as of July 18, 2014.
10.21*	Third Amendment to Lease Agreement by and between Oncobiologics, Inc. and Cedar Brook 7 Corporate Center, LP, dated as of January 16, 2015.
10.22*	Fourth Amendment to Lease Agreement by and between Oncobiologics, Inc. and Cedar Brook 7 Corporate Center, LP, dated as of February 9, 2015.

Exhibit Number	Description
10.23*	Fifth Amendment to Lease Agreement by and between Oncobiologics, Inc. and Cedar Brook 7 Corporate Center, LP, dated as of September 26, 2015.
10.24*	Lease Agreement by and between Cedar Brook East Corporate Center, LP and Oncobiologics, Inc., dated as of August 31, 2015.
10.25*	Employment Agreement between Oncobiologics, Inc. and Pankaj Mohan, Ph.D., dated February 22, 2016, to be in effect upon closing of this offering.
10.26*	Employment Agreement between Oncobiologics, Inc. and Kenneth Bahrt, M.D., dated February 22, 2016, to be in effect upon closing of this offering.
10.27*	Employment Agreement between Oncobiologics, Inc. and Elizabeth A. Yamashita, dated February 24, 2016, to be in effect upon closing of this offering.
10.28*	Employment Agreement between Oncobiologics, Inc. and Lawrence A. Kenyon, dated February 18, 2016, to be in effect upon closing of this offering.
10.29*	Form of Amended and Restated Performance Stock Unit Agreement for 2011 Stock Incentive Plan.
10.30	Form of Warrant to Purchase Common Stock.
23.1	Consent of independent registered public accounting firm.
23.2	Consent of Cooley LLP (included in Exhibit 5.1).
24.1*	Power of Attorney (included on signature page to the original filing of the registration statement).

† 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.

* Previously filed.

Exhibit 1.1

Oncobiologics, Inc.

[_____] Units [1]

Each Unit Consisting of
One Share of Common Stock ($0.01 par value),
One Half of a Series A Warrant to purchase One Share of Common Stock
and
One Half of a Series B Warrant to purchase One Share of Common Stock

Underwriting Agreement

New York, New York
[____], 2016

Jefferies LLC
Barclays Capital Inc.
As Representatives of the several Underwriters,
c/o Jefferies LLC
520 Madison Avenue
New York, New York 10022

c/o Barclays Capital Inc.
745 Seventh Avenue
New York, New York 10019

Ladies and Gentlemen:

Oncobiologics, Inc., a corporation organized under the laws of Delaware (the "Company"), proposes to sell to the several underwriters named in Schedule I hereto (the "Underwriters"), for whom you (the "Representatives") are acting as representatives, an aggregate of [•] units (the "Underwritten Securities"), each Underwritten Security consisting of (i) one share of common stock, $0.01 par value per share ("Common Stock"), of the Company (the "Underwritten Shares"), (ii) one half of a Series A warrant to purchase one share of Common Stock (the "Underwritten Series A Warrants") and (iii) one half of a Series B warrant to purchase one share of Common Stock (the "Underwritten Series B Warrants" and together with the Underwritten Series A Warrants, the "Firm Warrants"). In addition, the Company proposes to grant to the Underwriters the option to purchase from the Company up to an additional [•] units (the "Option Securities"), each Option Security consisting of (i) one share of Common Stock (the "Option Shares"), (ii) one half of a Series A warrant to purchase one share of Common Stock (the "Option Series A Warrants") and (iii) one half of a Series B warrant to purchase one share of Common Stock (the "Option Series B Warrants" and together with the Option Series A Warrants, the "Option Warrants"), to cover over-allotments, if any. The Common Stock issuable upon exercise of the Underwritten Warrants and Option Warrants are collectively referred to as the "Warrant Shares." The Underwritten Securities and the Option Securities and, where applicable, the Warrant Shares, are hereinafter collectively sometimes referred to as the "Securities." The Underwritten Shares and the Option Shares are hereinafter collectively sometimes referred to as the "Shares," and the Firm Warrants and the Option Warrants are hereinafter collectively sometimes referred to as the "Warrants." To the extent there are no additional Underwriters listed on Schedule I other than you, the term Representatives as used herein shall mean you, as Underwriters, and the terms Representatives and Underwriters shall mean either the singular or plural as the context requires. Certain terms used herein are defined in Section 20 hereof. The offering and sale of the Securities contemplated by this Agreement is referred to herein as the "Offering."

As part of the offering contemplated by this Agreement, Jefferies LLC has agreed to reserve out of the Securities set forth opposite its name on the Schedule II to this Agreement, up to [____] Underwritten Securities [2], for sale to the Company's employees, officers, and directors and other parties associated with the Company (collectively, "Participants"), as set forth in the Prospectus under

[1] Plus an option to purchase from the Company, up to [_____] units to cover over-allotments , if any.

[2] 5% of the Underwritten Securities (excluding the Option Securities that may be issued upon the Underwriters' exercise of their over-allotment option)

the heading “Underwriting” (the “Directed Unit Program”). The Securities to be sold by Jefferies LLC pursuant to the Directed Unit Program (the “Directed Units ”) will be sold by Jefferies LLC pursuant to this Agreement at the public offering price. Any Directed Units not orally confirmed for purchase by any Participants by 7:30 A.M. New York City time on the business day following the date on which this Agreement is executed will be offered to the public by Jefferies LLC as set forth in the Prospectus.

1. Representations and Warranties. The Company represents and warrants to, and agrees with, each Underwriter as set forth below in this Section 1.

(a) The Company has prepared and filed with the Commission a registration statement (file number 333-209011) on Form S-1, including a related preliminary prospectus, for registration under the Act of the offering and sale of the Securities. Such Registration Statement, including any amendments thereto filed prior to the Execution Time, has become effective. The Company may have filed one or more amendments thereto, including a related preliminary prospectus, each of which has previously been furnished to you. The Company will file with the Commission a final prospectus in accordance with Rule 424(b). As filed, such final prospectus shall contain all information required by the Act and the rules thereunder and, except to the extent the Representatives shall agree in writing to a modification, shall be in all substantive respects in the form furnished to you prior to the Execution Time or, to the extent not completed at the Execution Time, shall contain only such specific additional information and other changes (beyond that contained in the latest Preliminary Prospectus) as the Company has advised you, prior to the Execution Time, will be included or made therein.

(b) On the Effective Date, the Registration Statement did, and when the Prospectus is first filed in accordance with Rule 424(b) and on the Closing Date (as defined herein) and on any date on which Option Securities are purchased, if such date is not the Closing Date (a “settlement date”), the Prospectus (and any supplement thereto) will, comply in all material respects with the applicable requirements of the Act and the rules thereunder; on the Effective Date and at the Execution Time, the Registration Statement did not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein not misleading; and on the date of any filing pursuant to Rule 424(b) and on the Closing Date and any settlement date, the Prospectus (together with any supplement thereto) will not include any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided, however, that the Company makes no representations or warranties as to the information contained in or omitted from the Registration Statement, or the Prospectus (or any supplement thereto) in reliance upon and in conformity with information furnished in writing to the Company by or on behalf of any Underwriter through the Representatives specifically for inclusion in the Registration Statement or the Prospectus (or any supplement thereto), it being understood and agreed that the only such information furnished by any Underwriter consists of the information described as such in Section 8 hereof.

(c) (i) The Disclosure Package and the price to the public, the number of Underwritten Securities and the number of Option Securities to be included on the cover page of the Prospectus, when taken together as a whole, (ii) each electronic road show, when taken together as a whole with the Disclosure Package and the price to the public, the number of Underwritten Securities and the number of Option Securities to be included on the cover page of the Prospectus, and (iii) any individual Written Testing-the-Waters Communication, when taken together as a whole with the Disclosure Package and the price to the public, the number of Underwritten Securities and the number of Option Securities to be included on the cover page of the Prospectus, does not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The preceding sentence does not apply to statements in or omissions from the Disclosure Package based upon and in conformity with written information furnished to the Company by any Underwriter through the Representatives specifically for use therein, it being understood and agreed that the only such information furnished by or on behalf of any Underwriter consists of the information described as such in Section 8 hereof.

(d) (i) At the time of filing the Registration Statement and (ii) as of the Execution Time (with such date being used as the determination date for purposes of this clause (ii)), the Company was not and is not an Ineligible Issuer (as defined in Rule 405), without taking account of any determination by the Commission pursuant to Rule 405 that it is not necessary that the Company be considered an Ineligible Issuer.

(e) From the time of initial confidential submission of the Registration Statement to the Commission (or, if earlier, the first date on which the Company engaged directly or through any Person authorized to act on its behalf in any Testing-the-Waters Communication) through the Execution Time, the Company has been and is an “emerging growth company,” as defined in Section 2(a) of the Act (an “Emerging Growth Company”). Testing-the-Waters Communication” means any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the Act.

(f) The Company (i) has not alone engaged in any Testing-the-Waters Communication other than Testing-the-Waters Communications with the consent of the Representatives with entities that are qualified institutional buyers within the meaning of Rule 144A under the Act or institutions that are accredited investors within the meaning of Rule 501 under the Act and (ii) has not authorized anyone other than the Representatives to engage in Testing-the-Waters Communications. The Company reconfirms that the Representatives have been authorized to act on its behalf in undertaking Testing-the-Waters Communications. The Company has not distributed any Written Testing-the-Waters Communications other than those listed on Schedule III hereto. "Written Testing-the-Waters Communication" means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the Act.

(g) Each Issuer Free Writing Prospectus does not include any information that conflicts with the information contained in the Registration Statement. The foregoing

sentence does not apply to statements in or omissions from any Issuer Free Writing Prospectus based upon and in conformity with written information furnished to the Company by any Underwriter through the Representatives specifically for use therein, it being understood and agreed that the only such information furnished by or on behalf of any Underwriter consists of the information described as such in Section 8 hereof.

(h) Each of the Company and its Subsidiaries has been duly incorporated and is validly existing as a corporation in good standing under the laws of the jurisdiction in which it is chartered or organized with full corporate power and authority to own or lease, as the case may be, and to operate its properties and conduct its business as described in the Disclosure Package and the Prospectus, and is duly qualified to do business as a foreign corporation and is in good standing under the laws of each jurisdiction which requires such qualification, except where the failure to qualify would not reasonably expected to have a Material Adverse Effect.

(i) The Units have been duly and validly authorized and, when issued and delivered against payment therefor as provided herein, will constitute legal, valid and binding obligations of the Company, enforceable in accordance with their terms except as the enforceability thereof may be limited by bankruptcy, insolvency, reorganization, receivership, liquidation, fraudulent conveyance, moratorium or other similar laws affecting the enforcement of creditors' rights generally and by general equitable principles; the Shares to be combined with Warrants to form the Units to be issued and sold by the Company to the Underwriters hereunder have been duly and validly authorized and, when issued and delivered against payment therefor as provided herein, will be duly and validly issued, fully paid and nonassessable and free of statutory and contractual preemptive rights, resale rights, rights of first refusal and similar rights; the Warrants have been duly and validly authorized and, when executed, issued and delivered against payment therefor as provided herein and in the Warrants, will constitute legal, valid and binding obligations of the Company, enforceable in accordance with their terms except as the enforceability thereof may be limited by bankruptcy, insolvency, reorganization, receivership, liquidation, fraudulent conveyance, moratorium or other similar laws affecting the enforcement of creditors' rights generally and by general equitable principles; the Warrant Shares have been duly and validly authorized and validly reserved for issuance upon exercise of the Warrants in a number sufficient to meet the current exercise requirements; upon exercise of the Warrants in accordance with their terms, the Warrant Shares issuable thereupon will be duly and validly issued, fully paid and non-assessable and free of statutory and contractual preemptive rights, resale rights, rights of first refusal and similar rights. All the outstanding shares of capital stock of each Subsidiary have been duly and validly authorized and issued and are fully paid and nonassessable, and except as otherwise set forth in the Disclosure Package and the Prospectus, all outstanding shares of capital stock of the Subsidiaries are owned by the Company either directly or through wholly owned Subsidiaries free and clear of any perfected security interest or any other security interests, claims, liens or encumbrances.

(j) There is no franchise, contract or other document of a character required to be described in the Registration Statement or Prospectus, or to be filed as an exhibit thereto, which is not described or filed as required (and the Preliminary Prospectus contains in all material respects the same description of the foregoing matters contained in the Prospectus); and the statements in the Preliminary Prospectus and the Prospectus under the headings "Business — Intellectual Property," "Business— Regulatory" and "Material U.S. Federal Income Tax Considerations for Non-U.S. Holders," insofar as such statements summarize legal matters, agreements, documents or proceedings discussed therein, are accurate and fair summaries of such legal matters, agreements, documents or proceedings.

(k) This Agreement has been duly authorized, executed and delivered by the Company.

(l) The Company is not and, after giving effect to the offering and sale of the Securities and the application of the proceeds thereof as described in the Disclosure Package and the Prospectus, will not be an "investment company" as defined in the Investment Company Act of 1940, as amended.

(m) No consent, approval, authorization, filing with or order of any court or governmental agency or body is required in connection with the transactions contemplated herein, except (i) such as have been obtained under the Act; (ii) such as are required by the listing rules of the NASDAQ Global Market; (iii) such as are required by the applicable rules of the Financial Industry Regulatory Authority ("FINRA"); and (iv) such as may be required under the blue sky laws of any jurisdiction in connection with

the purchase and distribution of the Securities by the Underwriters in the manner contemplated herein and in the Disclosure Package and the Prospectus.

(n) Neither the issue and sale of the Securities nor the consummation of any other of the transactions herein contemplated nor the fulfillment of the terms hereof will conflict with, result in a breach or violation of, or imposition of any lien, charge or encumbrance upon any property or assets of the Company or any of its Subsidiaries pursuant to, (i) the charter or by-laws of the Company or any of its Subsidiaries; (ii) the terms of any indenture, contract, lease, mortgage, deed of trust, note agreement, loan agreement or other agreement, obligation, condition, covenant or instrument to which the Company or any of its Subsidiaries is a party or bound or to which its or their property is subject; or (iii) any statute, law, rule, regulation, judgment, order or decree applicable to the Company or any of its Subsidiaries of any court, regulatory body, administrative agency, governmental body, arbitrator or other authority having jurisdiction over the Company or any of its Subsidiaries or any of its or their properties, except in the cases of clauses (ii) and (iii) for such conflict, breach, violation or imposition as would not reasonably be expected to have a Material Adverse Effect.

(o) No holders of securities of the Company have rights to the registration of such securities under the Registration Statement, except to the extent such registration rights have been waived in connection with the offering of the securities.

(p) The consolidated historical financial statements and schedules of the Company and its consolidated subsidiaries included in the Preliminary Prospectus, the Prospectus and the Registration Statement present fairly the financial condition, results of operations and cash flows of the Company as of the dates and for the periods indicated, comply as to form, in all material respects, with the applicable accounting requirements of the Act and have been prepared in conformity with generally accepted accounting principles applied on a consistent basis throughout the periods involved (except as otherwise noted therein). The selected financial data set forth under the caption “Selected Financial Data” in the Preliminary Prospectus, the Prospectus and Registration Statement fairly present, in all material respects, on the basis stated in the Preliminary Prospectus, the Prospectus and the Registration Statement, the information included therein.

(q) No action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its Subsidiaries or its or their property is pending or, to the knowledge of the Company, threatened that would reasonably be expected to have a Material Adverse Effect, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any supplement thereto).

(r) Each of the Company and each of its Subsidiaries owns or leases all such properties as are necessary to the conduct of its operations as presently conducted, except for intellectual property which is separately addressed in subsection (mm) below and except as would not reasonably be expected to have a Material Adverse Effect.

(s) Neither the Company nor any Subsidiary is in violation or default of (i) any provision of its charter or bylaws; (ii) the terms of any indenture, contract, lease, mortgage, deed of trust, note agreement, loan agreement or other agreement, obligation, condition, covenant or instrument to which it is a party or bound or to which its property is subject; or (iii) any statute, law, rule, regulation, judgment, order or decree of any court, regulatory body, administrative agency, governmental body, arbitrator or other authority having jurisdiction over the Company or such Subsidiary or any of its properties, as applicable, except in the case of clauses (ii) and (iii), for such violation or default as would not reasonably be expected to have a Material Adverse Effect.

(t) KPMG LLP, who have certified certain financial statements of the Company and its consolidated subsidiaries and delivered their report with respect to the audited consolidated financial statements and schedules included in the Disclosure Package and the Prospectus, are independent public accountants with respect to the Company within the meaning of the Act and the applicable published rules and regulations thereunder.

(u) There are no transfer taxes or other similar fees or charges under Federal law or the laws of any state, or any political subdivision thereof, required to be paid in connection with the execution and delivery of this Agreement or the issuance by the Company or sale by the Company of the Securities.

(v) The Company has filed all tax returns that are required to be filed or has requested extensions thereof (except in any case in which the failure so to file would not reasonably be expected to have a Material Adverse Effect, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any supplement thereto)) and has paid all taxes required to be paid by it and any other assessment, fine or penalty levied against it, to the extent that any of the foregoing is due and payable, except for any such assessment, fine or penalty that is currently being contested in good faith or as would not reasonably be expected to have a Material Adverse Effect, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any supplement thereto).

(w) No labor problem or dispute with the employees of the Company or any of its Subsidiaries exists or, to the knowledge of the Company, is threatened or imminent, and the Company is not aware of any existing or imminent labor disturbance by the employees of any of its or its Subsidiaries' principal suppliers, contractors or customers, that would reasonably be expected to have a Material Adverse Effect, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any supplement thereto).

(x) The Company and each of its Subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as the Company reasonably believes are prudent and customary in the businesses in which they are engaged; all policies of insurance and fidelity or surety bonds insuring the Company or any of its Subsidiaries or their respective businesses, assets, employees, officers and directors are in full force and effect; the Company and its Subsidiaries are in

compliance with the terms of such policies and instruments in all material respects; and there are no claims by the Company or any of its Subsidiaries under any such policy or instrument as to which any insurance company is denying liability or defending under a reservation of rights clause; neither the Company nor any such Subsidiary has been refused any insurance coverage sought or applied for; and neither the Company nor any such Subsidiary has a reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not reasonably be expected to have a Material Adverse Effect, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any supplement thereto).

(y) No Subsidiary of the Company is currently prohibited, directly or indirectly, from paying any dividends to the Company, from making any other distribution on such Subsidiary's capital stock, from repaying to the Company any loans or advances to such Subsidiary from the Company or from transferring any of such Subsidiary's property or assets to the Company or any other Subsidiary of the Company, except as described in or contemplated by the Disclosure Package and the Prospectus (exclusive of any supplement thereto).

(z) The Company and its Subsidiaries possess all material licenses, certificates, permits and other authorizations required to be issued by all applicable authorities necessary to conduct their respective businesses, and neither the Company nor any such Subsidiary has received any notice of proceedings relating to the revocation or modification of any such certificate, authorization or permit which, singly or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would reasonably be expected to have a Material Adverse Effect, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any supplement thereto).

(aa) The Company and each of its Subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company and its Subsidiaries' internal controls over financial reporting are effective at the reasonable assurance level and the Company and its Subsidiaries are not aware of any material weakness in their internal controls over financial reporting (it being understood that, as of the date hereof, the Company is not required to comply with Section 404 of the Sarbanes-Oxley Act (as defined below)).

(bb) The Company and its Subsidiaries maintain "disclosure controls and procedures" (as such term is defined in Rule 13a-15(e) under the Exchange Act); and such disclosure controls and procedures are effective at the reasonable assurance level.

(cc) The Company has not taken, directly or indirectly, without giving effect to activities by the Underwriters, any action designed to or that would constitute or that would reasonably be expected to cause or result in, under the Exchange Act or otherwise, stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities.

(dd) The Company and its Subsidiaries are (i) in compliance with any and all applicable foreign, federal, state and local laws and regulations relating to the protection of human health and safety, the environment or hazardous or toxic substances or wastes, pollutants or contaminants ("Environmental Laws"); (ii) have received and are in compliance with all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses; and (iii) have not received notice of any actual or potential liability under any environmental law, except where such non-compliance with Environmental Laws, failure to receive and hold required permits, licenses or other approvals, or liability would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any supplement thereto). Except as set forth in the Disclosure Package and the Prospectus, neither the Company nor any of its Subsidiaries has been named as a "potentially responsible party" under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended.

(ee) In the ordinary course of its business, the Company periodically reviews the effect of Environmental Laws on the business, operations and properties of the Company and its Subsidiaries, in the course of which it identifies and evaluates associated costs and liabilities (including, without limitation, any capital or operating expenditures required for clean-up, closure of properties or compliance with Environmental Laws, or any permit, license or approval, any related constraints on operating activities and any potential liabilities to third parties). On the basis of such review, the Company has reasonably concluded that such associated costs and liabilities would not, singly or in the aggregate, reasonably be expected to have a Material Adverse Effect, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any supplement thereto).

(ff) None of the following events has occurred or exists: (i) a failure to fulfill the obligations, if any, under the minimum funding standards of Section 302 of the United States Employee Retirement Income Security Act of 1974, as amended ("ERISA"), and the regulations and published interpretations thereunder with respect to a Plan, determined without regard to any waiver of such obligations or extension of any amortization period; (ii) an audit or investigation by the Internal Revenue Service, the U.S. Department of Labor, the Pension Benefit Guaranty Corporation or any other federal or state governmental agency or any foreign regulatory agency with respect to the employment or compensation of employees by any of the Company or any of its Subsidiaries that would reasonably be expected to have a Material Adverse Effect; (iii) any breach of any contractual obligation, or any violation of law or applicable qualification standards, with respect to the employment or compensation of employees by the Company or any of its Subsidiaries that would reasonably be expected to have a

Material Adverse Effect. None of the following events has occurred or is reasonably likely to occur: (i) a material increase in the aggregate amount of contributions required to be made to all Plans in the current fiscal year of the Company and its Subsidiaries compared to the amount of such contributions made in the most recently completed fiscal year of the Company and its Subsidiaries; (ii) a material increase in the "accumulated post-retirement benefit obligations" (within the meaning of Statement of Financial Accounting Standards 106) of the Company and its Subsidiaries compared to the amount of such obligations in the most recently completed fiscal year of the Company and its Subsidiaries; (iii) any event or condition giving rise to a liability under Title IV of ERISA that would reasonably be expected to have a Material Adverse Effect; or (iv) the filing of a claim by one or more employees or former employees of the Company or any of its Subsidiaries related to their employment that would reasonably be expected to have a Material Adverse Effect. For purposes of this paragraph, the term "Plan" means a plan (within the meaning of Section 3(3) of ERISA) subject to Title IV of ERISA with respect to which the Company or any of its Subsidiaries may have any liability.

(gg) There is and has been no failure on the part of the Company and any of the Company's directors or officers, in their capacities as such, to comply with any provision of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated in connection therewith (the "Sarbanes-Oxley Act") that are in effect and with which the Company is required to comply as of the effectiveness of the Registration Statement, including Section 402 relating to loans and Sections 302 and 906 relating to certifications.

(hh) Neither the Company nor any of its Subsidiaries nor, to the knowledge of the Company, any director, officer, agent, employee or affiliate of the Company or any of its Subsidiaries is aware of or has taken any action, directly or indirectly, that would result in a violation or a sanction for violation by such persons of the Foreign Corrupt Practices Act of 1977 or the U.K. Bribery Act 2010, each as may be amended, or similar law of any other relevant jurisdiction, or the rules or regulations thereunder; and the Company and its Subsidiaries have instituted and maintain policies and procedures to ensure compliance therewith. No part of the proceeds of the offering will be used, directly or indirectly, in violation of the Foreign Corrupt Practices Act of 1977 or the U.K. Bribery Act 2010, each as may be amended, or similar law of any other relevant jurisdiction, or the rules or regulations thereunder.

(ii) The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements and the money laundering statutes and the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "Money Laundering Laws") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its Subsidiaries with respect to the Money Laundering Laws is pending or, to the best knowledge of the Company, threatened.

(jj) Neither the Company nor any of its Subsidiaries nor, to the knowledge of the Company, any director, officer, agent, employee or affiliate of the Company or any of its Subsidiaries (i) is, or is controlled or 50% or more owned by or is acting on behalf of, an individual or entity that is currently subject to any sanctions administered or enforced by the United States (including any administered or enforced by the Office of Foreign Assets Control of the U.S. Treasury Department, the U.S. Department of State, or the Bureau of Industry and Security of the U.S. Department of Commerce), the United Nations Security Council, the European Union, the United Kingdom (including sanctions administered or enforced by Her Majesty's Treasury) or other relevant sanctions authority (collectively, "Sanctions" and such persons, "Sanctioned Persons"); (ii) is located, organized or resident in a country or territory that is, or whose government is, the subject of Sanctions that broadly prohibit dealings with that country or territory (collectively, "Sanctioned Countries" and each, a "Sanctioned Country"); or (iii) will, directly or indirectly, use the proceeds of this offering, or lend, contribute or otherwise make available such proceeds to any Subsidiary, joint venture partner or other individual or entity in any manner that would result in a violation of any Sanctions by, or would result in the imposition of Sanctions against, any individual or entity (including any individual or entity participating in the offering, whether as underwriter, advisor, investor or otherwise).

(kk) Except as has been disclosed to the Underwriters or is not material to the analysis under any Sanctions, neither the Company nor any of its Subsidiaries have engaged in any dealings or transactions with or for the benefit of a Sanctioned Person, or with or in a Sanctioned Country, in the preceding three years, nor does the Company or any of its Subsidiaries have any plans to increase its dealings or transactions with or for the benefit of Sanctioned Persons, or with or in Sanctioned Countries.

(ll) The subsidiaries listed on Annex A attached hereto are the only significant subsidiaries of the Company as defined by Rule 1-02 of Regulation S-X (the "Subsidiaries").

(mm) The Company and its Subsidiaries own, possess, license or have other rights to use, on reasonable terms, all patents, patent applications, trade and service marks, trade and service mark registrations, trade names, copyrights, licenses, inventions, trade secrets, technology, know-how and other intellectual property (collectively, the "Intellectual Property") necessary for the conduct of the Company's business as now conducted or as proposed in the Disclosure Package and Prospectus to be conducted and (i) to the Company's knowledge, there are no rights of third parties to any such Intellectual Property; (ii) to the Company's knowledge, there is no material infringement by third parties of any such Intellectual Property; (iii) there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others challenging the Company's rights in or to any such Intellectual Property; (iv) there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others challenging the validity or scope of any such Intellectual Property; (v) there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others that the Company infringes or otherwise violates any patent, trademark, copyright, trade secret or other proprietary rights of others; (vi) to the Company's knowledge, there is no

U.S. patent or published U.S. patent application which contains claims that dominate or may dominate any Intellectual Property described in the Disclosure Package and the Prospectus as being owned by or licensed to the Company or that interferes with the issued or pending claims of any such Intellectual Property; and (vii) there is no prior art of which the Company is aware that may render any U.S. patent held by the Company invalid or any U.S. patent application held by the Company unpatentable which has not been disclosed to the U.S. Patent and Trademark Office.

(nn) Except as disclosed in the Registration Statement, the Disclosure Package and the Prospectus, the Company (i) does not have any material lending or other relationship with any bank or lending affiliate of any of the Underwriters and (ii) does not intend to use any of the proceeds from the sale of the Securities hereunder to repay any outstanding debt owed to any affiliate of any of the Underwriters.

(oo) Except as described in the Registration Statement, the Disclosure Package and the Prospectus, as applicable, the Company and its Subsidiaries (i) are and at all times have been in compliance in all material respects with all statutes, rules and regulations applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, advertising, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product manufactured or distributed by the Company including, without limitation, the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §301 et seq.), the federal Anti-Kickback Statute (42 U.S.C. §1320a-7b(b)), the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. §1320d et seq.), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (42 U.S.C. §17921 et seq.), and the Patient Protection and Affordable Care Act of 2010 (Pub. Law 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. Law 111-152), the regulations promulgated pursuant to such laws, and any successor government programs and comparable state laws, regulations relating to Good Clinical Practice and Good Laboratory Practice and all other local, state, federal, national, supranational and foreign laws, manual provisions, policies and administrative guidance relating to the regulation of the Company (collectively, the "Applicable Laws"); (ii) have not received any written notice from any court or arbitrator or governmental or regulatory authority or third party alleging or asserting noncompliance with any Applicable Laws or any licenses, exemptions, certificates, approvals, clearances, authorizations, permits, registrations and supplements or amendments thereto required by any such Applicable Laws ("Authorizations"), except for such non-compliance as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect; (iii) possess all Authorizations and such Authorizations are valid and in full force and effect and are not in violation of any term of any such Authorizations, except where the absence of any such Authorization would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect; (iv) have not received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation arbitration or other action from any court or arbitrator or governmental or regulatory authority or third party alleging that any product operation or activity is in violation of any Applicable Laws or Authorizations nor, to the Company's knowledge, has any such claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action threatened; (v) have not received

written notice that any court or arbitrator or governmental or regulatory authority has taken, is taking or intends to take, action to limit, suspend, materially modify or revoke any Authorizations nor, to the Company's knowledge, has any such limitation, suspension, modification or revocation threatened; (vi) have filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and accurate on the date filed in all material respects (or were corrected or supplemented by a subsequent submission), except where the failure to so file, obtain, maintain or submit or the failure of such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments to be complete or accurate or corrected or supplemented by a subsequent submission, would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect; and (vii) are not a party to any corporate integrity agreements, monitoring agreements, consent decrees, settlement orders, or similar agreements with or imposed by any governmental or regulatory authority.

(pp) The nonclinical studies and clinical trials conducted by or on behalf of or sponsored by the Company or any of its Subsidiaries, or in which the Company or any of its Subsidiaries have participated, that are described in the Registration Statement, the Disclosure Package and the Prospectus or the results of which are referred to in the Registration Statement, the Disclosure Package and the Prospectus, as applicable, were and, if still pending, are being conducted in all material respects in accordance with standard medical and scientific research procedures and all applicable statutes, rules and regulations of the FDA and comparable drug regulatory agencies outside of the United States to which it is subject (collectively, the "Regulatory Authorities"), including, without limitation, 21 C.F.R. Parts 50, 54, 56, 58, and 312, and current Good Clinical Practice and Good Laboratory Practice; the descriptions in the Registration Statement, the Disclosure Package or the Prospectus of the results of such studies and trials are accurate and complete in all material respects and fairly present the data derived from such trials; the Company has no knowledge of any other trials the results of which are inconsistent with or otherwise call into question the results described or referred to in the Registration Statement, Disclosure Package and the Prospectus; the Company and its Subsidiaries have operated and are currently in compliance in all material respects with all applicable statutes, rules and regulations of the Regulatory Authorities; neither the Company nor any Subsidiary have received any written notices, correspondence or other communication from the Regulatory Authorities or any governmental authority requiring the termination or suspension of any nonclinical studies or clinical trials that are described in the Registration Statement, the Disclosure Package or the Prospectus or the results of which are referred to in the Registration Statement, Disclosure Package or the Prospectus, and to the Company's knowledge, there are no reasonable grounds for same.

(qq) The Company possesses all licenses, exemptions, certificates, approvals, clearances, permits, registrations and other authorizations and supplements or amendments thereto (collectively, "Permits") issued by, and has made all declarations and filings with, the applicable federal, state, local or foreign governmental or regulatory authorities that are necessary for the ownership or lease of its properties or the conduct of

its businesses as described in the Registration Statement, the Disclosure Package and the Prospectus, or to permit all nonclinical studies and clinical trials conducted by or on behalf of the Company, including, without limitation, all necessary FDA and applicable foreign regulatory agency Permits, except as would not be expected to have a Material Adverse Effect; the Company is not in violation of, or in default under, any such Permit; and the Company has not received written notice of any revocation or modification of any such Permit and does not have any reason to believe that any such Permit will not be renewed in the ordinary course. The Company (i) is, and at all times has been, in compliance in all material respects with all Applicable Laws and (ii) has not received any FDA Form 483, written notice of adverse finding, warning letter, untitled letter or other correspondence or written notice from any court or arbitrator or governmental or regulatory authority alleging or asserting non-compliance with (A) any Applicable Laws or (B) any Permits required by any such Applicable Laws.

(rr) To the Company's knowledge, the manufacturing facilities and operations of its suppliers are operated in compliance in all material respects with all applicable statutes, rules, regulations and policies of the Regulatory Authorities.

(ss) None of the Company's product candidates have received marketing approval from any Regulatory Authority.

Furthermore, the Company represents and warrants to each Underwriter that (i) the Registration Statement, the Prospectus, any preliminary prospectus and any Issuer Free Writing Prospectuses comply, and any further amendments or supplements thereto will comply, with any applicable laws or regulations of foreign jurisdictions in which the Prospectus or any preliminary prospectus and any Issuer Free Writing Prospectus, as amended or supplemented, if applicable, are distributed in connection with the Directed Unit Program, and that (ii) no authorization, approval, consent, license, order, registration or qualification of or with any government, governmental instrumentality or court, other than such as have been obtained, is necessary under the securities laws and regulations of foreign jurisdictions in which the Directed Units are offered outside the United States. The Company has not offered, or caused the Underwriters to offer, Securities to any person pursuant to the Directed Unit Program with the specific intent to unlawfully influence (i) a customer or supplier of the Company to alter the customer's or supplier's level or type of business with the Company, or (ii) a trade journalist or publication to write or publish favorable information about the Company or its products.

Any certificate signed by any officer of the Company and delivered to the Representatives or counsel for the Underwriters in connection with the offering of the Securities shall be deemed a representation and warranty by the Company, as to matters covered thereby, to each Underwriter.

2. Purchase and Sale.

(a) Subject to the terms and conditions and in reliance upon the representations and warranties herein set forth, the Company agrees to sell to each Underwriter, and each Underwriter agrees, severally and not jointly, to purchase from the

Company, at a purchase price of $[____] per unit , the amount of the Underwritten Securities set forth opposite such Underwriter's name in Schedule I hereto.

(b) Subject to the terms and conditions and in reliance upon the representations and warranties herein set forth, the Company hereby grants an option to the several Underwriters to purchase, severally and not jointly, up to [____] Option Securities at the same purchase price per share as the Underwriters shall pay for the Underwritten Securities. Said option may be exercised only to cover over-allotments in the sale of the Underwritten Securities by the Underwriters. Said option may be exercised in whole or in part at any time on or before the 30th day after the date of the Prospectus upon written notice by the Representatives to the Company setting forth the number of shares of the Option Securities as to which the several Underwriters are exercising the option and the settlement date. The number of Option Securities to be purchased by each Underwriter shall be the same percentage of the total number of shares of the Option Securities to be purchased by the several Underwriters as such Underwriter is purchasing of the Underwritten Securities, subject to such adjustments as you in your absolute discretion shall make to eliminate any fractional shares.

3. Delivery and Payment. Delivery of and payment for the Underwritten Securities and the Option Securities (if the option provided for in Section 2(b) hereof shall have been exercised on or before the third Business Day immediately preceding the Closing Date) shall be made at 10:00 AM, New York City time, on [_____ , 20__], or at such time on such later date not more than three Business Days after the foregoing date as the Representatives shall designate, which date and time may be postponed by agreement between the Representatives and the Company or as provided in Section 9 hereof (such date and time of delivery and payment for the Securities being herein called the "Closing Date"). Delivery of the Securities shall be made to the Representatives for the respective accounts of the several Underwriters against payment by the several Underwriters through the Representatives of the purchase price thereof to or upon the order of the Company by wire transfer payable in same-day funds to an account specified by the Company. Delivery of the Underwritten Securities and the Option Securities shall be made through the facilities of The Depository Trust Company unless the Representatives shall otherwise instruct.

If the option provided for in Section 2(b) hereof is exercised after the third Business Day immediately preceding the Closing Date, the Company will deliver the Option Securities (at the expense of the Company) to the Representatives, at 388 Greenwich Street, New York, New York 10013, on the date specified by the Representatives (which shall be within three Business Days after exercise of said option) for the respective accounts of the several Underwriters, against payment by the several Underwriters through the Representatives of the purchase price thereof to or upon the order of the Company by wire transfer payable in same-day funds to an account specified by the Company. If settlement for the Option Securities occurs after the Closing Date, the Company will deliver to the Representatives on the settlement date for the Option Securities, and the obligation of the Underwriters to purchase the Option Securities shall be conditioned upon receipt of, supplemental opinions, certificates and letters confirming as of such date the opinions, certificates and letters delivered on the Closing Date pursuant to Section 6 hereof.

4. Offering by Underwriters. It is understood that the several Underwriters propose to offer the Securities for sale to the public as set forth in the Prospectus.

5. Agreements. The Company agrees with the several Underwriters that:

(a) Prior to the termination of the offering of the Securities, the Company will not file any amendment of the Registration Statement or supplement to the Prospectus or any Rule 462(b) Registration Statement unless the Company has furnished you a copy for your review prior to filing and will not file any such proposed amendment or supplement to which you reasonably object. The Company will cause the Prospectus, properly completed, and any supplement thereto to be filed in a form approved by the Representatives with the Commission pursuant to the applicable paragraph of Rule 424(b) within the time period prescribed and will provide evidence satisfactory to the Representatives of such timely filing. The Company will promptly advise the Representatives (i) when the Prospectus, and any supplement thereto, shall have been filed (if required) with the Commission pursuant to Rule 424(b) or when any Rule 462(b) Registration Statement shall have been filed with the Commission; (ii) when, prior to termination of the offering of the Securities, any amendment to the Registration Statement shall have been filed or become effective; (iii) of any request by the Commission or its staff for any amendment of the Registration Statement, or any Rule 462(b) Registration Statement, or for any supplement to the Prospectus or for any additional information; (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or of any notice objecting to its use or the institution or threatening of any proceeding for that purpose; and (v) of the receipt by the Company of any notification with respect to the suspension of the qualification of the Securities for sale in any jurisdiction or the institution or threatening of any proceeding for such purpose. The Company will use its reasonable best efforts to prevent the issuance of any such stop order or the occurrence of any such suspension or objection to the use of the Registration Statement and, upon such issuance, occurrence or notice of objection, to obtain as soon as possible the withdrawal of such stop order or relief from such occurrence or objection, including, if necessary, by filing an amendment to the Registration Statement or a new registration statement and using its reasonable best efforts to have such amendment or new registration statement declared effective as soon as practicable.

(b) If, at any time prior to the filing of the Prospectus pursuant to Rule 424(b), any event occurs as a result of which the Disclosure Package would include any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein in the light of the circumstances under which they were made at such time not misleading, the Company will (i) notify promptly the Representatives so that any use of the Disclosure Package may cease until it is amended or supplemented; (ii) amend or supplement the Disclosure Package to correct such statement or omission; and (iii) supply any amendment or supplement to you in such quantities as you may reasonably request.

(c) If, at any time when a prospectus relating to the Securities is required to be delivered under the Act (including in circumstances where such requirement may be

satisfied pursuant to Rule 172), any event occurs as a result of which the Prospectus as then supplemented would include any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein in the light of the circumstances under which they were made or the circumstances then prevailing not misleading, or if it shall be necessary to amend the Registration Statement or supplement the Prospectus to comply with the Act or the rules thereunder, the Company promptly will (i) notify the Representatives of any such event; (ii) prepare and file with the Commission, subject to the second sentence of paragraph (a) of this Section 5, an amendment or supplement which will correct such statement or omission or effect such compliance; and (iii) supply any supplemented Prospectus to you in such quantities as you may reasonably request.

(d) As soon as practicable, the Company will make generally available to its security holders and to the Representatives an earnings statement or statements of the Company and its Subsidiaries which will satisfy the provisions of Section 11(a) of the Act and Rule 158.

(e) Upon request, the Company will furnish to the Representatives and counsel for the Underwriters, without charge, signed copies of the Registration Statement (including exhibits thereto) and to each other Underwriter a copy of the Registration Statement (without exhibits thereto) and, so long as delivery of a prospectus by an Underwriter or dealer may be required by the Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172), as many copies of each Preliminary Prospectus, the Prospectus and each Issuer Free Writing Prospectus and any supplement thereto as the Representatives may reasonably request. The Company will pay the expenses of printing or other production of all documents relating to the offering.

(f) The Company will use its reasonable best efforts to arrange, if necessary, for the qualification of the Securities for sale under the laws of such jurisdictions as the Representatives may reasonably designate and will use its reasonable best efforts to maintain such qualifications in effect so long as required for the distribution of the Securities; provided that in no event shall the Company be obligated to qualify to do business in any jurisdiction where it is not now so qualified or to take any action that would subject it to service of process in suits, other than those arising out of the offering or sale of the Securities, in any jurisdiction where it is not now so subject.

(g) The Company will not, without the prior written consent of the Representatives, offer, sell, contract to sell, pledge, or otherwise dispose of (or enter into any transaction which is designed to, or might reasonably be expected to, result in the disposition (whether by actual disposition or effective economic disposition due to cash settlement or otherwise) by the Company or any affiliate of the Company or any person in privity with the Company or any affiliate of the Company), directly or indirectly, including the filing (or participation in the filing) of a registration statement with the Commission in respect of, or establish or increase a put equivalent position or liquidate or decrease a call equivalent position within the meaning of Section 16 of the Exchange Act, any other shares of Common Stock or any securities convertible into, or exercisable, or exchangeable for, shares of Common Stock; or publicly announce an intention to effect

any such transaction, for a period of 180 days after the date of the Underwriting Agreement, provided, however, that the Company may (i) issue and sell Common Stock (or any securities convertible into, or exercisable or exchangeable for shares of Common Stock) pursuant to any employee stock option plan, incentive plan, stock ownership plan or dividend reinvestment plan of the Company in effect at the Execution Time, (ii) issue Common Stock issuable upon the conversion or exercise of securities outstanding at the Execution Time, (iii) file one or more registration statements on Form S-8, (iv) issue the Warrant Shares upon exercise of the Warrants, and (v) offer, issue and sell shares of Common Stock or any securities convertible into, or exercisable, or exchangeable for, Common Stock in connection with any merger, acquisition or strategic investment (including any joint venture, strategic alliance or partnership) as long as (x) the aggregate number of shares of Common Stock issued or issuable does not exceed 10% of the number of shares of Common Stock outstanding immediately after the issuance and sale of the Securities and (y) each recipient of any such Common Stock issued or issuable agrees to the restrictions on the resale of securities that are consistent with the lock-up letters described in Section 6(l) hereof for the remainder of the 180-day restricted period.

(h) If the Representatives, in their sole discretion, agree to release or waive the restrictions set forth in a lock-up letter described in Section 6(l) hereof for an officer or director of the Company and provides the Company with notice of the impending release or waiver at least three Business Days before the effective date of the release or waiver, the Company agrees to announce the impending release or waiver by a press release substantially in the form of Exhibit B hereto through a major news service at least two Business Days before the effective date of the release or waiver.

(i) The Company will not take, directly or indirectly, any action designed to or that would constitute or that might reasonably be expected to cause or result in, under the Exchange Act or otherwise, stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities.

(j) The Company agrees to pay the costs and expenses relating to the following matters: (i) the preparation, printing or reproduction and filing with the Commission of the Registration Statement (including financial statements and exhibits thereto), each Preliminary Prospectus, the Prospectus and each Issuer Free Writing Prospectus, and each amendment or supplement to any of them; (ii) the printing (or reproduction) and delivery (including postage, air freight charges and charges for counting and packaging) of such copies of the Registration Statement, each Preliminary Prospectus, the Prospectus and each Issuer Free Writing Prospectus, and all amendments or supplements to any of them, as may, in each case, be reasonably requested for use in connection with the offering and sale of the Securities; (iii) the preparation, printing, authentication, issuance and delivery of certificates for the Securities, including any stamp or transfer taxes in connection with the original issuance and sale of the Securities; (iv) the printing (or reproduction) and delivery of this Agreement, any blue sky memorandum and all other agreements or documents printed (or reproduced) and delivered in connection with the offering of the Securities; (v) the registration of the Securities under the Exchange Act and the listing of the Securities on the NASDAQ Global Market; (vi) any registration or qualification of the Securities for offer and sale

under the securities or blue sky laws of the several states (including filing fees and the reasonable fees and expenses of counsel for the Underwriters relating to such registration and qualification); (vii) any filings required to be made with FINRA (including filing fees and the reasonable fees and expenses of counsel for the Underwriters relating to such filings, with such fees and expenses of counsel contained in clauses (vi) and (vii) not to exceed $35,000 in the aggregate); (viii) the transportation and other expenses incurred by or on behalf of Company representatives in connection with presentations to prospective purchasers of the Securities, provided, however, that the Company shall only be responsible for one-half of the cost and expenses of any aircraft chartered in connection with the "road show" for the Securities and the Underwriters shall be responsible for the remaining one-half; (ix) the fees and expenses of the Company's accountants and the fees and expenses of counsel (including local and special counsel) for the Company; and (x) all other costs and expenses incident to the performance by the Company of its obligations hereunder.

(k) The Company agrees to pay (i) all fees and disbursements of counsel incurred by the Underwriters in connection with the Directed Unit Program in an amount not to exceed $10,000; (ii) all costs and expenses incurred by the Underwriters in connection with the printing (or reproduction) and delivery (including postage, air freight charges and charges for counting and packaging) of copies of the Directed Unit Program material; and (iii) all stamp duties, similar taxes or duties or other taxes, if any, incurred by the Underwriters in connection with the Directed Unit Program.

(l) The Company agrees that, unless it has or shall have obtained the prior written consent of the Representatives, and each Underwriter, severally and not jointly, agrees with the Company that, unless it has or shall have obtained, as the case may be, the prior written consent of the Company, it has not made and will not make any offer relating to the Securities that would constitute an Issuer Free Writing Prospectus or that would otherwise constitute a "free writing prospectus" (as defined in Rule 405) required to be filed by the Company with the Commission or retained by the Company under Rule 433; provided that the prior written consent of the parties hereto shall be deemed to have been given in respect of the Free Writing Prospectuses included in Schedule II hereto and any electronic road show. Any such free writing prospectus consented to by the Representatives or the Company is hereinafter referred to as a "Permitted Free Writing Prospectus." The Company agrees that (x) it has treated and will treat, as the case may be, each Permitted Free Writing Prospectus as an Issuer Free Writing Prospectus and (y) it has complied and will comply, as the case may be, with the requirements of Rules 164 and 433 applicable to any Permitted Free Writing Prospectus, including in respect of timely filing with the Commission, legending and record keeping.

(m) The Company will reserve and keep available for the exercise of the Warrants such number of authorized but unissued shares of Common Stock as are sufficient to permit exercise in full of the Warrants.

(n) The Company will notify promptly the Representatives if the Company ceases to be an Emerging Growth Company at any time prior to the later of (a) completion of the distribution of the Securities within the meaning of the Act and (b) completion of the 180-day restricted period referred to in Section 5(g) hereof.

(o) If at any time following the distribution of any Written Testing-the-Waters Communication, any event occurs as a result of which such Written Testing-the-Waters

Communication would include any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein in the light of the circumstances under which they were made at such time not misleading, the Company will (i) notify promptly the Representatives so that use of the Written Testing-the-Waters Communication may cease until it is amended or supplemented; (ii) amend or supplement the Written Testing-the-Waters Communication to correct such statement or omission; and (iii) supply any amendment or supplement to the Representatives in such quantities as may be reasonably requested.

Furthermore, the Company covenants with Jefferies LLC that the Company will comply with all applicable securities and other applicable laws, rules and regulations in each foreign jurisdiction in which the Directed Units are offered in connection with the Directed Unit Program.

6. Conditions to the Obligations of the Underwriters. The obligations of the Underwriters to purchase the Underwritten Securities and the Option Securities, as the case may be, shall be subject to the accuracy of the representations and warranties on the part of the Company contained herein as of the Execution Time, the Closing Date and any settlement date pursuant to Section 3 hereof, to the accuracy of the statements of the Company made in any certificates pursuant to the provisions hereof, to the performance by the Company of its obligations hereunder and to the following additional conditions:

(a) The Prospectus, and any supplement thereto, have been filed in the manner and within the time period required by Rule 424(b); any material required to be filed by the Company pursuant to Rule 433(d) under the Act shall have been filed with the Commission within the applicable time periods prescribed for such filings by Rule 433; and no stop order suspending the effectiveness of the Registration Statement or any notice objecting to its use shall have been issued and no proceedings for that purpose shall have been instituted or threatened.

(b) The Company shall have requested and caused Cooley LLP, counsel for the Company, to have furnished to the Representatives their opinion and negative assurance letter, each dated the Closing Date and addressed to the Representatives, in form and substance reasonably satisfactory to the Representatives.

(c) The Company shall have requested and caused Cooley LLP, intellectual property counsel for the Company, to have furnished to the Representatives their intellectual property opinion, dated the Closing Date and addressed to the Representatives, in form and substance reasonably satisfactory to the Representatives.

(d) The Company shall have requested and caused Greenbaum Rowe Smith & Davis LLP, New Jersey counsel for the Company, to have furnished to the Representatives their opinion, dated the Closing Date and addressed to the Representatives, in form and substance reasonably satisfactory to the Representatives.

(e) The Representatives shall have received from Goodwin Procter LLP, counsel for the Underwriters, such opinion or opinions, dated the Closing Date and

addressed to the Representatives, with respect to the issuance and sale of the Securities, the Registration Statement, the Disclosure Package, the Prospectus (together with any supplement thereto) and other related matters as the Representatives may reasonably require, and the Company shall have furnished to such counsel such documents as they request for the purpose of enabling them to pass upon such matters.

(f) The Company shall have furnished to the Representatives a certificate of the Company, signed by the Chairman of the Board, Chief Executive Officer or the President and the principal financial or accounting officer of the Company, dated the Closing Date, to the effect that the signers of such certificate have carefully examined the Registration Statement, the Disclosure Package, the Prospectus and any amendment or supplement thereto, as well as each electronic road show used in connection with the offering of the Securities, and this Agreement and that:

(i) the representations and warranties of the Company in this Agreement are true and correct on and as of the Closing Date with the same effect as if made on the Closing Date and the Company has complied with all the agreements and satisfied all the conditions on its part to be performed or satisfied at or prior to the Closing Date;

(ii) no stop order suspending the effectiveness of the Registration Statement or any notice objecting to its use has been issued and no proceedings for that purpose have been instituted or, to the Company's knowledge, threatened; and

(iii) since the date of the most recent financial statements included in the Disclosure Package and the Prospectus (exclusive of any supplement thereto), there has been no Material Adverse Effect, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any supplement thereto).

(g) The Representatives shall have received from KPMG LLP, independent registered public accounting firm for the Company, at the Execution Time and at the Closing Date, letters, dated respectively as of the Execution Time and as of the Closing Date, in form and substance reasonably satisfactory to the Representatives, containing statements and information of the type ordinarily included in accountant's "comfort letters" to underwriters, delivered according to Statement of Auditing Standards No. 72 (or any successor bulletin), with respect to the audited and unaudited financial statements and certain financial information contained in the Registration Statement, the Disclosure Package, and each free writing prospectus, if any.

(h) Subsequent to the Execution Time or, if earlier, the dates as of which information is given in the Registration Statement (exclusive of any amendment thereof) and the Prospectus (exclusive of any amendment or supplement thereto), there shall not have been (i) any change or decrease specified in the letter or letters referred to in paragraph (g) of this Section 6 or (ii) any change, or any development involving a prospective change, in or affecting the condition (financial or otherwise), earnings,

business or properties of the Company and its Subsidiaries taken as a whole, whether or not arising from transactions in the ordinary course of business, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any supplement thereto), the effect of which, in any case referred to in clause (i) or (ii) above, is, in the sole judgment of the Representatives, so material and adverse as to make it impractical or inadvisable to proceed with the offering or delivery of the Securities as contemplated by the Registration Statement (exclusive of any amendment thereof), the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto).

(i) Prior to the Closing Date, the Company shall have furnished to the Representatives such further information, certificates and documents as the Representatives may reasonably request.

(j) Subsequent to the Execution Time, there shall not have been any decrease in the rating of any of the Company's debt securities by any "nationally recognized statistical rating organization" (as defined for purposes of Rule 3(a)(62) under the Exchange Act) or any notice given of any intended or potential decrease in any such rating or of a possible change in any such rating that does not indicate the direction of the possible change.

(k) The Securities , shares and warrants shall have been listed and admitted and authorized for trading on the NASDAQ Global Market, and satisfactory evidence of such actions shall have been provided to the Representatives.

(l) At the Execution Time, the Company shall have furnished to the Representatives a letter substantially in the form of Exhibit A hereto from each officer and director of the Company and specified stockholders of the Company addressed to the Representatives.

If any of the conditions specified in this Section 6 shall not have been fulfilled when and as provided in this Agreement, or if any of the opinions and certificates mentioned above or elsewhere in this Agreement shall not be reasonably satisfactory in form and substance to the Representatives and counsel for the Underwriters, this Agreement and all obligations of the Underwriters hereunder may be canceled at, or at any time prior to, the Closing Date by the Representatives. Notice of such cancellation shall be given to the Company in writing or by telephone or facsimile confirmed in writing.

The documents required to be delivered by this Section 6 shall be delivered at the office of Goodwin Procter LLP, counsel for the Underwriters, at Goodwin Procter LLP, 620 Eighth Avenue, New York, New York 10018, on the Closing Date.

7. Reimbursement of Underwriters' Expenses. If the sale of the Securities provided for herein is not consummated because any condition to the obligations of the Underwriters set forth in Section 6 hereof is not satisfied, because of any termination pursuant to Section 10 hereof or because of any refusal, inability or failure on the part of the Company to perform any agreement herein or comply with any provision hereof other than by reason of a default by any of the Underwriters, the Company will reimburse the Underwriters severally

through Jefferies LLC on demand for all out-of-pocket expenses (including reasonable fees and disbursements of counsel) that shall have been reasonably incurred by them in connection with the proposed purchase and sale of the Securities.

8. Indemnification and Contribution. (a) The Company agrees to indemnify and hold harmless each Underwriter, the directors, officers, employees, affiliates within the meaning of Rule 405 under the Act and agents of each Underwriter and each person who controls any Underwriter within the meaning of either the Act or the Exchange Act against any and all losses, claims, damages or liabilities, joint or several, to which they or any of them may become subject under the Act, the Exchange Act or other Federal or state statutory law or regulation, at common law or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement for the registration of the Securities as originally filed or in any amendment thereof, or in any Preliminary Prospectus, or the Prospectus, any Issuer Free Writing Prospectus, or any Written Testing-the-Waters Communication or in any amendment thereof or supplement thereto or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, and agrees to reimburse each such indemnified party, as incurred, for any legal or other expenses reasonably incurred by them in connection with investigating or defending any such loss, claim, damage, liability or action; provided, however, that the Company will not be liable in any such case to the extent that any such loss, claim, damage or liability arises out of or is based upon any such untrue statement or alleged untrue statement or omission or alleged omission made therein in reliance upon and in conformity with written information furnished to the Company by or on behalf of any Underwriter through the Representatives specifically for inclusion therein. This indemnity agreement will be in addition to any liability which the Company may otherwise have.

(b) Each Underwriter severally and not jointly agrees to indemnify and hold harmless the Company, each of its directors, each of its officers who signs the Registration Statement, and each person who controls the Company within the meaning of either the Act or the Exchange Act, to the same extent as the foregoing indemnity from the Company to each Underwriter, but only with reference to written information relating to such Underwriter furnished to the Company by or on behalf of such Underwriter through the Representatives specifically for inclusion in the documents referred to in the foregoing indemnity. This indemnity agreement will be in addition to any liability which any Underwriter may otherwise have. The Company acknowledges that the statements set forth (i) in the last paragraph of the cover page regarding delivery of the Securities and (ii) under the heading "Underwriting": (a) the list of Underwriters and their respective participation in the sale of the Securities; (b) the sentences related to concessions and reallowances; and (c) the paragraph related to stabilization, syndicate covering transactions and penalty bids in the Preliminary Prospectus and the Prospectus constitute the only information furnished in writing by or on behalf of the several Underwriters for inclusion in the Preliminary Prospectus, the Prospectus or any Issuer Free Writing Prospectus.

(c) The Company agrees to indemnify and hold harmless Jefferies LLC, the directors, officers, employees, affiliates and agents of Jefferies LLC and each person who

controls Jefferies LLC , within the meaning of either the Act or the Exchange Act ("Jefferies Entities"), from and against any and all losses, claims, damages and liabilities to which they may become subject under the Act, the Exchange Act or other Federal or state statutory law or regulation, at common law or otherwise (including, without limitation, any legal or other expenses reasonably incurred in connection with defending or investigating any such action or claim), insofar as such losses, claims damages or liabilities (or actions in respect thereof) (i) arise out of or are based upon any untrue statement or alleged untrue statement of a material fact contained in the prospectus wrapper material prepared by or with the consent of the Company for distribution in foreign jurisdictions in connection with the Directed Unit Program attached to the Prospectus, any preliminary prospectus or any Issuer Free Writing Prospectus, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statement therein, when considered in conjunction with the Prospectus or any applicable preliminary prospectus, not misleading; (ii) caused by the failure of any Participant to pay for and accept delivery of the securities which immediately following the Effective Date of the Registration Statement, were subject to a properly confirmed agreement to purchase; or (iii) related to, arising out of, or in connection with the Directed Unit Program, except that this clause (iii) shall not apply to the extent that such loss, claim, damage or liability is finally judicially determined to have resulted primarily from the gross negligence or willful misconduct of the Jefferies Entities.

(d) Promptly after receipt by an indemnified party under this Section 8 of notice of the commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against the indemnifying party under this Section 8, notify the indemnifying party in writing of the commencement thereof; but the failure so to notify the indemnifying party (i) will not relieve it from liability under paragraph (a) or (b) above unless and to the extent it did not otherwise learn of such action and such failure results in the forfeiture by the indemnifying party of substantial rights and defenses and (ii) will not, in any event, relieve the indemnifying party from any obligations to any indemnified party other than the indemnification obligation provided in paragraph (a) or (b) above. The indemnifying party shall be entitled to appoint counsel of the indemnifying party's choice at the indemnifying party's expense to represent the indemnified party in any action for which indemnification is sought (in which case the indemnifying party shall not thereafter be responsible for the fees and expenses of any separate counsel retained by the indemnified party or parties except as set forth below); provided, however, that such counsel shall be satisfactory to the indemnified party. Notwithstanding the indemnifying party's election to appoint counsel to represent the indemnified party in an action, the indemnified party shall have the right to employ separate counsel (including local counsel), and the indemnifying party shall bear the reasonable fees, costs and expenses of such separate counsel (which, if the Company is the indemnifying party, shall be limited to one such separate counsel and one local counsel for any Underwriter together with all persons who control such Underwriter within the meaning of the Exchange Act or the Act, and no more than two such separate counsel and two local counsel for all of the Underwriters) if (i) the use of counsel chosen by the indemnifying party to represent the indemnified party would present such counsel with a conflict of interest; (ii) the actual or potential defendants in, or targets of, any such

action include both the indemnified party and the indemnifying party and the indemnified party shall have reasonably concluded that there may be legal defenses available to it and/or other indemnified parties which are different from or additional to those available to the indemnifying party; (iii) the indemnifying party shall not have employed counsel satisfactory to the indemnified party to represent the indemnified party within a reasonable time after notice of the institution of such action; or (iv) the indemnifying party shall authorize the indemnified party to employ separate counsel at the expense of the indemnifying party. An indemnifying party will not, without the prior written consent of the indemnified parties, settle or compromise or consent to the entry of any judgment with respect to any pending or threatened claim, action, suit or proceeding in respect of which indemnification or contribution may be sought hereunder (whether or not the indemnified parties are actual or potential parties to such claim or action) unless such settlement, compromise or consent (i) includes an unconditional release of each indemnified party from all liability arising out of such claim, action, suit or proceeding and (ii) does not include an admission of fault. Notwithstanding anything contained herein to the contrary, if indemnity may be sought pursuant to Section 8(c) hereof in respect of such action or proceeding, then in addition to such separate firm for the indemnified parties, the indemnifying party shall be liable for the reasonable fees and expenses of not more than one separate firm (in addition to any local counsel) for Jefferies LLC, the directors, officers, employees and agents of Jefferies LLC, and all persons, if any, who control Jefferies LLC within the meaning of either the Act or the Exchange Act for the defense of any losses, claims, damages and liabilities arising out of the Directed Unit Program.

(e) In the event that the indemnity provided in paragraph (a), (b) or (c) of this Section 8 is unavailable to or insufficient to hold harmless an indemnified party for any reason, the Company and the Underwriters severally agree to contribute to the aggregate losses, claims, damages and liabilities (including legal or other expenses reasonably incurred in connection with investigating or defending the same) (collectively, "Losses") to which the Company and one or more of the Underwriters may be subject in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and by the Underwriters on the other from the offering of the Securities. If the allocation provided by the immediately preceding sentence is unavailable for any reason, the Company and the Underwriters severally shall contribute in such proportion as is appropriate to reflect not only such relative benefits but also the relative fault of the Company on the one hand and of the Underwriters on the other in connection with the statements or omissions which resulted in such Losses as well as any other relevant equitable considerations. Benefits received by the Company shall be deemed to be equal to the total net proceeds from the offering (before deducting expenses) received by it, and benefits received by the Underwriters shall be deemed to be equal to the total underwriting discounts and commissions, in each case as set forth on the cover page of the Prospectus. Relative fault shall be determined by reference to, among other things, whether any untrue or any alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information provided by the Company on the one hand or the Underwriters on the other, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such untrue statement or omission. The Company and the Underwriters agree that it would not

be just and equitable if contribution were determined by pro rata allocation or any other method of allocation which does not take account of the equitable considerations referred to above. Notwithstanding the provisions of this paragraph (e), in no event shall an Underwriter be required to contribute any amount in excess of the amount by which the total underwriting discounts and commissions received by such Underwriter with respect to the offering of the Securities exceeds the amount of any damages that such Underwriter has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission. Notwithstanding the provisions of this paragraph (e), no person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 8, each person who controls an Underwriter within the meaning of either the Act or the Exchange Act and each director, officer, employee, affiliate (within the meaning of Rule 405 under the Act) and agent of an Underwriter shall have the same rights to contribution as such Underwriter, and each person who controls the Company within the meaning of either the Act or the Exchange Act, each officer of the Company who shall have signed the Registration Statement and each director of the Company shall have the same rights to contribution as the Company, subject in each case to the applicable terms and conditions of this paragraph (e).

9. Default by an Underwriter. If any one or more Underwriters shall fail to purchase and pay for any of the Securities agreed to be purchased by such Underwriter or Underwriters hereunder and such failure to purchase shall constitute a default in the performance of its or their obligations under this Agreement, the remaining Underwriters shall be obligated severally to take up and pay for (in the respective proportions which the amount of Securities set forth opposite their names in Schedule I hereto bears to the aggregate amount of Securities set forth opposite the names of all the remaining Underwriters) the Securities which the defaulting Underwriter or Underwriters agreed but failed to purchase; provided, however, that in the event that the aggregate amount of Securities which the defaulting Underwriter or Underwriters agreed but failed to purchase shall exceed 10% of the aggregate amount of Securities set forth in Schedule I hereto, the remaining Underwriters shall have the right to purchase all, but shall not be under any obligation to purchase any, of the Securities, and if such nondefaulting Underwriters do not purchase all the Securities, this Agreement will terminate without liability to any nondefaulting Underwriter or the Company. In the event of a default by any Underwriter as set forth in this Section 9, the Closing Date shall be postponed for such period, not exceeding five Business Days, as the Representatives shall determine in order that the required changes in the Registration Statement and the Prospectus or in any other documents or arrangements may be effected. Nothing contained in this Agreement shall relieve any defaulting Underwriter of its liability, if any, to the Company and any nondefaulting Underwriter for damages occasioned by its default hereunder.

10. Termination. This Agreement shall be subject to termination in the absolute discretion of the Representatives, by notice given to the Company prior to delivery of and payment for the Securities, if at any time prior to such delivery and payment (i) trading in the Company's Common Stock shall have been suspended by the Commission or the NASDAQ Global Market or trading in securities generally on the New York Stock Exchange shall have been suspended or limited or minimum prices shall have been established on such exchange;

(ii) a banking moratorium shall have been declared either by Federal or New York State authorities; (iii) there shall have occurred a material disruption in commercial banking or securities settlement or clearance services; or (iv) there shall have occurred any outbreak or escalation of hostilities, declaration by the United States of a national emergency or war, or other calamity or crisis the effect of which on financial markets is such as to make it, in the sole judgment of the Representatives, impractical or inadvisable to proceed with the offering or delivery of the Securities as contemplated by the Preliminary Prospectus or the Prospectus (exclusive of any supplement thereto).

11. Representations and Indemnities to Survive. The respective agreements, representations, warranties, indemnities and other statements of the Company or its officers and of the Underwriters set forth in or made pursuant to this Agreement will remain in full force and effect, regardless of any investigation made by or on behalf of any Underwriter or the Company or any of the officers, directors, employees, agents, affiliates within the meaning of Rule 405 under the Act or controlling persons referred to in Section 8 hereof, and will survive delivery of and payment for the Securities. The provisions of Sections 7 and 8 hereof shall survive the termination or cancellation of this Agreement.

12. Notices. All communications hereunder will be in writing and effective only on receipt, and, if sent to the Representatives, will be mailed, delivered or telefaxed to Jefferies LLC, Attention: Jeff Whyte, Esq., Managing Director (fax no.: 1 (646) 786-5061), 520 Madison Avenue, New York, New York 10022 and to Barclays Capital Inc., Attention: Bret Ganis, Director (fax no.: [_____]), 745 Seventh Avenue, New York, New York 10019; or, if sent to the Company, will be mailed, delivered or telefaxed to 1 (609) 228-4113 and confirmed to it at 7 Clarke Drive, Cranbury, New Jersey 08512, attention of Lawrence Kenyon.

13. Successors. This Agreement will inure to the benefit of and be binding upon the parties hereto and their respective successors and the officers, directors, employees, agents and controlling persons referred to in Section 8 hereof, and no other person will have any right or obligation hereunder.

14. No fiduciary duty. The Company hereby acknowledges that (a) the purchase and sale of the Securities pursuant to this Agreement is an arm's-length commercial transaction between the Company, on the one hand, and the Underwriters and any affiliate through which it may be acting, on the other; (b) the Underwriters are acting as principal and not as an agent or fiduciary of the Company; and (c) the Company's engagement of the Underwriters in connection with the offering and the process leading up to the offering is as independent contractors and not in any other capacity. Furthermore, the Company agrees that it is solely responsible for making its own judgments in connection with the offering (irrespective of whether any of the Underwriters has advised or is currently advising the Company on related or other matters). The Company agrees that it will not claim that the Underwriters have rendered advisory services of any nature or respect, or owe an agency, fiduciary or similar duty to the Company, in connection with such transaction or the process leading thereto.

15. Integration. This Agreement supersedes all prior agreements and understandings (whether written or oral) between the Company and the Underwriters, or any of them, with respect to the subject matter hereof.

16. Applicable Law. This Agreement will be governed by and construed in accordance with the laws of the State of New York applicable to contracts made and to be performed within the State of New York.

17. Waiver of Jury Trial. The Company and the Underwriters hereby irrevocably waive, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

18. Counterparts. This Agreement may be signed in one or more counterparts, each of which shall constitute an original and all of which together shall constitute one and the same agreement.

19. Headings. The section headings used herein are for convenience only and shall not affect the construction hereof.

20. Definitions. The terms that follow, when used in this Agreement, shall have the meanings indicated.

"Act" shall mean the Securities Act of 1933, as amended, and the rules and regulations of the Commission promulgated thereunder.

"Business Day" shall mean any day other than a Saturday, a Sunday or a legal holiday or a day on which banking institutions or trust companies are authorized or obligated by law to close in New York City.

"Commission" shall mean the Securities and Exchange Commission.

"Disclosure Package" shall mean (i) the Preliminary Prospectus that is generally distributed to investors and used to offer the Securities, (ii) the Issuer Free Writing Prospectuses, if any, identified in Schedule II hereto, and (iii) any other Free Writing Prospectus that the parties hereto shall hereafter expressly agree in writing to treat as part of the Disclosure Package.

"Effective Date" shall mean each date and time that the Registration Statement, any post-effective amendment or amendments thereto and any Rule 462(b) Registration Statement became or becomes effective.

"Exchange Act" shall mean the Securities Exchange Act of 1934, as amended, and the rules and regulations of the Commission promulgated thereunder.

"Execution Time" shall mean the date and time that this Agreement is executed and delivered by the parties hereto.

"Free Writing Prospectus" shall mean a free writing prospectus, as defined in Rule 405.

"Issuer Free Writing Prospectus" shall mean an issuer free writing prospectus, as defined in Rule 433.

"Material Adverse Effect" shall mean (i) a material adverse effect on the performance of this Agreement or the consummation of any of the transactions contemplated hereby or (ii) a material adverse effect on the condition (financial or otherwise), prospects, earnings, business or properties of the Company, taken as a whole, whether or not arising from transactions in the ordinary course of business.

"Preliminary Prospectus" shall mean any preliminary prospectus referred to in paragraph 1(a) above and any preliminary prospectus included in the Registration Statement at the Effective Date that omits Rule 430A Information.

"Prospectus" shall mean the prospectus relating to the Securities that is first filed pursuant to Rule 424(b) after the Execution Time.

"Registration Statement" shall mean the registration statement referred to in paragraph 1(a) above, including exhibits and financial statements and any prospectus supplement relating to the Securities that is filed with the Commission pursuant to Rule 424(b) and deemed part of such registration statement pursuant to Rule 430A, as amended at the Execution Time and, in the event any post-effective amendment thereto or any Rule 462(b) Registration Statement becomes effective prior to the Closing Date, shall also mean such registration statement as so amended or such Rule 462(b) Registration Statement, as the case may be.

"Rule 158", "Rule 163", "Rule 164", "Rule 172", "Rule 405", "Rule 415", "Rule 424", "Rule 430A" and "Rule 433" refer to such rules under the Act.

"Rule 430A Information" shall mean information with respect to the Securities and the offering thereof permitted to be omitted from the Registration Statement when it becomes effective pursuant to Rule 430A.

"Rule 462(b) Registration Statement" shall mean a registration statement and any amendments thereto filed pursuant to Rule 462(b) relating to the offering covered by the registration statement referred to in Section 1(a) hereof.

If the foregoing is in accordance with your understanding of our agreement, please sign and return to us the enclosed duplicate hereof, whereupon this letter and your acceptance shall represent a binding agreement among the Company and the several Underwriters.

Very truly yours,

Oncobiologics, Inc.

By: _____
Name:
Title:

[Signature Page to Underwriting Agreement]

The foregoing Agreement is hereby confirmed and accepted as of the date first above written.

Jefferies LLC

By: _____
Name:
Title:

Barclays Capital Inc.

By: _____
Name:
Title:

For themselves and the other several Underwriters named in Schedule I to the foregoing Agreement.

SCHEDULE I

Underwriters	Number of Underwritten Securities to be Purchased
Jefferies LLC	
Barclays Capital Inc.	
Cantor Fitzgerald & Co.	
Total	

SCHEDULE II

Schedule of Free Writing Prospectuses included in the Disclosure Package

SCHEDULE III

Schedule of Written Testing-the-Waters Communication

Schedule III

[Form of Lock-Up Agreement] EXHIBIT A

Oncobiologics, Inc.
Public Offering of Common Stock

, 2015

Jefferies LLC
Barclays Capital Inc.
As Representatives of the several Underwriters,

c/o Jefferies LLC
520 Madison Avenue
New York, New York 10022

c/o Barclays Capital Inc.
745 Seventh Avenue
New York, New York 10019

Ladies and Gentlemen:

This letter is being delivered to you in connection with the proposed Underwriting Agreement (the "Underwriting Agreement"), between Oncobiologics, Inc., a Delaware corporation (the "Company"), and each of you as representatives of a group of underwriters named therein (the "Underwriters"), relating to an underwritten public offering of Common Stock, $0.01 par value (the "Common Stock"), of the Company (the "Offering").

In order to induce you and the other Underwriters to enter into the Underwriting Agreement, the undersigned will not, without the prior written consent of Jefferies LLC and Barclays Capital Inc. (collectively, the "Representatives"), offer, sell, contract to sell, pledge or otherwise dispose of, (or enter into any transaction which is designed to, or might reasonably be expected to, result in the disposition (whether by actual disposition or effective economic disposition due to cash settlement or otherwise) by the undersigned or any affiliate of the undersigned or any person in privity with the undersigned or any affiliate of the undersigned), directly or indirectly, including the filing (or participation in the filing) of a registration statement with the Securities and Exchange Commission in respect of, or establish or increase a put equivalent position or liquidate or decrease a call equivalent position within the meaning of Section 16 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the rules and regulations of the Securities and Exchange Commission promulgated thereunder with respect to, any shares of capital stock of the Company or any securities convertible into, or exercisable or exchangeable for such capital stock, or publicly announce an intention to effect any such transaction, for a period from the date hereof until 180 days after the date of the Underwriting Agreement (the "Lock-Up Period"), other than:

(i) sales of Common Stock by the undersigned to the underwriters pursuant to the Underwriting Agreement;

(ii) transactions relating to shares of Common Stock or other securities acquired in the Offering or in open market transactions after the completion of the Offering;

(iii) transfers of shares of Common Stock or any security convertible into Common Stock as a bona fide gift or charitable contribution;

(iv) exercise of stock options or warrants to purchase shares of Common Stock or the vesting of stock awards of Common Stock and any related transfer of shares of Common Stock to the Company in connection therewith (x) deemed to occur upon the "cashless" or "net" exercise of such options or warrants or (y) for the purpose of paying the exercise price of such options or warrants or for paying taxes due as a result of the exercise of such options or warrants, the vesting of such options, warrants or stock awards, or as a result of the vesting of such shares of Common Stock, it being understood that all shares of Common Stock received upon such exercise, vesting or transfer will remain subject to the restrictions of this agreement during the Lock-Up Period;

(v) transfers to the spouse, domestic partner, parent, child or grandchild or first cousin of the undersigned (each, an "Immediate Family Member") or to a trust formed for the direct or indirect benefit of the undersigned or an Immediate Family Member;

(vi) transfers by will, other testamentary document or intestate succession to the legal representative, heir, beneficiary, trustee or Immediate Family Member of the undersigned;

(vii) transfers pursuant to a divorce settlement agreement or decree or a qualified domestic relations order as defined in the United States Employee Retirement Income Security Act of 1974, as amended;

(viii) transfers of Common Stock or securities convertible into or exchangeable for Common Stock to any affiliate (as such term is defined in Rule 405 of the Securities Act of 1933, as amended), limited partners, general partners, limited liability company members or stockholders of the undersigned, or if the undersigned is a corporation to any wholly owned subsidiary of such corporation; and

(ix) the establishment of a trading plan pursuant to Rule 10b-5-1 under the Exchange Act for the transfer of shares of Common Stock or securities convertible into or exchangeable for Common Stock, *provided* that such plan does not provide for the transfer of shares of Common Stock during the Lock-Up Period and no filing or other public announcement shall be made during the Lock-Up Period;

provided that in the case of clauses (i) and (ii) (a) no filing under Section 13 or Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of shares of Common Stock shall be required, other than Forms 5 and Schedule 13F and (b) no filing under Section 13 or Section 16(a) of the Exchange Act or other public announcement shall be voluntarily made by the undersigned, in the case of both clauses (a) and (b), during the Lock-Up Period, other than Forms 5 and Schedule 13F; provided further that in the case of any transfer or distribution pursuant to clauses (iii), (v), (vi), (vii) and (viii) (a) the recipient agrees to be bound in writing by the same restrictions set forth herein for the duration of the Lock-Up Period, (b) no filing under Section 13 or Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of shares of Common Stock shall be required during the Lock-Up Period, other than Forms 5 and Schedule 13F and (c) no filing under Section 13 or Section 16(a) of the Exchange Act or other public announcement shall be voluntarily made by the undersigned or the transferee during the Lock-Up Period, other than Forms 5 and Schedule 13F and (d) any such transfer shall not involve a disposition for value.

If the undersigned is an officer or director of the Company, the undersigned further agrees that the foregoing restrictions shall be equally applicable to any issuer-directed shares of Common Stock the undersigned may purchase in the Offering.

If the undersigned is an officer or director of the Company, (i) the Representatives agree that, at least three business days before the effective date of any release or waiver of the foregoing restrictions in connection with a transfer of shares of Common Stock, the Representatives will notify the Company of the impending release or waiver, and (ii) the Company has agreed in the Underwriting Agreement to announce the impending release or waiver by press release through a major news service at least two business days before the effective date of the release or waiver. Any release or waiver granted by the Representatives hereunder to any such officer or director shall only be effective two business days after the publication date of such press release. The provisions of this paragraph will not apply if (a) the release or waiver is effected solely to permit a transfer not for consideration and (b) the transferee has agreed in writing to be bound by the same terms described in this letter to the extent and for the duration that such terms remain in effect at the time of the transfer.

This agreement shall automatically terminate upon the earliest to occur, if any, of (i) the date that the Company advises the Representatives, in writing, prior to the execution of the Underwriting Agreement, that it has determined not to proceed with the Offering, (ii) the date of termination of the Underwriting Agreement if prior to the closing of the Offering, or (iii) June 30, 2016, if the Offering has not been completed by such date.

Yours very truly,

If an individual, please sign here:

Signature: _____

Print Name: _____

Print Address: _____

_____

If a corporation, a limited partnership or other legal entity, please sign here:

[NAME]
BY:
ITS:

By: _____

Name: _____

Title: _____

[Form of Press Release] EXHIBIT B

Oncobiologics, Inc.
[Date]

Oncobiologics, Inc. (the "Company") announced today that Jefferies LLC and Barclays Capital Inc., the lead book-running managers in the Company's recent public sale of shares of common stock, are [waiving] [releasing] a lock-up restriction with respect to shares of the Company's common stock held by [certain officers or directors] [an officer or director] of the Company. The [waiver] [release] will take effect on , 20 , and the shares may be sold on or after such date.

This press release is not an offer for sale of the securities in the United States or in any other jurisdiction where such offer is prohibited, and such securities may not be offered or sold in the United States absent registration or an exemption from registration under the United States Securities Act of 1933, as amended.

[Form of Waiver of Lock-up]

ADDENDUM

[Letterhead of Representatives]

Oncobiologics, Inc.
Public Offering of Common Stock

, 20__

[Name and Address of
Officer or Director
Requesting Waiver]

Dear Mr./Ms. [Name]:

This letter is being delivered to you in connection with the offering by Oncobiologics, Inc. (the "Company") of shares of common stock, $0.01 par value (the "Common Stock"), of the Company and the lock-up letter dated , 20 (the "Lock-up Letter"), executed by you in connection with such offering, and your request for a [waiver] [release] dated , 20 , with respect to shares of Common Stock (the "Shares").

Jefferies LLC and Barclays Capital Inc. hereby agree to [waive] [release] the transfer restrictions set forth in the Lock-up Letter, but only with respect to the Shares, effective , 20 ; provided, however, that such [waiver] [release] is conditioned on the Company announcing the impending [waiver] [release] by press release through a major news service at least two business days before effectiveness of such [waiver] [release]. This letter will serve as notice to the Company of the impending [waiver] [release].

Except as expressly [waived] [released] hereby, the Lock-up Letter shall remain in full force and effect.

Yours very truly,

[Signature of Jefferies Representative]

[Name and title of Jefferies Representative]

[Signature of Barclays Representative]

[Name and title of Barclays Representative]

cc: Company

Addendum

ANNEX A

[List all significant subsidiaries as defined by Rule 1-02 of Regulation S-X]

Exhibit 4.1

NUMBER **UNITS**

SEE REVERSE FOR
CERTAIN DEFINITIONS

ONCOBIOLOGICS, INC.

CUSIP [—]

**UNITS CONSISTING OF ONE SHARE OF COMMON STOCK
AND ONE-HALF OF A SERIES A WARRANT TO PURCHASE ONE SHARE OF COMMON STOCK
AND ONE-HALF OF A SERIES B WARRANT TO PURCHASE ONE SHARE OF COMMON STOCK**

THIS CERTIFIES THAT [—] is the owner of [—] Units.

Each Unit ("**Unit**") consists of one (1) share of common stock, $0.01 par value per share ("**Common Stock**"), of Oncobiologics, Inc., a company incorporated under the laws of Delaware (the "**Company**"), one-half (½) of a Series A warrant, with an estimated exercise price of $ [●] to purchase one share of our common stock and one-half (½) of a Series B warrant, with an estimated exercise price of $ [●] to purchase one share of common stock.

Each Series A warrant becomes exercisable during the period commencing on [—], 2016 and ending at 5:00 p.m. New York City time on February [●] 2017 . Each Series B warrant becomes exercisable during the period commencing on [—], 2016 and ending at 5:00 p.m. New York City time on May [●], 2018. The Series A warrants, Series B warrants and shares of our common stock will trade together as units only during the first 30 days following the date of this prospectus, and thereafter, the units will automatically separate and the common stock, Series A warrants and Series B warrants will trade separately, unless Jefferies LLC and Barclays Capital Inc., as representatives of the underwriters, determine that an earlier date is acceptable based upon, among other things, its assessment of the relative strengths of the securities markets and small capitalization companies in general, and the trading pattern of, and demand for, our securities in particular .

This Unit Certificate shall be governed by and construed in accordance with the internal laws of the State of New York, without regard to conflicts of laws principles thereof.

This Unit Certificate is not valid unless countersigned by the Transfer Agent and Registrar of the Company.

Witness the facsimile signature of its duly authorized officers.

By _____
Pankaj Mohan, Ph.D.
Chairman, President and Chief Executive Officer

By _____
Lawrence A. Kenyon
Chief Financial Officer

Oncobiologics, Inc.

The Company will furnish without charge to each shareholder who so requests, a statement of the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof of the Company and the qualifications, limitations, or restrictions of such preferences and/or rights.

The following abbreviations, when used in the inscription on the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations:

TEN COM – as tenants in common
TEN ENT – as tenants by the entireties
JT TEN – as joint tenants with right of survivorship and not as tenants in common
UNIF GIFT MIN ACT – under Uniform Gifts to Minors Act

Additional Abbreviations may also be used though not in the above list.

For value received, *hereby sell, assign and transfer unto*

PLEASE INSERT SOCIAL SECURITY OR OTHER IDENTIFYING NUMBER OF ASSIGNEE

(PLEASE PRINT OR TYPEWRITE NAME AND ADDRESS, INCLUDING ZIP CODE, OF ASSIGNEE)

Units represented by the within Certificate, and hereby irrevocably constitute(s) and appoint(s)

Attorney to transfer the said Units on the books of the within named Company with full power of substitution in the premises.

Dated:

Notice: The signature(s) to this assignment must correspond with the name(s) as written upon the face of the certificate in every particular, without alteration or enlargement or any change whatever.

Signature(s) Guaranteed:

THE SIGNATURE(S) SHOULD BE GUARANTEED BY AN ELIGIBLE GUARANTOR INSTITUTION (BANKS, STOCKBROKERS, SAVINGS AND LOAN ASSOCIATIONS AND CREDIT UNIONS WITH MEMBERSHIP IN AN APPROVED SIGNATURE GUARANTEE MEDALLION PROGRAM, PURSUANT TO S.E.C. RULE 17Ad-15).

Exhibit 4.4

WARRANT AGREEMENT

ONCOBIOLOGICS, INC.

AND

AMERICAN STOCK TRANSFER & TRUST COMPANY, LLC, AS WARRANT AGENT

THIS WARRANT AGREEMENT (this "***Agreement***"), dated as of May [●], 2016, is by and between Oncobiologics, Inc., a Delaware corporation (the "***Company***"), and American Stock Transfer & Trust Company, LLC, a New York limited liability trust company, as Warrant Agent (the "***Warrant Agent***").

WHEREAS, the Company is engaged in an initial public offering (the "***Offering***") of units (the "***Units***," and each a "***Unit***"), with each unit consisting of (i) one share of common stock, $0.01 par value per share (the "***Common Stock***"), of the Company, (ii) one-half of a Series A warrant to purchase one share of Common Stock at a purchase price of $ [●] per share, subject to adjustment as described herein (each, a "***Series A Warrant***") and (iii) one-half of a Series B warrant to purchase one share of Common Stock at a purchase price of $ [●] per share, subject to adjustment as described herein (each, a "***Series B Warrant***," and, together with the Series A Warrants, hereinafter referred to as the "***Warrants***");

WHEREAS, the Company has filed with the Securities and Exchange Commission (the "***Commission***") a registration statement, as amended, on Form S-1, No. 333-209011 (the "***Registration Statement***") and prospectus (the "***Prospectus***"), for the registration, under the Securities Act of 1933, as amended (the "***Securities Act***"), of the offer and sale of the Units, the Common Stock underlying the Units, the Warrants and the Common Stock issuable upon exercise of the Warrants;

WHEREAS, the Company desires the Warrant Agent to act on behalf of the Company, and the Warrant Agent is willing to so act, in connection with the issuance, registration, transfer, exchange and exercise of the Warrants;

WHEREAS, the Company desires to provide for the form and provisions of the Warrants, the terms upon which they shall be issued and exercised, and the respective rights, limitation of rights, and immunities of the Company, the Warrant Agent, and the holders of the Warrants (each a "***Holder***"); and

WHEREAS, all acts and things have been done and performed which are necessary to make the Warrants, when executed on behalf of the Company and countersigned by or on behalf of the Warrant Agent, as provided herein, the valid, binding and legal obligations of the Company, and to authorize the execution and delivery of this Agreement.

NOW, THEREFORE, in consideration of the mutual agreements herein contained, the parties hereto agree as follows:

1. Appointment of Warrant Agent. The Company hereby appoints the Warrant Agent to act as agent for the Company for the Warrants, and the Warrant Agent hereby accepts such appointment and agrees to perform the same in accordance with the terms and conditions set forth in this Agreement.

2. Warrants.

2.1 Form of Warrants. Each Series A Warrant and Series B Warrant shall be issued in registered form only and shall be in substantially the forms attached hereto as Exhibit A and Exhibit B, respectively, the provisions of which are incorporated herein. Each Warrant shall be signed by, or bear the facsimile signature of, the President, Chief Executive Officer or Chief Financial Officer of the Company. In the event the person whose facsimile signature has been placed upon any Warrant shall have ceased to serve in the capacity in which such person signed the Warrant before such Warrant is issued, it may be issued with the same effect as if he or she had not ceased to be such at the date of issuance.

2.2 Effect of Countersignature. Unless and until countersigned by the Warrant Agent pursuant to this Agreement, a

Warrant shall be invalid and of no effect and may not be exercised by the Holder thereof.

2.3 Registration.

2.3.1 Warrant Register. The Warrant Agent shall maintain books (the "***Warrant Register***"), for the registration of original issuance and the registration of transfer of the Warrants. Upon the initial issuance of the Warrants, the Warrant Agent shall issue and register the Warrants in the names of the respective Holders thereof in such denominations and otherwise in accordance with instructions delivered to the Warrant Agent by the Company.

2.3.2 Registered Holder. Prior to due presentment for registration of transfer of any Warrant, the Company and the Warrant Agent may deem and treat the person in whose name such Warrant is registered in the Warrant Register (the "***Registered Holder***") as the absolute owner of such Warrant and of each Warrant represented thereby (notwithstanding any notation of ownership or other writing on the Warrant Certificate (as defined below) made by anyone other than the Company or the Warrant Agent), for the purpose of any exercise thereof, and for all other purposes, and neither the Company nor the Warrant Agent shall be affected by any notice to the contrary.

3. Terms and Exercise of Warrants.

3.1 Detachability of Warrants. Each of the Common Stock and the Warrants comprising the Units will begin to trade separately on (i) the first trading day following the 30th day after the effectiveness of the Registration Statement, or (ii) such earlier date as Jefferies LLC and Barclays Capital Inc., as representatives of the underwriters in the Offering (the "***Representatives***"), shall determine is acceptable (such date, the "***Detachment Date***"). In no event will separate trading of the securities comprising the Units commence until the Company issues a press release announcing when such separate trading will begin.

3.2 Exercise Price.

3.2.1 Series A Warrants. Each Series A Warrant shall, when countersigned by the Warrant Agent, entitle the Registered Holder thereof, subject to the provisions of such Series A Warrant and of this Agreement, to purchase from the Company the number of shares of Common Stock of the Company stated therein, at the price of $ [●] per share, subject to the adjustments provided herein; provided, however, that only whole Series A Warrants may be exercised.

3.2.2 Series B Warrants. Each Series B Warrant shall, when countersigned by the Warrant Agent, entitle the Registered Holder thereof, subject to the provisions of such Series B Warrant and of this Agreement, to purchase from the Company the number of shares of Common Stock of the Company stated therein, at the price of $ [●] per share, subject to the adjustments provided herein; provided, however, that only whole Series B Warrants may be exercised.

3.2.3 The term "***Exercise Price***" as used in this Agreement shall mean the price per share at which the shares of Common Stock may be purchased at the time a whole Series A Warrant or whole Series B Warrant, as the case may be, is exercised.

3.3 Duration of Warrants.

3.3.1 Series A Warrants. Each Series A Warrant may be exercised, in whole or in part, at any time during the period commencing on the Detachment Date and ending at 5:00pm New York City time on February [●], 2017.

3.3.2 Series B Warrants. Each Series B Warrant may be exercised, in whole or in part, at any time during the period commencing on the Detachment Date and ending at 5:00pm New York City time on May [●], 2018.

3.3.3 For purposes of this Agreement, the term "***Expiration Date***" means February [●], 2017 with respect to the Series A Warrants and May [●], 2018 with respect to the Series B Warrants and the term "***Exercise Period***" means the period during which the Series A Warrant or Series B Warrant, as the case may be, is exercisable, as described in subsection 3.1, 3.3.1 or 3.3.2 hereof. Each Warrant not exercised on or before the Expiration Date shall become void, and all rights thereunder and all rights in respect thereof under this Warrant Agreement shall cease at the close of business on the Expiration Date. The Company may extend the duration of the Warrants by delaying the Expiration Date; provided, however, that the Company will provide notice of not less than 20 days to Registered Holders of such extension and that such extension shall be identical in duration among all of the then outstanding Warrants.

3.3.4 The exercise of any Warrant shall be subject to the satisfaction of any applicable conditions, as set forth in subsection 3.3.2 below with respect to an effective registration statement. Any Warrant not exercised on or before the applicable Expiration Date shall become void, and all rights thereunder and all rights in respect thereof under this Agreement shall cease at 5:00 p.m. New York City time on such Expiration Date.

3.4 Exercise of Warrants.

3. 4 .1 Payment. Subject to the provisions of the Warrant and this Agreement, a Warrant, when countersigned by the Warrant Agent, may be exercised by the Registered Holder thereof by submitting a duly executed election to purchase attached to the applicable Warrant, at the office of the Warrant Agent in the Borough of Brooklyn, City and State of New York or at the office of its successor as Warrant Agent, in the Borough of Brooklyn, City and State of New York, which may be done by paying, within two (2) days of the date of exercise, in full the Exercise Price for each whole share of Common Stock as to which the Warrant is exercised, in lawful money of the United States of America, by wire transfer or in good certified check or good bank draft payable to the order of the Company or by Cashless Exercise solely in accordance with Section 3.3.2 hereof. The Registered Holder shall not be required to deliver the original Warrant being exercised in order to effect an exercise hereunder. Upon delivery of an exercise notice, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Common Stock with respect to which such Warrant has been exercised, irrespective of the date such shares of Common Stock are credited to the Holder's DTC account or the date of delivery of the certificates evidencing such shares of Common Stock (as the case may be).

***Checks should be payable to American Stock Transfer & Trust Company, LLC. Originals need to be mailed to American Stock Transfer, Attention: [—]. Wired funds for exercise should be wired to:

JP MORGAN CHASE BANK
ABA # [—]
ACCT # [—]
ACCT NAME: AMERICAN STOCK TRANSFER & TRUST CO
AS AGENT FOR WARRANTS
ATTN: [—]

3.4.2 Cashless Exercise. Notwithstanding anything contained herein to the contrary, if and only if an effective registration statement covering the offer and sale of the shares of Common Stock that are subject to the exercise notice is not available for the issuance of such shares of Common Stock, the Registered Holder may exercise , by submitting a duly executed election to Cashless Exercise (as defined below) to the Company pursuant to Section 8.2 herein, a Warrant in whole or in part and, in lieu of making the cash payment otherwise contemplated to be made to the Company upon such exercise in payment of the aggregate Exercise Price, elect instead to receive upon such exercise the "Net Number" of shares of Common Stock determined according to the following formula (a "***Cashless Exercise***"):

$$\text{Net Number} = \frac{(A \times B) - (A \times C)}{B}$$

For purposes of the foregoing formula:

A = the total number of shares with respect to which the Warrant is then being exercised.

B = the arithmetic average of the Closing Sale Prices (as defined below) of the Common Stock for the five (5) consecutive Trading Days ending on the date immediately preceding the date of the Exercise Notice.

C = the Exercise Price then in effect for the applicable shares of Common Stock at the time of such exercise.

The term "***Closing Sale Price***" means, for any security as of any date, the last closing bid price and last closing trade price, respectively, for such security on the Nasdaq Global Market, as reported by Bloomberg, L.P. ("***Bloomberg***"), or, if the Nasdaq Global Market begins to operate on an extended hours basis and does not designate the closing bid price or the closing trade price, as the case may be, then the last bid price or the last trade price, respectively, of such security prior to 4:00:00 p.m., New York time, as reported by Bloomberg, or, if the Nasdaq Global Market is not the principal securities exchange or trading market for such security, the last closing bid price or last trade price, respectively, of such security on the principal securities exchange or trading market where such security is listed or traded as reported by Bloomberg, or if the foregoing do not apply, the last closing bid price or last trade price, respectively, of such security in the over-the-counter market on the electronic bulletin board for such security as reported by Bloomberg, or, if no closing bid price or last trade price, respectively, is reported for such security by Bloomberg, the average of the bid prices, or the ask prices, respectively,

of any market makers for such security as reported in the OTC Link or "pink sheets" by OTC Markets Group Inc. (formerly Pink OTC Markets Inc.). If the Closing Sale Price cannot be calculated for a security on a particular date on any of the foregoing bases, the Closing Sale Price of such security on such date shall be the fair market value as mutually determined by the Company and the Registered Holder. If the Company and the Registered Holder are unable to agree upon the fair market value of such security, then such dispute shall be resolved pursuant to Section 8.4 hereof. All such determinations to be appropriately adjusted for any stock dividend, stock split, stock combination or other similar transaction during the applicable calculation period.

For purposes of Rule 144(d) promulgated under the Securities Act, as in effect on the date hereof, assuming the Registered Holder is not an affiliate of the Company, the shares of Common Stock issued in a Cashless Exercise shall be deemed to have been acquired by the Registered Holder, and the holding period for the Common Stock shall be deemed to have commenced, on the date the Warrant was originally issued.

3.4.3 Issuance of Common Stock on Exercise. Assuming funds for exercise are paid on or before the second trading day following the date of receipt by the Company of an exercise notice, then on or before the third trading day following the date upon which the Company has received an exercise notice for a Warrant, the Company shall cause its transfer agent to (i) provided that the transfer agent is participating in The Depository Trust Company ("***DTC***") Fast Automated Securities Transfer Program, credit such aggregate number of shares of Common Stock to which the Holder is entitled pursuant to such exercise to the Holder's or its designee's balance account with DTC through its Deposit/Withdrawal at Custodian System, or (ii) if the transfer agent is not participating in the DTC Fast Automated Securities Transfer Program, issue and deliver to the Holder, or at the Holder's instruction pursuant to the delivered exercise notice, the Holder's agent or designee, in each case pursuant to this clause (ii), sent by reputable overnight courier to the address specified in the applicable exercise notice, a certificate, registered in the Company's share register in the name of the Holder or its designee (as indicated in the applicable exercise notice), for the number of shares of Common Stock to which the Holder is entitled pursuant to such exercise.

3.4.4 Valid Issuance. All shares of Common Stock issued or issuable upon the proper exercise of a Warrant in conformity with this Agreement shall be validly issued, fully paid and nonassessable.

3.4.5 Share Delivery Failure. If the Company shall fail, for any reason or for no reason, to issue to the Holder within three (3) trading days after receipt of the applicable exercise notice (the "***Share Delivery Deadline***"), a certificate for the number of shares of Common Stock to which the Holder is entitled upon Holder's exercise of a Warrant, or credit the Holder's balance account with DTC for such number of shares of Common Stock to which the Holder is entitled upon the Holder's exercise of a Warrant (as the case may be, but in each case without a restrictive legend) (a "***Delivery Failure***"), then the Holder will have the right to rescind such exercise by giving written notice to the Company.

3.5 Beneficial Ownership Limitation on Exercises. The Company shall not affect the exercise of any portion of a Warrant, and the Registered Holder of such Warrant shall not have the right to exercise any portion of such Warrant, to the extent that after giving effect to such exercise, the Registered Holder (together with the Registered Holder's affiliates, and any persons acting as a group together with the Holder or any Registered Holder's affiliates) would beneficially own in excess of 9.99% (the "***Maximum Percentage***") of the shares of Common Stock outstanding immediately after giving effect to such exercise, provided, however, that the foregoing limitation on exercise shall not apply to any Registered Holder who, together with such Registered Holder's affiliates, and any persons acting as a group together with such Registered Holder and such Registered Holder's affiliates, owns in excess of the Maximum Percentage immediately prior to the closing of the Offering. For purposes of the foregoing sentence, the aggregate number of shares of Common Stock beneficially owned by such Registered Holder and its affiliates shall include the number of shares of Common Stock issuable upon exercise of a Warrant with respect to which the determination of such sentence is being made, but shall exclude Common Stock which would be issuable upon (i) exercise of the remaining, unexercised portion of such Warrant beneficially owned by the Registered Holder and its affiliates and (ii) exercise or conversion of the unexercised or unconverted portion of any other securities of the Company beneficially owned by the Registered Holder and its affiliates (including, without limitation, any convertible notes or convertible preferred stock or warrants) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Registered Holder or any of its affiliates. Except as set forth in the preceding sentence, for purposes of this paragraph, beneficial ownership shall be calculated in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"). To the extent that the limitation contained in this Section 3.4

applies, the Registered Holder's submission of an Election to Purchase shall be deemed to be the Registered Holder's determination of whether a Warrant is exercisable (in relation to any other securities owned by the Registered Holder together with any affiliates) and of which portion of a Warrant is exercisable, in each case subject to the Maximum Percentage, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of the Warrants, in determining the number of outstanding shares of Common Stock, the Registered Holder may rely on the number of outstanding shares of Common Stock as reflected in the most recent of (A) the Company's most recent Form 10-K, Form 10-Q, Form 8-K or other public filing with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) any other notice by the Company or its transfer agent setting forth the number of shares of Common Stock outstanding. For any reason at any time, upon the written or oral request of the Registered Holder, the Company shall within three (3) trading days confirm to the Registered Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including any Warrant, by the Registered Holder and its affiliates since the date as of which such number of outstanding shares of Common Stock was reported. By written notice to the Company, the Registered Holder may from time to time increase or decrease the Maximum Percentage to any other percentage of the number of shares of Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of a Warrant and the provisions of this Section 3.4 shall continue to apply; provided that (i) any such increase will not be effective until the sixty-first (61st) day after such notice is delivered to the Company, and (ii) any such increase or decrease will apply only to that Registered Holder. For purposes of clarity, the Common Stock underlying any Warrant in excess of the Maximum Percentage for a Registered Holder shall not be deemed to be beneficially owned by that Registered Holder for any purpose including for purposes of Section 13(d) or Rule 16a-1(a)(1) of the Exchange Act. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 3.4 to the extent necessary to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended beneficial ownership limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation.

4. Adjustments.

4.1 Stock Dividends.

4.1.1 Share Dividends and Splits. If after the date hereof, and subject to the provisions of Section 4.5 below, the number of outstanding shares of Common Stock is increased by a stock dividend payable in shares of Common Stock, or by a stock split of the Common Stock or other similar event, then, on the effective date of such stock dividend, stock split or similar event (which, for the avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of the Warrants), the number of shares of Common Stock issuable on exercise of each Warrant shall be increased in proportion to such increase in the outstanding shares of Common Stock and the Exercise Price shall be proportionally decreased such that the aggregate Exercise Price, after such adjustments, remains the same for each Warrant.

4.1.2 Other Distributions. If the Company shall declare any distribution (which, for the avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of the Warrants) of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction), except to the extent an adjustment was already made pursuant to Section 4.1.1 or 4.2 (a "***Distribution***"), at any time after the issuance of a Warrant, then, in each such case, the Company shall reserve and put aside the maximum Distribution amount the Holder would have been entitled to receive if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of such Warrant (without regard to any limitations on exercise thereof, including without limitation, the Maximum Percentage) immediately before the date on which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of Common Stock are to be determined for the participation in such Distribution. Upon exercise of a Warrant, in whole or in part, the Company shall, contemporaneously with the delivery of the Common Stock, distribute to the Holder a pro rata portion of such Distribution based on the portion of the Warrant that has been exercised (provided, however, to the extent that the Holder's right to participate in any such Distributions would result in the Holder exceeding

the Maximum Percentage, then the Holder shall not be entitled to participate in such Distribution at such time and to such extent (or the beneficial ownership of any such shares of Common Stock as a result of such Distribution to such extent) and such Distribution to such extent shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Maximum Percentage, at which time or times the Holder shall be granted such Distribution (and any Distributions declared or made on such initial Distribution or on any subsequent Distribution to be held similarly in abeyance) to the same extent as if there had been no such limitation).

4.2 Aggregation of Shares. If after the date hereof, and subject to the provisions of Section 4.5 hereof, the number of outstanding shares of Common Stock is decreased by a consolidation, combination, reverse stock split or reclassification of the Common Stock or other similar event, then, on the effective date of such consolidation, combination, reverse stock split, reclassification or similar event, the number of shares of Common Stock issuable on exercise of each Warrant shall be decreased in proportion to such decrease in outstanding shares of Common Stock and the Exercise Price shall be proportionally increased such that the aggregate Exercise Price, after such adjustments, remains the same for each Warrant.

4.3 Purchase Rights. If at any time the Company grants, issues or sells any options, convertible securities or rights to purchase stock, warrants, securities or other property pro rata to the record holders of Common Stock (the "***Purchase Rights***"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of a Warrant (without regard to any limitations on exercise hereof, including without limitation, the Maximum Percentage) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Maximum Percentage, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Maximum Percentage, at which time or times the Holder shall be granted such right (and any Purchase Right granted, issued or sold on such initial Purchase Right or on any subsequent Purchase Right to be held similarly in abeyance) to the same extent as if there had been no such limitation).

4.4 Fundamental Transactions. If, at any time while the Warrants are outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another person, (ii) the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding shares of Common Stock, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another person or group of persons whereby such other person or group acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other person or other persons making or party to, or associated or affiliated with the other persons making or party to, such stock or share purchase agreement or other business combination) (each, a "***Fundamental Transaction***"), then, upon any subsequent exercise of a Warrant, the Registered Holder of such Warrant shall be entitled to receive, for each share of Common Stock that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction (without regard to any limitation in Section 3.4 on the exercise of the Warrants), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "***Alternate Consideration***") which, in all cases, was received as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which a Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 3.4 on the exercise of the Warrants). If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental

Transaction, then each Registered Holder shall be given the same choice. Notwithstanding anything to the contrary, (a) if the holders of Common Stock received, as a result of such Fundamental Transaction, a consideration or Alternate Consideration (whether from the Company or from any other person, and whether such consideration or Alternate Consideration is comprised of cash, securities or other property) (such consideration attributed to one share of Common Stock: the "***Fundamental Transaction Consideration Per Share of Common Stock***") with respect to some but not all of their shares of Common Stock (including in the event that they have tendered only some of the shares of Common Stock which such shareholders have initially requested to tender) then, upon any subsequent exercise of a Warrant, the Registered Holder of such Warrant shall be entitled to receive such consideration on a pro-rata basis, based on the number of shares of Common Stock underlying its Warrant; and (b) in the event that the Fundamental Transaction Consideration Per Share of Common Stock paid as a result of such Fundamental Transaction is paid by the Successor Entity (as defined below) or by any other person other than the Company, then such Successor Entity or the other person shall assume and be responsible to pay the Fundamental Transaction Consideration Per Share of Common Stock upon any subsequent exercise of a Warrant. The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "***Successor Entity***") to assume in writing all obligations of the Company under each Warrant in accordance with the provisions of this Section 4.4 pursuant to agreements in form and substance reasonably satisfactory to the Registered Holders and approved by the Registered Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of each Registered Holder, deliver to such Registered Holder in exchange for such Registered Holder's Warrant a written instrument substantially similar in form and substance to such Registered Holder's Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of such Warrant (without regard to the limitations on exercise set forth in Section 3.4) prior to such Fundamental Transaction, and with an exercise price which applies the Exercise Price hereunder to such shares of capital stock (but taking into account the relative value of the Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of such Warrant immediately prior to the consummation of such Fundamental Transaction). Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Agreement and each Warrant referring to the "Company" shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Agreement and each Warrant with the same effect as if such Successor Entity had been named as the Company herein.

4.5 Calculations. All calculations under this Section 4 shall be made to the nearest cent or the nearest whole share, as the case may be. For purposes of this Section 4, any calculation of the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall not include treasury shares, if any. Notwithstanding anything to the contrary in this Section 4, no adjustment in the Exercise Price shall be required unless such adjustment would require an increase or decrease of at least 1% in such price; provided, however, that any adjustments which by reason of the immediately preceding sentence are not required to be made shall be carried forward and taken into account in any subsequent adjustment. In any case in which this Section 4 shall require that an adjustment in the Exercise Price be made effective as of a record date for a specified event, if the Registered Holder exercises a Warrant after such record date, the Company may elect to defer, until the occurrence of such event, the issuance of Common Stock and other capital stock of the Company in excess of the Common Stock and other capital stock of the Company, if any, issuable upon such exercise on the basis of the Exercise Price in effect prior to such adjustment; provided, however, that in such case the Company or the Warrant Agent shall deliver to the Registered Holder a due bill or other appropriate instrument evidencing the Registered Holder's right to receive such additional shares and/or other capital securities upon the occurrence of the event requiring such adjustment.

4.6 Notices of Changes in Warrant. Upon every adjustment of the Exercise Price or the number of shares issuable upon exercise of a Warrant, the Company shall give written notice thereof to the Warrant Agent, which notice shall state the Exercise Price resulting from such adjustment and the increase or decrease, if any, in the number of shares purchasable at such price upon the exercise of a Warrant, setting forth in reasonable detail the method of calculation and the facts upon which such calculation is based. Upon occurrence of any event specified in Sections 4.1, 4.2, 4.3 or 4.4, the Company shall give written notice of the occurrence of such event to each Warrant holder, at the last address set forth for such holder in the Warrant Register, of the record date or the effective date of the event. Failure to give such notice, or any defect therein, shall not affect the legality or validity of such event.

4.7 No Fractional Shares. Notwithstanding any provision contained in this Agreement to the contrary, the Company shall not issue fractional shares upon exercise of Warrants. If, by reason of any adjustment made pursuant to this Section 4, the holder of any whole Warrant would be entitled, upon the exercise of such Warrant, to receive a fractional interest in a share, the Company shall, upon such exercise, round to the nearest whole number, the number of shares of Common Stock to be issued to such holder.

4.8 Form of Warrant. The form of Series A Warrant and Series B Warrant need not be changed because of any adjustment pursuant to this Section 4, and Warrants issued after such adjustment may state the same Exercise Price and the same number of shares as is stated in the Warrants initially issued pursuant to this Agreement.

4.9 Other Events. In case any event shall occur affecting the Company as to which none of the provisions of preceding subsections of this Section 4 are strictly applicable, but which would require an adjustment to the terms of the Warrants in order to (i) avoid an adverse impact on the Warrants and (ii) effectuate the intent and purpose of this Section 4, then, in each such case, the Company shall appoint a firm of independent public accountants, investment banking or other appraisal firm of recognized national standing, which shall give its opinion as to whether or not any adjustment to the rights represented by the Warrants is necessary to effectuate the intent and purpose of this Section 4 and, if they determine that an adjustment is necessary, the terms of such adjustment. The Company shall adjust the terms of the Warrants in a manner that is consistent with any adjustment recommended in such opinion.

5. Transfer and Exchange of Warrants.

5.1 Registration of Transfer. The Warrant Agent shall register the transfer, from time to time, of any outstanding Warrant upon the Warrant Register, upon surrender of such Warrant for transfer, properly endorsed with signatures properly guaranteed and accompanied by appropriate instructions for transfer. Upon any such transfer, a new Warrant representing an equal aggregate number of Warrants shall be issued and the old Warrant shall be cancelled by the Warrant Agent. The Warrants so cancelled shall be delivered by the Warrant Agent to the Company from time to time upon request.

5.2 Procedure for Surrender of Warrants. Warrants may be surrendered to the Warrant Agent, together with a written request for exchange or transfer, and thereupon the Warrant Agent shall issue in exchange therefor one or more new Warrants as requested by the Registered Holder of the Warrants so surrendered, representing an equal aggregate number of Warrants.

5.3 Warrant Execution and Countersignature. The Warrant Agent is hereby authorized to countersign and to deliver, in accordance with the terms of this Agreement, the Warrants required to be issued pursuant to the provisions of this Section 5.

6. Other Provisions Relating to Rights of Holders of Warrants.

6.1 No Rights as Stockholder. A Warrant does not entitle the Registered Holder thereof to any of the rights of a stockholder of the Company, including, without limitation, except as otherwise set forth herein or in any Warrant, the right to receive dividends, or other distributions, exercise any preemptive rights to vote or to consent or to receive notice as stockholders in respect of the meetings of stockholders or the election of directors of the Company or any other matter.

6.2 Lost, Stolen, Mutilated, or Destroyed Warrants. If any Warrant is lost, stolen, mutilated, or destroyed, the Company and the Warrant Agent may on such terms as to indemnity bond or otherwise as they may in their discretion impose (which shall, in the case of a mutilated Warrant, include the surrender thereof), issue a new Warrant of like denomination, tenor, and date as the Warrant so lost, stolen, mutilated, or destroyed. Any such new Warrant shall constitute a substitute contractual obligation of the Company, whether or not the allegedly lost, stolen, mutilated, or destroyed Warrant shall be at any time enforceable by anyone.

6.3 Reservation of Common Stock. The Company shall at all times reserve and keep available a number of its authorized but unissued shares of Common Stock that shall be sufficient to permit the exercise in full of all outstanding Warrants issued pursuant to this Agreement.

6.4 Registration of Common Stock. The Company registered the Warrants and the Common Stock underlying the Warrants in the Registration Statement. The Company will use its reasonable best efforts to maintain the effectiveness of such Registration Statement and the current status of the Prospectus or to file and maintain the effectiveness of another registration statement and another current prospectus covering the Common Stock issuable upon exercise of the Warrants at any time that the Warrants are exercisable. In addition, the Company agrees to use its reasonable best efforts to register such shares of Common Stock under the blue sky laws of the states of residence of the exercising Warrant holders to the extent an exemption from such registration is not available.

7. Concerning the Warrant Agent and Other Matters.

7.1 Payment of Taxes. The Company shall from time to time promptly pay all taxes and charges that may be imposed upon the Company or the Warrant Agent in respect of the issuance or delivery of the Common Stock upon the exercise of the Warrants, but the Company shall not be obligated to pay any transfer taxes in respect of the Warrants or such shares. Except as otherwise required by law, the Company shall not be obligated to honor the exercise of any Warrant by or on behalf of a Registered Holder until all tax consequences (if any) arising from the exercise of such Warrant are resolved in a manner reasonably acceptable to the Company.

7.2 Resignation, Consolidation, or Merger of Warrant Agent.

7.2.1 Appointment of Successor Warrant Agent. The Warrant Agent, or any successor hereafter appointed, may resign its duties and be discharged from all further duties and liabilities hereunder after giving sixty (60) days' notice in writing to the Company. If the office of the Warrant Agent becomes vacant by resignation or incapacity to act or otherwise, the Company shall appoint in writing a successor Warrant Agent in place of the Warrant Agent. If the Company shall fail to make such appointment within a period of thirty (30) days after it has been notified in writing of such resignation or incapacity by the Warrant Agent or by the holder of a Warrant (who shall, with such notice, submit his Warrant for inspection by the Company), then the holder of any Warrant may apply to the Supreme Court of the State of New York for the County of New York for the appointment of a successor Warrant Agent at the Company's cost. Any successor Warrant Agent, whether appointed by the Company or by such court, shall be a corporation in good standing in the State of New York and having its principal office in the Borough of Brooklyn, City and State of New York, and authorized under such laws to exercise corporate trust powers and subject to supervision or examination by federal or state authority. After appointment, any successor Warrant Agent shall be vested with all the authority, powers, rights, immunities, duties, and obligations of its predecessor Warrant Agent with like effect as if originally named as Warrant Agent hereunder, without any further act or deed; but if for any reason it becomes necessary or appropriate, the predecessor Warrant Agent shall execute and deliver, at the expense of the Company, an instrument transferring to such successor Warrant Agent all the authority, powers, and rights of such predecessor Warrant Agent hereunder; and upon request of any successor Warrant Agent the Company shall make, execute, acknowledge, and deliver any and all instruments in writing for more fully and effectually vesting in and confirming to such successor Warrant Agent all such authority, powers, rights, immunities, duties, and obligations.

7.2.2 Notice of Successor Warrant Agent. In the event a successor Warrant Agent shall be appointed, the Company shall give notice thereof to the predecessor Warrant Agent and the transfer agent for the Common Stock not later than the effective date of any such appointment.

7.2.3 Merger or Consolidation of Warrant Agent. Any company into which the Warrant Agent may be merged or with which it may be consolidated or any corporation resulting from any merger or consolidation to which the Warrant Agent shall be a party shall be the successor Warrant Agent under this Agreement without any further act.

7.3 Fees and Expenses of Warrant Agent.

7.3.1 Remuneration. The Company agrees to pay the Warrant Agent reasonable remuneration for its services as such Warrant Agent hereunder and any transfer agent fees which are in addition thereto and shall, pursuant to its obligations under this Agreement, reimburse the Warrant Agent upon demand for all expenditures that the Warrant Agent may reasonably incur in the execution of its duties hereunder.

7.3.2 Further Assurances. The Company agrees to perform, execute, acknowledge, and deliver or cause to be performed, executed, acknowledged, and delivered all such further and other acts, instruments, and assurances as may reasonably be required by the Warrant Agent for the carrying out or performing of the provisions of this Agreement.

7.4 Liability of Warrant Agent.

7.4.1 Reliance on Company Statement. Whenever in the performance of its duties under this Agreement, the Warrant Agent shall deem it necessary or desirable that any fact or matter be proved or established by the Company prior to taking or suffering any action hereunder, such fact or matter (unless other evidence in respect thereof be herein specifically prescribed) may be deemed to be conclusively proved and established by a statement signed by the President, Chief Executive Officer or Chief Financial Officer of the Company and delivered to the Warrant Agent. The Warrant Agent may rely upon such statement for any action taken or suffered in good faith by it pursuant to the provisions of this Agreement.

7.4.2 Indemnity. The Warrant Agent shall be liable hereunder only for its own gross negligence, willful misconduct or bad faith. The Company agrees to indemnify the Warrant Agent and save it harmless against any and all liabilities, including judgments, costs and reasonable counsel fees, for anything done or omitted by the Warrant Agent in the execution of this Agreement, except as a result of the Warrant Agent's gross negligence, willful misconduct or bad faith.

7.4.3 Exclusions. The Warrant Agent shall have no responsibility with respect to the validity of this Agreement or with respect to the validity or execution of any Warrant (except its countersignature thereof). The Warrant Agent shall not be responsible for any breach by the Company of any covenant or condition contained in this Agreement or in any Warrant. The Warrant Agent shall not be responsible to make any adjustments required under the provisions of Section 4 hereof or responsible for the manner, method, or amount of any such adjustment or the ascertaining of the existence of facts that would require any such adjustment; nor shall it by any act hereunder be deemed to make any representation or warranty as to the authorization or reservation of any shares of Common Stock to be issued pursuant to this Agreement or any Warrant or as to whether any shares of Common Stock shall, when issued, be valid and fully paid and nonassessable.

7.5 Acceptance of Agency. The Warrant Agent hereby accepts the agency established by this Agreement and agrees to perform the same upon the terms and conditions herein set forth and among other things, shall account promptly to the Company with respect to Warrants exercised and concurrently account for, and pay to the Company, all monies received by the Warrant Agent for the purchase of Common Stock through the exercise of the Warrants.

8. Miscellaneous Provisions.

8.1 Successors. All the covenants and provisions of this Agreement by or for the benefit of the Company or the Warrant Agent shall bind and inure to the benefit of their respective successors and assigns.

8.2 Notices. Any notice, statement or demand authorized by this Agreement to be given or made by the Warrant Agent or by the holder of any Warrant to or on the Company shall be sufficiently given (i) when so delivered if by hand or overnight delivery, (ii) when sent, if delivered by facsimile (provided confirmation of transmission is mechanically or electronically generated and kept on file by the sending party) or by electronic mail, or (iii) if sent by certified mail or private courier service within five (5) days after deposit of such notice, postage prepaid, addressed (until another address is filed in writing by the Company with the Warrant Agent), as follows:

Oncobiologics, Inc.
7 Clarke Drive
Cranbury, New Jersey 08512
Attention: Lawrence A. Kenyon

By Telefax (which constitutes notice): (609) 228-4113

By Email (which constitutes notice): lawrencekenyon@oncobiologics.com

with copies to (which shall not constitute notice):

Cooley LLP
1114 Avenue of the Americas
New York, New York 10036
Attention: Yvan-Claude Pierre and Daniel I. Goldberg

Any notice, statement or demand authorized by this Agreement to be given or made by the holder of any Warrant or by the Company to the Warrant Agent shall be sufficiently given (i) upon receipt if by hand or overnight delivery, (ii) when sent, if delivered by facsimile (provided confirmation of transmission is mechanically or electronically generated and kept on file by the sending party) or by electronic mail or (iii) if sent by certified mail or private courier service within five (5) days after deposit of such notice, postage prepaid, addressed (until another address is filed in writing by the Warrant Agent with the Company), as follows:

American Stock Transfer & Trust Company, LLC
6201 15th Avenue, 3rd Floor
Brooklyn, New York 11219
Attention: Corporate Actions

By Email (which constitutes notice):[—]@amstock.com

8.3 Additional Rights. Notwithstanding the foregoing or anything else herein to the contrary, other than as expressly provided in Section 3.3.5 hereof, if the Company is for any reason unable to issue and deliver the number of shares of Common Stock to which the Holder is entitled upon Holder's exercise of a Warrant, as required pursuant to the terms hereof, the Company shall have no obligation to pay to the Holder any cash or other consideration or otherwise net cash settle this Warrant.

8.4 Applicable Law. The validity, interpretation, and performance of this Agreement and of the Warrants shall be governed in all respects by the laws of the State of New York, without giving effect to conflicts of law principles that would result in the application of the substantive laws of another jurisdiction. The Company hereby agrees that any action, proceeding or claim against it arising out of or relating in any way to this Agreement shall be brought and enforced in the courts of the State of New York or the United States District Court for the Southern District of New York, and irrevocably submits to such jurisdiction, which jurisdiction shall be exclusive. The Company hereby waives any objection to such exclusive jurisdiction and that such courts represent an inconvenient forum.

8.5 Persons Having Rights under this Agreement. Nothing in this Agreement shall be construed to confer upon, or give to, any person or corporation other than the parties hereto and the Registered Holders of the Warrants any right, remedy, or claim under or by reason of this Agreement or of any covenant, condition, stipulation, promise, or agreement hereof. All covenants, conditions, stipulations, promises, and agreements contained in this Agreement shall be for the sole and exclusive benefit of the parties hereto and their successors and assigns and of the Registered Holders of the Warrants.

8.6 Examination of the Agreement. A copy of this Agreement shall be available at all reasonable times at the office of the Warrant Agent in the Borough of Brooklyn, City of New York and State of New York, for inspection by the Registered Holder of any Warrant. The Warrant Agent may require any such holder to submit his Warrant for inspection by it.

8.7 Counterparts. This Agreement may be executed in any number of original or facsimile counterparts and each of such counterparts shall for all purposes be deemed to be an original, and all such counterparts shall together constitute but one and the same instrument.

8.8 Effect of Headings. The section headings herein are for convenience only and are not part of this Agreement and shall not affect the interpretation thereof.

8.9 Amendments. This Agreement may be amended by the parties hereto without the consent of any Registered Holder for the purpose of curing any ambiguity, or curing, correcting or supplementing any defective provision contained herein or adding or changing any other provisions with respect to matters arising under this Agreement as the parties may deem necessary or desirable and that the parties deem shall not adversely affect the interest of the Registered Holders. All other modifications or amendments shall require the written consent of the Company and the Registered Holders holding Warrants to purchase at least a majority of the shares of Common Stock underlying the then outstanding Warrants. No consideration shall be offered by the Company to any Registered Holder in connection with a modification, amendment or waiver of this Agreement or any Warrant without also offering the same consideration to all Registered Holders.

8.10 Severability. This Agreement shall be deemed severable, and the invalidity or unenforceability of any term or provision hereof shall not affect the validity or enforceability of this Agreement or of any other term or provision hereof. Furthermore, in lieu of any such invalid or unenforceable term or provision, the parties hereto intend that there shall be added as a part of this Agreement a provision as similar in terms to such invalid or unenforceable provision as may be possible and be valid and enforceable.

[*Signature page follows*]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the date first above written.

COMPANY:

ONCOBIOLOGICS, INC.

By: _____
Name: Pankaj Mohan, Ph.D.
Title: President and Chief Executive Officer

WARRANT AGENT:

AMERICAN STOCK TRANSFER & TRUST COMPANY, LLC

By: _____
Name:
Title:

[*Signature Page to Warrant Agreement*]

EXHIBIT A

[FORM OF SERIES A WARRANT CERTIFICATE]

Number:

Warrants

THIS WARRANT SHALL BE VOID IF NOT EXERCISED PRIOR TO
THE EXPIRATION OF THE EXERCISE PERIOD PROVIDED FOR
IN THE WARRANT AGREEMENT DESCRIBED BELOW

ONCOBIOLOGICS, INC.

CUSIP [●]

Warrant Certificate

This Warrant Certificate certifies that, or registered assigns, is the registered holder of warrant(s) (the "***Warrants***" and each, a "***Warrant***") to purchase shares of common stock, $0.01 par value per share (the "***Common Stock***"), of Oncobiologics, Inc., a Delaware corporation (the "***Company***"). Each Warrant entitles the holder, upon exercise during the period set forth in the Warrant Agreement referred to below, to receive from the Company that number of fully paid and nonassessable shares of Common Stock as set forth below, at the exercise price (the "***Exercise Price***") as determined pursuant to the Warrant Agreement, payable in lawful money (or through "***cashless exercise***" solely as provided for in the Warrant Agreement) of the United States of America upon surrender of this Warrant Certificate and payment of the Exercise Price at the office or agency of the Warrant Agent referred to below, subject to the conditions set forth herein and in the Warrant Agreement. Defined terms used in this Warrant Certificate but not defined herein shall have the meanings given to them in the Warrant Agreement (as defined on the reverse hereof).

Only whole Warrants may be exercised. Each whole Warrant is initially exercisable for one fully paid and non-assessable share of Common Stock. The number of shares of Common Stock issuable upon exercise of the Warrants is subject to adjustment upon the occurrence of certain events set forth in the Warrant Agreement.

The initial Exercise Price per share of Common Stock for any Warrant is equal to $ [●] per share. The Exercise Price is subject to adjustment upon the occurrence of certain events set forth in the Warrant Agreement.

Subject to the conditions set forth in the Warrant Agreement, the Warrants may be exercised only during the Exercise Period and to the extent not exercised by the end of such Exercise Period, such Warrants shall become void.

Reference is hereby made to the further provisions of this Warrant Certificate set forth on the reverse hereof and such further provisions shall for all purposes have the same effect as though fully set forth at this place.

This Warrant Certificate shall not be valid unless countersigned by the Warrant Agent, as such term is used in the Warrant Agreement.

This Warrant Certificate shall be governed by and construed in accordance with the internal laws of the State of New York, without regard to conflicts of laws principles thereof.

COMPANY:

ONCOBIOLOGICS, INC.

By: _____
Name: Pankaj Mohan, Ph.D.
Title: President and Chief Executive Officer

WARRANT AGENT:

AMERICAN STOCK TRANSFER & TRUST COMPANY, LLC

By: _____
Name:
Title:

[*Signature Page to Warrant Certificate*]

[Form of Series A Warrant Certificate]

[Reverse]

The Warrants evidenced by this Warrant Certificate are part of a duly authorized issue of Warrants entitling the holder on exercise to receive shares of Common Stock and are issued or to be issued pursuant to a Warrant Agreement, dated as of May [●], 2016 (the "***Warrant Agreement***"), duly executed and delivered by the Company to American Stock Transfer & Trust Company, LLC, as warrant agent (the "***Warrant Agent***"), which Warrant Agreement is hereby incorporated by reference in and made a part of this instrument and is hereby referred to for a description of the rights, limitation of rights, obligations, duties and immunities thereunder of the Warrant Agent, the Company and the holders (the words "***holders***" or "***holder***" meaning the Registered Holders or Registered Holder) of the Warrants. A copy of the Warrant Agreement may be obtained by the holder hereof upon written request to the Company. Defined terms used in this Warrant Certificate but not defined herein shall have the meanings given to them in the Warrant Agreement.

Warrants may be exercised at any time during the Exercise Period set forth in Section 3.2.1 of the Warrant Agreement.

Notwithstanding anything else in this Warrant Certificate or the Warrant Agreement, no Warrant may be exercised unless at the time of exercise (i) a registration statement covering offer and sale of the Common Stock to be issued upon exercise is effective under the Securities Act and (ii) a prospectus thereunder relating to the Common Stock is current, except through "***cashless exercise***" as provided for in the Warrant Agreement.

The Warrant Agreement provides that upon the occurrence of certain events the number of shares of Common Stock issuable upon exercise of the Warrants set forth on the face hereof may, subject to certain conditions, be adjusted. If, upon exercise of a whole Warrant, the holder thereof would be entitled to receive a fractional interest in a share of Common Stock, the Company shall, upon exercise, round to the nearest whole share of Common Stock to be issued to the holder of the Warrant.

Warrant Certificates, when surrendered at the principal corporate trust office of the Warrant Agent by the Registered Holder thereof in person or by legal representative or attorney duly authorized in writing, may be exchanged, in the manner and subject to the limitations provided in the Warrant Agreement, but without payment of any service charge, for another Warrant Certificate or Warrant Certificates of like tenor evidencing in the aggregate a like number of Warrants.

Upon due presentation for registration of transfer of this Warrant Certificate at the office of the Warrant Agent a new Warrant Certificate or Warrant Certificates of like tenor and evidencing in the aggregate a like number of Warrants shall be issued to the transferee(s) in exchange for this Warrant Certificate, subject to the limitations provided in the Warrant Agreement, without charge except for any tax or other governmental charge imposed in connection therewith.

The Company and the Warrant Agent may deem and treat the Registered Holder(s) hereof as the absolute owner(s) of this Warrant Certificate (notwithstanding any notation of ownership or other writing hereon made by anyone), for the purpose of any exercise hereof, of any distribution to the holder(s) hereof, and for all other purposes, and neither the Company nor the Warrant Agent shall be affected by any notice to the contrary. Neither the Warrants nor this Warrant Certificate entitles any holder hereof to any rights of a stockholder of the Company.

Election to Purchase

(To Be Executed Upon Exercise of Warrant)

The undersigned hereby irrevocably elects to exercise the right, represented by this Warrant Certificate, to receive shares of common stock, par value $0.01 per share (the "***Common Stock***"), of Oncobiologics, Inc., a Delaware corporation (the "***Company***") and herewith tenders payment for such shares to the order of the Company in the amount of $___ in accordance with the terms hereof. The undersigned requests that a certificate for such shares be registered in the name of _____, whose address is and that such shares be delivered to whose address is _____. If said number of shares is less than all of the shares of Common Stock purchasable hereunder, the undersigned requests that a new Warrant Certificate representing the remaining balance of such shares be registered in the name of _____, whose address is _____, and that such Warrant Certificate be delivered to _____, whose address is _____.

In the event that the Warrant is to be exercised on a "cashless" basis pursuant to Section 3.3.2 of the Warrant Agreement, the number of shares of Common Stock that this Warrant is exercisable for shall be determined in accordance with Section 3.3.2 of the Warrant Agreement.

_____a "Cash Exercise" with respect to _____ Warrant Shares; and/or

_____a "Cashless Exercise" with respect to _____ Warrant Shares, resulting in a delivery obligation by the Company to the Holder of Common Stock representing the applicable Net Number, subject to adjustment.

In the event that the Warrant may be exercised, to the extent allowed by the Warrant Agreement, through cashless exercise (i) the number of shares that this Warrant is exercisable for would be determined in accordance with the relevant section of the Warrant Agreement which allows for such cashless exercise and (ii) the holder hereof shall complete the following: The undersigned hereby irrevocably elects to exercise the right, represented by this Warrant Certificate, through the cashless exercise provisions of the Warrant Agreement, to receive Common Stock. If said number of shares is less than all of the shares of Common Stock purchasable hereunder (after giving effect to the cashless exercise), the undersigned requests that a new Warrant Certificate representing the remaining balance of such shares be registered in the name of_____, whose address is_____, and that such Warrant Certificate be delivered to_____, whose address is_____.

Date: _____, 201__

(Signature)

(Address)

(Tax Identification Number)

EXHIBIT B

[FORM OF SERIES B WARRANT CERTIFICATE]

Number:

Warrants

THIS WARRANT SHALL BE VOID IF NOT EXERCISED PRIOR TO
THE EXPIRATION OF THE EXERCISE PERIOD PROVIDED FOR
IN THE WARRANT AGREEMENT DESCRIBED BELOW

ONCOBIOLOGICS, INC.

CUSIP [●]

Warrant Certificate

This Warrant Certificate certifies that, or registered assigns, is the registered holder of warrant(s) (the "***Warrants***" and each, a "***Warrant***") to purchase shares of common stock, $0.01 par value per share (the "***Common Stock***"), of Oncobiologics, Inc., a Delaware corporation (the "***Company***"). Each Warrant entitles the holder, upon exercise during the period set forth in the Warrant Agreement referred to below, to receive from the Company that number of fully paid and nonassessable shares of Common Stock as set forth below, at the exercise price (the "***Exercise Price***") as determined pursuant to the Warrant Agreement, payable in lawful money (or through "***cashless exercise***" solely as provided for in the Warrant Agreement) of the United States of America upon surrender of this Warrant Certificate and payment of the Exercise Price at the office or agency of the Warrant Agent referred to below, subject to the conditions set forth herein and in the Warrant Agreement. Defined terms used in this Warrant Certificate but not defined herein shall have the meanings given to them in the Warrant Agreement (as defined on the reverse hereof).

Only whole Warrants may be exercised. Each whole Warrant is initially exercisable for one fully paid and non-assessable share of Common Stock. The number of shares of Common Stock issuable upon exercise of the Warrants is subject to adjustment upon the occurrence of certain events set forth in the Warrant Agreement.

The initial Exercise Price per share of Common Stock for any Warrant is equal to $ [●] per share. The Exercise Price is subject to adjustment upon the occurrence of certain events set forth in the Warrant Agreement.

Subject to the conditions set forth in the Warrant Agreement, the Warrants may be exercised only during the Exercise Period and to the extent not exercised by the end of such Exercise Period, such Warrants shall become void.

Reference is hereby made to the further provisions of this Warrant Certificate set forth on the reverse hereof and such further provisions shall for all purposes have the same effect as though fully set forth at this place.

This Warrant Certificate shall not be valid unless countersigned by the Warrant Agent, as such term is used in the Warrant Agreement.

This Warrant Certificate shall be governed by and construed in accordance with the internal laws of the State of New York, without regard to conflicts of laws principles thereof.

COMPANY:

ONCOBIOLOGICS, INC.

By: _____
Name: Pankaj Mohan, Ph.D.
Title: President and Chief Executive Officer

WARRANT AGENT:

AMERICAN STOCK TRANSFER & TRUST COMPANY, LLC

By: _____
Name:
Title:

[*Signature Page to Warrant Certificate*]

[Form of Warrant Certificate]

[Reverse]

The Warrants evidenced by this Warrant Certificate are part of a duly authorized issue of Warrants entitling the holder on exercise to receive Common Stock and are issued or to be issued pursuant to a Warrant Agreement, dated as of May [●], 2016 (the "***Warrant Agreement***"), duly executed and delivered by the Company to American Stock Transfer & Trust Company, LLC, as warrant agent (the "***Warrant Agent***"), which Warrant Agreement is hereby incorporated by reference in and made a part of this instrument and is hereby referred to for a description of the rights, limitation of rights, obligations, duties and immunities thereunder of the Warrant Agent, the Company and the holders (the words "***holders***" or "***holder***" meaning the Registered Holders or Registered Holder) of the Warrants. A copy of the Warrant Agreement may be obtained by the holder hereof upon written request to the Company. Defined terms used in this Warrant Certificate but not defined herein shall have the meanings given to them in the Warrant Agreement.

Warrants may be exercised at any time during the Exercise Period set forth in Section 3.2.2 of the Warrant Agreement.

Notwithstanding anything else in this Warrant Certificate or the Warrant Agreement, no Warrant may be exercised unless at the time of exercise (i) a registration statement covering the offer and sale of shares of Common Stock to be issued upon exercise is effective under the Securities Act and (ii) a prospectus thereunder relating to the shares of Common Stock is current, except through "***cashless exercise***" as provided for in the Warrant Agreement.

The Warrant Agreement provides that upon the occurrence of certain events the number of shares of Common Stock issuable upon exercise of the Warrants set forth on the face hereof may, subject to certain conditions, be adjusted. If, upon exercise of a whole Warrant, the holder thereof would be entitled to receive a fractional interest in a share of Common Stock, the Company shall, upon exercise, round to the nearest whole share of Common Stock to be issued to the holder of the Warrant.

Warrant Certificates, when surrendered at the principal corporate trust office of the Warrant Agent by the Registered Holder thereof in person or by legal representative or attorney duly authorized in writing, may be exchanged, in the manner and subject to the limitations provided in the Warrant Agreement, but without payment of any service charge, for another Warrant Certificate or Warrant Certificates of like tenor evidencing in the aggregate a like number of Warrants.

Upon due presentation for registration of transfer of this Warrant Certificate at the office of the Warrant Agent a new Warrant Certificate or Warrant Certificates of like tenor and evidencing in the aggregate a like number of Warrants shall be issued to the transferee(s) in exchange for this Warrant Certificate, subject to the limitations provided in the Warrant Agreement, without charge except for any tax or other governmental charge imposed in connection therewith.

The Company and the Warrant Agent may deem and treat the Registered Holder(s) hereof as the absolute owner(s) of this Warrant Certificate (notwithstanding any notation of ownership or other writing hereon made by anyone), for the purpose of any exercise hereof, of any distribution to the holder(s) hereof, and for all other purposes, and neither the Company nor the Warrant Agent shall be affected by any notice to the contrary. Neither the Warrants nor this Warrant Certificate entitles any holder hereof to any rights of a stockholder of the Company.

Election to Purchase

(To Be Executed Upon Exercise of Warrant)

The undersigned hereby irrevocably elects to exercise the right, represented by this Warrant Certificate, to receive shares of common stock, par value $0.01 per share (the "***Common Stock***"), of Oncobiologics, Inc., a Delaware corporation (the "***Company***") and herewith tenders payment for such shares to the order of the Company in the amount of $___ in accordance with the terms hereof. The undersigned requests that a certificate for such shares be registered in the name of _____, whose address is and that such shares be delivered to whose address is _____. If said number of shares is less than all of the shares of Common Stock purchasable hereunder, the undersigned requests that a new Warrant Certificate representing the remaining balance of such shares be registered in the name of the undersigned, and that such Warrant Certificate be delivered to _____, whose address is _____.

In the event that the Warrant is to be exercised on a "cashless" basis pursuant to Section 3.3.2 of the Warrant Agreement, the number of shares of Common Stock that this Warrant is exercisable for shall be determined in accordance with Section 3.3.2 of the Warrant Agreement.

_____a "Cash Exercise" with respect to _____ Warrant Shares; and/or

_____a "Cashless Exercise" with respect to _____ Warrant Shares, resulting in a delivery obligation by the Company to the Holder of Common Stock representing the applicable Net Number, subject to adjustment.

In the event that the Warrant may be exercised, to the extent allowed by the Warrant Agreement, through cashless exercise (i) the number of shares that this Warrant is exercisable for would be determined in accordance with the relevant section of the Warrant Agreement which allows for such cashless exercise and (ii) the holder hereof shall complete the following: The undersigned hereby irrevocably elects to exercise the right, represented by this Warrant Certificate, through the cashless exercise provisions of the Warrant Agreement, to receive Common Stock. If said number of shares is less than all of the shares of Common Stock purchasable hereunder (after giving effect to the cashless exercise), the undersigned requests that a new Warrant Certificate representing the remaining balance of such shares be registered in the name of the undersigned, and that such Warrant Certificate be delivered to_____, whose address is_____.

Date: _____, 201_

(Signature)

(Address)

(Tax Identification Number)

Exhibit 5.1

Cooley

Yvan-Claude Pierre
+1 212 479 6721
ypierre@cooley.com

May 11 , 2016

Oncobiologics, Inc.
7 Clarke Drive
Cranbury, New Jersey 08512

Ladies and Gentlemen:

You have requested our opinion, as counsel to Oncobiologics, Inc., a Delaware corporation (the "***Company***"), in connection with the filing by the Company of a Registration Statement (No. 333-209011) on Form S-1 (the "***Registration Statement***") with the Securities and Exchange Commission, including a related prospectus filed with the Registration Statement (the "***Prospectus***"), covering an underwritten public offering of (i) up to 6,708,334 units (the "***Units***") of the Company, including up to 875,000 Units that may be sold pursuant to the exercise of an option to purchase additional Units, with each Unit consisting of one share of common stock, par value $0.01 per share (the "***Common Stock***"), of the Company (collectively, the "***Shares***"), one-half of a Series A warrant to purchase one share of Common Stock (collectively, the "***Series A Warrants***") and one-half of a Series B warrant to purchase one share of Common Stock (the "***Series B Warrants***" and together with the Series A Warrants, the "***Warrants***"), (ii) up to 3,354,167 shares of Common Stock issuable upon exercise of the Series A Warrants (the "***Series A Warrant Shares***") and (iii) up to 3,354,167 shares of Common Stock issuable upon exercise of the Series B Warrants (together with the Series A Warrant Shares, the "***Warrant Shares***") . All of the Units are to be sold by the Company as described in the Registration Statement and the Prospectus. The Warrants are to be issued pursuant to a Warrant Agreement between the Company and American Stock Trust & Transfer Company, LLC, as warrant agent (the " ***Warrant Agreement*** ").

In connection with this opinion, we have (i) examined and relied upon (a) the Registration Statement and the Prospectus, (b) the Company's Certificate of Incorporation and Bylaws, as amended, each as currently in effect, (c) the Company's Amended and Restated Certificate of Incorporation, and Amended and Restated Bylaws, each as filed as an exhibit to the Registration Statement and to be in effect immediately following the closing of the offering contemplated by the Registration Statement, (d) the form of the Warrant Agreement filed as an exhibit to the Registration Statement, including the forms of Series A Warrants and Series B Warrants attached thereto, (e) the form of Unit Certificate filed as an exhibit to the Registration Statement and (f) originals or copies certified to our satisfaction of such records, documents, certificates, memoranda and other instruments as in our judgment are necessary or appropriate to enable us to render the opinion expressed below, and (ii) assumed that the final terms of the sale and issuance of the Units will be authorized by the Board of Directors of the Company or a pricing committee thereof in accordance with Sections 152 and 153 of the General Corporation Law of the State of Delaware (the "***DGCL***"). We have undertaken no independent verification with respect to such matters. We have assumed the genuineness and authenticity of all documents submitted to us as originals, and the conformity to originals of all documents submitted to us as copies and the due execution and delivery of all documents where due execution and delivery are a prerequisite to the effectiveness thereof. As to certain factual matters, we have relied upon a certificate of an officer of the Company and have not sought independently to verify such matters.

Our opinion is expressed only with respect to the law of the State of New York and the DGCL. We express no opinion as to whether the laws of any particular jurisdiction are applicable to the subject matter hereof. We are not rendering any opinion as to compliance with any federal or state antifraud law, rule or regulation relating to securities, or to the sale or issuance thereof.

On the basis of the foregoing, and in reliance thereon, we are of the opinion that: (i) the Units and the Warrants, when sold and issued against payment therefor as described in the Registration Statement and the Prospectus, will constitute valid and binding obligations of the Company, subject to applicable bankruptcy, insolvency and

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similar laws affecting creditors' rights generally and to equitable principles of general applicability; (ii) the Shares, when sold and issued against payment therefor as described in the Registration Statement and the Prospectus, will be validly issued, fully paid and non-assessable; and (iii) the Warrant Shares, when issued and sold by the Company in accordance with the Warrant Agreement, will be validly issued, fully paid and non-assessable.

We consent to the reference to our firm under the caption "Legal Matters" in the Prospectus included in the Registration Statement and to the filing of this opinion as an exhibit to the Registration Statement.

Sincerely,

Cooley LLP

By: /s/ Yvan-Claude Pierre
Yvan-Claude Pierre

Cooley LLP 1114 Avenue of the Americas New York, NY 10036
t: (212) 479-6000 f: (212) 479-6275 cooley.com

Exhibit 10.1

EXECUTION COPY

INVESTORS' RIGHTS AGREEMENT

by and among

ONCOBIOLOGICS, INC.,

STRIDES PHARMA INC.

and

CERTAIN KEY HOLDERS

March 10, 2014

TABLE OF CONTENTS

INVESTORS' RIGHTS AGREEMENT

THIS INVESTORS' RIGHTS AGREEMENT (this "**Agreement**"), is made as of the 10th day of March, 2014, by and among Oncobiologics, Inc., a New Jersey corporation (the "**Company**"), Strides Pharma Inc., a company incorporated under the laws of New Jersey (the "**Investor**"), and each of the shareholders listed on Schedule A hereto, each of whom is referred to herein as a "**Key Holder**".

RECITALS

WHEREAS, the Company and the Investor are parties to the Securities Purchase Agreement of even date herewith (the "**Purchase Agreement**"); and

WHEREAS, in order to induce the Company to enter into the Purchase Agreement and to induce the Investor to invest funds in the Company pursuant to the Purchase Agreement, the Investor and the Company hereby agree that this Agreement shall govern the rights of the Investor to cause the Company to register shares of Common Stock issuable to the Investor, to receive certain information from the Company, and to participate in future equity offerings by the Company, and shall govern certain other matters as set forth in this Agreement;

NOW, **THEREFORE**, the parties hereby agree as follows:

1. Definitions. For purposes of this Agreement:

1.1 "**Adjustment Period**" means the time from the date hereof through the date on which the Company has engaged in a Qualified IPO or a Qualified Liquidation Event.

1.2 "**Affiliate**" means, with respect to any specified Person, any other Person who, directly or indirectly, controls, is controlled by, or is under common control with such Person, including without limitation any general partner, managing member, officer or director of such Person or any venture capital fund now or hereafter existing that is controlled by one or more general partners or managing members of, or shares the same management company with, such Person.

1.3 "**Board of Directors**" means the Company's board of directors.

1.4 "**Common Stock**" means the Company's common stock, no par value per share.

1.5 "**Damages**" means any loss, damage, claim or liability (joint or several) to which a party hereto may become subject under the Securities Act, the Exchange Act, or other federal or state law, insofar as such loss, damage, claim or liability (or any action in respect thereof) arises out of or is based upon: (i) any untrue statement or alleged untrue statement of a material fact contained in any registration statement of the Company, including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto; (ii) an omission or alleged omission to state therein a material fact required to be stated therein, or necessary to

make the statements therein not misleading; or (iii) any violation or alleged violation by the indemnifying party (or any of its agents or Affiliates) of the Securities Act, the Exchange Act, any state securities law, or any rule or regulation promulgated under the Securities Act, the Exchange Act, or any state securities law.

1.6 "**Derivative Securities**" means any securities or rights convertible into, or exercisable or exchangeable for (in each case, directly or indirectly), Common Stock, including options and warrants.

1.7 "**Excepted Securities**" means (i) securities of the Company issued upon the conversion or exercise of any currently issued debenture, warrant, option, or other convertible security and that have not been amended to either reduce their conversion or exercise price and/or to increase the number of shares issuable upon any such exercise or conversion; (ii) Common Stock issuable upon a stock split, stock dividend, or any subdivision of shares of Common Stock; (iii) shares of Common Stock (or options to purchase such shares of Common Stock) issued or issuable to employees or directors of, or consultants to, the Company pursuant to any plan approved by the Board of Directors and shareholders; (iv) securities of the Company issued in connection with business combinations with a business that the Company, in good faith, determines to be synergistic with the Company; and (v) securities of the Company issued in strategic transactions in which the Board of Directors expects, in good faith, to derive substantial benefits, so long as such transactions are not for the principal purpose of raising capital

1.8 "**Exchange Act**" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

1.9 "**Excluded Registration**" means (i) a registration relating to the sale of securities to employees of the Company or a subsidiary pursuant to a stock option, stock purchase, or similar plan; (ii) a registration relating to an SEC Rule 145 transaction; (iii) a registration on any form that does not include substantially the same information as would be required to be included in a registration statement covering the sale of the Registrable Securities; or (iv) a registration in which the only Common Stock being registered is Common Stock issuable upon conversion of debt securities that are also being registered.

1.10 "**Form S-1**" means such form under the Securities Act as in effect on the date hereof or any successor registration form under the Securities Act subsequently adopted by the SEC.

1.11 "**Form S-3**" means such form under the Securities Act as in effect on the date hereof or any registration form under the Securities Act subsequently adopted by the SEC that permits incorporation of substantial information by reference to other documents filed by the Company with the SEC.

1.12 "**GAAP**" means generally accepted accounting principles in the United States.

1.13 "**Holder**" means any holder of Registrable Securities who is a party to this Agreement.

1.14 "**Immediate Family Member**" means a child, stepchild, grandchild, parent, stepparent, grandparent, spouse, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, including, adoptive relationships, of a natural person referred to herein.

1.15 "**Initiating Holder**" means the Holder who properly initiates a registration request under this Agreement.

1.16 "**Key Employee**" means any executive-level employee (including, division director and vice president-level positions) as well as any employee who, either alone or in concert with others, develops, invents, programs, or designs any Company Intellectual Property (as defined in the Purchase Agreement).

1.17 "**New Securities**" means, collectively, equity securities of the Company, whether or not currently authorized, as well as rights, options, or warrants to purchase such equity securities, or securities of any type whatsoever that are, or may become, convertible or exchangeable into or exercisable for such equity securities.

1.18 "**Person**" means any individual, corporation, partnership, trust, limited liability company, association or other entity.

1.19 "**Preferred Stock**" means, collectively, shares of the Company's Series A Preferred Stock and Series B Preferred Stock.

1.20 "**Qualified IPO**" means the closing by the Company of a firm commitment underwritten public offering with a price of at least 4.3 times the Per Share Purchase Price (as defined in the Purchase Agreement) and gross proceeds to the Company of not less than $50 million.

1.21 "**Qualified Liquidation Event**" means a merger or consolidation (other than one in which shareholders of the Company own a majority of the voting power of the outstanding shares of the surviving or acquiring corporation) or a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of the Company in which the consideration is either all cash or securities that are either registered for sale on an exchange or quotation system or otherwise unrestricted and pursuant to which the equity value of the Company (exclusive of any liabilities being assumed by the surviving or acquiring corporation) is at least $300 million.

1.22 "**Registrable Securities**" means the Purchased Shares (as defined in the Purchase Agreement), the Additional Shares (as defined in the Purchase Agreement) and the Ratchet Shares (as defined in the Purchase Agreement); excluding in all cases, however, any Registrable Securities sold by a Person in a transaction in which the applicable rights under this Agreement are not assigned pursuant to Subsection 6.1, and excluding for purposes of Section 2 any shares for which registration rights have terminated pursuant to Subsection 2.13 of this Agreement.

1.23 "**Registrable Securities then outstanding**" means the number of shares determined by adding the number of shares of outstanding Common Stock that are Registrable Securities and the number of shares of Common Stock issuable (directly or indirectly) pursuant to then exercisable and/or convertible securities that are Registrable Securities.

1.24 "**Reporting Event**" means the Company's initial public offering of its Common Stock pursuant to an effective registration statement under the Securities Act, or equivalent law of another jurisdiction, or upon such date as the Company becomes subject to the reporting requirements of Section 13(a) or 15(d) of the Exchange Act, including, without limitation, upon consummation of a reverse merger or upon the effectiveness of a registration statement on Form 10 filed by the Company under the Exchange Act or equivalent document.

1.25 "**Restricted Securities**" means the securities of the Company required to be notated with the legend set forth in Subsection 2.12(b) hereof.

1.26 "**Sale of the Company**" a merger or consolidation (other than one in which shareholders of the Company own a majority of the voting power of the outstanding shares of the surviving or acquiring corporation) or a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of the Company in which the consideration is either all cash or securities that are either registered for sale on an exchange or quotation system or otherwise unrestricted.

1.27 "**SEC**" means the Securities and Exchange Commission.

1.28 "**SEC Rule 144**" means Rule 144 promulgated by the SEC under the Securities Act.

1.29 "**SEC Rule 145**" means Rule 145 promulgated by the SEC under the Securities Act.

1.30 "**Securities Act**" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

1.31 "**Selling Expenses**" means all underwriting discounts, selling commissions, and stock transfer taxes applicable to the sale of Registrable Securities, and fees and disbursements of counsel for any Holder, except for the fees and disbursements of the Selling Holder Counsel borne and paid by the Company as provided in Subsection 2.6.

2. Registration Rights. The Company covenants and agrees as follows:

2.1 Demand Registration.

(a) Form S-1 Demand. If at any time after one hundred eighty (180) days after the effective date of the registration statement for a Reporting Event, the Company receives a request from the Investor that the Company file a Form S-1 registration statement with

respect to some or all of the Registrable Securities then outstanding, then, provided that the anticipated aggregate offering price, net of Selling Expenses, would exceed $5 million, the Company shall (x) within ten (10) days after the date such request is given, give notice thereof (the "**Demand Notice**") to all Holders other than the Initiating Holder; and (y) as soon as practicable, and in any event within thirty (30) days after the date such request is given by the Initiating Holder, file a Form S-1 registration statement under the Securities Act covering all Registrable Securities that the Initiating Holder requested to be registered and any additional Registrable Securities requested to be included in such registration by any other Holders, as specified by notice given by each such Holder to the Company within ten (10) days of the date the Demand Notice is given, and in each case, subject to the limitations of Subsections 2.1(c), 2.1(d) and 2.3.

(b) Form S-3 Demand. If at any time when it is eligible to use a Form S-3 registration statement, the Company receives a request from the Investor that the Company file a Form S-3 registration statement with respect to Registrable Securities then outstanding, provided that the anticipated aggregate offering price, net of Selling Expenses, would exceed $1 million, then the Company shall (i) within ten (10) days after the date such request is given, give a Demand Notice to all Holders other than the Initiating Holder; and (ii) as soon as practicable, and in any event within thirty (30) days after the date such request is given by the Initiating Holder, file a Form S-3 registration statement under the Securities Act covering all Registrable Securities requested to be included in such registration by any other Holders, as specified by notice given by each such Holder to the Company within ten (10) days of the date the Demand Notice is given, and in each case, subject to the limitations of Subsections 2.1(c) and 2.3.

(c) Notwithstanding the foregoing obligations, if the Company furnishes to Holders requesting a registration pursuant to this Subsection 2.1 a certificate signed by the Company's chief executive officer stating that in the good faith judgment of the Board of Directors it would be materially detrimental to the Company and its shareholders for such registration statement to either become effective or remain effective for as long as such registration statement otherwise would be required to remain effective, because such action would (i) materially interfere with a significant acquisition, corporate reorganization, or other similar transaction involving the Company; (ii) require premature disclosure of material information that the Company has a bona fide business purpose for preserving as confidential; or (iii) render the Company unable to comply with requirements under the Securities Act or Exchange Act, then the Company shall have the right to defer taking action with respect to such filing, and any time periods with respect to filing or effectiveness thereof shall be tolled correspondingly, for a period of not more than sixty (60) days after the request of the Initiating Holder is given; provided, however, that the Company may not invoke this right more than twice in any twelve (12) month period; and provided further that the Company shall not register any securities for its own account or that of any other shareholder during such sixty (60) day period other than pursuant to a registration relating to the sale of securities to employees of the Company or a subsidiary pursuant to a stock option, stock purchase, or similar plan; a registration on any form that does not include substantially the same information as would be required to be included in a registration statement covering the sale of the Registrable Securities; or a registration in which the only Common Stock being registered is Common Stock issuable upon conversion of debt securities that are also being registered.

(d) The Company shall not be obligated to effect, or to take any action to effect, any registration pursuant to Subsection 2.1(a), (i) during the period that is seventy-five (75) days before the Company's good faith estimate of the date of filing of, and ending on a date that is one hundred eighty (180) days after the effective date of, a Company-initiated registration, provided that the Company is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective; (ii) after the Company has effected two registrations pursuant to Subsection 2.1(a); or (iii) if the Initiating Holder proposes to dispose of shares of Registrable Securities that may be immediately registered on Form S-3 pursuant to a request made pursuant to Subsection 2.1(b). The Company shall not be obligated to effect, or to take any action to effect, any registration pursuant to Subsection 2.1(b), (i) during the period that is thirty (30) days before the Company's good faith estimate of the date of filing of, and ending on a date that is ninety (90) days after the effective date of, a Company-initiated registration, provided that the Company is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective; or (ii) if the Company has effected two registrations pursuant to Subsection 2.1(b) within the twelve (12) month period immediately preceding the date of such request. A registration shall not be counted as "effected" for purposes of this Subsection 2.1(d) until such time as the applicable registration statement has been declared effective by the SEC, unless the Initiating Holder withdraws its request for such registration, except as a result of a material adverse change to the Company or its operations, and forfeits its right to one demand registration statement pursuant to Subsection 2.6, in which case such withdrawn registration statement shall be counted as "effected" for purposes of this Subsection 2.1(d).

2.2 Company Registration. If the Company proposes to register (including, for this purpose, a registration effected by the Company for shareholders other than the Holders) any of its Common Stock under the Securities Act in connection with the public offering of such securities solely for cash (other than in an Excluded Registration), the Company shall, at such time, promptly give each Holder notice of such registration. Upon the request of each Holder given within twenty (20) days after such notice is given by the Company, the Company shall, subject to the provisions of Subsection 2.3, cause to be registered all of the Registrable Securities that each such Holder has requested to be included in such registration. The Company shall have the right to terminate or withdraw any registration initiated by it under this Subsection 2.2 before the effective date of such registration, whether or not any Holder has elected to include Registrable Securities in such registration. The expenses (other than Selling Expenses) of such withdrawn registration shall be borne by the Company in accordance with Subsection 2.6.

2.3 Underwriting Requirements.

(a) If, pursuant to Subsection 2.1, the Initiating Holder intends to distribute the Registrable Securities covered by their request by means of an underwriting, they shall so advise the Company as a part of their request made pursuant to Subsection 2.1, and the Company shall include such information in the Demand Notice. The underwriter(s) will be selected by the Initiating Holder, subject only to the reasonable approval of the Company. In such event, the right of any Holder to include such Holder's Registrable Securities in such registration shall be conditioned upon such Holder's participation in such underwriting and the inclusion of such Holder's Registrable Securities in the underwriting to the extent provided

herein. All Holders proposing to distribute their securities through such underwriting shall (together with the Company as provided in Subsection 2.4(e)) enter into an underwriting agreement in customary form with the underwriter(s) selected for such underwriting. Notwithstanding any other provision of this Subsection 2.3, if the managing underwriter(s) advise(s) the Initiating Holder in writing that marketing factors require a limitation on the number of shares to be underwritten, then the Initiating Holder shall so advise all Holders of Registrable Securities that otherwise would be underwritten pursuant hereto, and the number of Registrable Securities that may be included in the underwriting shall be allocated among such Holders of Registrable Securities, including the Initiating Holder, in proportion (as nearly as practicable) to the number of Registrable Securities owned by each Holder or in such other proportion as shall mutually be agreed to by all such selling Holders; provided, however, that the number of Registrable Securities held by the Holders to be included in such underwriting shall not be reduced unless all other securities are first entirely excluded from the underwriting.

(b) In connection with any offering involving an underwriting of shares of the Company's capital stock pursuant to Subsection 2.2, the Company shall not be required to include any of the Holders' Registrable Securities in such underwriting unless the Holders accept the terms of the underwriting as agreed upon between the Company and its underwriters, and then only in such quantity as the underwriters in their sole discretion determine will not jeopardize the success of the offering by the Company. If the total number of securities, including Registrable Securities, requested by shareholders to be included in such offering exceeds the number of securities to be sold (other than by the Company) that the underwriters in their reasonable discretion determine is compatible with the success of the offering, then the Company shall be required to include in the offering only that number of such securities, including Registrable Securities, which the underwriters and the Company in their sole discretion determine will not jeopardize the success of the offering. If the underwriters determine that less than all of the Registrable Securities requested to be registered can be included in such offering, then the Registrable Securities that are included in such offering shall be allocated among the selling Holders in proportion (as nearly as practicable to) the number of Registrable Securities owned by each selling Holder or in such other proportions as shall mutually be agreed to by all such selling Holders. Notwithstanding the foregoing, in no event shall (i) the number of Registrable Securities included in the offering be reduced unless all other securities (other than securities to be sold by the Company) are first entirely excluded from the offering, or (ii) the number of Registrable Securities included in the offering be reduced below thirty percent (30%) of the total number of securities included in such offering, unless such offering is a Reporting Event, in which case the selling Holders may be excluded further if the underwriters make the determination described above and no other shareholder's securities are included in such offering. For purposes of the provision in this Subsection 2.3(b) concerning apportionment, for any selling Holder that is a partnership, limited liability company, or corporation, the partners, members, retired partners, retired members, shareholders, and Affiliates of such Holder, or the estates and Immediate Family Members of any such partners, retired partners, members, and retired members and any trusts for the benefit of any of the foregoing Persons, shall be deemed to be a single "selling Holder," and any pro rata reduction with respect to such "selling Holder" shall be based upon the aggregate number of Registrable Securities owned by all Persons included in such "selling Holder," as defined in this sentence.

(c) For purposes of Subsection 2.1, a registration shall not be counted as "effected" if, as a result of an exercise of the underwriter's cutback provisions in Subsection 2.3(a), fewer than fifty percent (50%) of the total number of Registrable Securities that Holders have requested to be included in such registration statement are actually included.

2.4 Obligations of the Company. Whenever required under this Section 2 to effect the registration of any Registrable Securities, the Company shall, as expeditiously as reasonably possible:

(a) prepare and file with the SEC a registration statement with respect to such Registrable Securities and use its best efforts to cause such registration statement to become effective and, upon the request of the Holders of a majority of the Registrable Securities registered thereunder, keep such registration statement effective for a period of up to one year or, if earlier, until the distribution contemplated in the registration statement has been completed; provided, however, that (i) such one year period shall be extended for a period of time equal to the period the Holder refrains, at the request of an underwriter of Common Stock (or other securities) of the Company, from selling any securities included in such registration, and (ii) in the case of any registration of Registrable Securities on Form S-3 that are intended to be offered on a continuous or delayed basis, subject to compliance with applicable SEC rules, such one year period shall be extended for up to one additional year, if necessary, to keep the registration statement effective until all such Registrable Securities are sold;

(b) prepare and file with the SEC such amendments and supplements to such registration statement, and the prospectus used in connection with such registration statement, as may be necessary to comply with the Securities Act in order to enable the disposition of all securities covered by such registration statement;

(c) furnish to the selling Holders such numbers of copies of a prospectus, including a preliminary prospectus, as required by the Securities Act, and such other documents as the Holders may reasonably request in order to facilitate their disposition of their Registrable Securities;

(d) use its commercially reasonable efforts to register and qualify the securities covered by such registration statement under such other securities or blue-sky laws of such jurisdictions within the United States as shall be reasonably requested by the selling Holders; provided that the Company shall not be required to qualify to do business or to file a general consent to service of process in any such states or jurisdictions, unless the Company is already subject to service in such jurisdiction and except as may be required by the Securities Act;

(e) in the event of any underwritten public offering, enter into and perform its obligations under an underwriting agreement, in usual and customary form, with the underwriter(s) of such offering;

(f) use its commercially reasonable efforts to cause all such Registrable Securities covered by such registration statement to be listed on a national securities exchange or trading system and each securities exchange and trading system (if any) on which similar securities issued by the Company are then listed;

(g) provide a transfer agent and registrar for all Registrable Securities registered pursuant to this Agreement and provide a CUSIP number for all such Registrable Securities, in each case not later than the effective date of such registration;

(h) promptly make available for inspection by the selling Holders, any managing underwriter(s) participating in any disposition pursuant to such registration statement, and any attorney or accountant or other agent retained by any such underwriter or selected by the selling Holders, all financial and other records, pertinent corporate documents, and properties of the Company, and cause the Company's officers, directors, employees, and independent accountants to supply all information reasonably requested by any such seller, underwriter, attorney, accountant, or agent, in each case, as necessary or advisable to verify the accuracy of the information in such registration statement and to conduct appropriate due diligence in connection therewith;

(i) notify each selling Holder, promptly after the Company receives notice thereof, of the time when such registration statement has been declared effective or a supplement to any prospectus forming a part of such registration statement has been filed; and

(j) after such registration statement becomes effective, notify each selling Holder of any request by the SEC that the Company amend or supplement such registration statement or prospectus.

In addition, the Company shall ensure that, at all times after any registration statement covering a public offering of securities of the Company under the Securities Act shall have become effective, its insider trading policy shall provide that the Company's directors may implement a trading program under Rule 10b5-1 of the Exchange Act.

2.5 Furnish Information. It shall be a condition precedent to the obligations of the Company to take any action pursuant to this Section 2 with respect to the Registrable Securities of any selling Holder that such Holder shall furnish to the Company such information regarding itself, the Registrable Securities held by it, and the intended method of disposition of such securities as is reasonably required to effect the registration of such Holder's Registrable Securities.

2.6 Expenses of Registration. All expenses (other than Selling Expenses) incurred in connection with registrations, filings, or qualifications pursuant to Section 2 including all registration, filing, and qualification fees; printers' and accounting fees; fees and disbursements of counsel for the Company; and the fees and disbursements not to exceed $10,000 of one counsel for the selling Holders ("**Selling Holder Counsel**"), shall be borne and paid by the Company; provided, however, that the Company shall not be required to pay for any expenses of any registration proceeding begun pursuant to Subsection 2.1 if the registration request is subsequently withdrawn at the request of the Holders of a majority of the Registrable Securities to be registered (in which case all selling Holders shall bear such expenses pro rata based upon the number of Registrable Securities that were to be included in the withdrawn

registration), unless the Holders of a majority of the Registrable Securities agree to forfeit their right to one registration pursuant to Subsections 2.1(a) or 2.1(b), as the case may be; provided further that if, at the time of such withdrawal, the Holders shall have learned of a material adverse change in the condition, business, or prospects of the Company from that known to the Holders at the time of their request and have withdrawn the request with reasonable promptness after learning of such information then the Holders shall not be required to pay any of such expenses and shall not forfeit their right to one registration pursuant to Subsections 2.1(a) or 2.1(b). All Selling Expenses relating to Registrable Securities registered pursuant to this Section 2 shall be borne and paid by the Holders pro rata on the basis of the number of Registrable Securities registered on their behalf

2.7 Delay of Registration. No Holder shall have any right to obtain or seek an injunction restraining or otherwise delaying any registration pursuant to this Agreement as the result of any controversy that might arise with respect to the interpretation or implementation of this Section 2.

2.8 Indemnification. If any Registrable Securities are included in a registration statement under this Section 2:

(a) To the extent permitted by law, the Company will indemnify and hold harmless each selling Holder, and the partners, members, officers, directors, and shareholders of each such Holder; legal counsel and accountants for each such Holder; any underwriter (as defined in the Securities Act) for each such Holder; and each Person, if any, who controls such Holder or underwriter within the meaning of the Securities Act or the Exchange Act, against any Damages, and the Company will pay to each such Holder, underwriter, controlling Person, or other aforementioned Person any legal or other expenses reasonably incurred thereby in connection with investigating or defending any claim or proceeding from which Damages may result, as such expenses are incurred; provided, however, that the indemnity agreement contained in this Subsection 2.8(a) shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the Company, which consent shall not be unreasonably withheld, nor shall the Company be liable for any Damages to the extent that they arise out of or are based upon actions or omissions made in reliance upon and in conformity with written information furnished by or on behalf of any such Holder, underwriter, controlling Person, or other aforementioned Person expressly for use in connection with such registration.

(b) To the extent permitted by law, each selling Holder, severally and not jointly, will indemnify and hold harmless the Company, and each of its directors, each of its officers who has signed the registration statement, each Person (if any), who controls the Company within the meaning of the Securities Act, legal counsel and accountants for the Company, any underwriter (as defined in the Securities Act), any other Holder selling securities in such registration statement, and any controlling Person of any such underwriter or other Holder, against any Damages, in each case only to the extent that such Damages arise out of or are based upon actions or omissions made in reliance upon and in conformity with written information furnished by or on behalf of such selling Holder expressly for use in connection with such registration; and each such selling Holder will pay to the Company and each other aforementioned Person any legal or other expenses reasonably incurred thereby in connection

with investigating or defending any claim or proceeding from which Damages may result, as such expenses are incurred; provided, however, that the indemnity agreement contained in this Subsection 2.8(b) shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the Holder, which consent shall not be unreasonably withheld; and provided further that in no event shall the aggregate amounts payable by any Holder by way of indemnity or contribution under Subsections 2.8(b) and 2.8(d) exceed the proceeds from the offering received by such Holder (net of any Selling Expenses paid by such Holder), except in the case of fraud or willful misconduct by such Holder.

(c) Promptly after receipt by an indemnified party under this Subsection 2.8 of notice of the commencement of any action (including any governmental action) for which a party may be entitled to indemnification hereunder, such indemnified party will, if a claim in respect thereof is to be made against any indemnifying party under this Subsection 2.8, give the indemnifying party notice of the commencement thereof. The indemnifying party shall have the right to participate in such action and, to the extent the indemnifying party so desires, participate jointly with any other indemnifying party to which notice has been given, and to assume the defense thereof with counsel mutually satisfactory to the parties; provided, however, that an indemnified party (together with all other indemnified parties that may be represented without conflict by one counsel) shall have the right to retain one separate counsel, with the fees and expenses to be paid by the indemnifying party, if representation of such indemnified party by the counsel retained by the indemnifying party would be inappropriate due to actual or potential differing interests between such indemnified party and any other party represented by such counsel in such action.

(d) To provide for just and equitable contribution to joint liability under the Securities Act in any case in which either: (i) any party otherwise entitled to indemnification hereunder makes a claim for indemnification pursuant to this Subsection 2.8 but it is judicially determined (by the entry of a final judgment or decree by a court of competent jurisdiction and the expiration of time to appeal or the denial of the last right of appeal) that such indemnification may not be enforced in such case, notwithstanding the fact that this Subsection 2.8 provides for indemnification in such case, or (ii) contribution under the Securities Act may be required on the part of any party hereto for which indemnification is provided under this Subsection 2.8, then, and in each such case, such parties will contribute to the aggregate losses, claims, damages, liabilities, or expenses to which they may be subject (after contribution from others) in such proportion as is appropriate to reflect the relative fault of each of the indemnifying party and the indemnified party in connection with the statements, omissions, or other actions that resulted in such loss, claim, damage, liability, or expense, as well as to reflect any other relevant equitable considerations. The relative fault of the indemnifying party and of the indemnified party shall be determined by reference to, among other things, whether the untrue or allegedly untrue statement of a material fact, or the omission or alleged omission of a material fact, relates to information supplied by the indemnifying party or by the indemnified party and the parties' relative intent, knowledge, access to information, and opportunity to correct or prevent such statement or omission; provided, however, that, in any such case (x) no Holder will be required to contribute any amount in excess of the public offering price of all such Registrable Securities offered and sold by such Holder pursuant to such registration statement, and (y) no Person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any Person who was not guilty of such

fraudulent misrepresentation; and provided further that in no event shall a Holder's liability pursuant to this Subsection 2.8(d), when combined with the amounts paid or payable by such Holder pursuant to Subsection 2.8(b), exceed the proceeds from the offering received by such Holder (net of any Selling Expenses paid by such Holder), except in the case of willful misconduct or fraud by such Holder.

(e) Notwithstanding the foregoing, to the extent that the provisions on indemnification and contribution contained in the underwriting agreement entered into in connection with the underwritten public offering are in conflict with the foregoing provisions, the provisions in the underwriting agreement shall control.

(f) Unless otherwise superseded by an underwriting agreement entered into in connection with the underwritten public offering, the obligations of the Company and Holders under this Subsection 2.8 shall survive the completion of any offering of Registrable Securities in a registration under this Section 2, and otherwise shall survive the termination of this Agreement.

2.9 Reports Under Exchange Act. With a view to making available to the Holders the benefits of SEC Rule 144 and any other rule or regulation of the SEC that may at any time permit a Holder to sell securities of the Company to the public without registration or pursuant to a registration on Form S-3, the Company shall:

(a) make and keep available adequate current public information, as those terms are understood and defined in SEC Rule 144, at all times after a Reporting Event;

(b) use commercially reasonable efforts to file with the SEC in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act (at any time after the Company has become subject to such reporting requirements); and

(c) furnish to any Holder, so long as the Holder owns any Registrable Securities, forthwith upon request (i) to the extent accurate, a written statement by the Company that it has complied with the reporting requirements of SEC Rule 144 (at any time after ninety (90) days after the Reporting Event), the Securities Act, and the Exchange Act (at any time after the Company has become subject to such reporting requirements), or that it qualifies as a registrant whose securities may be resold pursuant to Form S-3 (at any time after the Company so qualifies); and (ii) such other information as may be reasonably requested in availing any Holder of any rule or regulation of the SEC that permits the selling of any such securities without registration (at any time after the Company has become subject to the reporting requirements under the Exchange Act) or pursuant to Form S-3 (at any time after the Company so qualifies to use such form).

2.10 Limitations on Subsequent Registration Rights. From and after the date of this Agreement, the Company shall not, without the prior written consent of the Holders of a majority of the Registrable Securities then outstanding, enter into any agreement with any holder or prospective holder of any securities of the Company that (i) would provide to such holder the right to include securities in any registration on other than either a pro rata basis with

respect to the Registrable Securities or on a subordinate basis after all Holders have had the opportunity to include in the registration and offering all shares of Registrable Securities that they wish to so include; or (ii) allow such holder or prospective holder to initiate a demand for registration of any securities held by such holder or prospective holder; provided that this limitation shall not apply to any additional Investor who becomes a party to this Agreement in accordance with Subsection 6.9.

2.11 "Market Stand-off" Agreement. Each Holder hereby agrees that it will not, without the prior written consent of the managing underwriter, during the period commencing on the date of the final prospectus relating a Qualified IPO, and ending on the date specified by the Company and the managing underwriter (such period not to exceed one hundred eighty (180) days), (i) lend; offer; pledge; sell; contract to sell; sell any option or contract to purchase; purchase any option or contract to sell; grant any option, right, or warrant to purchase; or otherwise transfer or dispose of directly or indirectly, any shares of Common Stock or any securities convertible into or exercisable or exchangeable (directly or indirectly) for Common Stock held immediately before the effective date of the registration statement for such offering or (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of such securities, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of Common Stock or other securities, in cash, or otherwise. The foregoing provisions of this Subsection 2.11 shall apply only to a Qualified IPO, shall not apply to the sale of any shares to an underwriter pursuant to an underwriting agreement, or the transfer of any shares to any trust for the direct or indirect benefit of the Holder or the immediate family of the Holder, provided that the trustee of the trust agrees to be bound in writing by the restrictions set forth herein, and provided further that any such transfer shall not involve a disposition for value, and shall be applicable to the Holders only if all officers and directors are subject to the same restrictions and the Company uses commercially reasonable efforts to obtain a similar agreement from all shareholders individually owning more than five percent (5%) of the Company's outstanding Common Stock (after giving effect to conversion into Common Stock of all outstanding Preferred Stock). The underwriters in connection with such registration are intended third-party beneficiaries of this Subsection 2.11 and shall have the right, power and authority to enforce the provisions hereof as though they were a party hereto. Each Holder further agrees to execute such agreements as may be reasonably requested by the underwriters in connection with such registration that are consistent with this Subsection 2.11 or that are necessary to give further effect thereto. Any discretionary waiver or termination of the restrictions of any or all of such agreements by the Company or the underwriters shall apply pro rata to all Holders subject to such agreements, based on the number of shares subject to such agreements.

2.12 Restrictions on Transfer.

(a) The Registrable Securities shall not be sold, pledged, or otherwise transferred, and the Company shall not recognize and shall issue stop-transfer instructions to its transfer agent with respect to any such sale, pledge, or transfer, except upon the conditions specified in this Agreement, which conditions are intended to ensure compliance with the provisions of the Securities Act. A transferring Holder will cause any proposed purchaser, pledgee, or transferee of the Registrable Securities held by such Holder to agree to take and hold such securities subject to the provisions and upon the conditions specified in this Agreement.

(b) Each certificate, instrument, or book entry representing (i) the Registrable Securities, and (ii) any other securities issued in respect of the securities referenced in clause (i), upon any stock split, stock dividend, recapitalization, merger, consolidation, or similar event, shall (unless otherwise permitted by the provisions of Subsection 2.12(c)) be notated with a legend substantially in the following form:

THE SECURITIES REPRESENTED HEREBY HAVE BEEN ACQUIRED FOR INVESTMENT AND HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933. SUCH SHARES MAY NOT BE SOLD, PLEDGED, OR TRANSFERRED IN THE ABSENCE OF SUCH REGISTRATION OR A VALID EXEMPTION FROM THE REGISTRATION AND PROSPECTUS DELIVERY REQUIREMENTS OF SAID ACT.

THE SECURITIES REPRESENTED HEREBY MAY BE TRANSFERRED ONLY IN ACCORDANCE WITH THE TERMS OF AN AGREEMENT BETWEEN THE COMPANY AND THE SHAREHOLDER, A COPY OF WHICH IS ON FILE WITH THE SECRETARY OF THE COMPANY.

The Holders consent to the Company making a notation in its records and giving instructions to any transfer agent of the Restricted Securities in order to implement the restrictions on transfer set forth in this Subsection 2.12.

(c) The holder of such Restricted Securities, by acceptance of ownership thereof, agrees to comply in all respects with the provisions of this Section 2. Before any proposed sale, pledge, or transfer of any Restricted Securities, unless there is in effect a registration statement under the Securities Act covering the proposed transaction, the Holder thereof shall give notice to the Company of such Holder's intention to effect such sale, pledge, or transfer. Each such notice shall describe the manner and circumstances of the proposed sale, pledge, or transfer in sufficient detail and, if reasonably requested by the Company, shall be accompanied at such Holder's expense by either (i) a written opinion of legal counsel who shall, and whose legal opinion shall, be reasonably satisfactory to the Company, addressed to the Company, to the effect that the proposed transaction may be effected without registration under the Securities Act; (ii) a "no action" letter from the SEC to the effect that the proposed sale, pledge, or transfer of such Restricted Securities without registration will not result in a recommendation by the staff of the SEC that action be taken with respect thereto; or (iii) any other evidence reasonably satisfactory to counsel to the Company to the effect that the proposed sale, pledge, or transfer of the Restricted Securities may be effected without registration under the Securities Act, whereupon the Holder of such Restricted Securities shall be entitled to sell, pledge, or transfer such Restricted Securities in accordance with the terms of the notice given by the Holder to the Company. The Company will not require such a legal opinion or "no action" letter (x) in any transaction in compliance with SEC Rule 144; or (y) in any transaction in which such Holder distributes Restricted Securities to an Affiliate of such Holder for no consideration; provided that each transferee agrees in writing to be subject to the terms of this Subsection 2.12. Each certificate, instrument, or book entry representing the Restricted Securities transferred as above provided shall be notated with, except if such transfer is made pursuant to SEC Rule 144, the appropriate restrictive legend set forth in Subsection 2.12(b), except that such certificate instrument, or book entry shall not be notated with such restrictive legend if, in the opinion of counsel for such Holder and the Company, such legend is not required in order to establish compliance with any provisions of the Securities Act.

2.13 Termination of Registration Rights. The right of any Holder to request registration or inclusion of Registrable Securities in any registration pursuant to Subsections 2.1 or 2.2 shall terminate upon:

(a) the closing of a Qualified Liquidation Event; and

(b) such time as Rule 144 or another similar exemption under the Securities Act is available for the sale of all of such Holder's shares without limitation during a three-month period without registration.

3. Information and Observer Rights.

3.1 Delivery of Financial Statements. The Company shall deliver to the Investor:

(a) as soon as practicable, but in any event within ninety (90) days after the end of each fiscal year of the Company (i) a balance sheet as of the end of such year, (ii) statements of income and of cash flows for such year, and a comparison between (x) the actual amounts as of and for such fiscal year and (y) the comparable amounts for the prior year and as included in the Budget (as defined in Subsection 3.1(d)) for such year, with an explanation of any material differences between such amounts and a schedule as to the sources and applications of funds for such year, and (iii) a statement of shareholders' equity as of the end of such year, all such financial statements audited and certified by independent public accountants of nationally recognized standing selected by the Company;

(b) as soon as practicable, but in any event within forty-five (45) days after the end of each of the first three (3) quarters of each fiscal year of the Company, unaudited statements of income and cash flows for such fiscal quarter, and an unaudited balance sheet and a statement of shareholders' equity as of the end of such fiscal quarter, all prepared in accordance with the Accounting and Review standards of the American Institute of Certified Public Accountants (the "**AICPA**") (except that such financial statements may (i) be subject to normal year-end audit adjustments; and (ii) not contain all notes thereto that may be required in accordance with the Accounting and Review standards of the AICPA);

(c) as soon as practicable, but in any event within forty-five (45) days after the end of each of the first three (3) quarters of each fiscal year of the Company, a statement showing the number of shares of each class and series of capital stock and securities convertible into or exercisable for shares of capital stock outstanding at the end of the period, the Common Stock issuable upon conversion or exercise of any outstanding securities convertible or exercisable for Common Stock and the exchange ratio or exercise price applicable thereto, and the number of shares of issued stock options and stock options not yet issued but reserved for issuance, if any, all in sufficient detail as to permit the Investor to calculate its percentage equity ownership in the Company, and certified by the chief financial officer or chief executive officer of the Company as being true, complete, and correct;

(d) as soon as practicable, but in any event thirty (30) days before the end of each fiscal year, a budget and business plan for the next fiscal year (collectively, the "**Budget**"), approved by the Board of Directors and prepared on a monthly basis, including balance sheets, income statements, and statements of cash flow for such months and, promptly after prepared, any other budgets or revised budgets prepared by the Company;

(e) with respect to (i) the financial statements called for in Subsection 3.1(a), an instrument executed by the chief financial officer and chief executive officer of the Company certifying that the audited financial statements were prepared in accordance with GAAP consistently applied with prior practice for earlier periods and fairly present the financial condition of the Company and its results of operation for the periods specified therein, and (ii) the financial statements called for in Subsection 3.1(b), an instrument executed by the chief financial officer and chief executive officer of the Company certifying that the financial statements were prepared in accordance with the Accounting and Review standards of the AICPA consistently applied with prior practice for earlier periods and fairly present the financial condition of the Company and if the Financial Statements were prepared in accordance with GAAP consistently applied with prior practice for earlier periods, then any difference between the Financial Statements and the Financial Statements prepared in accordance with GAAP for any applicable period would be non-material; and

(f) such other information relating to the financial condition, business, prospects, or corporate affairs of the Company as the Investor may from time to time reasonably request; provided, however, that the Company shall not be obligated under this Subsection 3.1 to provide information (i) that the Company reasonably determines in good faith to be a trade secret or confidential information (unless covered by an enforceable confidentiality agreement, in a form acceptable to the Company); or (ii) the disclosure of which would adversely affect the attorney-client privilege between the Company and its counsel.

If, for any period, the Company has any subsidiary whose accounts are consolidated with those of the Company, then in respect of such period the financial statements delivered pursuant to the foregoing sections shall be the consolidated and consolidating financial statements of the Company and all such consolidated subsidiaries.

Notwithstanding anything else in this Subsection 3.1 to the contrary, the Company may cease providing the information set forth in this Subsection 3.1 during the period starting with the date thirty (30) days before the Company's good-faith estimate of the date of filing of a registration statement if it reasonably concludes it must do so to comply with the SEC rules applicable to such registration statement and related offering; provided that the Company's covenants under this Subsection 3.1 shall be reinstated at such time as the Company is no longer actively employing its commercially reasonable efforts to cause such registration statement to become effective.

3.2 Inspection. The Company shall permit the Investor, at the Investor's expense, to visit and inspect the Company's properties; examine its books of account and records; and discuss the Company's affairs, finances, and accounts with its officers, during normal business hours of the Company as may be reasonably requested by the Investor; provided, however, that the Company shall not be obligated pursuant to this Subsection 3.2 to

provide access to any information that it reasonably and in good faith considers to be a trade secret or confidential information (unless covered by an enforceable confidentiality agreement, in form acceptable to the Company) or the disclosure of which would adversely affect the attorney-client privilege between the Company and its counsel.

3.3 Observer Rights. As long as the Investor owns not less than fifty percent (50%) of the shares of the Common Stock it is purchasing under the Purchase Agreement, the Company shall invite a representative of the Investor to attend all meetings of its Board of Directors in a nonvoting observer capacity and, in this respect, shall give such representative copies of all notices, minutes, consents, and other materials that it provides to its directors at the same time and in the same manner as provided to such directors; provided, however, that such representative shall agree to hold in confidence and trust and to act in a fiduciary manner with respect to all information so provided; and provided further, that the Company reserves the right to withhold any information and to exclude such representative from any meeting or portion thereof if access to such information or attendance at such meeting could adversely affect the attorney-client privilege between the Company and its counsel.

3.4 Termination of Information and Observer Rights. The covenants set forth in Subsection 3.1, Subsection 3.2, and Subsection 3.3 shall terminate and be of no further force or effect (i) immediately before the consummation of the Qualified IPO, or (ii) upon a Qualified Liquidation Event, whichever event occurs first.

3.5 Confidentiality. The Investor agrees that the Investor will keep confidential and will not disclose, divulge, or use for any purpose (other than to monitor its investment in the Company) any confidential information obtained from the Company pursuant to the terms of this Agreement (including notice of the Company's intention to file a registration statement), unless such confidential information (a) is known or becomes known to the public in general (other than as a result of a breach of this Subsection 3.5 by the Investor), (b) is or has been independently developed or conceived by the Investor without use of the Company's confidential information, or (c) is or has been made known or disclosed to the Investor by a third party without a breach of any obligation of confidentiality such third party may have to the Company; provided, however, that the Investor may disclose confidential information (i) to its attorneys, accountants, consultants, and other professionals to the extent necessary to obtain their services in connection with monitoring its investment in the Company; (ii) to any prospective purchaser of any Registrable Securities from the Investor, if such prospective purchaser agrees to be bound by the provisions of this Subsection 3.5; (iii) to any existing or prospective Affiliate, partner, member, shareholder, or wholly owned subsidiary of the Investor in the ordinary course of business, provided that the Investor informs such Person that such information is confidential and directs such Person to maintain the confidentiality of such information; or (iv) as may otherwise be required by law, provided that the Investor promptly notifies the Company of such disclosure and takes reasonable steps to minimize the extent of any such required disclosure.

4. Rights to Future Stock Issuances.

4.1 Right of First Offer. Subject to the terms and conditions of this Subsection 4.1 and applicable securities laws, if the Company proposes to offer or sell any New Securities, the Company shall first offer such New Securities to the Investor. The Investor shall be entitled to apportion the right of first offer hereby granted to it in such proportions as it deems appropriate, among (i) itself and (ii) its Affiliates.

(a) The Company shall give notice (the "**Offer Notice**") to the Investor, stating (i) its bona fide intention to offer such New Securities, (ii) the number of such New Securities to be offered, and (iii) the price and terms, if any, upon which it proposes to offer such New Securities.

(b) By notification to the Company within twenty (20) days after the Offer Notice is given, the Investor may elect to purchase or otherwise acquire, at the price and on the terms specified in the Offer Notice, up to that portion of such New Securities which equals the proportion that the Common Stock then held by the Investor (including all shares of Common Stock then issuable (directly or indirectly) upon conversion and/or exercise, as applicable, of the Preferred Stock and any other Derivative Securities then held by the Investor) bears to the total Common Stock of the Company then held by all holders of the Company's securities (including all shares of Common Stock issuable (directly or indirectly) upon conversion and/or exercise, as applicable, of the Preferred Stock and any other Derivative Securities then held by all holders of the Company's securities). The closing of any sale pursuant to this Subsection 4.1(b) shall occur within the later of ninety (90) days of the date that the Offer Notice is given and the date of initial sale of New Securities pursuant to Subsection 4.1(c).

(c) If all New Securities referred to in the Offer Notice are not elected to be purchased or acquired as provided in Subsection 4.1(b), the Company may, during the ninety (90) day period following the expiration of the periods provided in Subsection 4.1(b), offer and sell the remaining unsubscribed portion of such New Securities to any Person or Persons at a price not less than, and upon terms no more favorable to the offeree than, those specified in the Offer Notice. If the Company does not enter into an agreement for the sale of the New Securities within such period, or if such agreement is not consummated within thirty (30) days of the execution thereof, the right provided hereunder shall be deemed to be revived and such New Securities shall not be offered unless first reoffered to the Investor in accordance with this Subsection 4.1.

(d) The right of first offer in this Subsection 4.1 shall not be applicable to Excepted Securities.

4.2 Termination. The covenants set forth in Subsection 4.1 shall terminate and be of no further force or effect (i) immediately before the consummation of the Qualified IPO, or (ii) upon a Qualified Liquidation Event, whichever event occurs first.

5. Additional Covenants.

5.1 Insurance. The Company shall use its commercially reasonable efforts to obtain, within ninety (90) days of the date hereof, from financially sound and reputable insurers Directors and Officers liability insurance and term "key-person" insurance on Pankaj Mohan, Ph.D., in an amount and on terms and conditions satisfactory to the Board of Directors, and will use commercially reasonable efforts to cause such insurance policies to be maintained

until such time as the Board of Directors determines that such insurance should be discontinued. The key-person policy shall name the Company as loss payee, and neither policy shall be cancelable by the Company without prior approval by the Board of Directors. Each Key Holder hereby covenants and agrees that, to the extent such Key Holder is named under such key-person policy, such Key Holder will execute and deliver to the Company, as reasonably requested, a written notice and consent form with respect to such policy.

5.2 Employee Agreements. The Company will, cause (1) each person now or hereafter employed by it or by any subsidiary (or engaged by the Company or any subsidiary as a consultant/independent contractor) with access to confidential information and/or trade secrets to enter into a nondisclosure and proprietary rights assignment agreement; and (ii) each Key Employee to enter into a one (1) year noncompetition and nonsolicitation agreement, substantially in the form approved by the Board of Directors. In addition, the Company shall not amend, modify, terminate, waive, or otherwise alter, in whole or in part, any of the above-referenced agreements or any restricted stock agreement between the Company and any employee, without the unanimous consent of the Board of Directors.

5.3 Matters Requiring Investor Approval. At any time during the Adjustment Period, so long as the Investor and its Affiliates own and hold at least 75% of the Purchased Shares outstanding, the Company hereby covenants and agrees with the Investor that it shall not, without approval of the Investor, such approval not to be unreasonably withheld or delayed:

(a) change the principal business of the Company, enter new lines of business, or exit the current line of business of the Company;

(b) enter into a Sale of the Company;

(c) voluntarily commence a winding up proceeding for insolvency or bankruptcy of the Company or a general assignment for the benefit of its creditors or consent to the entry of a decree or order for relief from creditors under any applicable law or any admission by the Company of: (i) its inability to pays its debts, or (ii) any other action constituting a cause for the involuntary declaration of insolvency or bankruptcy;

(d) issue any equity or debt securities for the purpose of raising capital prior to an initial public offering of the Common Stock, pursuant to which the equity of the Company is valued at less than $100 million prior to consummation of such offering, as calculated on a fully diluted basis;

(e) consummate an initial public offering of the Common Stock, pursuant to which the equity of the Company is valued at less than $300 million prior to consummation of such offering, as calculated on a fully diluted basis;

(f) sell all or substantially all of the Company’s assets or close an existing business or engage any business beyond the scope of the Business Plan (as defined in the Purchase Agreement);

(g) sell, transfer, lease or encumber any material part of the Company's business or assets;

(h) amend the Company's Certificate of Incorporation;

(i) change the name of the Company or transfer any Company Intellectual Property (as defined in the Purchase Agreement), unless such transfer is between the Company and its Affiliates;

(j) apply to list the shares of Common Stock on any stock exchange or quotation service; or

(k) change the registered office of the Company.

5.4 Matters Requiring Investor Notice. At any time during the Adjustment Period, so long as the Investor and its Affiliates own and hold at least 75% of the Purchased Shares outstanding, the Company hereby covenants and agrees with the Investor that it shall notify the Investor of the following actions:

(a) any acquisition by the Company of any business or division of a third party by way of share purchase, business transfer, slump sale, asset purchase or any other mode of acquiring a business;

(b) formation of joint ventures or partnerships by the Company or creation of a subsidiary by the Company;

(c) any increase, decrease, buy back or other alteration, amendment or modification of authorized or issued equity capital of the Company or any alteration, amendment or modification to the rights of the holders of any equity capital of the Company or the creation of any rights or securities containing anti-dilution protection terms and the details of such terms thereof;

(d) any declaration or payment of any dividend or distribution of profits or commissions to the shareholders, employees or directors of the Company;

(e) any increase or decrease in the size of the Board of Directors;

(f) entering into any transaction between the Company and a Related Party (as defined in the Purchase Agreement);

(g) a material amendment or modification to a material compensatory plan, contract or arrangement of a Key Employee, or a material grant or award to any such Key Employee under any such plan, contract or arrangement;

(h) any capital expenditure in excess of $2,000,000;

(i) an incurrence of any debt of the Company beyond three (3) times current debt as per the most recent audited financial statements, where debt includes without limitation short and long term debt and guarantees by the Company;

(j) any litigation of the Company involving any amount in excess of $2,000,000; and

(k) a termination or modification of any material contract or arrangement disclosed in Subsection 2.10 of the Disclosure Schedule to the Purchase Agreement, or any material contract or arrangement that would have been disclosed in Subsection 2.10 of the Disclosure Schedule to the Purchase Agreement if such contract or arrangement had been entered into as of the date hereof.

5.5 Board Matters. Unless otherwise determined by the vote of a majority of the directors then in office, the Board of Directors shall meet at least quarterly in accordance with an agreed-upon schedule.

5.6 Successor Indemnification. If the Company or any of its successors or assignees consolidates with or merges into any other Person and is not the continuing or surviving corporation or entity of such consolidation or merger, then to the extent necessary, proper provision shall be made so that the successors and assignees of the Company assume the obligations of the Company with respect to indemnification of members of the Board of Directors as in effect immediately before such transaction, whether such obligations are contained in the Company's Bylaws, its Certificate of Incorporation, or elsewhere, as the case may be.

5.7 Expenses of Counsel. In the event of a transaction which is a Sale of the Company, the reasonable fees and disbursements, of one counsel for the Investor ("**Investor Counsel**"), in their capacities as shareholders, not to exceed $10,000 shall be borne and paid by the Company. At the outset of considering a transaction which, if consummated would constitute a Sale of the Company, the Company shall obtain the ability to share with the Investor Counsel (and such counsel's clients) and shall share the confidential information (including, without limitation, the initial and all subsequent drafts of memoranda of understanding, letters of intent and other transaction documents and related noncompete, employment, consulting and other compensation agreements and plans) pertaining to and memorializing any of the transactions which, individually or when aggregated with others would constitute the Sale of the Company. The Company shall be obligated to share (and cause the Company's counsel and investment bankers to share) such materials when distributed to the Company's executives and/or any one or more of the other parties to such transaction(s). In the event that Investor Counsel deems it appropriate, in its reasonable discretion, to enter into a joint defense agreement or other arrangement to enhance the ability of the parties to protect their communications and other reviewed materials under the attorney client privilege, the Company shall, and shall direct its counsel to, execute and deliver to Investor Counsel and its clients such an agreement in form and substance reasonably acceptable to Investor Counsel. In the event that one or more of the other party or parties to such transactions require the clients of Investor Counsel to enter into a confidentiality agreement and/or joint defense agreement in order to receive such information, then the Company shall share whatever information can be shared

without entry into such agreement and shall, at the same time, in good faith work expeditiously to enable Investor Counsel and its clients to negotiate and enter into the appropriate agreement(s) without undue burden to the clients of Investor Counsel.

5.8 FCPA. The Company represents that it shall not (and shall not permit any of its subsidiaries or affiliates or any of its or their respective directors, officers, managers, employees, independent contractors, representatives or agents to) promise, authorize or make any payment to, or otherwise contribute any item of value to, directly or indirectly, to any third party, including any Non-U.S. Official (as (as such term is defined in the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "**FCPA**")), in each case, in violation of the FCPA, the U.K. Bribery Act, or any other applicable anti-bribery or anti-corruption law. The Company further represents that it shall (and shall cause each of its subsidiaries and affiliates to) cease all of its or their respective activities, as well as remediate any actions taken by the Company, its subsidiaries or affiliates, or any of their respective directors, officers, managers, employees, independent contractors, representatives or agents in violation of the FCPA, the U.K. Bribery Act, or any other applicable anti-bribery or anti-corruption law. The Company further represents that it shall (and shall cause each of its subsidiaries and affiliates to) maintain systems of internal controls (including, but not limited to, accounting systems, purchasing systems and billing systems) to ensure compliance with the FCPA, the U.K. Bribery Act, or any other applicable anti-bribery or anti-corruption law. Upon request, the Company agrees to provide responsive information and/or certifications concerning its compliance with applicable anti-corruption laws. The Company shall promptly notify the Investor if the Company becomes aware of any Enforcement Action (as defined in the Purchase Agreement). The Company shall, and shall cause any direct or indirect subsidiary or entity controlled by it, whether now in existence or formed in the future, to comply with the FCPA. The Company shall use its best efforts to cause any direct or indirect subsidiary, whether now in existence or formed in the future to, comply in all material respects with all applicable laws.

5.9 Cooperation of Key Holders. The Key Holders shall use commercially reasonable efforts to (a) participate with or otherwise support the Company in its marketing, investor relations or other activities with respect to the issuance of any equity or debt securities by the Company for the purpose of raising capital, and (b) to cause the Company to consummate an initial public offering of the Common Stock.

5.10 Termination of Covenants. The covenants set forth in this Section 5, except for Subsections 5.6 and 5.7, shall terminate and be of no further force or effect (i) immediately before the consummation of the Qualified IPO or (ii) upon a Qualified Liquidation Event, whichever event occurs first.

6. Miscellaneous.

6.1 Successors and Assigns. The rights under this Agreement may be assigned (but only with all related obligations) by a Holder to a transferee of Registrable Securities that (i) is an Affiliate of a Holder; (ii) is a Holder's Immediate Family Member or trust for the benefit of an individual Holder or one or more of such Holder's Immediate Family Members; or (iii) after such transfer, holds at least 1,000,000 shares of Registrable Securities (subject to appropriate adjustment for stock splits, stock dividends, combinations, and other

recapitalizations); provided, however, that (x) the Company is, within a reasonable time after such transfer, furnished with written notice of the name and address of such transferee and the Registrable Securities with respect to which such rights are being transferred; and (y) such transferee agrees in a written instrument delivered to the Company to be bound by and subject to the terms and conditions of this Agreement, including the provisions of Subsection 2.11. For the purposes of determining the number of shares of Registrable Securities held by a transferee, the holdings of a transferee (1) that is an Affiliate or stockholder of a Holder; (2) who is a Holder's Immediate Family Member; or (3) that is a trust for the benefit of an individual Holder or such Holder's Immediate Family Member shall be aggregated together and with those of the transferring Holder; provided further that all transferees who would not qualify individually for assignment of rights shall have a single attorney-in-fact for the purpose of exercising any rights, receiving notices, or taking any action under this Agreement. The terms and conditions of this Agreement inure to the benefit of and are binding upon the respective successors and permitted assignees of the parties. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assignees any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided herein.

6.2 Governing Law. This Agreement shall be governed by the internal law of the State of New York.

6.3 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

6.4 Titles and Subtitles. The titles and subtitles used in this Agreement are for convenience only and are not to be considered in construing or interpreting this Agreement.

6.5 Notices. All notices and other communications given or made pursuant to this Agreement shall be in writing and shall be deemed effectively given upon the earlier of actual receipt or (a) personal delivery to the party to be notified; (b) when sent, if sent by electronic mail or facsimile during the recipient's normal business hours, and if not sent during normal business hours, then on the recipient's next business day; (c) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid; or (d) one (1) business day after the business day of deposit with a nationally recognized overnight courier, freight prepaid, specifying next-day delivery, with written verification of receipt. All communications shall be sent to the respective parties at their addresses as set forth on the signature pages hereto or Schedule A (as applicable) hereto, or to the principal office of the Company and to the attention of the Chief Executive Officer, in the case of the Company, or to such email address, facsimile number, or address as subsequently modified by written notice given in accordance with this Subsection 6.5. If notice is given to the Company, a copy shall also be sent to W. Raymond Felton, Greenbaum, Rowe, Smith & Davis LLP, 99 Wood Avenue South, Iselin, NJ 08830-2712 and if notice is given to the Investor, a copy shall also be given to Rick Werner, Haynes and Boone, LLP, 30 Rockefeller Plaza, 26th Floor, New York, NY 10112.

6.6 Amendments and Waivers. Any term of this Agreement may be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance, and either retroactively or prospectively) only with the written consent of the Company and the holders of a majority of the Registrable Securities then outstanding; provided that the Company may in its sole discretion waive compliance with Subsection 2.12(c) (and the Company's failure to object promptly in writing after notification of a proposed assignment allegedly in violation of Subsection 2.12(c) shall be deemed to be a waiver); and provided further that any provision hereof may be waived by any waiving party on such party's own behalf, without the consent of any other party. Notwithstanding the foregoing, this Agreement may not be amended or terminated and the observance of any term hereof may not be waived with respect to the Investor without the written consent of the Investor. The Company shall give prompt notice of any amendment or termination hereof or waiver hereunder to any party hereto that did not consent in writing to such amendment, termination, or waiver. Any amendment, termination, or waiver effected in accordance with this Subsection 6.6 shall be binding on all parties hereto, regardless of whether any such party has consented thereto. No waivers of or exceptions to any term, condition, or provision of this Agreement, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of any such term, condition, or provision.

6.7 Severability. In case any one or more of the provisions contained in this Agreement is for any reason held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provision of this Agreement, and such invalid, illegal, or unenforceable provision shall be reformed and construed so that it will be valid, legal, and enforceable to the maximum extent permitted by law.

6.8 Aggregation of Stock. All shares of Registrable Securities held or acquired by Affiliates shall be aggregated together for the purpose of determining the availability of any rights under this Agreement and such Affiliated persons may apportion such rights as among themselves in any manner they deem appropriate.

6.9 Additional Investors. Notwithstanding anything to the contrary contained herein, if the Company issues additional shares of Common Stock after the date hereof, any purchaser of such shares may become a party to this Agreement, upon written consent of the Investor, by executing and delivering a joinder agreement to this Agreement, and thereafter shall be deemed an "Investor" for all purposes hereunder.

6.10 Entire Agreement. This Agreement (including any Schedules and Exhibits hereto) constitutes the full and entire understanding and agreement among the parties with respect to the subject matter hereof, and any other written or oral agreement relating to the subject matter hereof existing between the parties is expressly canceled.

6.11 Dispute Resolution. The parties (a) hereby irrevocably and unconditionally submit to the jurisdiction of the state courts of New York and to the jurisdiction of the United States District Court for the Southern District of New York for the purpose of any suit, action or other proceeding arising out of or based upon this Agreement, (b) agree not to commence any suit, action or other proceeding arising out of or based upon this Agreement except in the state courts of New York or the United States District Court for the Southern

District of New York, and (c) hereby waive, and agree not to assert, by way of motion, as a defense, or otherwise, in any such suit, action or proceeding, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that the suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action or proceeding is improper or that this Agreement or the subject matter hereof may not be enforced in or by such court.

WAIVER OF JURY TRIAL: EACH PARTY HEREBY WAIVES ITS RIGHTS TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT, THE OTHER TRANSACTION DOCUMENTS, THE SECURITIES OR THE SUBJECT MATTER HEREOF OR THEREOF. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL-ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT AND THAT RELATE TO THE SUBJECT MATTER OF THIS TRANSACTION, INCLUDING, WITHOUT LIMITATION, CONTRACT CLAIMS, TORT CLAIMS (INCLUDING NEGLIGENCE), BREACH OF DUTY CLAIMS, AND ALL OTHER COMMON LAW AND STATUTORY CLAIMS. THIS SECTION HAS BEEN FULLY DISCUSSED BY EACH OF THE PARTIES HERETO AND THESE PROVISIONS WILL NOT BE SUBJECT TO ANY EXCEPTIONS. EACH PARTY HERETO HEREBY FURTHER WARRANTS AND REPRESENTS THAT SUCH PARTY HAS REVIEWED THIS WAIVER WITH ITS LEGAL COUNSEL, AND THAT SUCH PARTY KNOWINGLY AND VOLUNTARILY WAIVES ITS JURY TRIAL RIGHTS FOLLOWING CONSULTATION WITH LEGAL COUNSEL.

The prevailing party shall be entitled to reasonable attorney's fees, costs, and necessary disbursements in addition to any other relief to which such party may be entitled. Each of the parties to this Agreement consents to personal jurisdiction for any equitable action sought in the U.S. District Court for the Southern District of New York or any court of the State of New York having subject matter jurisdiction.

6.12 Delays or Omissions. No delay or omission to exercise any right, power, or remedy accruing to any party under this Agreement, upon any breach or default of any other party under this Agreement, shall impair any such right, power, or remedy of such nonbreaching or nondefaulting party, nor shall it be construed to be a waiver of or acquiescence to any such breach or default, or to any similar breach or default thereafter occurring, nor shall any waiver of any single breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. All remedies, whether under this Agreement or by law or otherwise afforded to any party, shall be cumulative and not alternative.

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IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

COMPANY:

ONCOBIOLOGICS, INC.

By: /s/ Pankaj Mohan

Name: Pankaj Mohan

Title: Chief Executive Officer

Address: 7 Clarke Drive
Cranbury, New Jersey 08512

INVESTOR:

STRIDES PHARMA INC.

By: /s/ Joe Thomas

Name: Joe Thomas
(print)

Title: Director

Address: 201 South Main Street, Suite 3,
Lambertville, New Jersey 08530

KEY HOLDERS:

Signature: /s/ Pankaj Mohan

Name: Pankaj Mohan

SCHEDULE A
Key Holders

Pankaj Mohan, Ph.D., MBA
c/o Oncobiologics, Inc.
7 Clarke Drive
Cranbury, New Jersey 08512

AMENDMENT NO. 1 TO INVESTORS' RIGHTS AGREEMENT

THIS AMENDMENT NO. 1 TO INVESTORS' RIGHTS AGREEMENT (this "**Amendment**") is made as of the _26 day of June, 2014, by and among Oncobiologics, Inc., a New Jersey corporation (the "**Company**"), Strides Pharma, Inc., a company incorporated under the laws of New Jersey (the "**Investor**"), and the Key Holder signatory to this Amendment.

WHEREAS, on March 10, 2013, the Company and the Investor entered into that certain Securities Purchase Agreement (the "**First Purchase Agreement**"), pursuant to which the Investor agreed to purchase shares of Common Stock; and

WHEREAS, in connection with the First Purchase Agreement, the Company, the Investor, and the Key Holder entered into that certain Investors' Rights Agreement (the "**Investors' Rights Agreement**"), dated as of March 10, 2013;

WHEREAS, the Company and the Investor are parties to that certain Securities Purchase Agreement (the "**Second Purchase Agreement**"), of even date hereof, pursuant to which the Investor has agreed to purchase additional shares of Common Stock;

WHEREAS, in connection with the Second Purchase Agreement, the parties to the Investors' Rights Agreement desire to amend the Investors' Rights Agreement to make conforming changes and to acknowledge that the shares of Common Stock purchased by the Investor pursuant to the Second Purchase Agreement are subject to the Investors' Rights Agreement and the rights of the Investor thereunder;

WHEREAS, each of the Company, the Key Holder holding the majority of the Registrable Securities outstanding as of the date hereof, and the Investor is willing to give its consent to amend the Investors' Rights Agreement pursuant to Section 6.6 of the Investors' Rights Agreement as expressly provided herein; and

WHEREAS, all capitalized terms used but not otherwise .defined herein shall have the meanings ascribed to such terms in the Investors' Rights Agreement.

NOW, THEREFORE, the Company, the Key Holders and the Investor agree as follows:

1. Amendments.

1.1 In the recitals of the Investors' Rights Agreement, the following recital is hereby deleted:

"**WHEREAS**, the Company and the Investor are parties to the Securities Purchase Agreement of even date herewith (the "**Purchase Agreement**"); and"

and replaced in its entirety by the following:

"**WHEREAS**, the Company and the Investor are parties to the Securities Purchase Agreement, dated as of March 10, 2014 (the "**First Purchase**

Agreement"), and the Securities Purchase Agreement, dated as of June __, 2014 (the "**Second Purchase Agreement**", and together with the First Purchase Agreement, the "**Purchase Agreement**") pursuant to which the Investor has agreed to purchase shares of Common Stock; and"

1.2 Definitions. The following definitions in Section 1 of the Investors' Rights Agreement is amended and replaced in its entirety by the following:

"**Qualified IPO**" means the closing by the Company of a firm commitment underwritten public offering with a price of at least $7.50 per share of Common Stock (as adjusted for stock dividends, splits, combinations and similar events) and gross proceeds to the Company of not less than $50 million."

2. Acknowledgement. The parties hereby acknowledge and agree that any shares of Common Stock acquired by the Investor pursuant to the Second Purchase Agreement are Registrable Securities under the Investors' Rights Agreement, subject to the terms and conditions stated therein.

3. Miscellaneous.

3.1 Continuing Effect. Except as expressly set forth in this Amendment, all of the terms and conditions of the Investors' Rights Agreement shall remain unmodified and in full force and effect after the execution of this Amendment and shall not be in any way changed, modified or superseded by the terms set forth herein.

3.2 Severability. The invalidity or unenforceability of any provision hereof shall in no way affect the validity or enforceability of any other provision.

3.3 Governing Law. This Amendment shall be governed by the internal law of the State of New York.

3.4 Titles and Subtitles. The titles and subtitles used in this Amendment are used for convenience only and are not to be considered in construing or interpreting this Amendment.

3.5 Counterparts. This Amendment may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties have executed this Amendment No. 1 to Investors' Rights Agreement as of the date first written above.

COMPANY:

ONCOBIOLOGICS, INC.

By: /s/ Pankaj Mohan PhD MBA

Name: Pankaj Mohan PhD MBA
(print)

Title: CEO

Address: 7 Clarke Drive, Cranbury, New Jersey 08512

INVESTOR:

STRIDES PHARMA INC.

By: /s/ Joe Thomas

Name: Joe Thomas
(print)

Title: Director

Address: 201 South Main Street, Suite 3,
Lambertville, New Jersey 08530

KEY HOLDER:

Signature: /s/ Pankaj Mohan PhD MBA

Name: Pankaj Mohan, PhD., MBA

ONCOBIOLOGICS, INC.

AMENDMENT AND WAIVER

This Amendment and Waiver (this "***Amendment***") by the undersigned holders (the "***Investors***") of shares of common stock, no par value per share (the "***Common Stock***"), of Oncobiologics, Inc., a New Jersey corporation (together with any successor thereto, the ***"Company***"), is entered into as of September 28, 2015.

RECITALS

WHEREAS, the Company has entered into a Securities Purchase Agreement with each of the Investors for the sale and issuance of Common Stock, of an aggregate purchase price of up to $67,000,000 (each a "***Purchase Agreement***" and together, the "***Purchase Agreements***");

WHEREAS, the Company has entered into that certain Investors' Rights Agreement, by and among Strides Pharma Inc. ("***Strides***") and Dr. Pankaj Mohan, dated as of March 10, 2014 (the "***Rights Agreement***");

WHEREAS, the Company has entered into a Joinder Agreement with each of the Investors other than Strides, joining each such Investor as a party to the Rights Agreement, as an "Investor" thereunder;

WHEREAS, the Company intends to file a registration statement on Form S-1 with the U.S. Securities and Exchange Commission in connection with a proposed initial public offering of its Common Stock, which will be offered on an underwritten basis (the "***Proposed IPO***");

WHEREAS, the Rights Agreement provides the parties thereto with certain rights with respect to the Common Stock that terminate upon the consummation of the Proposed IPO;

WHEREAS, the underwriters of the Proposed IPO have directed the Company to amend the definition of "Qualified IPO";

WHEREAS, pursuant to Section 2.2 of the Rights Agreement, each Investor (as defined in the Rights Agreement) is entitled to receive notice of the filing by the Company of any registration statement under the Securities Act of 1933, as amended, for the purposes of a public offering of Common Stock of the Company (the "***Notice Rights***") and, under certain circumstances, hold rights (the "***Registration Rights***") with respect to the registration of their Registrable Securities in connection therewith, including the Proposed IPO;

WHEREAS, each Investor agrees to (i) amend the definition of Qualified IPO, (ii) waive its Notice Rights and Registration Rights pursuant to Section 2.2 of the Rights Agreement in connection with the Proposed IPO and (iii) clarify certain other provisions of the Rights Agreement;

WHEREAS, pursuant to Section 6.6 of the Rights Agreement, the Rights Agreement may be amended with the written consent of the Company and the holders of a majority of the Registrable Securities outstanding (the "***Rights Agreement Threshold***"); and

WHEREAS, the undersigned represent the Rights Agreement Threshold.

AGREEMENT

Pursuant to Section 6.6 of the Rights Agreement, the undersigned parties hereby agree:

a) to amend and restate Section 1.2 of the Rights Agreement as follows:

"**Affiliate**" means, with respect to any specified Person, any other Person who, directly or indirectly, controls, is controlled by, or is under common control with such Person, including, without limitation, any general partner, managing member, officer or director of such Person or any venture capital, private equity or similar investment fund now or hereafter existing that is controlled by one or more general partners or managing members of, or shares the same management company with, such Person.;

b) to amend and restate Section 1.20 of the Rights Agreement as follows:

"**Qualified IPO**" means the closing by the Company of a firm commitment underwritten public offering with gross proceeds to the Company of not less than $50 million.;

c) to waive its Notice Rights and Registration Rights pursuant to Section 2.2 of the Rights Agreement with respect to the Proposed IPO;

d) that the term "Registrable Securities" as used in the Rights Agreement shall be amended to include, in addition to all shares of equity securities currently included in the definition of "Registrable Securities", all securities purchased by Investors pursuant to the Purchase Agreements such that each Investor shall be considered a "Holder" under the Rights Agreement;

e) that for the avoidance of doubt, a customary arrangement in connection with the deposit of Registrable Securities in a non-margin custodial account shall not be deemed a sale, transfer or pledge for purposes of Section 2.12 of the Rights Agreement, so long as such Registrable Securities are in certificated form (it being understood that the Company may require the exchange of any such certificated securities for book-entry shares upon an underwritten public offering);

f) that notwithstanding anything in this Agreement or in the Rights Agreement to the contrary, the terms of Section 4 of the Rights Agreement may not be amended, modified or terminated with respect to any Investor without the written consent of such Investor;

g) that for the purposes of Sections 5.3 and 5.4 of the Rights Agreement, the applicable covenants shall terminate (i) with respect to all of the Investors, at such time as all Investors and their respective affiliates, in the aggregate, own and hold less than fifty percent (50%) of the aggregate shares purchased and sold pursuant to the Purchase Agreements (as defined herein) and the Purchase Agreement (as defined in the Rights Agreement) and (ii) with respect to each individual Investor, at such time as such Investor and its respective affiliates, in the aggregate, own and hold less than seventy-five percent (75%) of the shares purchased

by such Investor pursuant to the Purchase Agreements (as defined herein) or the Purchase Agreement (as defined in the Rights Agreement), as applicable;

h) that for the purposes of Section 6.6 of the Rights Agreement exclusively, the term "Investor" shall mean the Investors collectively holding a majority of Registrable Securities held by all of the Investors; and

i) that for the purpose of Section 6.9 of the Rights Agreement exclusively, the term "Investor" shall mean the Investors collectively holding a majority of Registrable Securities held by all of the Investors.

j) to add the following text as a new Section 5.11 of the Rights Agreement:

"5.11. Additional Matters Requiring Investor Approval. The Company hereby covenants and agrees with each Investor that (i) so long as the Investor, together with its affiliates, continues to own and hold at least seventy-five percent (75%) of the shares purchased by such Investor pursuant to the Purchase Agreements (as defined herein) or the Purchase Agreement (as defined in the Rights Agreement), as applicable, and (ii) all Investors and their respective affiliates, in the aggregate, own and hold at least fifty-percent (50%) of the aggregate shares purchased and sold pursuant to the Purchase Agreements (as defined herein) and the Purchase Agreement (as defined in the Rights Agreement), the Company shall not (by amendment, merger, consolidation or otherwise), without approval of such Investor:

a. redeem, purchase or otherwise acquire (or pay into or set aside for a sinking fund for such purpose) any share or shares of Preferred Stock or Common Stock; provided, however, that this restriction shall not apply to (i) the repurchase of shares of Common Stock from employees, officers, directors, consultants or other persons performing services for the Company or any subsidiary pursuant to agreements under which the Company has the option to repurchase such shares upon the occurrence of certain events, such as the termination of employment or service, or pursuant to a right of first refusal, (ii) the redemption of any share or shares of Preferred Stock in accordance with Section 3 of the Certificate of Designation adopted with respect to each of the Series A Preferred Stock and Series B Preferred Stock (the "Certificates of Designation") or (iii) a redemption, repurchase or acquisition on a pro-rata basis for all classes of stock of the Company;

b. pay or declare any dividend on any shares of capital stock of the Company other than (i) the dividend obligations of the Company in accordance with Section 1 of the Certificates of Designation, or (ii) dividends payable on a pro-rata basis to all classes of stock of the Company;

c. amend, alter or repeal any provision of the Company's Certificate of Incorporation (including any Certificates of Designation) or Bylaws so as to materially increase the rights of the holders of Preferred Stock; or

d. enter into or modify any transaction or agreement between the Company and any of its shareholders with respect to the rights that have been granted (or that have not been granted) to any shareholder of the Company."

MISCELLANEOUS

Except as set forth above, all the terms and provisions of the Rights Agreement shall continue in full force and effect.

This Amendment may be executed in one or more counterparts (including via PDF copy), each of which shall be deemed an original, and all of which together shall constitute one instrument.

(*Signature Pages Follow*)

IN WITNESS WHEREOF, each of the undersigned hereby executes this Amendment as of the date first above written.

ONCOBIOLOGICS, INC.:

By: /s/ Pankaj Mohan, Ph.D.

Name: Pankaj Mohan, Ph.D.

Title: President and Chief Executive Officer

INVESTOR:

By: _____

Name: _____

Title: _____

ONCOBIOLOGICS, INC.

AMENDMENT AND WAIVER NO. 2

This Amendment and Waiver No. 2 (this "***Amendment***") by the undersigned holders (the "***Investors***") of shares of common stock, $0.01 par value per share (the "***Common Stock***"), of Oncobiologics, Inc., a Delaware corporation (together with any successor thereto, the "***Company***"), is entered into as of April 26, 2016. Capitalized terms used herein and not defined shall have the respective meanings ascribed to such terms in the Rights Agreement, as amended to date (as defined below).

RECITALS

WHEREAS, the Company has entered into that certain Investors' Rights Agreement, by and among Strides Pharma ("***Strides***") and Dr. Pankaj Mohan, dated as of March 10, 2014 (as amended to date, the "***Rights Agreement***");

WHEREAS, Strides has assigned its shares of Common Stock to Strides Pharma Limited;

WHEREAS, the Company has entered into a Joinder Agreement with each of the Investors other than Strides Pharma Limited, joining each such Investor as a party to the Rights Agreement, as an "Investor" thereunder;

WHEREAS, the Company has filed a registration statement on Form S-1 with the U.S. Securities and Exchange Commission in connection with a proposed initial public offering of its Common Stock, which will be offered on a firm commitment underwritten basis (the "***Proposed IPO***");

WHEREAS, the Rights Agreement provides the parties thereto with certain rights with respect to the Common Stock that terminate upon the consummation of the Proposed IPO;

WHEREAS, the underwriters of the Proposed IPO have directed the Company to amend the definition of "Qualified IPO";

WHEREAS, each Investor agrees to the removal and deletion of Section 5.3(e) of the Rights Agreement in connection with the Proposed IPO;

WHEREAS, pursuant to Section 5.3(h) and Section 5.11(d) of the Rights Agreement, each Investor agrees to the filing with the Secretary of State of the State of Delaware a Certificate of Amendment of the Company's Certificate of Incorporation substantially in the form attached to this Amendment as Exhibit A (the "***Certificate of Amendment***") to effect a reverse stock split of the Company's Common Stock;

WHEREAS, the Company agrees, in consideration for the execution and delivery of this Amendment, to provide certain of the Investors with warrants to purchase shares of Common Stock under certain circumstances;

WHEREAS, pursuant to Section 6.6 of the Rights Agreement, the Rights Agreement may be amended with the written consent of the Company and the holders of a majority of the Registrable Securities outstanding (the "***Rights Agreement Threshold***");

WHEREAS, each Investor agrees to amend Section 6.6 of the Rights Agreement as provided herein; and

WHEREAS, the undersigned represent the Rights Agreement Threshold; NOW, THEREFORE, in consideration of the foregoing and the agreements hereinafter set forth, and intending to be legally bound hereby, the parties hereto agree as follows:

AGREEMENT

Pursuant to Section 6.6 of the Rights Agreement, the undersigned parties hereby agree:

a) to amend and restate Section 1.20 of the Rights Agreement as follows:

"**Qualified IPO**" means the closing by the Company of a firm commitment underwritten public offering.;

b) to the removal and deletion of Section 5.3(e) of the Rights Agreement;

c) to the filing with the Secretary of State of the State of Delaware a Certificate of Amendment pursuant to Section 5.3(h) of the Rights Agreement pursuant to which the Board of Directors may effect a reverse stock split of the Company's Common Stock in a ratio of 1-for-3.45;

d) to add the following section as Section 5.12 of the Rights Agreement:

"5.12. IPO Warrant Shares. In the event of a Qualified IPO in which the pre-money valuation (on a fully diluted basis) of the Company immediately prior to the Qualified IPO is less than $300 million, then each Investor, who invested at a pre-money valuation (on a fully diluted basis) of the Company in excess of $300 million shall receive, upon the consummation of the Qualified IPO, a warrant, substantially in the form attached to this Amendment as Exhibit B (the "***Warrant***"), to purchase that number of shares of Common Stock equal to 65% of the number of shares of Common Stock purchased by such Investor at a pre-money valuation (on a fully diluted basis) of at least $300 million (the "***Warrant Shares***"); *provided*, that such number of warrant shares shall be adjusted for any forward or reverse stock split effected by the Company. Each Investor hereby acknowledges that their existing lock-up agreement shall include the Warrant and the Warrant Shares.

For the avoidance of doubt, if an Investor invested $100,000 and purchased 11,876 shares of Common Stock for a purchase price of $8.42 per share, based on a pre-money valuation (on a fully diluted basis) of $395 million, and assuming a pre-money valuation (on a fully diluted basis) of the Company of $200 million immediately prior to the Qualified IPO, then such investor shall receive at the closing of such Qualified IPO a warrant to purchase 7,719 shares of Common Stock at an exercise price of $0.01 per share.

Further, if an Investor invested $100,000 and purchased 13,378 shares of Common Stock for a purchase price of $7.475 per share, based on a pre-money valuation (on a fully diluted basis) of the Company of $300 million, and assuming a pre-money valuation (on a fully diluted basis) of $200 million immediately prior to the Qualified IPO, then such Investor shall receive at the closing of such Qualified IPO a warrant to purchase 8,696 shares of Common Stock at an exercise price of $0.01 per share.

Assuming in each case above, that a reverse stock split of 1-for-3.45 is effected by the Company, then the warrant to purchase 7,719 and 8,696, respectively, will be 2,237 and 2,520, respectively."

e) to amend Section 6.6 of the Rights Agreement to delete the following sentence:

"Notwithstanding the foregoing, this Agreement may not be amended or terminated and the observance of any term hereof may not be waived with respect to the Investor without the written consent of the Investor."; and

f) to add the following section as Section 6.13 of the Rights Agreement:

"Notwithstanding the foregoing, (i) this Agreement, except for Section 2, Subsection 3.5, Section 5.12 and Section 6, as amended, shall terminate and be of no further force or effect immediately before the consummation of the Proposed IPO and (ii) this Agreement, in the event of a Qualified Liquidation Event, shall terminate in its entirety and be of no further force or effect."

MISCELLANEOUS

Except as set forth above, all the terms and provisions of the Rights Agreement shall continue in full force and effect.

This Amendment may be executed in one or more counterparts (including via PDF copy), each of which shall be deemed an original, and all of which together shall constitute one instrument.

(*Signature Pages Follow*)

IN WITNESS WHEREOF, each of the undersigned hereby executes this Amendment as of the date first above written.

ONCOBIOLOGICS, INC.:

By: /s/ Pankaj Mohan, Ph.D.

Name: Pankaj Mohan, Ph.D.

Title: President and Chief Executive Officer

INVESTOR:

By: _____

Name: _____

Title: _____

Exhibit A

Form of Certificate of Amendment

Exhibit B

Form of Warrant

EXHIBIT B

NEITHER THIS WARRANT, NOR THE SECURITIES ISSUABLE UPON EXERCISE OF THIS WARRANT (COLLECTIVELY, THE "SECURITIES"), HAVE BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), OR UNDER ANY STATE SECURITIES OR BLUE SKY LAWS. THE SECURITIES ARE SUBJECT TO RESTRICTIONS ON TRANSFERABILITY AND RESALE AND MAY NOT BE OFFERED, SOLD, PLEDGED, HYPOTHECATED OR OTHERWISE TRANSFERRED EXCEPT AS PERMITTED UNDER THE SECURITIES ACT AND APPLICABLE STATE SECURITIES OR BLUE SKY LAWS, PURSUANT TO REGISTRATION OR QUALIFICATION OR EXEMPTION THEREFROM. INVESTORS SHOULD BE AWARE THAT THEY MAY BE REQUIRED TO BEAR THE FINANCIAL RISKS OF THIS INVESTMENT FOR AN INDEFINITE PERIOD OF TIME. THE COMPANY MAY REQUIRE AN OPINION OF COUNSEL IN FORM AND SUBSTANCE REASONABLY SATISFACTORY TO THE COMPANY TO THE EFFECT THAT ANY PROPOSED TRANSFER IS IN COMPLIANCE WITH THE SECURITIES ACT AND ANY APPLICABLE STATE SECURITIES OR BLUE SKY LAWS. THIS WARRANT IS SUBJECT TO THE TRANSFER RESTRICTIONS SET FORTH HEREIN AND IN THE RIGHTS AGREEMENT (DEFINED HEREIN).

THIS WARRANT IS NOT EXERCISABLE PRIOR TO NOVEMBER [·], 2016. VOID AFTER 5:30 P.M., NEW YORK TIME, NOVEMBER [·], 2019.

ONCOBIOLOGICS, INC.

FORM OF WARRANT TO PURCHASE COMMON STOCK

Warrant No.: 2016-_____
Number of Shares of Common Stock: [·]
Date of Issuance: May [·], 2016 ("**Issuance Date**")

Oncobiologics, Inc., a Delaware corporation (the "**Company**"), certifies that, for good and valuable consideration, the receipt and sufficiency of which are acknowledged, [·], the registered holder hereof or its permitted assigns (the "**Holder**"), is entitled, subject to the terms set forth below, to purchase from the Company, at the Exercise Price (as defined below) then in effect, upon surrender of this Warrant to Purchase Common Stock (including any Warrants to Purchase Common Stock issued in exchange, transfer or replacement hereof, the "**Warrant**"), at any time or times on or after November [·], 2016 (the "**Exercisability Date**")[1], but not after November [·] , 2019[2], 5:30 p.m., New York Time, on the Expiration Date (as defined below), [·] **(**[·]**)** fully paid and nonassessable shares of Common Stock (the "**Warrant Shares**"). This Warrant is one of a series of warrants to purchase shares of Common Stock (collectively, the "**Warrants**") issued on May [·], 2016 (the "**Issuance Date**"), pursuant to that certain Investors' Rights Agreement, by and between the Company and the Holder and certain other Investors, dated March 10, 2014, as amended through the date hereof (the "**Rights Agreement**"). In addition to the defined terms set forth in Section 13 herein, capitalized terms that are not otherwise defined herein shall have the meanings assigned to such terms in the Rights Agreement.

1. EXERCISE OF WARRANT.

(a) Mechanics of Exercise. Subject to the terms and conditions hereof (including, without limitation, the limitations set forth in Section 1(f)), this Warrant may be exercised by the Holder on any day on or after the Exercisability Date, in whole or in part (but not as to fractional shares), by (i) delivery of a written notice, in the form attached hereto as Exhibit A (the "**Exercise Notice**"), of the Holder's election to exercise this Warrant and (ii) within three Trading Days of the date said Exercise Notice is delivered to the Company, payment to the Company of an amount equal to the applicable Exercise Price multiplied by the number of Warrant Shares as to which this Warrant is being exercised (the "**Aggregate Exercise Price**") in cash or wire transfer of immediately available funds (a "**Cash Exercise**") (the items under (i) and (ii) above, the "**Exercise Delivery Documents**"). The Holder shall not be required to surrender this Warrant in order to effect an exercise hereunder; *provided, however*,

[1] Date which is 6 months after the effective date of the Registration Statement.

[2] Date which is 3 years from the Exercisability Date.

that in the event that this Warrant is exercised in full or for the remaining unexercised portion hereof, the Holder shall deliver this Warrant to the Company for cancellation within a reasonable time after such exercise. No ink-original Exercise Notice shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Exercise Notice be required. On or before the Trading Day following the date on which the Company has received the Exercise Notice (the date upon which the Company has received the Exercise Notice, the "**Exercise Date**"), the Company shall transmit by facsimile or e-mail transmission an acknowledgment of confirmation of receipt of the Exercise Notice to the Holder and the Company's transfer agent for the Common Stock (the "**Transfer Agent**"). The Company shall deliver any objection to the Exercise Delivery Documents on or before the second Trading Day following the date on which the Company has received all of the Exercise Notice. On or before the third Trading Day following the date on which the Company has received all of the Exercise Notice (the "**Share Delivery Date**"), the Company shall cause the Transfer Agent to credit the account of the Holder's prime broker with the Depository Trust Company System (as directed by such Holder) with the number of Warrant Shares to which the Holder is entitled, provided, however, the Company shall not be required to deliver such Warrant Shares if the Company has not received the Aggregate Exercise Price for such Warrant Shares on or before the Share Delivery Date. Upon delivery of the Exercise Notice, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares to such Holder's prime broker account with the Depository Trust Company System. If this Warrant is submitted in connection with any exercise pursuant to this Section 1(a) and the number of Warrant Shares represented by this Warrant submitted for exercise is greater than the number of Warrant Shares being acquired upon an exercise, then the Company shall as soon as practicable and in no event later than five Trading Days after any such submission and at its own expense, issue a new Warrant (in accordance with Section 6(e)) representing the right to purchase the number of Warrant Shares purchasable immediately prior to such exercise under this Warrant, less the number of Warrant Shares with respect to which this Warrant has been and/or is exercised. The Company shall pay any and all taxes that may be payable with respect to the issuance and delivery of Warrant Shares upon exercise of this Warrant; *provided*, *however*, that the Company shall not be required to pay any tax which may be payable in respect of any transfer involved in the registration of any certificates for Warrants in a name other than that of the Holder or an affiliate thereof. The Holder shall be responsible for all other tax liability that may arise as a result of holding or transferring this Warrant or receiving Warrant Shares upon exercise hereof. Notwithstanding the foregoing, if there is no effective registration statement with respect to the Warrant Shares, and the Holder chooses to exercise the warrant for cash not in accordance with Section 1(d) herein, then the Holder shall receive certificated shares with the appropriate restrictive legends, including as required by the Securities Act or under any state securities or blue sky laws.

(b) Exercise Price. For purposes of this Warrant, "**Exercise Price**" means $0.01 per share of Common Stock, subject to adjustment as provided herein; *provided however*, if upon the Exercisability Date, the aggregate market value of Common Stock the Holder initially purchased at the time as such Holder became a party to the Rights Agreement (subject to any stock split or similar transaction) (the "**Initial Shares**") is equal to or greater than the aggregate purchase price of the Initial Shares paid by the Holder, then the Exercise Price shall automatically increase, with no further action by the Holder or the Company, to $1.00 per share of Common Stock, subject to adjustment as provided herein.

(c) Failure to Timely Deliver Shares. In addition to any other rights available to a Holder, if the Company fails to deliver the Warrant Shares to the Holder by the fifth Trading Day after the Exercise Date, then the Holder will have the right to rescind such exercise by giving written notice to the Company.

(d) Cashless Exercise. Notwithstanding anything contained herein to the contrary, the Holder may, in its sole discretion, exercise this Warrant in whole or in part and, in lieu of making the cash payment otherwise contemplated to be made to the Company upon such exercise in payment of the Aggregate Exercise Price, elect instead to receive upon such exercise the "Net Number" of shares of Common Stock determined according to the following formula (a "**Cashless Exercise**"):

$$\text{Net Number} = \frac{(A \times B) - (A \times C)}{B}$$

For purposes of the foregoing formula:

A = the total number of shares with respect to which this Warrant is then being exercised.

B = the Weighted Average Price of the shares of Common Stock (as reported by Bloomberg) on the date immediately preceding the date of the Exercise Notice.

C = the Exercise Price then in effect for the applicable Warrant Shares at the time of such exercise.

For purposes of Rule 144(d) promulgated under the Securities Act, as in effect on the date hereof, assuming the Holder is not an affiliate of the Company, it is intended that the Warrant Shares issued in a Cashless Exercise shall be deemed to have been acquired by the Holder, and the holding period for the Warrant Shares shall be deemed to have commenced, on the date the Holder is deemed to have acquired this Warrant.

(e) Disputes. In the case of a dispute as to the determination of the Exercise Price or the arithmetic calculation of the number of Warrant Shares to be issued pursuant to the terms hereof, the Company shall promptly issue to the Holder the number of Warrant Shares that are not disputed and resolve such dispute in accordance with Section 12 herein.

(f) Limitations on Exercises. (1) The Company shall not effect the exercise of this Warrant, and the Holder shall not have the right to exercise this Warrant, to the extent that after giving effect to such exercise, such Holder (together with such Holder's affiliates and any other Persons acting as a group together) would beneficially own in excess of 9.99% (the "**Maximum Percentage**") of the shares of Common Stock outstanding immediately after giving effect to such exercise. For purposes of the foregoing sentence, the aggregate number of shares of Common Stock beneficially owned by such Person and its affiliates shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which the determination of such sentence is being made, but shall exclude shares of Common Stock which would be issuable upon (i) exercise of the remaining, unexercised portion of this Warrant beneficially owned by such Person and its affiliates and (ii) exercise or conversion of the unexercised or unconverted portion of any other securities of the Company beneficially owned by such Person and its affiliates (including, without limitation, any convertible notes or convertible preferred stock or warrants) subject to a limitation on conversion or exercise analogous to the limitation contained herein. Except as set forth in the preceding sentence, for purposes of this paragraph, beneficial ownership shall be calculated in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), it being acknowledged that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act, and the Holder is solely responsible for any schedules required to be filed in accordance therewith. For purposes of this Warrant, in determining the number of outstanding shares of Common Stock, the Holder may rely on the number of outstanding shares of Common Stock as reflected in (1) the Company's most recent Form 10-K, Form 10-Q, Current Report on Form 8-K or other public filing with the Securities and Exchange Commission, as the case may be, (2) a more recent public announcement by the Company or (3) any other notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. For any reason at any time, upon the written or oral request of the Holder, where such request indicates that it is being made pursuant to this Warrant, the Company shall within five Trading Days confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including the Warrants, by the Holder and its affiliates since the date as of which such number of outstanding shares of Common Stock was reported. By written notice to the Company, the Holder may increase or decrease the Maximum Percentage to any other percentage specified in such notice; *provided*, that (i) any such increase will not be effective until the 61st day after such notice is delivered to the Company and (ii) any such increase or decrease will apply only to the Holder and not to any other holder of Warrants. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 1(f) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended beneficial ownership limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation.

(g) No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share that the Holder

would otherwise be entitled to purchase upon such exercise, the Company shall pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Weighted Average Price.

2. ADJUSTMENT OF EXERCISE PRICE AND NUMBER OF WARRANT SHARES. The Exercise Price and the number of Warrant Shares shall be adjusted from time to time as follows:

(a) Adjustment upon Subdivision or Combination of Shares of Common Stock. If the Company at any time on or after the Issuance Date subdivides (by any stock split, stock dividend, recapitalization or otherwise) one or more classes of its outstanding shares of Common Stock into a greater number of shares, the Exercise Price in effect immediately prior to such subdivision will be proportionately reduced and the number of Warrant Shares will be proportionately increased. If the Company at any time on or after the Issuance Date combines (by combination, reverse stock split or otherwise) one or more classes of its outstanding shares of Common Stock into a smaller number of shares, the Exercise Price in effect immediately prior to such combination will be proportionately increased and the number of Warrant Shares will be proportionately decreased. Any adjustment under this Section 2(a) shall become effective at the close of business on the date the subdivision or combination becomes effective.

(b) Other Events. If any event occurs of the type contemplated by the provisions of Section 2(a) but not expressly provided for by such provisions (except with respect to any awards granted by the Company's Board of Directors (the "**Board**") pursuant to Company's 2015 Equity Incentive Plan, or any other similar incentive plans authorized by the Board), then the Board will make an appropriate adjustment in the Exercise Price and the number of Warrant Shares so as to protect the rights of the Holder; *provided*, that no such adjustment pursuant to this Section 2(b) will increase the Exercise Price or decrease the number of Warrant Shares as otherwise determined pursuant to this Section 2.

(c) Notwithstanding anything to the contrary in this Warrant, in no event shall the Exercise Price be reduced below the par value of the Company's Common Stock.

3. PURCHASE RIGHTS; FUNDAMENTAL TRANSACTIONS.

(a) Purchase Rights. In addition to any adjustments pursuant to Section 2 above, if at any time prior to the Expiration Date the Company grants, issues or sells any Options, Convertible Securities or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "**Purchase Rights**"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (*provided, however*, that to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Maximum Percentage, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Maximum Percentage, at which time the Holder shall be granted such right to the same extent as if there had been no such limitation).

(b) Fundamental Transactions. Upon the occurrence of any Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant referring to the "Company" shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant with the same effect as if such Successor Entity had been named as the Company herein. Upon consummation of the Fundamental Transaction, the Successor Entity shall deliver to the Holder confirmation that there shall be issued upon exercise of this Warrant at any time after the consummation of the Fundamental Transaction, in lieu of the shares of the Common Stock (or other securities, cash, assets or other property purchasable upon the exercise of the Warrant prior to such Fundamental Transaction), such shares of stock, securities, cash, assets or any other property whatsoever (including warrants or other purchase or subscription

rights), if any, that the Holder would have been entitled to receive upon the happening of such Fundamental Transaction had this Warrant been exercised immediately prior to such Fundamental Transaction, as adjusted in accordance with the provisions of this Warrant. In addition to and not in substitution for any other rights hereunder, prior to the consummation of any Fundamental Transaction pursuant to which holders of shares of Common Stock are entitled to receive securities or other assets with respect to or in exchange for shares of Common Stock (a "**Corporate Event**"), the Company shall make appropriate provision to ensure that the Holder will thereafter have the right to receive upon an exercise of this Warrant within 90 days after the consummation of the Fundamental Transaction but, in any event, prior to the Expiration Date, in lieu of the shares of the Common Stock (or other securities, cash, assets or other property) purchasable upon the exercise of the Warrant prior to such Fundamental Transaction, such shares of stock, securities, cash, assets or any other property whatsoever (including warrants or other purchase or subscription rights) which the Holder would have been entitled to receive upon the happening of such Fundamental Transaction had the Warrant been exercised immediately prior to such Fundamental Transaction and shall be applied without regard to any limitations on the exercise of this Warrant. Provision made pursuant to the preceding sentence shall be in a form and substance reasonably satisfactory to the Required Holders. The provisions of this Section 4(b) shall apply similarly and equally to successive Fundamental Transactions and Corporate Events and shall be applied without regard to any limitations on the exercise of this Warrant.

4. RESERVATION OF WARRANT SHARES. The Company covenants that it will at all times reserve and keep available out of the aggregate of its authorized but unissued and otherwise unreserved Common Stock, solely for the purpose of enabling it to issue Warrant Shares upon exercise of this Warrant as herein provided, the number of shares of Common Stock which are then issuable and deliverable upon the exercise of this entire Warrant, free from preemptive or any other contingent purchase rights of Persons other than the Holder (taking into account the adjustments and restrictions in Section 2). Such reservation shall comply with the provisions of Section 1. The Company covenants that all shares of Common Stock so issuable and deliverable shall, upon issuance and the payment of the applicable Exercise Price in accordance with the terms hereof, be duly and validly authorized, issued and fully paid and nonassessable. The Company will take all such actions as may be necessary to assure that such shares of Common Stock may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of any securities exchange or automated quotation system upon which the Common Stock may be listed. If, notwithstanding the foregoing, and not in limitation thereof, at any time while this Warrant remains outstanding the Company does not have a sufficient number of authorized and unreserved shares of Common Stock to satisfy its obligation to reserve for issuance upon exercise of this Warrant at least a number of shares of Common Stock equal to the maximum number of shares of Common Stock as shall from time to time be necessary to effect the exercise of all this Warrant (without regard to any limitations on exercise contained herein) (the "**Required Reserve Amount**") (an "**Authorized Share Failure**"), then the Company shall immediately take all action necessary to increase the Company's authorized shares of Common Stock to an amount sufficient to allow the Company to reserve the Required Reserve Amount for this entire Warrant.

5. WARRANT HOLDER NOT DEEMED A STOCKHOLDER. Except as otherwise specifically provided herein, the Holder, solely in such Person's capacity as a holder of this Warrant, shall not be entitled to vote or receive dividends or be deemed the holder of share capital of the Company for any purpose, nor shall anything contained in this Warrant be construed to confer upon the Holder, solely in such Person's capacity as the Holder of this Warrant, any of the rights of a stockholder of the Company or any right to vote, give or withhold consent to any corporate action (whether any reorganization, issue of stock, reclassification of stock, consolidation, merger, conveyance or otherwise), receive notice of meetings, receive dividends or subscription rights, or otherwise, prior to the issuance to the Holder of the Warrant Shares which such Person is then entitled to receive upon the due exercise of this Warrant. In addition, nothing contained in this Warrant shall be construed as imposing any liabilities on the Holder to purchase any securities (upon exercise of this Warrant or otherwise) or as a stockholder of the Company, whether such liabilities are asserted by the Company or by creditors of the Company.

6. REGISTRATION AND REISSUANCE OF WARRANTS.

(a) Registration of Warrant. The Company shall register this Warrant, upon the records to be maintained by the Company for that purpose (the "**Warrant Register**"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other

purposes, absent actual notice to the contrary. The Company shall also register any transfer, exchange, reissuance or cancellation of any portion of this Warrant in the Warrant Register.

(b) Transfer of Warrant. This Warrant may be offered for sale, sold, transferred or assigned without the consent of the Company, except as may otherwise be required by applicable securities laws. Subject to applicable securities laws, if this Warrant is to be transferred, the Holder shall surrender this Warrant to the Company together with all applicable transfer taxes, whereupon the Company will forthwith issue and deliver upon the order of the Holder a new Warrant (in accordance with Section 6(e)), registered as the Holder may request, representing the right to purchase the number of Warrant Shares being transferred by the Holder and, if less than the total number of Warrant Shares then underlying this Warrant is being transferred, a new Warrant (in accordance with Section 6(e)) to the Holder representing the right to purchase the number of Warrant Shares not being transferred. Notwithstanding the foregoing, any transfer of this Warrant shall be subject to same terms and conditions as the Initial Shares as set forth in section 2.12 of the Rights Agreement

(c) Lost, Stolen or Mutilated Warrant. Upon receipt by the Company of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant, and, in the case of loss, theft or destruction, of any indemnification undertaking by the Holder to the Company in customary form or the provision of reasonable security by the Holder to the Company and, in the case of mutilation, upon surrender and cancellation of this Warrant, the Company shall execute and deliver to the Holder a new Warrant (in accordance with Section 6(e)) representing the right to purchase the Warrant Shares then underlying this Warrant.

(d) Exchangeable for Multiple Warrants. This Warrant is exchangeable, upon the surrender hereof by the Holder at the principal office of the Company together with all applicable transfer taxes, for a new Warrant or Warrants (in accordance with Section 6(e)) representing in the aggregate the right to purchase the number of Warrant Shares then underlying this Warrant, and each such new Warrant will represent the right to purchase such portion of such Warrant Shares as is designated by the Holder at the time of such surrender; *provided*, *however*, that the Company shall not be required to issue Warrants for fractional shares of Common Stock hereunder.

(e) Issuance of New Warrants. Whenever the Company is required to issue a new Warrant pursuant to the terms of this Warrant, such new Warrant shall (i) be of like tenor with this Warrant, (ii) represent, as indicated on the face of such new Warrant, the right to purchase the Warrant Shares then underlying this Warrant (or in the case of a new Warrant being issued pursuant to Section 6(b) or Section 6(c), the Warrant Shares designated by the Holder which, when added to the number of shares of Common Stock underlying the other new Warrants issued in connection with such issuance, does not exceed the number of Warrant Shares then underlying this Warrant), (iii) have an issuance date, as indicated on the face of such new Warrant which is the same as the Issuance Date and (iv) have the same rights and conditions as this Warrant.

7. NOTICES. Whenever notice is required to be given under this Warrant, unless otherwise provided herein, such notice shall be given in accordance with the information set forth in the Warrant Register. The Company shall provide the Holder with prompt written notice of all actions taken pursuant to this Warrant, including, in reasonable detail, a description of such action and the reason or reasons therefore. Without limiting the generality of the foregoing, the Company will give written notice to the Holder (i) immediately upon any adjustment of the Exercise Price, setting forth in reasonable detail, and certifying, the calculation of such adjustment and (ii) at least 20 days prior to the date on which the Company closes its books or takes a record (A) with respect to any dividend or distribution upon the shares of Common Stock, (B) with respect to any grants, issuances or sales of any Options, Convertible Securities or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock or (C) for determining rights to vote with respect to any Fundamental Transaction, dissolution or liquidation; *provided*, that in each case, such information shall be made known to the public prior to or in conjunction with such notice being provided to the Holder.

8. NONCIRCUMVENTION. The Company hereby covenants and agrees that the Company will not, by amendment of its Certificate of Incorporation, Bylaws or through any reorganization, transfer of assets, consolidation, merger, scheme of arrangement, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, and will

at all times in good faith carry out all the provisions of this Warrant and take all action as may be required to protect the rights of the Holder. Without limiting the generality of the foregoing, the Company (i) shall not increase the par value of any shares of Common Stock receivable upon the exercise of this Warrant above the Exercise Price then in effect, (ii) shall use all reasonable efforts to take all such actions as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable shares of Common Stock upon the exercise of this Warrant and (iii) shall, so long as any of the Warrants are outstanding, take all action necessary to reserve and keep available out of its authorized and unissued shares of Common Stock, solely for the purpose of effecting the exercise of the Warrants, the number of shares of Common Stock as shall from time to time be necessary to effect the exercise of the Warrants then outstanding (without regard to any limitations on exercise).

9. AMENDMENT AND WAIVER. Except as otherwise provided herein, the provisions of this Warrant may be amended and the Company may take any action herein prohibited, or omit to perform any act herein required to be performed by it, only if the Company has obtained the written consent of the Holder. No such amendment shall be effective to the extent that it applies to less than all of the holders of the Warrants then outstanding.

10. GOVERNING LAW. This Warrant shall be governed by and construed and enforced in accordance with, and all questions concerning the construction, validity, interpretation and performance of this Warrant shall be governed by, the internal laws of the State of New York, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of New York or any other jurisdictions) that would cause the application of the laws of any jurisdictions other than the State of New York.

11. CONSTRUCTION; HEADINGS. This Warrant shall be deemed to be jointly drafted by the Company and all the Investors and shall not be construed against any person as the drafter hereof. The headings of this Warrant are for convenience of reference and shall not form part of, or affect the interpretation of, this Warrant.

12. DISPUTE RESOLUTION. In the case of a dispute as to the determination of the Exercise Price or the arithmetic calculation of the Warrant Shares, the Company shall submit the disputed determinations or arithmetic calculations via facsimile within three Trading Days of receipt of the Exercise Notice giving rise to such dispute, as the case may be, to the Holder. If the Holder and the Company are unable to agree upon such determination or calculation of the Exercise Price or the Warrant Shares within five Trading Days of such disputed determination or arithmetic calculation being submitted to the Holder, then the Company shall, within three Trading Days submit via facsimile (a) the disputed determination of the Exercise Price to an independent, reputable investment bank selected by the Company and approved by the Holder or (b) the disputed arithmetic calculation of the Warrant Shares to the Company's independent, outside accountant. The Company shall cause the investment bank or the accountant, as the case may be, to perform the determinations or calculations and notify the Company and the Holder of the results no later than 10 Trading Days from the time it receives the disputed determinations or calculations. Such investment bank's or accountant's determination or calculation, as the case may be, shall be binding upon all parties absent demonstrable error. The expenses of the investment bank and accountant will be borne by the Company unless the investment bank or accountant determines that the determination of the Exercise Price or the arithmetic calculation of the Warrant Shares by the Holder was incorrect, in which case the expenses of the investment bank and accountant will be borne by the Holder.

13. REMEDIES, OTHER OBLIGATIONS, BREACHES AND INJUNCTIVE RELIEF. The remedies provided in this Warrant shall be cumulative and in addition to all other remedies available under this Warrant, at law or in equity (including a decree of specific performance and/or other injunctive relief), and nothing herein shall limit the right of the Holder to pursue actual damages for any failure by the Company to comply with the terms of this Warrant. The Company acknowledges that a breach by it of its obligations hereunder may cause irreparable harm to the Holder and that the remedy at law for any such breach may be inadequate. The Company therefore agrees that, in the event of any such breach or threatened breach, the holder of this Warrant shall be entitled, in addition to all other available remedies, to seek an injunction restraining any breach. Notwithstanding the foregoing or anything else herein to the contrary, other than as expressly provided in Section 1(c) hereof, if the Company is for any reason unable to issue and deliver Warrant Shares upon exercise of this Warrant as required pursuant to the terms hereof, the Company shall have no obligation to pay to the Holder any cash or other consideration or otherwise "net cash settle" this Warrant.

14. LIMITATION ON LIABILITY. No provisions hereof, in the absence of affirmative action by the Holder to purchase Warrant Shares hereunder, shall give rise to any liability of the Holder to pay the Exercise Price or as a shareholder of the Company (whether such liability is asserted by the Company or creditors of the Company).

15. SUCCESSORS AND ASSIGNS. This Warrant shall bind and inure to the benefit of and be enforceable by the Company and the Holder and their respective permitted successors and assigns.

16. CERTAIN DEFINITIONS. For purposes of this Warrant, the following terms shall have the following meanings:

(a) "**Bloomberg**" means Bloomberg LP.

(b) "**Common Stock**" means (i) the Company's shares of Common Stock, $0.01 par value per share, and (ii) any share capital into which such Common Stock shall have been changed or any share capital resulting from a reclassification of such Common Stock.

(c) "**Convertible Securities**" means any stock or securities (other than Options) directly or indirectly convertible into or exercisable or exchangeable for shares of Common Stock.

(d) "**Eligible Market**" means The New York Stock Exchange, Inc., the NYSE MKT or The Nasdaq Stock Market.

(e) "**Expiration Date**" means November [—], 2019 or, if such date falls on a day other than a Trading Day or on which trading does not take place on the Principal Market, or, if the Principal Market is not the principal trading market for the Common Stock, then on the principal securities exchange or securities market on which the Common Stock is then traded (a "**Holiday**"), the next date that is not a Holiday.

(f) "**Fundamental Transaction**" means that the Company shall, directly or indirectly, in one or more related transactions, (i) consolidate or merge with or into another Person, (ii) sell, assign, transfer, convey or otherwise dispose of all or substantially all of the properties or assets of the Company to another Person, (iii) allow another Person to make a purchase, tender or exchange offer that is accepted by the holders of more than 50% of either the outstanding shares of Common Stock (not including any shares of Common Stock held by the Person or Persons making or party to, or associated or affiliated with the Persons making or party to, such purchase, tender or exchange offer), (iv) consummate a stock purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person whereby such other Person acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock purchase agreement or other business combination), (v) reorganize, recapitalize or reclassify its Common Stock or (vi) any "person" or "group" (as these terms are used for purposes of Sections 13(d) and 14(d) of the Exchange Act) is or shall become the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of 50% of the aggregate ordinary voting power represented by issued and outstanding Common Stock.

(g) "**Options**" means any rights, warrants or options to subscribe for or purchase shares of Common Stock or Convertible Securities.

(h) "**Parent Entity**" of a Person means an entity that, directly or indirectly, controls the applicable Person and whose common stock or equivalent equity security is quoted or listed on an Eligible Market, or, if there is more than one such Person or Parent Entity, the Person or Parent Entity with the largest public market capitalization as of the date of consummation of the Fundamental Transaction.

(i) "**Person**" means an individual, a limited liability company, a partnership, a joint venture, a corporation, a trust, an unincorporated organization, any other entity and a government or any department or agency thereof.

(j) "**Principal Market**" means The NASDAQ Stock Market.

(k) "**Required Holders**" means the holders of the Warrants representing at least a majority of shares of Common Stock underlying the Warrants then outstanding.

(l) "**Successor Entity**" means the Person (or, if so elected by the Required Holders, the Parent Entity) formed by, resulting from or surviving any Fundamental Transaction or the Person (or, if so elected by the Required Holders, the Parent Entity) with which such Fundamental Transaction shall have been entered into.

(m) "**Trading Day**" means any day on which the Common Stock is traded on the Principal Market, or, if the Principal Market is not the principal trading market for the Common Stock, then on the principal securities exchange or securities market on which the Common Stock is then traded; *provided* that "Trading Day" shall not include any day on which the Common Stock is scheduled to trade on such exchange or market for less than 4.5 hours or any day that the Common Stock is suspended from trading during the final hour of trading on such exchange or market (or if such exchange or market does not designate in advance the closing time of trading on such exchange or market, then during the hour ending at 4:00:00 p.m., New York Time).

(n) "**Weighted Average Price**" means, for any security as of any date, the dollar volume-weighted average price for such security on the Principal Market, or, if the Principal Market is not the principal trading market for the Common Stock, then on the principal securities exchange on which the Common Stock is then traded, during the period beginning at 9:30:01 a.m., New York City time, and ending at 4:00:00 p.m., New York City time, as reported by Bloomberg through its "Volume at Price" function or, if the foregoing does not apply, the dollar volume-weighted average price of such security in the over-the-counter market on the electronic bulletin board for such security during the period beginning at 9:30:01 a.m., New York City time, and ending at 4:00:00 p.m., New York City time, as reported by Bloomberg, or, if no dollar volume-weighted average price is reported for such security by Bloomberg for such hours, the average of the highest closing bid price and the lowest closing ask price of any of the market makers for such security as reported in the "pink sheets" by OTC Markets Inc.. If the Weighted Average Price cannot be calculated for such security on such date on any of the foregoing bases, the Weighted Average Price of such security on such date shall be the fair market value as mutually determined by the Company and the Required Holders. If the Company and the Required Holders are unable to agree upon the fair market value of such security, then such dispute shall be resolved pursuant to Section 12 with the term "Weighted Average Price" being substituted for the term "Exercise Price." All such determinations shall be appropriately adjusted for any share dividend, share split or other similar transaction during such period.

[Signature Page Follows]

IN WITNESS WHEREOF, the Company has caused this Warrant to Purchase Common Stock to be duly executed as of the Issuance Date set out above.

ONCOBIOLOGICS, INC.

By: _____

Name:
Title:

EXHIBIT A

EXERCISE NOTICE

TO BE EXECUTED BY THE REGISTERED HOLDER TO EXERCISE THIS WARRANT TO PURCHASE COMMON STOCK

ONCOBIOLOGICS, INC.

The undersigned holder hereby exercises the right to purchase _____ of the shares of Common Stock ("**Warrant Shares**") of Oncobiologics, Inc., a Delaware corporation (the "**Company**"), evidenced by the attached Warrant to Purchase Common Stock (the "**Warrant**"). Capitalized terms used herein and not otherwise defined shall have the respective meanings set forth in the Warrant.

1. Exercise Price. The Holder intends that payment of the Exercise Price shall be made as (check one):

☐ Cash Exercise under Section 1(a).

☐ Cashless Exercise under Section 1(d).

2. Cash Exercise. If the Holder has elected a Cash Exercise, the Holder shall pay the sum of $ to the Company in accordance with the terms of the Warrant.

3. Delivery of Warrant Shares. The Company shall deliver to the holder _____ Warrant Shares in accordance with the terms of the Warrant. If the shares are to be delivered electronically, please complete the Depository Trust Company ("**DTC**") DWAC information below.

4. Representations and Warranties. By its delivery of this Exercise Notice, the undersigned represents and warrants to the Company that in giving effect to the exercise evidenced hereby the Holder will not beneficially own in excess of the number of shares of Common Stock (determined in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended) permitted to be owned under Section 1(f) of this Warrant to which this notice relates.

Date: _____ __, _____

_____	_____
Name of Registered Holder	Name of Signatory

By: _____
Name:
Title :

If shares are to be delivered electronically:

Broker Name: _____

Broker DTC DWAC #: _____

Account at Broker shares are to be delivered to: _____

ACKNOWLEDGMENT

The Company hereby acknowledges this Exercise Notice.

ONCOBIOLOGICS, INC.

By: _____

Name:

Title:

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Oncobiologics, Inc.:

We consent to the use of our report included herein and to the reference to our firm under the heading “Experts” in the prospectus. Our report dated November 16, 2015, except as to the recapitalization described in Note 3, which is as of April 26, 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, 2015 of $94.1 million and $14.2 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
May 11, 2016