

As filed with the Securities and Exchange Commission on January 4, 2017.

Registration No. 333-212351

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

**POST-EFFECTIVE  
AMENDMENT NO. 1 TO  
FORM S-1  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933**

**Oncobiologics, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**2836**  
(Primary Standard Industrial  
Classification Code Number)

**38-3982704**  
(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)

**Lawrence A. Kenyon  
Chief Financial 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)

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**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     Smaller reporting company   
(Do not check if a smaller reporting company)

**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.**

**EXPLANATORY NOTE**

This Post-Effective Amendment No. 1, "Post-Effective Amendment", to the Registration Statement on Form S-1 (333-212351), the "Registration Statement", as declared effective by the Securities and Exchange Commission, the "SEC", on July 14, 2016, is being filed to update certain disclosures in the Registration Statement and the prospectus contained therein to, among other things, include the information contained in the Company's Annual Report on Form 10-K, the "Annual Report" for the fiscal year ended September 30, 2016 that was filed with the SEC on December 29, 2016, and to make certain other updates contained herein. No additional securities are being registered under this Post-Effective Amendment. Accordingly, this Post-Effective Amendment concerns only the resale by the selling stockholder of up to 1,666,664 shares of common stock and the 416,666 Series A warrants and 416,666 Series B warrants registered under the Registration Statement. All applicable registration fees were paid at the time of the original filing of the Registration Statement.

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The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS

SUBJECT TO COMPLETION  
DATED JANUARY 4, 2017

**1,666,664 Shares of Common Stock**  
**416,666 Series A Warrants**  
**416,666 Series B Warrants**



Oncobiologics™  
Targeting Healthy Outcomes

This prospectus relates to the resale by the selling stockholder identified in this prospectus of up to 833,332 shares of our common stock, 416,666 of our Series A warrants and 416,666 of our Series B warrants that we sold to the selling stockholder, as well as an aggregate of 833,332 shares of common stock that are issuable upon the exercise of the Series A warrants and Series B warrants to purchase our common stock. The shares of our common stock and Series A warrants and Series B warrants were issued to the selling stockholder in a private placement completed on May 18, 2016. We will not receive any proceeds from the sale of the shares or warrants by the selling stockholder.

We are not selling any shares of common stock or warrants and will not receive any proceeds from the sale of the shares or warrants under this prospectus. Upon the exercise of the Series A warrants for 416,666 shares of our common stock by payment of cash, however, we will receive the exercise price of the warrants, which is \$6.60 per share, and upon the exercise of the Series B warrants for 416,666 shares of our common stock by payment of cash, however, we will receive the exercise price of the warrants, which is \$8.50 per share.

We have agreed to bear all of the expenses incurred in connection with the registration of these shares and warrants. The selling stockholder will pay or assume brokerage commissions and similar charges, if any, incurred for the sale of the shares or the warrants.

The selling stockholder identified in this prospectus, or their pledgees, donees, transferees or other successors-in-interest, may offer the shares or warrants from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices. For additional information on the methods of sale that may be used by the selling stockholder, see the section entitled "Plan of Distribution" beginning on page 50. For information regarding the selling stockholder, see the section entitled "Selling Stockholder" beginning on page 49.

We may amend or supplement this prospectus from time to time by filing amendments or supplements as required. You should read the entire prospectus and any amendments or supplements carefully before you make your investment decision.

Our common stock, Series A warrants and Series B warrants are traded on the NASDAQ Global Market under the symbols "ONS," "ONSIW" and "ONSIZ," respectively. On January 3, 2017, the closing sale prices of our common stock, Series A warrants and Series B warrants on the NASDAQ Global Market were \$3.28 per share, \$0.18 per Series A warrant and \$0.85 per Series B warrant, respectively. You are urged to obtain current market quotations for the common stock and the warrants.

We are an "emerging growth company" under the federal securities laws and are 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 4.**

**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.**

Prospectus dated \_\_\_\_\_, 2017

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We are responsible for the information contained in this prospectus and in any free-writing prospectus we file with the Securities and Exchange Commission. 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 selling stockholder is 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 September 30, 2016, or CHF 0.9694 = \$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 develop these biosimilars in a cost-effective manner on an accelerated timeline, which is fundamental to our success and we believe positions us to be a leading biosimilar company. We have leveraged our team's biopharmaceutical expertise to establish fully integrated in-house development and manufacturing capabilities, which we refer to as our BioSymphony Platform. We believe this platform addresses the numerous complex technical and regulatory challenges in developing and commercializing mAb biosimilars and has been designed to provide significant pricing flexibility. We have identified eight biosimilar product candidates for further development and have successfully advanced two of these product candidates through Phase 1 clinical trials and into preparations for Phase 3 clinical trials: ONS-3010, a biosimilar to adalimumab (Humira®), and ONS-1045, a biosimilar to bevacizumab (Avastin®).

### Recent Developments

In October, November and December 2016 we issued \$1.85 million of unsecured promissory notes to accredited investors.

On December 22, 2016, we entered into a Note and Warrant Purchase Agreement with the selling stockholder and the other accredited investors named therein providing for the issuance and sale of up to \$10.0 million of senior secured promissory notes, which bear interest at a rate of 5% per year and mature December 22, 2017 and five-year warrants to acquire an aggregate of 2.3 million shares of our common stock at an exercise price of \$3.00 per share. We closed the initial sale and purchase of the notes and warrants on December 22, 2016, issuing \$8.35 million principal amount of senior secured notes and warrants to acquire an aggregate 1,920,500 shares of our common stock in exchange for \$6.5 million of cash and \$1.85 million of existing unsecured bridge notes issued in October, November and December 2016. We may issue up to \$1.65 million of additional senior secured notes and warrants to acquire 379,500 shares of our common stock in additional closings over the next 90 days without approval of holders of the senior secured notes. Under the Note and Warrant Purchase Agreement, we agreed to customary negative covenants restricting our ability to repay indebtedness to officers, pay dividends to stockholders, repay or incur other indebtedness other than as permitted, grant or suffer to exist a security interest in any of our assets, other than as permitted, or enter into any transactions with affiliates. In addition to the negative covenants in the Note and Warrant Purchase Agreement, the senior secured notes include customary events of default. In connection with the closing of the initial sale of the senior secured notes and warrants, we entered into a Security Agreement and an Intellectual Property Security Agreement, each dated December 22, 2016, granting the holders, including the selling stockholder, a security interest in all of our assets. We used \$2.4 million of the proceeds to pay off our existing senior secured bank loans, and will use the remainder for working capital purposes as we pursue strategic opportunities.

Two of our directors, Messrs. Canute and Dyrness, participated in the financing by exchanging unsecured bridge notes having an aggregate principal amount of \$400,000 that they acquired in November 2016 for the senior secured notes and warrants to acquire an aggregate 92,000 shares of our common stock.

### 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 from our initial public offering 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 securities.

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."

#### **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](http://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 the selling stockholder	1,666,664 shares of common stock (which includes 833,332 shares issuable upon exercise of the warrants), 416,666 Series A warrants and 416,666 Series B warrants. 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, and will expire at 5:00 p.m., New York City time on February 18, 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, and will expire at 5:00 p.m., New York City time on May 18, 2018.
Common stock outstanding	22,802,778 shares but excluding shares underlying the warrants.
Series A warrants outstanding	3,333,333
Series B warrants outstanding	3,333,333
Use of proceeds	We will not receive any proceeds from the sale of shares or warrants in this offering. See "Use of Proceeds."
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.
NASDAQ Global Market symbols	Our common stock, Series A warrants and Series B warrants are listed on the NASDAQ Global Market under the symbols "ONS," "ONSIW" and "ONSIZ," respectively.

The number of shares of common stock outstanding is based on 22,802,778 shares of common stock outstanding as of September 30, 2016, and excludes the following:

- 247,309 shares of common stock issuable upon the exercise of PSUs outstanding as of September 30, 2016 whose terms provide for settlement in shares of common stock or cash at our discretion, with a weighted-average exercise price of \$6.33;
- 1,094,351 shares issuable upon vesting of restricted stock unit awards, or RSUs, granted under our 2015 Equity Incentive Plan, or the 2015 Plan, outstanding as of September 30, 2016;
- 836,109 shares of common stock reserved for future issuance under the 2015 Plan as of September 30, 2016, 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 of September 30, 2016, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan;
- 1,520,268 shares of our common stock issuable as of September 30, 2016 upon the exercise of warrants;
- 5,833,334 shares of our common stock issuable upon the exercise of the Series A warrants and Series B warrants issued in our May 2016 initial public offering and 833,332 shares of our common stock issuable upon the exercise of the Series A warrants and Series B warrants issued in the May 2016 concurrent private placement to the selling stockholder outstanding as of September 30, 2016; and
- up to 2,300,000 shares of common stock issuable upon exercise of warrants issued or issuable subsequent to September 30, 2016.

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.

## 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 \$53.3 million and \$47.4 million for the years ended September 30, 2016 and 2015, respectively.

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

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

- continue preclinical studies and clinical development of our identified product candidates;
- expand the number of our current clinical trials for our product candidates;
- advance our programs into larger global clinical trials;
- initiate additional preclinical, clinical or other studies for our product candidates;
- change or add clinical research service providers, testing laboratories, device suppliers, legal service providers or other vendors or suppliers;
- invest in, and maintain, our development and manufacturing facilities and infrastructure;
- seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- seek to identify, assess, acquire or develop other biosimilar product candidates that may be complementary to our product candidates;
- make upfront, milestone, royalty or other payments under any license agreements;
- seek to create, maintain, protect and expand our intellectual property portfolio;
- engage in litigation, including patent litigation, with originator companies or others that may hold patents to the reference products for which we are developing biosimilars, or to methods of manufacture or methods of use we may employ in the production of our biosimilars;
- seek to attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts; and
- experience any delays or encounter issues with any of the above, including but not limited to failed clinical trials, conflicting results, safety issues or regulatory challenges that may require longer follow-up of existing studies, additional major studies or additional supportive studies in order to pursue marketing approval.



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

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

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

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

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

- completing preclinical and clinical development of our product candidates;
- developing and testing of our product candidate formulations;
- obtaining regulatory and marketing approvals for product candidates for which we complete clinical trials, including any delays as a result of petitions by reference product sponsors, or RPSs, or patent holders;
- obtaining extensions of approvals for our product candidates to other indications for which the reference product is approved and commercialized;
- developing a sustainable and scalable manufacturing process for any approved product candidates to support clinical development and the market demand for any such approved product candidates;
- launching and commercializing product candidates for which we obtain regulatory and marketing approval, either directly or with collaboration partners;
- obtaining adequate third-party coverage and reimbursements for our products;
- obtaining market acceptance of our product candidates as viable treatment options, including with respect to the efficacy, safety and biosimilarity of our product candidates to the reference products;
- addressing any competing technological and market developments;
- identifying, assessing and developing, or acquiring and in-licensing, new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- establishing through litigation or otherwise that we are not violating the intellectual property rights of innovators of reference products for which we are developing biosimilars, or that of other third parties;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

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

- the size of the markets in the territories for which we gain regulatory approval;
- the number of biosimilar and other competitors in such markets;
- the market acceptance of our products, or biosimilars in general, over the reference products;
- novel therapies for the approved indications in our biosimilar market that erode uptake;

- the accepted price for the product and the ability to get reimbursement at any price;
- the nature and degree of competition from originators and other biosimilar companies (including competition from large pharmaceutical companies entering the biosimilar market that may be able to gain advantages in the sale of biosimilar products based on brand recognition and/or existing relationships with providers, pharmacy benefit managers and payors);
- the quality and performance of our products compared to the reference products or other competing products, including the relative safety and efficacy; and
- whether we own, or have partnered, the commercial rights for that territory.

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

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

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

As of September 30, 2016, our cash was \$2.4 million. Including \$8.4 million of proceeds from our October, November and December 2016 note and warrant issuances, we expect that our current cash will be sufficient to fund our operations through February 2017. We expect that we will require substantial additional capital to commercialize ONS-3010, and to commence clinical trials, obtain regulatory approval for, and to commercialize, our product candidates, including our other preclinical product candidates and our future product candidates. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or a combination of these approaches. In any event, we will require additional capital to pursue preclinical and clinical activities, pursue regulatory approval for, and to commercialize, our longer term pipeline product candidates. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

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

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

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity and debt financings, as well as selectively continuing to enter into collaborations, strategic alliances

and licensing arrangements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a securityholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and may be secured by all or a portion of our assets.

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

#### **Risks Related to the Discovery and Development of Our Product Candidates**

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

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

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

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

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

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

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

*United States Regulatory Framework for Biosimilars*

We and our collaboration partners intend to pursue market authorization globally. In the United States an abbreviated pathway for approval of biosimilar products was established by the Biologics Price Competition and Innovation Act of 2009, or BPCIA, enacted on March 23, 2010, as part of the Patient Protection and Affordable Care Act. The BPCIA established this abbreviated pathway under section 351(k) of the Public Health Service Act, or PHSA. Subsequent to the enactment of the BPCIA, the FDA issued draft guidance regarding the demonstration of biosimilarity as well as the submission and review of biosimilar applications. To our knowledge, there have been only four mAb biosimilar product applications approved by the FDA under the 351(k) pathway to date. Moreover, market acceptance of biosimilar products in the United States is still in its infancy and continues to evolve. Numerous states are considering or have already enacted laws that regulate or restrict the substitution by state pharmacies of biosimilars for reference products already licensed by the FDA. Market success of biosimilar products will depend on demonstrating to patients, physicians, payors and relevant authorities that such products are similar in quality, safety and efficacy as compared to the reference product.

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

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

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

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

*Regulatory Framework for Biosimilars Outside the United States*

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

Generally speaking, under current EU regulations, an application for regulatory approval of a biosimilar drug cannot be submitted in the EU until expiration of an eight year data exclusivity period for the reference product, measured from the

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

In the EU, the approval of a biosimilar for marketing is based on an opinion issued by the EMA and a decision issued by the European Commission. Therefore, the marketing approval will cover the entire European Economic Area, or EEA. However, substitution of a biosimilar for the reference product is a decision that is made at the Member State level. Additionally, a number of countries do not permit the automatic substitution of biosimilars for the reference product. Therefore, even if we obtain marketing approval for the entire EEA, we may not receive substitution in one or more European nations, thereby restricting our ability to market our products in those jurisdictions.

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

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

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

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

The research, development, testing, manufacturing, labeling, packaging, approval, promotion, advertising, storage, marketing, distribution, post-approval monitoring and reporting and export and import of biologic products are subject to extensive regulation by the FDA and other regulatory authorities in the United States, by the EMA and Competent Authorities in the EEA, and by other regulatory authorities in other countries, where regulations differ from country to country. We are not permitted to market our product candidates in the United States until we receive approval from the FDA, or in the EEA until we receive European Commission or EEA Competent Authority approvals.

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

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

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

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

In addition, if we change the regulatory pathway through which we intend to seek approval of any of our product candidates, or alter their composition or method of manufacturing, we may have to conduct additional clinical trials, which may delay our ability to submit a marketing application for the product. Even if we or our collaboration partners were to obtain approval for any of our product candidates, regulatory agencies may limit the scope of such approval for fewer or more limited indications than we request, may grant approval contingent on the completion of costly additional clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing could harm the commercial prospects for our product candidates.

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

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

Although we have had several interactions with both the FDA and EMA for our lead product candidates and will continue to meet with regulators as necessary, we cannot be assured that results from our scientific studies will meet the rigorous requirements for approval. In addition, we cannot be certain of potential future changes to regulatory requirements that may require additional work before approval can be granted. It is also uncertain if regulatory authorities will grant the full

reference label to our biosimilar product candidates when they are approved. For example, an infliximab (Remicade<sup>®</sup>) biosimilar molecule was approved in the EU for the full reference label but did not receive the full reference label when approved in Canada. A similar outcome could occur with respect to one or more of our product candidates, which would have a negative impact on our ability to commercialize our products.

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

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

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

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

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

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

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

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

- inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of human clinical trials;
- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in obtaining required Institutional Review Board, or IRB, approval at each clinical trial site;
- imposition of a clinical hold by regulatory agencies, after review of an investigational new drug, or IND, application or amendment or equivalent filing, or an inspection of our clinical trial operations or trial sites, or as a result of adverse events reported during a clinical trial;
- delays in recruiting suitable patients to participate in our clinical trials;
- difficulty collaborating with patient groups and investigators;



- failure by our CROs, other third parties or us to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA's good clinical practice, or GCP, requirements or applicable regulatory guidelines in other countries;
- delays in having subjects complete participation in a study or return for post-treatment follow-up, or subjects dropping out of a study;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical trials of our product candidates being greater than we anticipate;
- inability to obtain sufficient quantities of reference product for the comparator arm of our studies;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in us deciding or regulators requiring us to conduct additional clinical trials or abandon product development programs; and
- delays in manufacturing, testing, releasing, validating or importing/exporting and/or distributing sufficient stable quantities of our product candidates and reference products for use in clinical trials or the inability to do any of the foregoing.

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

Drug-related side effects could affect patient recruitment for clinical trials, the ability of enrolled patients to complete our studies or result in potential product liability claims. We currently carry product liability insurance in the amount of \$10.0 million per product candidate and we are required to maintain product liability insurance pursuant to certain of our license agreements. We may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. A successful product liability claim or series of claims brought against us could negatively impact our results of operations and business. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, withdrawal of clinical trial participants, costs due to related litigation, distraction of management’s attention from our primary business, initiation of investigations by regulators, substantial

monetary awards to patients or other claimants, the inability to commercialize our product candidates and decreased demand for our product candidates, if approved for commercial sale. Furthermore, we may also not be able to take advantage of limitations on product liability lawsuits that apply to generic drug products, which could increase our exposure to liability for products deemed to be dangerous or defective.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

#### **Risks Related to Commercialization of Our Product Candidates**

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

We expect to enter highly competitive pharmaceutical markets. Successful competitors in the pharmaceutical markets have demonstrated the ability to effectively discover, obtain patents, develop, test and obtain regulatory approvals for products, as well as an ability to effectively commercialize, market and promote approved products. Numerous companies,

universities and other research institutions are engaged in developing, patenting, manufacturing and marketing of products competitive with those that we are developing. Many of these potential competitors are large, experienced pharmaceutical companies that enjoy significant competitive advantages, such as substantially greater financial, research and development, manufacturing, personnel and marketing resources. These companies also have greater brand recognition and more experience in conducting preclinical testing and clinical trials of product candidates and obtaining FDA and other regulatory approvals of products.

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

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able to and may be more effective in selling and marketing their products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop; they may also obtain patent protection that could block our products; and they may obtain regulatory approval, product commercialization and market penetration earlier than we do. Biosimilar product candidates developed by our competitors may render our potential product candidates uneconomical, less desirable or obsolete, and we may not be successful in marketing our product candidates against competitors. Competitors may also assert in their marketing or medical education programs that their biosimilar products demonstrate a higher degree of biosimilarity to the reference products than do ours or other competitor's biosimilar products, thereby seeking to influence healthcare practitioners to select their biosimilar products rather than ours or other competitors. Competitors may also develop "biobetter" versions of reference products we are targeting. A biobetter is a product that contains alterations to the reference product's chemical structure or delivery system that provide a clinical benefit over the original reference product. Biobetters developed by our competitors may compete advantageously against our products and limit our market success.

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

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

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

- settling patent lawsuits with biosimilar companies, resulting in such patents remaining an obstacle for biosimilar approval by others;
- submitting Citizen Petitions to request the FDA Commissioner to take administrative action with respect to prospective and submitted biosimilar applications;
- appealing denials of Citizen Petitions in United States federal district courts and seeking injunctive relief to reverse approval of biosimilar applications;
- restricting access to reference brand products for equivalence and biosimilarity testing that interferes with timely biosimilar development plans;
- attempting to influence potential market share by conducting medical education with physicians, payors, regulators and patients claiming that biosimilar products are too complex for biosimilar approval or are too dissimilar from reference products to be trusted as safe and effective alternatives;

- implementing payor market access tactics that benefit their brands at the expense of biosimilars;
- seeking state law restrictions on the substitution of biosimilar products at the pharmacy without the intervention of a physician or through other restrictive means such as excessive recordkeeping requirements or patient and physician notification;
- seeking federal or state regulatory restrictions on the use of the same nonproprietary name as the reference brand product for a biosimilar or interchangeable biologic;
- seeking changes to the United States Pharmacopeia, an industry-recognized compilation of drug and biologic standards;
- obtaining new patents covering existing products or processes that could extend patent exclusivity for a number of years or otherwise delay the launch of biosimilars; and
- influencing legislatures so that they attach special patent extension amendments to unrelated federal legislation.

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

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

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

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

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

- the safety and efficacy of the product as demonstrated to be "highly similar" in clinical trials, and potential advantages over competing treatments and the reference product;
- labeling or naming imposed by FDA or other regulatory agencies that suggest clinical differences between the product and the reference product;
- the publication of unfavorable safety or efficacy data concerning our product by third-parties;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- the clinical indications for which approval is granted;
- whether we achieve an interchangeability designation in the United States, and if such designation has a material effect on the perception of equivalence;
- the possibility that a competitor may achieve interchangeability and we may not;
- relative convenience and ease of administration as compared to the reference product;
- the extent to which our product may be more or less similar to the reference product than competing biosimilar product candidates;

- recognition and acceptance of our product candidates over our competitors' products;
- prevalence of the disease or condition for which the product is approved;
- the cost of treatment, particularly in relation to competing treatments;
- the willingness of the target patient population to try biosimilar therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations;
- publicity concerning our products or competing products and treatments;
- the extent to which third-party payors provide coverage and adequate reimbursement for our product candidates, if approved; and
- our ability to maintain compliance with regulatory requirements.

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

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

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

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

We currently have no marketing or sales organization. Our products have not yet been approved for sale, and we, as a company, have no experience selling and marketing our product candidates. To successfully commercialize any products that may result from our development programs, we will need to develop these capabilities, either on our own or with others. If our product candidates receive regulatory approval, we intend to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates in major markets where we may choose to retain commercialization rights. Doing so will be expensive, difficult and time-consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our products.

Further, given our lack of prior experience in marketing and selling biosimilar products, our initial estimate of the size of the required sales force may be materially more or less than the size of the sales force actually required to effectively commercialize our product candidates. As such, we may be required to hire substantially more sales representatives and medical support liaisons to adequately support the commercialization of our product candidates or we may incur excess costs as a result of hiring more sales representatives than necessary. With respect to certain geographical markets, we may enter into collaborations with other entities to utilize their local marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. If our future collaboration partners do not commit sufficient resources to commercialize our future products, if any, and we are unable to develop the necessary marketing capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. If we are unable



to establish sales and marketing capabilities for any approved product, whether on our own or through collaborations, our results of operations will be negatively impacted.

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

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

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

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

United States Adopted Name, or USAN, and International Nonproprietary Names, or INN, two important bodies involved in nonproprietary nomenclature, have no policy for the naming of biosimilar product candidates, and products are named on a case by case basis. Non-glycosylated proteins can follow the approach established for small molecule generics, which is to retain the same nonproprietary name if it is synthesized by a different route provided the substance is the same. Glycosylated proteins from different sources are given distinct names, as these proteins are expected to differ in their glycosylation profile. The same approach is valid for all other modifications to the protein that can occur in a cell after the cell has finished making the protein. A system currently under discussion at the World Health Organization that would enable the clear definition of all similar biotherapeutic proteins would include the INN of the reference product in the first part of the name, and some form of biological qualifier that could uniquely identify the substance. Currently the FDA and EMA have final authority regarding names in the United States and the EU, respectively, and it is unclear how they will handle nonproprietary nomenclature in the future. However, recent draft FDA guidance has recommended an approach to distinguish product manufacturers of the reference biologic, biosimilars, interchangeable, 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 repeat additional preclinical and clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with products produced under cGMP regulations. Failure to comply by any of the participating parties or ourselves with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if our CROs or any other participating parties violate federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

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

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

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

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

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

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

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

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

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

- failure to establish contracts with fill-finish contract manufacturing organization or CMOs, and device vendors;
- product loss due to contamination, equipment failure or improper installation or operation of equipment or vendor or operator error;
- failure to maintain fermentation or other manufacturing conditions necessary to achieving biosimilarity to the reference product;
- infringing intellectual property rights of third parties relating to manufacturing and quality testing;
- failure to achieve or maintain compliance with FDA's requirements for acceptance of our manufacturing facilities; and
- labor shortages, natural disasters and power failures.

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

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

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

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

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

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

We currently have a joint participation arrangement with Huahai that provides for the co-funding of the development of ONS-3010 in the United States, Canada, EU, Japan, Australia and New Zealand and the proportionate sharing of the

revenue from commercialization of ONS-3010 in such countries. We could also be required to further co-develop and commercialize ONS-3010 with Huahai in the agreed countries pursuant to a joint venture, if so requested by Huahai, as contemplated by our joint participation agreement. Although we had the option to terminate this joint participation agreement by exercising our option to pay Huahai a total of \$28.0 million, including an \$11.0 million initial payment, we decided not to make the \$11.0 million initial payment within the time frame required. Under the joint participation agreement, assuming Huahai funds its proportionate share of development costs incurred after completion of the "Phase-3 Ready Package" for ONS-3010, we will have a 49% value ownership interest with Huahai having a 51% value ownership interest in ONS-3010. Accordingly, our share of any potential revenues from the successful commercialization of ONS-3010 in the agreed countries, including major markets such as the United States and EU, would also be in proportion to such ownership interests. While we anticipate that we will each act in accordance with the terms of our agreement for the joint development and commercialization of ONS-3010, we cannot control Huahai, nor can we predict with any certainty that our interests will be aligned and that we will successfully collaborate.

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

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

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

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

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

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

The regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product

specifications or applicable regulations occurs independent of such an inspection or audit, the relevant regulatory authority may require remedial measures that may be costly and time-consuming for us to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of our facility. Any such remedial measures could harm our business.

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

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

### **Risks Related to Intellectual Property**

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

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

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

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. We have conducted patent searches for third-party patents with respect to each of our lead product candidates, and are aware of third-party patent families with claims that, if valid and enforceable, could be construed to cover such product candidates or their respective methods of manufacture or use. Some of these patents have expiration dates that could extend reference product exclusivity past our anticipated product launch dates. We cannot guarantee that any of our analyses are complete and thorough, nor can we be sure that we have identified each and every patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of our product candidates. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents covering our product candidates. We have not yet completed freedom to operate analysis on our early-stage pipeline or products we are evaluating for inclusion in our future biosimilar product pipeline and therefore, we do not know whether or to what extent these products may be subject to unexpired patents. The existence of any patent with valid and enforceable claims covering one or more of our product candidates could cause substantial delays in our ability to introduce a biosimilar candidate into the U.S. market if the term of such patent extends beyond our desired product launch date.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Although we have no issued patents, when and if we do obtain issued patents, we may discover that competitors are infringing those patents. Expensive and time-consuming litigation may be required to enforce our patents. If we or one of our collaboration partners were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including but not limited to lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone involved in the prosecution of the patent withheld relevant or material information related to the patentability of the invention from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly and decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy.

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during any litigation we initiate to enforce our patents. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a negative impact on the market price of our securities. Moreover, there can be no assurance that we will have sufficient



financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

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

We employ individuals and retain independent contractors and consultants and members on our board of directors who were previously employed at universities or other pharmaceutical companies, including our competitors or potential competitors. For example, our Chairman, President and Chief Executive Officer, Pankaj Mohan, Ph.D., our Chief Medical Officer, Kenneth M. Bahrt, M.D., our Senior Vice President of Business Strategy & Development, Stephen J. McAndrew, Ph.D., our Senior Vice President of Process Development & Manufacturing, Scott Gangloff, and our Vice President of Regulatory Affairs, Elizabeth A. Yamashita, are former employees of Bristol-Myers Squibb Company. Further, Dr. Mohan and Dr. Bahrt are former employees of Genentech, which is the reference product sponsor of bevacizumab (Avastin), for which we seek to develop ONS-1045 as a biosimilar, and trastuzumab (Herceptin), for which we seek to develop ONS-1050 as a biosimilar, and Kogan Bao, Ph.D., our Vice President of Analytical Sciences, is a former employee of Amgen, Inc., which is the reference product sponsor of denosumab (Prolia/Xgeva), for which we seek to develop ONS-4010 as a biosimilar. Additionally, Dr. McAndrew was a former employee of Roche. Two members of our board of directors, Scott Canute and Dr. Mohan, were former employees of Eli Lilly and Company and Ms. Yamashita was a former employee of ImClone Systems Inc., a subsidiary of Eli Lilly and Company, which is the reference product sponsor of cetuximab (Erbix), for which we seek to develop ONS-1055 as a biosimilar. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us and we are not currently subject to any claims that they have done so, we may in the future be subject to such claims. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

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

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

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



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

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

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

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

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

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

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

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

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

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

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

any of our patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we or our licensors or collaborators will be successful in defending the patent, which would result in a loss of the challenged patent right. It is not yet clear what, if any, impact the America Invents Act will have on the operation of our business. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any issued patents, all of which could harm our business and financial condition.

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

In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on future actions by the United States Congress, the Federal Courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce existing patents and patents that we might obtain in the future.

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

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

Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed. We cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may harm our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secret. We cannot guarantee that our employees, former employees or consultants will not file patent applications claiming our inventions. Because of the "first-to-file" laws in the United States, such unauthorized patent application filings may defeat our attempts to obtain patents on our own inventions.

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

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

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

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

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

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

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

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

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

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

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

The BPCIA created a new, elaborate and complex patent dispute resolution mechanism for biosimilars that could prevent us from launching our product candidates in the United States or could substantially delay such launches. This mechanism

has been referred to as the “patent dance.” Uncertainty over how courts will construe the patent dance, for example whether it is the exclusive pathway for litigation involving 351(k) biosimilar applications, may cause our assumptions regarding the scope, timing and expense of patent litigation to be incorrect, and may cause delays in the launch of products subject to such litigation.

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

- **Disclosure of the Biosimilar Application.** Within 20 days after receiving a notice from the FDA that its application has been accepted for review, a 351(k) biosimilar applicant provides a copy of its application information to the RPS. Providing of this information begins the patent dance. If the 351(k) biosimilar applicant chooses not to disclose such information, or opts out of later steps of the patent dance, the RPS may bring an immediate suit for patent infringement that will proceed under the conventional procedural rules for patent infringement actions.
- **Identification of Pertinent Patents.** Within 60 days of the date of receipt of the application, the RPS must identify the patents owned or controlled by it that it reasonably believes could be asserted against the biosimilar applicant.
- **Statement by the Biosimilar Applicant.** Following the receipt of the RPS’s patent list, the biosimilar applicant must state either that it will not market its product until the relevant patents have expired or alternatively provide its arguments of stating why the patents are invalid, unenforceable or would not be infringed by the proposed biosimilar product candidate. The biosimilar applicant may also provide the RPS with a list of patents it reasonably believes the RPS could assert against the biosimilar product.
- **Statement by the RPS.** In the event the biosimilar applicant has asserted that the patents are invalid, unenforceable or would not be infringed by the proposed follow-on product, the RPS must provide the biosimilar applicant with a response within 60 days. The response must provide the legal and factual basis of the opinion that such patent will be infringed by the commercial marketing of the proposed biosimilar.
- **Patent Resolution Negotiations.** If the RPS provides its detailed views that the proposed biosimilar would infringe valid and enforceable patents, then the parties are required to engage in good faith negotiations to identify which of the identified patents will be the subject of a patent infringement action. If the parties agree on the patents to be litigated, the RPS must bring an action for patent infringement within 30 days.
- **Simultaneous Exchange of Patents.** If those negotiations do not result in an agreement within 15 days, then the biosimilar applicant must notify the RPS of how many patents (but not the identity of those patents) that it wishes to litigate. Within five days, the parties are then required to exchange lists identifying the patents to be litigated. The number of patents identified by the RPS may not exceed the number provided by the biosimilar applicant. However, if the biosimilar applicant previously indicated that no patents should be litigated, then the RPS may identify one patent.
- **Commencement of Patent Litigation.** The RPS must then commence patent infringement litigation within 30 days. That litigation will involve all of the patents on the RPS’s list and all of the patents on the biosimilar applicant’s list. The biosimilar applicant must then notify the FDA of the litigation. The FDA must then publish a notice of the litigation in the Federal Register.
- **Notice of Commercial Marketing.** If the biosimilar applicant opts out of the patent dance, the BPCIA requires the biosimilar applicant to provide notice to the RPS after FDA licensure, and at least 180 days in advance of its first commercial marketing of its proposed follow-on biologic. It is not clear whether the biosimilar applicant must give notice if it complies with the patent dance, but courts may interpret the BPCIA to require such notice. If notice is not given, the RPS may immediately commence a patent infringement action on any patent that was listed (or listable) by the RPS during the dance, but not part of the first wave of patents being litigated. The RPS is allowed to seek a preliminary injunction blocking such marketing based upon any such patents. The litigants are required to “reasonably cooperate to expedite such further discovery as is needed” with respect to the preliminary injunction motion.

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

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

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

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

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

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

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

### **Risks Related to Our Business Operations**

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

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

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

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

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

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

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

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

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

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

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

Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to



integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future regulatory approvals, sales of our product candidates and our results of operations. Additionally, we do not currently maintain "key person" life insurance on the lives of our executives or any of our employees.

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

As of September 30, 2016, we had 83 full-time employees. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial, legal and other resources. Our management may need to divert a disproportionate amount of its attention away from our day-to-day operations and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational inefficiencies, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our current and potential future product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

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

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

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

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

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. For example, on August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2012 through 2021, was unable to reach required goals, thereby



triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2025 unless additional Congressional action is taken. Additionally, on January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which among other things, further reduced Medicare payments to certain providers, including physicians, hospitals and cancer treatment centers. In addition, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

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

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

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

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

report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

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

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

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

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us or our collaboration partners to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations by us or our collaboration partners;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems by our collaboration partners;
- limits in our or our collaboration partners' ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its books and records provisions or its anti-bribery provisions.

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.***

Our research, development and manufacturing activities and our third-party suppliers' activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could

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

### **Risks Related to Ownership of Our Securities**

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

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

- the success of competitive products or technologies;
- adverse results or delays in preclinical or clinical trials;
- any inability to obtain additional funding;
- any delay in filing an IND, BLA or other regulatory submission for any of our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory agency's review of that IND, BLA or other regulatory submission;
- the perception of limited market sizes or pricing for our product candidates;
- failure to successfully develop and commercialize our product candidates;
- post-marketing safety issues relating to our product candidates or biosimilars generally;
- failure to maintain our existing strategic collaborations or enter into new collaborations;
- failure by us or our licensors and strategic collaboration partners to prosecute, maintain or enforce our intellectual property rights;
- changes in laws or regulations applicable to our products;
- any inability to obtain adequate product supply for our product candidates or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products, services or technologies by our competitors, including biosimilars, interchangeable biosimilars, and biobetter versions of the same molecules we are targeting;
- failure to meet or exceed financial projections we may provide to the public;
- failure to meet or exceed the financial projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us, our strategic collaboration partners or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including stockholder litigation and litigation filed by us or filed against us pertaining to patent infringement or other violations of intellectual property rights;
- the outcomes of any citizens petitions filed by parties seeking to restrict or limit the approval of biosimilar products;
- if securities or industry analysts do not publish research or reports about our business or if they issue an adverse or misleading opinion regarding our stock;
- changes in the market valuations of similar companies;

- general economic, industry or market conditions;
- sales of our securities by us or our stockholders in the future;
- trading volume of our securities;
- issuance of patents to third parties that could prevent our ability to commercialize our product candidates;
- reductions in the prices of reference products that could reduce the overall market opportunity for our product candidates intended as biosimilars to such reference products;
- the loss of one or more employees constituting our leadership team;
- changes in biosimilar regulatory requirements that could make it more difficult for us to develop our product candidates; and
- the other factors described in this "Risk Factors" section.

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

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

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

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

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

- our ability to successfully develop, market and sell ONS-3010, ONS-1045, ONS-1050 and our other product candidates;
- the cost of clinical development for ONS-3010, ONS-1045 and ONS-1050;
- the success of competitive products or technologies;
- results of clinical trials of our product candidates or those of our competitors;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, manufacture, acquire or in-license additional product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

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

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

The trading market for our securities will depend in part on the research and reports that securities or industry analysts publish about us or our business, our market and our competitors. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our securities or change their opinion of our securities, the market price of

our securities would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause the market price of our securities or trading volume to decline.

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

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds \$700 million as of March 31 (the end of our second fiscal quarter) of any fiscal year before that time or if we have total annual gross revenue of \$1.0 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following September 30 (the last day of our fiscal year) or, if we issue more than \$1.0 billion in non-convertible debt during any three-year period before that time, we would cease to be an emerging growth company immediately. We cannot predict if investors will find our securities less attractive because we may rely on this exemption. If some investors find our securities less attractive as a result, there may be a less active trading market for our securities and the market price of our securities may be more volatile.

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

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

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

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

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

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

We will need additional capital in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time.

If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We will be required, pursuant to Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for our fiscal year ending September 30, 2017. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. Our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting until our first annual report required to be filed with the SEC following the later of the date we are deemed to be an "accelerated filer" or a "large accelerated filer," each as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act, or the date we are no longer an "emerging growth company," as defined in the JOBS Act. We will be required to disclose changes made in our internal control and procedures on a quarterly basis. To comply with the requirements of being a public company, we may need to undertake various actions, such as implementing new internal



controls and procedures and hiring accounting or internal audit staff. We are beginning the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404, and we may not be able to complete our evaluation, testing and any required remediation in a timely fashion.

***We may have to pay liquidated damages to the selling stockholder, which would increase our expenses and reduce our cash resources.***

In connection with the sale of the shares of common stock and Series A warrants and Series B warrants to the selling stockholder in the private placement, we granted the selling stockholder certain registration rights, which are in addition to any rights it may have under our investors' rights agreement, as amended. Subject to certain limited exceptions, if the registration statement of which this prospectus forms a part has not been declared effective within the time periods specified, we will be required to pay the selling stockholder, as liquidated damages, 2.0% of the amount invested for each monthly period (or a pro rata portion thereof) during which such failure continues until the shares are sold or can be sold without restriction under Rule 144 promulgated under the Securities Act of 1933, as amended, or the Securities Act. We have also agreed to pay interest at a rate of up to 18.0% per annum if we fail to pay such damages within the time periods required. There can be no assurance that the registration statement of which this prospectus forms a part will remain effective for the time periods necessary to avoid payment of liquidated damages. Any payment of liquidated damages would increase our expenses, reduce our cash resources and may limit or preclude us from advancing our product candidates through clinical trials or otherwise growing our business.

## 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 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 are filing the registration statement of which this prospectus forms a part to permit the holder of the shares of our common stock and warrants to purchase shares of our common stock described in the section entitled "Selling Stockholder" to resell such shares of common stock, warrants and shares of common stock issuable upon exercise of such warrants. We will not receive any proceeds from the resale of any shares or warrants offered by this prospectus by the selling stockholder. Upon the exercise of the Series A warrants for 416,666 shares of our common stock by payment of cash, however, we will receive the exercise price of the warrants, which is \$6.60 per share. Upon the exercise of the Series B warrants for 416,666 shares of our common stock by payment of cash, however, we will receive the exercise price of the warrants, which is \$8.50 per share. Any proceeds from the exercise of the warrants will be used for working capital and general corporate purposes.

### PRICE RANGE OF SECURITIES

Our units (which comprised one share of our common stock, one-half of a Series A warrant and one-half of a Series B warrant) began trading under the symbol "ONSIU" on the NASDAQ Global Market on May 13, 2016 in connection with our initial public offering. Following separation of the units, on June 13, 2016, our shares of common stock and the Series A warrants and Series B warrants began trading under the symbols "ONS," "ONSIW" and "ONSIZ," respectively, and our units were delisted. Prior to our initial public offering, there was no public market for our securities. The following table sets forth for the periods indicated the high and low sales prices for our securities as reported on the NASDAQ Global Market:

	Common Stock		Series A Warrants		Series B Warrants	
	High	Low	High	Low	High	Low
<b>Fiscal Year 2017 Year-to-Date</b>						
Second quarter (through January 3, 2017)	\$3.72	\$3.05	\$ 0.20	\$ 0.18	\$ 0.85	\$ 0.85
First quarter	3.61	3.40	0.36	0.33	0.84	0.79
<b>Fiscal Year Ended September 30, 2016</b>						
Fourth quarter	5.49	3.04	0.44	0.41	0.68	0.62
Third quarter (from June 13, 2016)	4.48	3.25	0.26	0.24	0.72	0.61

On January 3, 2017, the last reported sale price of our common stock was \$3.28 per share, the last reported sale price of our Series A warrants was \$0.18 per warrant and the last reported sale price of our Series B warrants was \$0.85 per warrant. American Stock Transfer & Trust Company, LLC is the transfer agent and registrar for our common stock and the warrant agent for the Series A warrants and Series B warrants. As of January 3, 2017, there were approximately 97 holders of record of our common stock, one holder of record of our Series A warrants and one holder of record of our Series B warrants.

### **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. Our outstanding senior secured notes issued in December 2016 restrict our ability to pay dividends.

## SELLING STOCKHOLDER

On May 18, 2016, pursuant to a securities purchase agreement with Sabby Healthcare Master Fund, Ltd., the selling stockholder, dated as of May 11, 2016, concurrent with the closing of our initial public offering, we sold in a private placement for approximately \$5.0 million of gross proceeds the following securities: 833,332 shares of our common stock, Series A warrants to purchase up to an aggregate of 416,666 shares of our common stock at a purchase price of \$6.60 per share, and Series B warrants to purchase up to an aggregate of 416,666 shares of our common stock at a purchase price of \$8.50 per share. The underwriters of our initial public offering acted as placement agents and received a fee of approximately \$350,000.

The table below sets forth, to our knowledge, information about the selling stockholder as of September 30, 2016. Beneficial ownership is determined in accordance with the rules of the SEC. Unless otherwise indicated below, to our knowledge, the selling stockholder named in the table has sole voting and/or investment power with respect to the securities beneficially owned. Beneficial ownership for the selling stockholder is based on 22,802,778 shares of our common stock issued and outstanding as of September 30, 2016. The inclusion of any securities in this table does not constitute an admission of beneficial ownership by the person named below. Percentage amounts in the table below reflect beneficial ownership of that class of security.

We do not know when or in what amounts the selling stockholder may offer shares or warrants for sale. The selling stockholder might not sell any or all of the shares or warrants registered pursuant to the registration statement of which this prospectus forms a part. Because the selling stockholder may offer all or some of the shares or warrants pursuant to the registration statement of which this prospectus forms a part and because there are currently no agreements or understandings with respect to the sale of any shares or warrants, we cannot estimate the number of shares or warrants that will be held by the selling stockholder after completion of this offering. However, for purposes of this table, we have assumed that, after completion of this offering, none of the shares or warrants covered by this prospectus will be held by the selling stockholder.

	Before Offering		After Offering	
	Securities Held	Percentage	Securities Held	Percentage
Common Stock	2,027,978 <sup>(1)</sup>	8.8%	1,392,974 <sup>(2)</sup>	6.0%
Series A Warrants	667,968	20.0%	251,302	7.5%
Series B Warrants	667,968	20.0%	251,302	7.5%

(1) Before offering includes (i) 1,723,702 shares of common stock and (ii) and 304,276 aggregate shares of common stock issuable upon exercise of the Series A warrants and Series B warrants held directly by Sabby Healthcare Master Fund, Ltd., or SHMF, the selling stockholder, as 1,031,210 shares of common stock issuable upon exercise of the Series A warrants and/or Series B warrants are not included as such warrants may not be exercised if such exercise would result in beneficial ownership of more than 9.99% of our common stock. Also does not include 252,047 shares of common stock issuable upon exercise of other warrants that are not currently exercisable. Sabby Management, LLC, a Delaware limited liability company serves as the investment manager of SHMF. Hal Mintz is manager of Sabby Management. Each of Sabby Management and Mr. Mintz may be deemed to beneficially own the shares held by SHMF by virtue of such relationships, but each disclaims beneficial ownership except to the extent of any pecuniary interest in such shares. The address of each of Sabby Management and Mr. Mintz is c/o Sabby Management, 10 Mountainview Road, Suite 205, Upper Saddle River, New Jersey 07458. See "Principal Stockholders" for additional information regarding beneficial ownership of Sabby Management.

(2) After offering includes (i) 890,370 shares of common stock and (ii) and 502,604 shares of common stock issuable upon exercise of the Series A warrants and Series B warrants held directly by SHMF. Does not include 252,047 shares of common stock issuable upon exercise of other warrants that are not currently exercisable.

When we refer to the shares of our common stock and warrants being offered by this prospectus on behalf of the selling stockholder, we are referring to the shares of our common stock, Series A warrants and Series B warrants sold in the concurrent private placement, unless otherwise indicated.

The selling stockholder may have sold or transferred, in transactions exempt from the registration requirements of the Securities Act, some or all of its shares of common stock or its warrants since the date on which the information in the table above is presented. Information about the selling stockholder may change over time.

## PLAN OF DISTRIBUTION

We are registering the shares of common stock, Series A warrants and Series B warrants previously issued and the shares of common stock issuable upon exercise of the Series A warrants and Series B warrants, to permit the resale of these securities by the holders of the common stock and warrants from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the selling stockholder of the securities. Upon the exercise of the Series A warrants and Series B warrants, each for 416,666 shares of our common stock, by payment of cash, however, we will receive the exercise price of the warrants, which is \$6.60 per share and \$8.50 per share, respectively. We will bear all fees and expenses incident to our obligation to register the shares of common stock and Series A warrants and Series B warrants, except that, if such securities are sold through underwriters or broker-dealers, the selling stockholder will be responsible for underwriting discounts or commissions or agent's commissions.

The selling stockholder may sell all or a portion of the securities beneficially owned by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. The securities may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions,

- on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale;
- in the over-the-counter market;
- in transactions otherwise than on these exchanges or systems or in the over-the-counter market;
- through the writing of options, whether such options are listed on an options exchange or otherwise;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales;
- sales pursuant to Rule 144 of the Securities Act;
- broker-dealers may agree with the selling stockholder to sell a specified number of such security at a stipulated price per security;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

If the selling stockholder effects such transactions by selling our securities to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling stockholder or commissions from purchasers of our securities for whom they may act as agent or to whom they may sell as principal (which discounts, concessions or commissions as to particular underwriters, broker-dealers or agents may be in excess of those customary in the types of transactions involved). In connection with sales of our securities or otherwise, the selling stockholder may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of our securities in the course of hedging in positions they assume. The selling stockholder may also sell our securities short and deliver our securities covered by this prospectus to close out short positions and to return borrowed securities in connection with such short sales. The selling stockholder may also loan or pledge our securities to broker-dealers that in turn may sell such securities.

The selling stockholder may pledge or grant a security interest in some or all of our securities owned by it and, if it defaults in the performance of its secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time pursuant to this prospectus or other applicable provisions of the Securities Act, amending, if necessary, the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholder also may transfer and donate our securities in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling stockholder and any broker-dealer participating in the distribution of our securities may be deemed to be "underwriters" within the meaning of the Securities Act, and any commission paid, or any discounts or concessions allowed to, any such broker-dealer may be deemed to be underwriting commissions or discounts under the Securities Act. At the



time a particular offering of our securities is made, a prospectus supplement, if required, will be distributed that will set forth the aggregate amount of our securities being offered and the terms of the offering, including the name or names of any broker-dealers or agents, any discounts, commissions and other terms constituting compensation from the selling stockholder and any discounts, commissions or concessions allowed or reallocated or paid to broker-dealers.

Under the securities laws of some states, our securities may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states our securities may not be sold unless such securities have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

There can be no assurance that the selling stockholder will sell any or all of our securities registered pursuant to the registration statement, of which this prospectus forms a part.

The selling stockholder and any other person participating in such distribution will be subject to applicable provisions of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the rules and regulations thereunder, including, without limitation, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of our securities by the selling stockholder and any other participating person. Regulation M may also restrict the ability of any person engaged in the distribution of our securities to engage in market-making activities with respect to our securities. All of the foregoing may affect the marketability of our securities and the ability of any person or entity to engage in market-making activities with respect to our securities.

We will pay all expenses of the registration of our securities pursuant to the registration statement of which this prospectus forms a part, estimated to be \$75,000 in total, including, without limitation, SEC filing fees and expenses of compliance with state securities or "blue sky" laws; provided, however, that the selling stockholder will pay all underwriting discounts and selling commissions, if any. We will indemnify the selling stockholder against liabilities, including some liabilities under the Securities Act, or the selling stockholder will be entitled to contribution. We may be indemnified by the selling stockholder against civil liabilities, including liabilities under the Securities Act, that may arise from any written information furnished to us by the selling stockholder specifically for use in this prospectus or we may be entitled to contribution.

Once sold under the registration statement of which this prospectus forms a part, the securities will be freely tradable in the hands of persons other than our affiliates.

## 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. We have identified eight biosimilar product candidates for further development and have advanced two of these product candidates through Phase 1 clinical trials and into preparations for Phase 3 clinical trials: ONS-3010, a biosimilar to adalimumab (Humira<sup>®</sup>), and ONS-1045, a biosimilar to bevacizumab (Avastin<sup>®</sup>).

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

Through September 30, 2016, we have funded substantially all of our operations through the sale and issuance of \$139.5 million net proceeds of our common stock, preferred stock and debt. Through September 30, 2016, we have also received \$24.0 million pursuant to our collaboration and licensing agreements. On May 18, 2016 we completed the initial public offering, or IPO, of our securities, through the sale of units. Each unit consisted of one share of common stock, one-half of a Series A warrant and one-half of a Series B warrant. Each whole Series A warrant entitles the holder to purchase one share of common stock at an initial exercise price of \$6.60, subject to adjustment. Each whole Series B warrant entitles the holder to purchase one share of common stock at an initial exercise price of \$8.50, subject to adjustment. The initial public offering price was \$6.00 per unit. We also completed a private placement of 833,332 shares of common stock,

416,666 Series A warrants and 416,666 Series B warrants for aggregate gross proceeds of approximately \$5.0 million that closed concurrent with the IPO. The units separated in accordance with their terms, and ceased trading, and on June 13, 2016, each of the component securities underlying the units (common stock, Series A warrants and Series B warrants) began trading on the NASDAQ Global Market. We raised net proceeds of approximately \$29.2 million from our IPO and an additional \$4.6 million of net proceeds from the concurrent private placement, in each case excluding any proceeds we may receive from the exercise of the Series A and Series B warrants. In addition, in October, November and December 2016 we issued an aggregate of \$1.85 million of unsecured promissory notes, which notes were exchanged for new senior secured promissory notes and warrants in December 2016 concurrent with the issuance of \$6.5 million aggregate principal amount of new senior secured promissory notes and warrants for cash.

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

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

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

### **Collaboration and License Agreements**

From time to time, we enter into collaboration and license agreements for the research and development, manufacture and/or commercialization of our biosimilar products and/or biosimilar product candidates. These agreements generally provide for non-refundable upfront license fees, development and commercial performance milestone payments, cost sharing, royalty payments and/or profit sharing. 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 September 30, 2016, we have received an aggregate of \$5.0 million of payments from IPCA under our various agreements.

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

In June 2014, we entered into a strategic license agreement with Laboratories Liomont, S.A. de C.V., or Liomont, under which we granted Liomont and its affiliates an exclusive, sublicenseable license in Mexico for the research, development, manufacture, use or sale of the ONS-3010 and ONS-1045 biosimilar product candidates in Mexico. Under the terms of the agreement, we received an upfront payment from Liomont, and we are eligible to earn milestone payments for each of ONS-3010 and ONS-1045. In addition, we are eligible to receive tiered royalties at upper single-digit to low teens percentage rates of annual net sales of products by Liomont and its affiliates in Mexico. As of September 30, 2016, we have received an aggregate of \$3.0 million of upfront and milestone payments from Liomont.

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

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

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

In December 2014, we received an option to reacquire all rights to ONS-3010 from Huahai, which would have terminated the joint participation agreement. We had to exercise the option prior to December 23, 2015 and pay Huahai a total of \$28.0 million, consisting of an \$11.0 million initial payment due within seven days of exercise, and four additional

installment payments of \$4.25 million payable over the course of the following year. We did not make the \$11.0 million initial payment within the time frame required.

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

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

## Components of Our Results of Operations

### Collaboration Revenue

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

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

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

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

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

Each of our collaboration and licensing agreements is considered to be a multiple-element arrangement for accounting purposes. We determined that there are two deliverables; specifically, the license to our biosimilar product candidate and the related research and development services that we are obligated to provide. We concluded that these deliverables

should be accounted for as a single unit of accounting. We determined that the upfront license payments received should be deferred and recognized as revenue on a straight-line basis through the estimated period of completion of our obligations under the agreement. We recognize revenues from the achievement of milestones if the milestone event is substantive and achievability of the milestone was not reasonably assured at the inception of the agreement.

#### **Research and Development Expenses**

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

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

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

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

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

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

#### **General and Administrative Expenses**

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

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

#### **Interest Expense**

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

#### **Income Taxes**

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

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

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

## **Results of Operations**

### **Comparison of Years Ended September 30, 2016 and 2015**

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



*Collaboration Revenues*

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

*Research and Development Expenses*

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

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

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

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

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

*General and Administrative Expenses*

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

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

General and administrative expenses increased \$8.7 million for the year ended September 30, 2016, compared to the year ended September 30, 2015. The increase was primarily attributable to increased stock-based compensation expense of \$5.0 million upon meeting the exercisability and vesting conditions of our PSUs and RSUs upon the completion of our IPO,

a \$1.0 million bonus payment earned by our chief executive officer upon completion of our IPO, as well as increased professional fees related to meeting public company compliance requirements.

#### *Interest Expense*

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

#### **Liquidity and Capital Resources**

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

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

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

#### **Cash Flows**

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

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

#### *Operating Activities*

During the year ended September 30, 2016, we used \$45.5 million of cash in operating activities, primarily resulting from our net loss of \$53.3 million and the net cash used from changes in our operating assets and liabilities of \$7.0 million.

These uses of cash in our operating activities were offset by \$14.9 million of noncash items such as stock-based compensation and depreciation and amortization expense. The change in our operating assets and liabilities was primarily due to decreases in accounts payable related to the timing of vendor payments for research and development and professional services in connection with preparations for our IPO in May 2016 and decreases in deferred revenues due to ratable recognition of upfront payments received under our collaboration arrangements. These outflows were offset by increases in our prepaid expenses and other current assets, and increases in accrued expenses, and other liabilities that relate to the timing of vendor payments and the recognition of research and development expenses.

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

#### *Investing Activities*

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

#### *Financing Activities*

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

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

#### **Funding Requirements**

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

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

As a publicly traded company we will incur significant legal, accounting and other expenses that we were not required to incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules adopted by the SEC and The NASDAQ Stock Market LLC, requires public companies to implement specified corporate governance practices that are currently inapplicable to us as a private company. We expect these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

We believe our existing cash as of September 30, 2016 together with the proceeds from our December 2016 note and warrant issuance will provide adequate financial resources to fund our planned operations through February 2017. We have

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

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

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

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

### Contractual Obligations and Commitments

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

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

- (1) Operating lease obligations reflect our obligation to make payments in connection with the leases for our office, manufacturing and laboratory facilities located in Cranbury, New Jersey.
- (2) Debt obligations reflect outstanding principal obligations due to investors on notes payable and institutions and financing organizations for non-lease related equipment.
- (3) Capital lease obligations reflect our outstanding principal payment obligations in connection with leased equipment used in our manufacturing facility.
- (4) This table does not include (a) any milestone payments that may become payable to third parties under license agreements as the timing and likelihood of such payments are not known with certainty, (b) any royalty payments to third parties as the amounts, timing and likelihood of such payments are not known, and (c) contracts that are entered into in the ordinary course of business that are not material in the aggregate in any period presented above.

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

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

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

### **Off-Balance Sheet Arrangements**

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

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

Our consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reported period. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions and conditions.

While our significant accounting policies are described in more detail in the notes to our audited consolidated financial statements appearing elsewhere in this 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, 2015, our outstanding stock-based compensation awards were substantially comprised of PSUs, which were liability classified as the PSUs settled in cash and therefore were subject to remeasurement until the award is settled or extinguished.

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

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

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

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

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

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

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

#### **Internal Controls and Procedures**

We will be required, pursuant to Section 404(a) of the Sarbanes-Oxley Act, or Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for the year following our first annual report required to be filed with the SEC. This assessment will need to include disclosure of any material

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

We have not initiated the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing or any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are designed and operating effectively, which could result in a loss of investor confidence in the accuracy and completeness of our financial reports. This could cause the market price of our securities to decline, and we may be subject to investigation or sanctions by the SEC.

### **JOBS Act Accounting Election**

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

### **Recently Issued and Adopted Accounting Pronouncements**

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

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

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

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

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

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

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

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



## BUSINESS

### Overview

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

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

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

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

In addition to our clinical candidates, we have six preclinical biosimilar product candidates in active development. Our most advanced preclinical product candidate, ONS-1050, a trastuzumab (Herceptin®) biosimilar, interferes with the human epidermal growth factor receptor 2, or HER2, a protein that stimulates cell proliferation, and when overexpressed, can cause certain cancers. ONS-4010 is a biosimilar to denosumab (Prolia®/Xgeva®), which is a fully human mAb with affinity and specificity for human RANKL (receptor activator of nuclear factor kappa-B ligand), and used for the treatment of osteoporosis, treatment-induced bone loss, bone metastases and giant cell tumor of the bone. Commencement of Phase 1 clinical trials of ONS-1050 and ONS-4010 are dependent on successful completion of comparative analytical and *in vitro* functional studies, receipt of necessary regulatory authorizations and additional funding. In addition to these preclinical products, we plan to expand our pipeline of complex biosimilar product candidates as additional products approach the loss of their respective patent exclusivities.

### Our Strategy

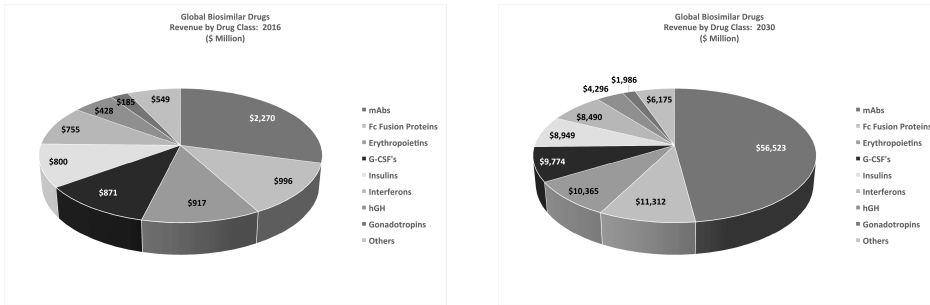
Our goal is to utilize the BioSymphony Platform to identify, develop, manufacture and commercialize technically challenging and commercially attractive mAb biosimilars on an accelerated timeline in a cost-effective manner, initially in the disease areas of immunology and oncology. The key elements of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

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

## The Biosimilar Industry

### Background

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

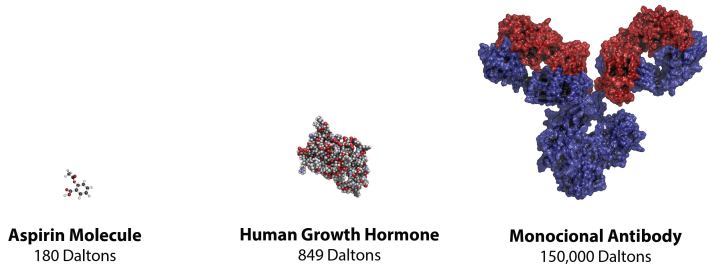


"The Biosimilar Drugs Market: Opportunities, Challenges, Strategies & Forecasts"; SNS Research Ltd.

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

**Technical Challenges**

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



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

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

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

#### Regulatory Challenges

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

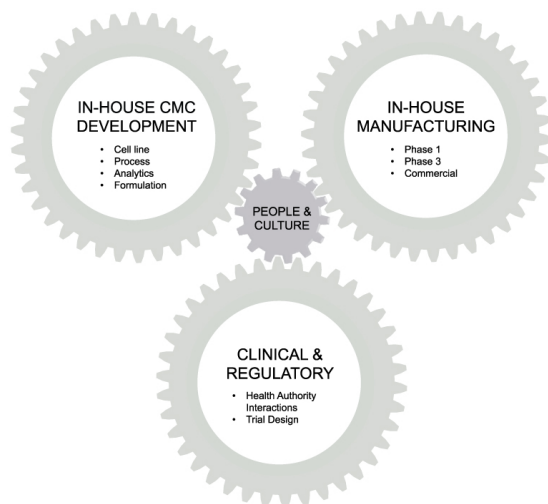
Regulatory hurdles associated with biosimilar development include:

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

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

#### Our BioSymphony Platform

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



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

#### **Technical Platform**

##### *In-House CMC Development Capabilities*

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

- **Reference Product Characterization and Cell Line Development:** We initially reverse engineer the amino acid sequence and identify the critical quality attributes of the reference product that in turn provides the criteria for the clone selection process. We utilize automated technologies to enable thousands of clones to be screened in an accelerated timeline.
- **Bioprocess:** We utilize high-throughput mini bioreactors to assess the screened clones and media components to determine which clone and bioreaction process will produce a biosimilar candidate with the closest match to the reference product. We have developed purification technology, including a platform of chromatography techniques that are strategically combined to maximize product-yield while meeting the critical quality attributes of the reference product.
- **Formulation:** The formulation that best preserves the stability of the biosimilar candidate may be different than the actual formulation of the reference product. We use high-throughput techniques to screen and evaluate many formulation variations to identify the most effective stable formulation.
- **Analytical Characterization and In Vitro Similarity:** We utilize numerous advanced analytical techniques and instruments to enable us to interpret the chemical and structural similarity between our biosimilar candidate and the reference product. We apply a rigorous analytical approach to characterize attributes such as structure

(primary, secondary and tertiary), size and glycosylation, among others. We test up to approximately 60 quality attributes with approximately 45 analytical methods. The biological characterization assays support establishing the *in vitro* similarity. Our in-house capabilities provide an expeditious and thorough assessment of biochemical, biophysical and functional attributes.

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

#### *In-House Manufacturing Capability*

We have established a state-of-the-art manufacturing facility capable of simultaneously producing multiple biosimilar candidates. Our manufacturing platform utilizes single-use technology, including the use of the largest single-use bioreactor available, which eliminates the need for rigorous cleaning and sterilization procedures, and related operational requirements necessary for manufacture in traditional stainless-steel based facilities. We have been able to construct single-use based antibody manufacturing plants in approximately four months as compared to the few years required for de novo biotechnology manufacturing facilities. We have developed and execute a quality system that meets U.S. and EU standards and have successfully completed two Qualified Person, or QP, audits resulting in cGMP declaration for both Phase 1 and Phase 3 manufacturing. We believe we have sufficient manufacturing capacity until 2018 and will be able to expand capacity in our current location once we build-out our new development infrastructure.

#### *Development-Manufacturing Integration*

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

#### *Regulatory and Clinical Approach for a Successful Global Launch*

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

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

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

provider who prescribed the reference product. We may also develop trial designs to demonstrate clinical advantages of our biosimilar product candidates over reference products.

Data from *in vivo* animal studies may not be required to initiate human clinical trials for biosimilars, and as such we only conduct animal studies if it is deemed necessary to meet regulatory requirements or to address safety questions. Our approach to confirm that there is no clinically meaningful impact of any observed analytical differences is to conduct a Phase 1 clinical trial in healthy volunteers, followed by a single Phase 3 confirmatory clinical trial in a sensitive population. Based on regulatory guidance as well as our recent interactions with regulatory bodies, we believe this approach will continue to be acceptable to the regulatory bodies. Because regulatory bodies generally do not require a repeat of the original efficacy and safety trials, we continue to explore the potential of novel approaches to trial design that can confirm similarity in shorter duration of treatment and/or with smaller patient numbers, which can result in shortened timelines to registration. In certain cases, we may even be able to demonstrate that our biosimilar product candidates are more effective or safer than the reference products.

### Our People and Culture

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

### Our Product Candidate Portfolio

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

Biosimilar Candidate	Reference Product	2015 WW Sales (\$bn) <sup>(1)</sup>	Commercial Rights	Product Characterization	Clone Selection	Lab Scale Similarity	Phase 1	Phase 3	Upcoming Milestones*
ONS-3010 (Adalimumab) <sup>(2)</sup>	HUMIRA®	\$14.1	Worldwide (ex-China, India and Mexico)						Phase 3 Trial 2017
ONS-1045 (Bevacizumab)	AVASTIN®	6.9	Worldwide (ex-China, India and Mexico)						Phase 3 Trial 2017
ONS-1050 (Trastuzumab)	HERCEPTIN®	6.8	Worldwide						Phase 1 Trial 2017
ONS-4010 (Denosumab)	PROLIA®/ XGEVA®	2.7	Worldwide						Phase 1 Trial 2018

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

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

### ONS-3010 — Adalimumab (Humira) Biosimilar

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



### Market Opportunity

Worldwide sales of Humira were \$14.1 billion in 2015, with approximately \$8.4 billion in the United States and projected to grow to \$18.0 billion worldwide by 2020, and it is one of the world's bestselling drugs. Humira has been approved by the FDA and the EMA for the treatment of 10 and 12 indications, respectively. Humira is currently approved in the United States for the following indications: rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult crohn's disease, pediatric crohn's disease, ulcerative colitis, plaque psoriasis, hidradenitis suppurativa and uveitis. We initially intend to seek approval of ONS-3010, a subcutaneous injectable, for the treatment of plaque psoriasis, and will pursue extrapolation of ONS-3010 across all eligible approved indications in order to maximize the commercial potential for ONS-3010. We have also designed our Phase 3 clinical trial for ONS-3010 in a way that we believe will enable us to also seek an interchangeability designation in the United States and have reviewed our trial design with the FDA and the EMA.

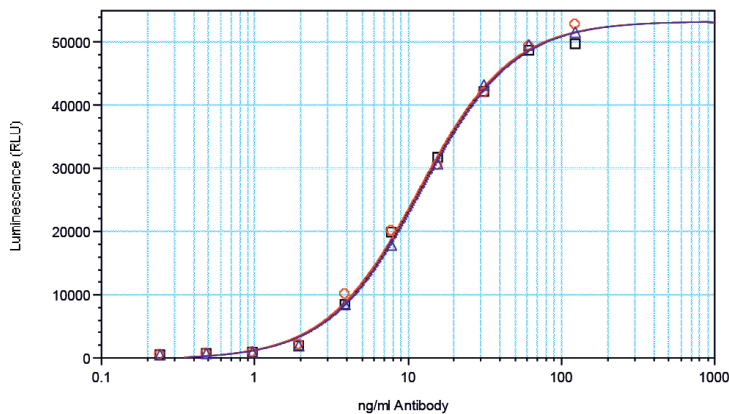
### Chemistry Manufacturing Controls, or CMC, Status

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

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

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

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



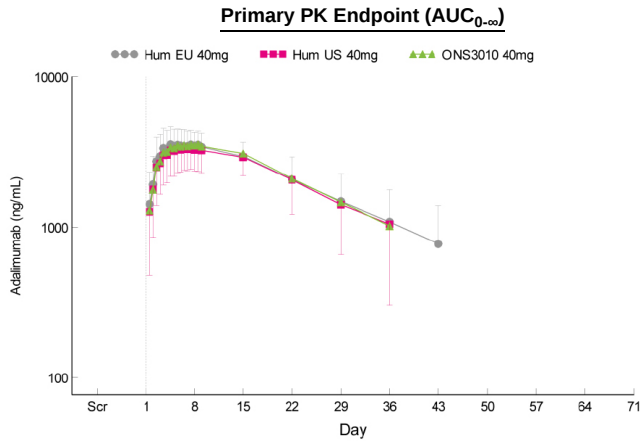
Using our commercial scale process at our manufacturing facility, we are manufacturing sufficient supply of ONS-3010 for Phase 3 clinical testing. We have contracted with a large U.S.-based pharmaceutical fill-finish facility to package ONS-3010 into a single-use, pre-filled syringe. We have also selected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

### Clinical Development Status and Clinical Trial Data

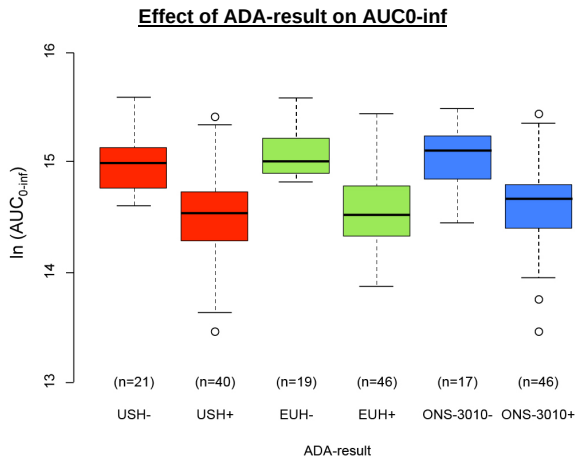
We have successfully completed a randomized, double-blind, single-dose and single-center Phase 1 clinical trial comparing ONS-3010 to Humira in 198 subjects receiving a 40 mg dose in three treatment arms: ONS-3010, U.S.-Humira and EU-Humira. This Phase 1 clinical trial was performed at the Center for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



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



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.



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

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

#### *Regulatory Status and Development Plan*

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

#### **ONS-1045 — Bevacizumab (Avastin) Biosimilar**

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

#### *Market Opportunity*

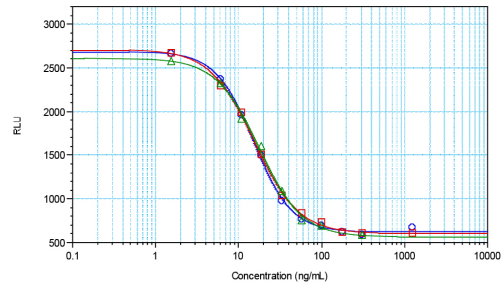
Worldwide sales of Avastin were approximately \$7.0 billion in 2014 and 2015 and are projected to remain relatively flat through 2019. Avastin has been approved by the FDA and the EMA for the treatment of seven and eight indications, respectively. Avastin is currently approved in the United States for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

#### *CMC Status*

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

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

**Comparative Potency of ONS-1045 versus Avastin (U.S. and EU)**  
 ONS-1045 (triangles), U.S.-Avastin (circles), EU-Avastin (squares)

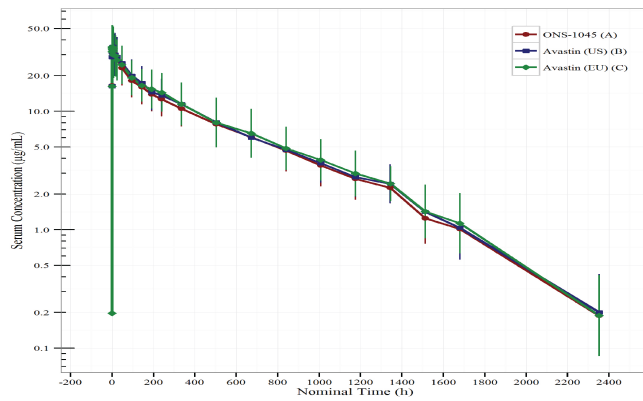


In preparation for producing Phase 3 clinical supplies, we are manufacturing ONS-1045 using our commercial scale process at our manufacturing facility. These batches will be filled into vials at a contracted U.S.-based commercial fill-finish facility.

*Clinical Development*

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

**Primary PK Endpoint ( $AUC_{0-\infty}$ )**



*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.

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

#### **ONS-1050 — Trastuzumab (Herceptin) Biosimilar**

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

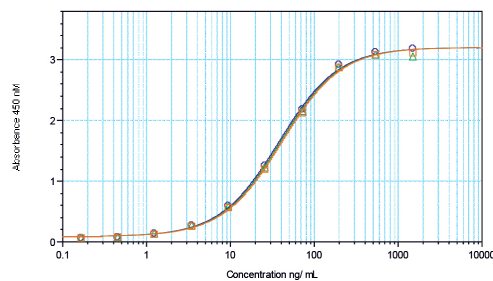
##### *Market Opportunity*

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

##### *CMC Status*

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

#### **Comparative Potency of ONS-1050 versus Herceptin (U.S. and EU).** ONS-1050 (squares), U.S.-Herceptin (circles), EU-Herceptin (triangles)



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

##### *Regulatory Status and Development Plans*

We received initial EMA guidance in the second quarter 2014 that supports our approach to the initial Phase 1 trial design. In accordance with our regulatory strategy and in advance of initiating Phase 1 clinical trials, we plan to interact with FDA, as well as other national regulatory agencies such as MHRA and the Federal Institute for Drugs and Medical Devices, to also obtain further guidance on study design. We expect to be ready to commence our Phase 1 clinical trial upon securing either a co-development or licensing partner for ONS-1050 or additional funding.

#### **Preclinical Biosimilar Pipeline**

In addition to the product candidates we are currently advancing through clinical development, we are leveraging our BioSymphony Platform to develop additional preclinical candidates. Further development of such preclinical product candidates is subject to ongoing commercial analysis, among other items. We have not yet determined the initial

indications for which we will seek approval for such preclinical product candidates. Our strategy will be to seek initial approval for an approved indication of the reference product, which will be determined in consultation with regulatory authorities regarding clinical trial and study design, and then seek to expand such approval to the same indications as the reference product. We also intend to deliver our biosimilars in the same manner as the reference product.

Two biosimilar product candidates, ONS-4010, a biosimilar to denosumab (Prolia/Xgeva), and ONS-1055, a biosimilar to cetuximab (Erbix<sup>®</sup>), 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. Erbix, administered by infusion, is currently approved in the United States for the following head and neck cancer treatments: locally or regionally advanced squamous cell carcinoma of the head and neck in combination with radiation therapy, recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck in combination with platinum-based therapy with 5-FU, and recurrent or metastatic squamous cell carcinoma of the head and neck progressing after platinum-based therapy; and for the following colorectal cancer treatments: K-Ras wild-type, EGFR-expressing, metastatic colorectal cancer as determined by FDA-approved tests in combination with FOLFIRI for first-line treatment, in combination with irinotecan in patients who are refractory to irinotecan-based chemotherapy, and as a single agent in patients who have failed oxaliplatin- and irinotecan-based chemotherapy or who are intolerant to irinotecan. We have completed preliminary characterization and the reverse engineering of the amino acid sequences of the reference products. We plan to complete process development for ONS-4010 in 2017 to prepare for commencement of a Phase 1 clinical trial. We plan to complete lab scale similarity of ONS-1055 in 2017. According to manufacturers' reports and recent filings with the Securities and Exchange Commission, 2015 worldwide sales of Prolia/Xgeva and Erbix were approximately \$2.7 billion and \$2.0 billion, respectively.

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

### Commercialization, Sales and Marketing

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

The United States and the EU are expected to be the largest and economically most attractive biosimilar markets and we plan to actively pursue licensing partners for both the United States and the EU. If required, we intend to build our

commercialization infrastructure through an option to outsource the sales and marketing work force via a contract sales organization. As such, we have engaged a consulting company to evaluate our options and to assist with the development of a U.S. sales and marketing strategy. We also recently entered into a strategic collaboration agreement with Premier Healthcare Alliance, L.P., or Premier, a developer of a network of U.S. hospitals and healthcare providers, focused on data-gathering and cost-reduction strategies to improve the outcome of its members. Under the agreement, we are partnering with Premier to share knowledge and strategize about how to most efficiently deliver our innovative and cost-effective mAb biosimilars in the U.S. market. We currently focus on those critical success factors associated with commercial success, namely the identification and interactions between (i) payors, (ii) providers, (iii) pharmacy benefit management organizations, (iv) patients and (v) physicians. We are currently developing a strategic roadmap that entails (i) developing and validating our commercialization strategy; (ii) exploring/establishing a distribution and commercialization relationship; and (iii) eventually developing our own sales and marketing force.

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

### **Collaboration and License Agreements**

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

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

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

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

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

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

*Commercial License Agreements*

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

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

Each of our commercial agreements with Selexis will expire in its entirety upon the expiration of all applicable Selexis patent rights. The licensed patent rights consist of two patent families. The first patent family relates to methods of transferring cells, and is filed in the United States, Australia, Canada, Europe, Japan and Singapore. This patent family will begin to expire worldwide in 2022. The second patent family claims DNA compositions of matter useful for having protein production increasing activity. This patent family is filed in the United States, Australia, Canada, China, Europe, Hong Kong, Israel, India, Japan, South Korea, Russia, Singapore and South Africa. This patent family will begin to expire worldwide in 2025. Either party may terminate the related agreement in the event of an uncured material breach by the other party or in the event the other party becomes subject to specified bankruptcy, winding up or similar circumstances. Either party may also terminate the related agreement under designated circumstances if the Selexis Technology infringes third-party intellectual property rights. In addition, we have the right to terminate each of the commercial agreements at any time for our convenience; however, with respect to the agreements relating to ONS-3010 and ONS-1045, this right is subject to Liomont's consent pursuant to a corresponding letter we executed in conjunction with the standby agreement entered into between Selexis and Liomont on November 11, 2014. The standby agreement permits Liomont to assume the license under the applicable commercial agreement for Mexico upon specified triggering events involving our bankruptcy, insolvency or similar circumstances.

***Ex-U.S. Collaboration and License Agreements***

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

Generally, our agreements expire on a product-by-product basis on the date of the expiration of the royalty revenue term for all products in the territory. The royalty revenue term is 10 years from the date of first commercial sale and any renewal is

subject to good faith negotiation. The license term for the agreed territory is perpetual. Either party may terminate the agreement in its entirety or with respect to a particular product if the other party materially breaches the agreement, subject to specified notice and cure periods. In addition, we have the right to terminate the agreement in connection with any interference, opposition or challenge of our patent rights. If the agreement is terminated due to our breach, our contract counterparty is generally free to use all applicable technology and know-how that we have provided under the agreement.

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

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

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

Unless terminated early upon mutual agreement of the parties, or due to a material breach of either party that is uncured, the joint participation agreement will terminate upon entry into a mutually acceptable collaboration agreement between us and Huahai for ongoing development and commercialization of ONS-3010 in the agreed countries, or we and Huahai enter into an agreed license with a third party for such ongoing development and commercialization of ONS-3010 in the agreed countries. If the joint participation agreement is terminated for cause due to our breach, we could be required to refund Huahai any amounts funded by Huahai to develop ONS-3010, as well as pay Huahai a 6% royalty on net sales made by us or an affiliate, as well as 25% of revenues we receive from a sublicensee for commercial sales of ONS-3010 until the aggregate of such payments is equal to 10 times the amount Huahai funded for the development of ONS-3010. Furthermore, if we were to file a voluntary petition in bankruptcy, or have an involuntary petition filed that we could not dismiss within 120 days, then Huahai would be granted an exclusive license to continue the development and commercialization of ONS-3010 in the agreed countries.

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

## Competition

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



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

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

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

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

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

### **Intellectual Property**

Our commercial success depends in part on our ability to avoid infringing the proprietary rights of third parties, our ability to obtain and maintain proprietary protection for our technologies where applicable and to prevent others from infringing our proprietary rights. We seek to protect our proprietary technologies by, among other methods, evaluating relevant patents, establishing defensive positions, monitoring EU oppositions and pending intellectual property rights, preparing litigation strategies in view of the U.S. legislative framework and filing U.S. and international patent applications on technologies, inventions and improvements that are important to our business. As of September 30, 2016, we own two pending international applications that were filed under the Patent Cooperation Treaty, or PCT, which relate to formulations developed for ONS-3010, as well as methods of antibody purification. We also own six provisional patent applications related to methods for purifying antibodies to separate isoforms, reducing high molecular weight species, and modulating afucosylated species, as well as buffer formulations for enhanced antibody stability and methods for determining the amino acid sequence of antibodies. Any patents that may eventually issue claiming priority to these six provisional patent applications are expected to expire in 2036 and 2037. The PCT is an international patent law treaty that provides a unified procedure for filing patent applications to protect inventions in each of its contracting states. Thus, a single PCT application can be converted into a patent application in any of the more than 145 PCT contracting states, and is considered a simple, cost-effective means for seeking patent protection in numerous regions or countries. This nationalization (converting into an application in any of the contracting states) typically occurs 18 months after the PCT application filing date. Our first PCT application was nationalized in April 2016 in Australia, Canada, China, Europe, Japan,

Mexico, and the United States. Our second PCT application is due to be nationalized in July 2017. We have not determined what countries to nationalize in. If granted, patents issuing from our two PCT applications are expected to expire in 2034 and 2036, absent any adjustment or extensions. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary position.

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

## Regulatory

### **Government Regulation and Product Approval**

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

### **FDA Approval Process for Biosimilars**

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

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

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

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

Clinical trials for biosimilars involve the administration of the new investigational product to healthy volunteers or patients with the condition under investigation, all under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

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

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

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

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

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

The approval of our product candidates may be significantly more limited than requested in the application, including limitations on the dosage forms (if multiple forms are filed) or the indications for use, which could restrict the commercial value of the product. In addition, as a condition of BLA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to minimize any risk associated with the product. REMS can include medication guides, communication plans for healthcare professionals and Elements To Assure Safe Use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. The requirement for a REMS can materially affect the potential market and

profitability of the product. Moreover, post-approval testing and surveillance to monitor the product's safety or efficacy may be required as a condition of approval. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

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

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

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

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

Moreover, the BPCIA provides for a designation of "interchangeability" between the reference and biosimilar products, whereby the biosimilar may be substituted for the reference product without the intervention of the healthcare provider who prescribed the reference product. After the assessment of biosimilarity, the higher standard of interchangeability must be demonstrated by information sufficient to show that the proposed product is expected to produce the same clinical result as the reference product in any given patient and for a product that is administered more than once to an individual, the risk to the patient in terms of safety or diminished efficacy of alternating or switching between the biosimilar and the reference product is no greater than the risk of using the reference product without such alternation or switch. FDA's implementation of the 351(k) approval pathway is still evolving, and the acceptance for filing and review of a 351(k) application is subject to the same refusals to file or approve that are described above for 351(a) BLAs. In addition, the FDA may accept a 351(k) application for filing but deny approval on the basis that the sponsor has not demonstrated biosimilarity, in which case the sponsor may choose to conduct further analytical, preclinical or clinical trials to demonstrate such biosimilarity under section 351(k) or submit a BLA for licensure as a new biologic under section 351(a).

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

result in a change in safety, purity, or potency. Therefore, one must determine whether a subsequent application for a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity, or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the "first licensure" of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

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

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

#### **Post-Approval Regulatory Requirements**

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

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

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

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

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

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

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

The federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in cash or in kind, either to induce or award the referral of an individual, for an item or service or the purchasing, recommending or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. The Anti-Kickback Statute is subject to evolving interpretations. In the past, the government has enforced the Anti-Kickback Statute to reach large settlements with healthcare companies based on, in certain cases, sham consulting and other financial arrangements with physicians. Further, the Affordable Care Act, among other things, amends the intent requirement of the federal Anti-Kickback Statute and the criminal statute governing healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to commit a violation. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties statute. The majority of states also have anti-kickback laws that establish similar prohibitions and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers.

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

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

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

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Affordable Care Act, among other things, via the Physician Payments Sunshine Act, imposes new reporting requirements on certain manufacturers of drugs, devices, biologics, and medical supplies for which

payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, for payments made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information to the Centers for Medicare & Medicaid Services, or CMS, may result in civil monetary penalties of up to an aggregate of \$150,000 per year (or up to an aggregate of \$1.0 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Such manufacturers must submit reports by the 90th day of each subsequent calendar year.

Certain states also mandate implementation of commercial compliance programs, impose restrictions on pharmaceutical manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians. Additionally, analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers. State laws may also apply that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, as well as state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

#### ***Healthcare Reform***

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

#### ***International Regulation***

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



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

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

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

#### **Employees**

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

#### **Facilities**

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

#### **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 September 30, 2016:

Name	Age	Position(s)
<b>Executive Officers</b>		
Pankaj Mohan, Ph.D.	52	Chairman, President and Chief Executive Officer
Kenneth M. Bahr, 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	51	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
<b>Non-Employee Directors</b>		
Todd C. Brady, M.D., Ph.D. <sup>(1)(3)</sup>	45	Director
Scott Canute <sup>(2)</sup>	56	Director
Albert D. Dyrness <sup>(2)(3)</sup>	53	Director
Donald J. Griffith	67	Director
Kurt J. Hilzinger <sup>(1)(2)</sup>	56	Director
Robin Smith Hoke <sup>(1)(3)</sup>	54	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. Bahr, M.D.** Dr. Bahr has served as our Chief Medical Officer since June 2015. Prior to joining us, from February 2014 to May 2015, Dr. Bahr served as the Vice President of U.S. Medical Affairs at NPS Pharmaceuticals, Inc., a biopharmaceutical company. From August 2011 to January 2014, Dr. Bahr 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. Bahr served as the Therapeutic Head of Immunology Medical Affairs at Genentech, Inc. From July 2007 to September 2009, Dr. Bahr served as the Global Medical Director for Immunology at Hoffman-La Roche, a Swiss healthcare company. Prior to this, Dr. Bahr 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 Spring Bank Pharmaceuticals, Inc., a clinical-stage biopharmaceutical company since July 2016, 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 board of directors of Akebia Therapeutics Inc., a biopharmaceutical company, since August 2016, served as a member of the technical advisory board of Moderna Therapeutics, Inc., a biotechnology 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. Dyrness 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 pharmaceuticals, 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 November 2016, Ms. Hoke has served as the President and Chief Executive Officer of Leiter's Holding, LLC. From July 2012 through November 2016, Ms. Hoke was 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 consists of seven members. 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 are divided among the three classes as follows:

- The Class I directors are 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 are 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 are 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, if any, 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 its initial listing.

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 is posted on our website at [www.oncobiologics.com](http://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 entered into director engagement letters with two of our non-employee directors, Dr. Brady and Mr. Canute, which letters governed their compensation prior to our initial public offering. Pursuant to Dr. Brady's director engagement letter, he was 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 were not granted to Dr. Brady. Pursuant to Mr. Canute's director engagement letter, he was 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 was 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 — Financings — 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, 2016. 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 <sup>(1)</sup> (\$)	Total (\$)
Todd C. Brady, M.D., Ph.D.	17,867	17,867
Scott Canute	19,212	19,212
Albert Dyrness	19,789	19,789
Donald J. Griffith	13,449	13,449
Kurt Hilzinger	24,015	24,015
Robin Smith Hoke	18,060	18,060

(1) Represents the annual cash fees per terms of director engagement letters prior to our May 2016 initial public offering and pro rata fees pursuant to our non-employee director compensation policy subsequent to our May 2016 initial public offering.

## Non-Employee Director Compensation Policy

We have adopted a non-employee director compensation policy that took effect in May 2016 in connection with our initial public offering pursuant to which our non-employee directors are eligible to receive compensation for service on our board of directors and committees of our board of directors.

### 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 through 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:

<b>Board Committee</b>	<b>Chairperson Fee</b>	<b>Member Fee</b>
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, 2016, 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;
- Lawrence A. Kenyon, our Chief Financial Officer; and
- Kogan Bao, Ph.D., our Vice President, Analytical Sciences.

### Summary Compensation Table

The following table provides information regarding the compensation earned by our named executive officers for the years ended September 30, 2016 and 2015.

Name and Principal Position	Year	Salary (\$)	Bonus (\$) <sup>(1)</sup>	Equity Plan Awards (\$) <sup>(2)</sup>	All Other Compensation (\$) <sup>(3)</sup>	Total (\$)
Pankaj Mohan, Ph.D. <i>Chairman, President and Chief Executive Officer</i>	2016	369,926	990,000	11,787,997	26,658	13,174,581
	2015	290,004	—	—	29,839	319,843
Lawrence A. Kenyon <sup>(4)</sup> <i>Chief Financial Officer</i>	2016	309,359	—	1,262,992	17,727	1,590,078
	2015	14,000	—	—	—	14,000
Kogan Bao, Ph.D. <sup>(5)</sup> <i>Vice President, Analytical Sciences</i>	2016	160,309	—	260,868	7,798	428,975
	2015	—	—	—	—	—

- (1) Discretionary bonus amounts for the fiscal year ended September 30, 2016 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 restricted stock unit, or RSU, awards granted computed in accordance with Financial Accounting Standard Board Accounting Standards Codification Topic 718, or ASC 718, for stock-based compensation transactions. Assumptions used in the calculation of these amounts are included in Note 11 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 vesting and settlement of the RSUs.
- (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.
- (4) Mr. Kenyon joined our company in September 2015.
- (5) Dr. Bao joined our company in January 2016.

### 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 our initial public 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.

Our 2015 Equity Incentive Plan, or the 2015 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 RSUs. In December 2015, our board of directors authorized an RSU grant to our executives, including Dr. Mohan and Mr. Kenyon, and subsequently granted RSUs to Dr. Bao in April 2016 upon commencement of his employment. 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 Mr. Kenyon and Dr. Bao 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 initially 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 original 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 agreed to pay all premiums associated with Dr. Mohan's health insurance. The term of Dr. Mohan's original employment agreement was to have continued 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 original employment agreement provided that we could have terminated 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

could have terminated 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 original employment agreement would have automatically terminated upon his death or the end of the term of the agreement. Dr. Mohan was also entitled to certain severance and change in control benefits pursuant to this 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 took effect in May 2016 in connection with our initial public 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 was also entitled to a one-time lump sum performance bonus of \$990,000 that was contingent upon the closing of our initial public 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."

*Mr. Kenyon.* We entered into an employment offer letter agreement with Mr. Kenyon for full-time services on an at-will basis in August 2015 setting forth the terms of his employment. Pursuant to that agreement, Mr. Kenyon was entitled to an initial annual base salary of \$280,000, a target annual discretionary bonus equal to \$120,000 and the grant of 150,000 RSUs that vest over a four-year period subject to Mr. Kenyon's continued service with us. His employment offer letter agreement did not have a specified term and his employment could have been terminated by us or Mr. Kenyon at any time, with or without cause. Mr. Kenyon was not entitled to any additional compensation or benefits under his employment offer letter agreement upon termination of his employment or a change of control.

In February, 2016, we entered into a new employment agreement with Mr. Kenyon that took effect in May 2016 in connection with our initial public offering. Under Mr. Kenyon's new employment agreement, Mr. Kenyon is entitled to an initial annual base salary of \$350,000 and is eligible to receive an annual performance bonus of up to 40% of his base salary as determined by our board of directors. Mr. Kenyon 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 Mr. Kenyon at any time, with or without cause. Mr. Kenyon 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."

*Dr. Bao.* We entered into an employment offer letter agreement with Dr. Bao for full-time services on an at-will basis in November 2015 setting forth the terms of his employment. Pursuant to that agreement, Dr. Bao was entitled to an initial annual base salary of \$225,000, a target annual discretionary bonus equal to 33% of his annual base salary in the event that sufficient revenue was generated and the grant of 75,000 RSUs that vest over a four-year period subject to Dr. Bao's continued service with us. His employment offer letter agreement did not have a specified term and his employment could have been terminated by us or Dr. Bao at any time, with or without cause. Dr. Bao was not entitled to any additional compensation or benefits under his employment offer letter agreement upon termination of his employment or a change of control.

In February, 2016, we entered into a new employment agreement with Dr. Bao that took effect in May 2016 in connection with our initial public offering. Under Dr. Bao's new employment agreement, Dr. Bao is entitled to an initial annual base salary of \$230,000 and is eligible to receive an annual performance bonus of up to 35% of his annual base salary as determined by our board of directors. Dr. Bao 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. Bao at any time, with or without cause. Dr. Bao 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."

**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 took effect in May 2016, 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.

*Mr. Kenyon.* Pursuant to Mr. Kenyon's employment agreement that took effect in May 2016, 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 Mr. Kenyon's employment is terminated by us or any successor entity (provided such successor entity either assumes Mr. Kenyon'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.

*Dr. Bao.* Pursuant to Dr. Bao's employment agreement that took effect in May 2016, 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 six months following the termination, employee benefit coverage for up to six 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. Bao's employment is terminated by us or any successor entity (provided such successor entity either assumes Dr. Bao'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 six months, 50% of his 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 him through the date of his termination. Additionally, 100% of his then unvested equity awards shall become fully vested.

For purposes of Dr. Mohan's, Mr. Kenyon's and Dr. Bao's employment agreements:

- "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, 2016.

	Grant Date	Equity Awards <sup>(1)</sup>			
		Number of Securities Underlying Unexercised RSUs Exercisable (#)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned RSUs (#)	Exercise Price (\$)	Expiration Date
Pankaj Mohan, Ph.D.	12/31/2015	405,797	—	—	—
Lawrence A. Kenyon	12/31/2015	43,478 <sup>(2)</sup>	—	—	—
Kogan Bao, Ph.D.	04/11/2016	21,739 <sup>(3)</sup>	—	—	—

- (1) All of the outstanding equity awards as of September 30, 2016 are RSUs that were granted under and subject to the terms of the 2015 Equity Incentive Plan, described below under "— Equity Benefit Plans." None of our named executive officers held any other stock awards at the end of 2016. Except as otherwise indicated, each RSU 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 — 2015 Equity Incentive Plan."
- (2) 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 our initial public offering, in each case subject to Mr. Kenyon's continued service with us through such event. Of these RSUs, 50% will satisfy the time-based vesting restrictions on each of September 15, 2018 and 2019, subject to Mr. Kenyon'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 Mr. Kenyon's continued service with us through such date.
- (3) 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 our initial public offering, in each case subject to Dr. Bao's continued service with us through such event. Of these RSUs, 50% will satisfy the time-based vesting restrictions on each of January 20, 2019 and 2020, subject to Dr. Bao'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 Dr. Bao's continued service with us through such date.

### Option Exercises and Stock Vested

Our named executive officers did not exercise any stock option or PSUs, nor have the RSUs vest, during the fiscal year ended September 30, 2016.

### 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, 2016. 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.

### 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 2016. Participants that are 50 years or older can also make “catch-up” contributions, which in calendar year 2016 may be up to an additional \$6,000 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 2016.

#### **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 number of shares of our common stock reserved for issuance as of September 30, 2016 under the 2015 Plan was 1,930,460 shares. 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 5,611,619. As of September 30, 2016, RSUs representing 1,094,351 shares of our common stock were outstanding under the 2015 Plan and 836,109 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 September 30, 2016, PSUs representing 247,309 shares of our common stock were outstanding under the 2011 Plan at a weighted-average base price of \$6.33 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 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.* 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 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. In December 2016, our board of directors elected not to provide for any increase in the ESPP share reserve for 2017.

*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 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**

Our amended and restated certificate of incorporation contains 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 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 also provides 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 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.

## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a summary of transactions since October 1, 2013 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

##### *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 our initial public offering, certain provisions of the investors' rights agreement terminated and the continuing provisions are described below. The co-sale agreement automatically terminated effective upon the completion of our initial public 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. The selling stockholder acquired 387,766 shares in such financing.

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 the completion of our initial public offering and pursuant to the documents governing such funds, these directors received shares of our common stock and warrants pro rata to their investments in such funds upon distribution of all of the shares of our common stock and warrants held by such funds as follows: Mr. Canute, 57,408 shares, 37,315 warrants; Mr. Hilzinger, 18,518 shares, 12,036 warrants; Ms. Hoke, 1,939 shares, 1,260 warrants.

**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 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.

In October, November and December 2016, we issued an aggregate of \$1.85 million of unsecured promissory notes to various accredited investors. These notes had a stated interest rate of 15% per year, and a one year maturity. Messrs. Canute, Dyrness and the selling stockholder acquired such notes, which had an aggregate principal amount of \$350,000, \$50,000 and \$500,000, respectively. All of these notes were exchanged in our December 2016 financing described below.

On December 22, 2016, we entered into a Note and Warrant Purchase Agreement with the accredited investors, which included our two directors, Messrs. Canute and Dyrness, as well as the selling stockholder and its affiliates, providing for the issuance and sale of up to \$10.0 million of senior secured promissory notes, which bear interest at a rate of 5.0% per year and mature December 22, 2017 and warrants to acquire an aggregate 2.3 million shares of our common stock. The warrants have a five-year term and an exercise price of \$3.00 per share. We closed the initial sale and purchase of the notes and warrants on December 22, 2016, issuing \$8.35 million aggregate principal amount of notes and warrants to acquire an aggregate 1,920,500 shares of our common stock in exchange for \$6.5 million of cash and an aggregate of \$1.85 million of existing unsecured bridge notes issued in October, November and December 2016. These included the \$900,000 aggregate principal amount of notes held by Messrs. Canute and Dyrness and the selling stockholder. The selling stockholder also invested an additional \$2.5 million. Under the agreement, we may issue up to \$1.65 million of additional notes and warrants to acquire up to an additional 379,500 shares of our common stock in additional closings over the next 90 days without approval of the holders of the notes. Under the agreement, we agreed to customary negative covenants restricting our ability to repay indebtedness to officers, pay dividends to stockholders, repay or incur other indebtedness other than as permitted, grant or suffer to exist a security interest in any of our assets, other than as permitted, or enter into any transactions with affiliates. In addition to the negative covenants in the agreement, the notes include customary events of default. In connection with the closing of the initial sale of the notes and warrants, we entered into a Security Agreement and an Intellectual Property Security Agreement, each dated December 22, 2016, granting the holders of the notes a security interest in all of our assets.

#### **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 — Narrative to Summary Compensation Table — Agreements with our Named Executive Officers."

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, 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 September 2015, we terminated the license and business development agreements with our former subsidiary, Parilis Biopharmaceuticals, LLC, or Parilis, of which we were the sole member, 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 bore interest at the annual rate of 3%. During the year ended September 30, 2016, Sonnet repaid the full balance of the promissory note.

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.

#### **May 2016 Concurrent Private Placement**

Sabby Healthcare Master Fund, Ltd., the selling stockholder, purchased approximately \$5.0 million of securities at the initial public offering price (or 833,332 shares and 416,666 Series A warrants and 416,666 Series B warrants) in a private placement that closed concurrently with our initial public offering. The securities that were sold in the concurrent

private placement were not registered under the Securities Act. We paid the underwriters of our initial public offering as placement agents in the 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 concurrent private placement was contingent upon, and occurred concurrently with, the closing of our initial public 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, in accordance therewith, issued certain of the investors three-year warrants to purchase an aggregate of 1,520,268 shares of our common stock following the closing of our initial public offering. Of these warrants, the selling stockholder received warrants to acquire 252,047 shares. The terms of such warrants are more fully described in "Description of Securities — Common Stock Equivalents." 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 — Stockholder Registration Rights."

### **Indemnification Agreements**

Our amended and restated certificate of incorporation contains provisions limiting the liability of directors, and our amended and restated bylaws 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 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 have adopted 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.

## PRINCIPAL STOCKHOLDERS

The following table sets forth certain information relating to the beneficial ownership of our common stock as of September 30, 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 22,802,778 shares of common stock outstanding, as of September 30, 2016.

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 exercise of warrants or upon vesting of outstanding equity awards that are exercisable or subject to vesting within 60 days after September 30, 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.

Name of Beneficial Owner	Number	Percentage of Shares Beneficially Owned
<b>Five Percent Stockholders (other than directors and officers):</b>		
Perceptive Advisors, LLC <sup>(1)</sup>	2,369,612	9.9%
Sabby Management, LLC <sup>(2)</sup>	2,291,202	9.9%
Strides Pharma (UK) Limited <sup>(3)</sup>	1,739,130	7.6%
<b>Named Executive Officers and Directors:</b>		
Pankaj Mohan, Ph.D., <i>Chairman, President and Chief Executive Officer</i> <sup>(4)</sup>	7,488,678	32.8%
Lawrence A. Kenyon, <i>Chief Financial Officer</i> <sup>(5)</sup>	—	—
Kogan Bao, Ph.D., <i>Vice President, Analytical Sciences</i> <sup>(6)</sup>	—	—
Todd C. Brady, M.D., Ph.D., <i>Director</i> <sup>(7)</sup>	124,303	*
Scott Canute, <i>Director</i> <sup>(8)</sup>	130,963	*
Albert D. Dyrness, <i>Director</i> <sup>(9)</sup>	—	—
Donald J. Griffith, <i>Director</i> <sup>(10)</sup>	—	—
Kurt J. Hilzinger, <i>Director</i> <sup>(11)</sup>	—	—
Robin Smith Hoke, <i>Director</i> <sup>(12)</sup>	—	—
<b>All executive officers and directors as a group (13 persons)</b>	<b>7,747,944</b>	<b>34.0%</b>

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

- (1) Includes (i) 1,248,990 shares of common stock and (ii) 1,120,622 aggregate shares of common stock issuable upon exercise of the aggregate Series A warrants and Series B warrants held; as 192,142 aggregate shares of common stock issuable upon exercise of the Series A warrants and/or Series B warrants are not included as they may not be exercised if such exercise would result in beneficial ownership of more than 9.99% of our common stock. Perceptive Advisors, LLC beneficially owns the shares (and shares issuable upon exercise of the Series A and Series B warrants), which are held by a private investment fund and a managed account to which Perceptive Advisors, LLC serves as the investment manager. Joseph Edelman is the managing member of Perceptive Advisors, LLC. The address for Perceptive Advisors, LLC is 499 Park Ave., 25th Floor, New York, NY 10022.
- (2) Includes (i) 1,723,702 shares of common stock held directly by the selling stockholder, Sabby Healthcare Master Fund, Ltd., a Cayman Islands exempted company, or SHMF, (ii) 250,000 shares of common stock held directly by Sabby Volatility Warrant Master Fund, Ltd., a Cayman Islands exempted company, or SVWMF, and (iii) 317,500 aggregate shares of common stock issuable upon exercise of the aggregate Series A warrants and Series B warrants held directly by SHMF and SVWMF; as 1,268,436 aggregate shares of common stock issuable upon exercise of the Series A warrants and/or Series B warrants are not included as they may not be exercised if such exercise would result in beneficial ownership of more than 9.99% of our common stock. Also excludes 252,047 shares of common stock issuable upon exercise of other warrants held by SHMF that are not currently exercisable. Sabby

Management, LLC, a Delaware limited liability company serves as the investment manager of SHMF and SVWMF. Hal Mintz is manager of Sabby Management. Each of Sabby Management and Mr. Mintz may be deemed to beneficially own the shares held by SHMF and SVWMF by virtue of such relationships, but each disclaims beneficial ownership except to the extent of any pecuniary interest in such shares. The address of each of Sabby Management and Mr. Mintz is c/o Sabby Management, 10 Mountainview Road, Suite 205, Upper Saddle River, New Jersey 07458.

- (3) 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.
- (4) Includes 39,405 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. Does not include 405,797 restricted stock unit awards, or RSUs, held by Dr. Mohan.
- (5) Does not include 43,478 RSUs held by Mr. Kenyon.
- (6) Does not include 21,739 RSUs held by Dr. Bao.
- (7) Does not include 57,971 RSUs held by Dr. Brady.
- (8) Does not include (x) 57,971 RSUs held by Mr. Canute nor (y) 57,408 shares or warrants to acquire 37,315 shares held in a special purpose fund, Proximare Lifesciences Fund LLC, over which he does not have voting or investment control.
- (9) Does not include 7,246 RSUs held by Mr. Dyrness.
- (10) Does not include 144,927 RSUs held by Mr. Griffith.
- (11) Does not include (x) 7,246 RSUs held by Mr. Hilzinger nor (y) 18,518 shares or warrants to acquire 12,036 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.
- (12) Does not include (x) 7,246 RSUs held by Ms. Hoke nor (y) 1,939 shares or warrants to acquire 1,260 shares held in a special purpose fund, Proximare Lifesciences Fund LLC, over which she does not have voting or investment control.

## DESCRIPTION OF SECURITIES

Our authorized capital stock consists of 200,000,000 shares of common stock, par value \$0.01 per share, and 10,000,000 shares of preferred stock, par value \$0.01 per share. 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, 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.

### **Common Stock**

As of September 30, 2016, there were 22,802,778 shares of common stock outstanding held by 97 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 66 $\frac{2}{3}$ % 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. Our outstanding senior secured notes issued December 2016 retain our ability to pay dividends.

#### ***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**

We currently have issued and outstanding an aggregate of 3,333,333 Series A warrants and 3,333,333 Series B warrants, which reflects (i) the 2,916,667 Series A warrants and Series B warrants issued as part of the units in our initial public offering and (ii) the 416,666 Series A warrants and Series B warrants issued to the selling stockholder in the concurrent private placement.

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 is currently exercisable and will expire at 5:00 p.m. New York City time on February 18, 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, subject to adjustment. Each whole Series B warrant is currently exercisable and will expire at 5:00 p.m. New York City time on May 18, 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 are in registered form, in each case pursuant to a warrant agreement between American Stock Transfer & Trust Company, LLC, as warrant agent, and us.

Our Series A warrants and Series B warrants are listed on the NASDAQ Global Market under the symbols "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**

Our board of directors has 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 September 30, 2016, we had RSUs outstanding for an aggregate of 1,094,351 shares of our common stock and up to 247,309 shares potentially issuable upon the exercise of outstanding PSUs whose terms provide for settlement in shares of common stock or cash at our discretion, with a weighted-average exercise price of \$6.33.

As of September 30, 2016, we also had issued and outstanding three-year warrants to acquire an aggregate of 1,520,268 shares of our common stock at an initial exercise price of \$0.01 per share issued pursuant to the investors' rights agreement, and the Series A warrants and Series B warrants to acquire an aggregate of 6,666,666 shares of our common stock. In December 2016, we issued warrants to acquire an aggregate of 1,920,500 shares of our common stock in connection with our senior secured note issuance, and may issue warrants to acquire up to an additional 379,500 shares under the agreement. These warrants have a term of five years and an initial exercise price of \$3.00 per share.

#### **Stockholder Registration Rights**

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 the selling stockholder, are 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. 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***

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:

- 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 is 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 requires approval by the holders of at least 66 $\frac{2}{3}$ % 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 may 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 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 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, Series A warrants and Series B warrants are listed on the NASDAQ Global Market under the symbols "ONS," "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.

## LEGAL MATTERS

The validity of the securities offered in this prospectus will be passed upon for us by Cooley LLP, New York, New York.

## EXPERTS

The consolidated financial statements of Oncobiologics, Inc. as of September 30, 2016 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, 2016 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, 2016 of \$147.4 million and \$4.6 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.

We file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information are 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](http://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 AUDITED CONSOLIDATED FINANCIAL STATEMENTS

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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders  
Oncobiologics, Inc.:

We have audited the accompanying consolidated balance sheets of Oncobiologics, Inc. and subsidiaries (the Company) as of September 30, 2016 and 2015, and the related consolidated statements of operations, redeemable preferred stock, common stock, noncontrolling interests and stockholders' equity (deficit), and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Oncobiologics, Inc. and subsidiaries as of September 30, 2016 and 2015, and the results of their operations and their cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

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

/s/ KPMG LLP

Philadelphia, Pennsylvania  
December 29, 2016

**Oncobiologics, Inc.**  
**Consolidated Balance Sheets**

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

See accompanying notes to consolidated financial statements.

**Oncobiologics, Inc.**  
**Consolidated Statements of Operations**

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

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

See accompanying notes to consolidated financial statements.

**Oncobiologics, Inc.**  
**Consolidated Statements of Cash Flows**

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

See accompanying notes to consolidated financial statements.



**Oncobiologics, Inc.**  
**Notes to Consolidated Financial Statements**

## **1. Organization and Operations**

### **Description of the Business**

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

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

In October 2015, the Company reincorporated in Delaware through the merger with and into Oncobiologics, Inc., a newly formed Delaware corporation, with the Delaware corporation surviving the merger. As a result of the merger, each share of the Company's previously issued and outstanding common stock converted into and became a share of common stock of the Delaware corporation on a 1-for-1 basis, each share of the Company's previously issued and outstanding Series A redeemable preferred stock converted into 289 shares of common stock and approximately 1,4035 shares of Series A preferred stock of the Delaware corporation, and each share of the Company's previously issued and outstanding Series B redeemable preferred stock converted into 289 shares of common stock and approximately 1,2867 shares of Series A preferred stock of the Delaware corporation. The holders of Series A and B also received an aggregate of 10,193 shares of Series A preferred stock of the Delaware corporation. Additionally, effective upon the reincorporation and in connection with the dissolution of the Company's business development subsidiary, Parilis Biopharmaceuticals ("Parilis"), the Company issued 226,663 shares of common stock and 1,626 shares of Series A preferred stock to the holders of outstanding Parilis preferred member units in exchange for all such units.

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

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

## **2. Liquidity**

The Company has incurred substantial losses and negative cash flows from operations since its inception and has an accumulated deficit of \$147.4 million as of September 30, 2016. In addition, the Company has \$4.6 million of indebtedness that is due on demand. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements have been prepared on a going concern basis, which

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contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

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

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

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

### **3. Basis of Presentation and Summary of Significant Accounting Policies**

#### **Basis of presentation**

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

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

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

#### **Use of estimates**

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. Actual

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results could differ from those estimates. Due to the uncertainty of factors surrounding the estimates or judgments used in the preparation of the consolidated financial statements, actual results may materially vary from these estimates. Estimates and assumptions are periodically reviewed and the effects of revisions are reflected in the consolidated financial statements in the period they are determined to be necessary.

**Recapitalization**

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

**Restricted cash**

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

**Fair value of financial instruments**

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

**Prepaid expenses and other current assets**

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

**Property and equipment**

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

**Long-lived assets**

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

**Deferred offering costs**

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

**Stock-based compensation**

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

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

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

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

### **Revenue recognition**

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

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

The Company typically receives upfront, nonrefundable payments when licensing its intellectual property. For intellectual property licenses that do not have stand-alone value from the other deliverables to be provided, the upfront fee is deferred and revenue is recognized over the contractual or estimated performance period, which is typically the term of the research and development obligations. The periods over which revenue is recognized are subject to estimates by management and may change over the course of the research and development agreement. Such a change could have a material impact on the amount of revenue the Company records in future periods. Payments or reimbursements resulting from the Company's research and development efforts are recognized as the services are performed. Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue.

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

### **Research and development**

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

Upfront milestone payments made to third parties who perform research and development services on the Company's behalf are expensed as services are rendered. Costs incurred in obtaining technology licenses are charged to research and

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development expense as acquired in-process research and development if the technology licensed has not reached technological feasibility and has no alternative future use.

**Income taxes**

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

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

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

**Net loss per share**

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

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

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

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

**Recently issued and adopted accounting pronouncements**

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

In May 2014, the FASB issued ASU, No. 2014-09, *Revenue from Contracts with Customers*. This guidance requires an entity to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the

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consideration to which the entity expects to be entitled in exchange for those goods or services. This guidance also requires an entity to disclose sufficient information to enable users of financial statements to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. Qualitative and quantitative information is required about:

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

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

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

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

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

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

#### **4. Fair Value Measurements**

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

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

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

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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)
<b>Liabilities</b>			
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, 2016 and 2015:

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

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

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

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

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

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**5. Property and Equipment**

Property and equipment, net, consists of:

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

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

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

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

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

**6. Accrued Expenses**

Accrued expenses consists of:

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



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**7. Stockholder Notes**

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

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

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

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

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

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

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

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

**8. Debt**

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

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

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

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

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

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

## 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.

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**Technology License**

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

**Leases**

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

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

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

**Employment Benefit Plan**

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

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

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

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

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

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

**Oncobiologics, Inc.**  
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**Series A warrants and Series B warrants**

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

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

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

**Common stock warrants**

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

**Deconsolidation of noncontrolling interests**

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

**Series A preferred stock**

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

**11. Stock-Based Compensation**

**2011 Equity Incentive Plan**

The Company's 2011 Equity Compensation Plan (the "2011 Plan") provided for the Company to sell or issue restricted common stock, restricted stock units ("RSUs"), performance-based awards, cash-based awards or to grant stock options for the purchase of common stock to officers, employees, consultants and directors of the Company. The 2011 Plan was administered by the board of directors or, at the discretion of the board of directors, by a committee of the board. The number of shares of common stock reserved for issuance under the 2011 Plan is 1,159,420. As of September 30, 2016, PSUs representing 247,309 shares of the Company's common stock were outstanding under the 2011 Plan. In light of the December 2015 adoption of the 2015 Equity Incentive Plan, no future awards under the 2011 Plan will be granted.

**2015 Equity Incentive Plan**

In December 2015, the Company adopted the 2015 Equity Incentive Plan (the "2015 Plan"). The 2015 Plan provides for the grant of stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards and other forms of equity compensation to Company employees, directors and consultants. On July 11, 2016

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**Notes to Consolidated Financial Statements**

the maximum number of shares of the 2015 plan increased by 684,083 shares or 3% of the outstanding common stock of the Company. This increase resulted from a provision in the plan that allows an annual increase of shares in the plan. The maximum number of shares of common stock that may be issued under the 2015 Plan is 1,930,460 shares. As of September 30, 2016, RSUs representing 1,094,351 shares of the Company's common stock were outstanding under the 2015 Plan and 836,109 shares remained available for grant under the 2015 Plan.

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

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

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

### Performance-based stock units

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

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

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

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

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

The PSU represents an award that is exercisable based upon the achievement of either a performance condition or a market condition. As a result, the Company measures and records compensation cost taking into consideration both conditions: (1)

**Oncobiologics, Inc.**  
**Notes to Consolidated Financial Statements**

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

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

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

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

### Restricted stock units

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

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

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

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

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

## 12. Collaboration Arrangements

### Huahai agreement

In May 2013, the Company entered into strategic license and collaboration arrangement with Zhejiang Huahai Pharmaceutical Co., Ltd ("Huahai") under which the Company granted Huahai and its affiliates an exclusive license for the

**Oncobiologics, Inc.**  
**Notes to Consolidated Financial Statements**

research, development, manufacture, use or sale of ONS-3010 or ONS-1045 in China, including, the People's Republic of China, Hong Kong, Macau and Taiwan. In addition, the Company granted Huahai a right and license under the Selexis Technology agreement to establish a production process for the products in the agreed territory and to market the products in the agreed territory pursuant to the relevant terms and conditions of the Company's commercial license agreement with Selexis.

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

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

#### **IPCA License and Collaboration Agreement**

In August 2013, the Company entered into a strategic license agreement with IPCA Laboratories Limited and its affiliates ("IPCA") under which the Company granted IPCA a license for the research, development, manufacture, use or sale of the ONS-3010 and, by amendment in May 2014, the ONS-1045 biosimilar product candidates with respect to India, Sri-Lanka, and Myanmar, and non-exclusive with respect to Nepal and Bhutan, or collectively, the agreed territory. In addition, the Company granted IPCA a right and license under the Selexis Technology to enable IPCA to establish an exclusive production process for the products in its agreed territory and to exclusively market the products in the agreed territory. The Company also agreed not to amend or terminate its rights under its commercial license agreement with Selexis without IPCA's prior written consent.

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

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

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

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

**Oncobiologics, Inc.**  
**Notes to Consolidated Financial Statements**

**Strategic Collaboration and Non-Exclusive License Agreement**

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

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

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

**Liomont agreement**

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

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

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

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

**13. Related-Party Transactions**

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

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



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- In March 2015, a director of the Company loaned \$1,000,000 to the Company with an interest rate of 24%. The loan was repaid in October 2015 and included \$128,219 in accrued interest.
- During the years ended September 30, 2015 and 2014, the Company repurchased 1,250 shares of Series A redeemable preferred stock and satisfied accrued dividends of \$326,354 from three directors of the Company in exchange for \$650,000 in cash payments and the issuance of \$1,850,000 in stockholder notes. The notes bear interest at 4% which are due on demand. Under the terms of the agreement, because the notes were not paid upon maturity, they now bear interest at 6%. Terms of the share repurchase were the same as non-related parties. Refer to notes 7 and 10.

#### 14. Income Taxes

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

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

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

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

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

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

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

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

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

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

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

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

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**Notes to Consolidated Financial Statements**

**15. Subsequent Events**

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

On December 22, 2016, the Company entered into a Note and Warrant Purchase Agreement with accredited investors providing for the issuance and sale of up to \$10.0 million of senior secured promissory notes (the "Notes"), which bear interest at a rate of 5% per year and mature December 22, 2017 and warrants (the "Warrants") to acquire an aggregate 2.3 million shares of the Company's common stock at an exercise price of \$3.00 per share which have a five-year term. The Company closed the initial sale and purchase of the Notes and Warrants on December 22, 2016, issuing \$8.35 million aggregate principal amount of Notes and Warrants to acquire 1,920,500 shares of the Company's common stock in exchange for \$6.5 million of cash and an aggregate of \$1.85 million of existing unsecured bridge notes issued by the Company in October, November and December 2016. The Company used \$2.4 million of the proceeds from the sale of the Notes to pay off its existing senior secured bank loans, and will use the remainder for working capital purposes. The Company may issue up to \$1.65 million of additional Notes and Warrants to acquire up to an additional 379,500 shares of the Company's common stock in additional closings over the next 90 days without approval of holders of the Notes. Under the Note and Warrant Purchase Agreement, the Company agreed to customary negative covenants restricting its ability to repay indebtedness to officers, pay dividends to stockholders, repay or incur other indebtedness other than as permitted, grant or suffer to exist a security interest in any of the Company's assets, other than as permitted, or enter into any transactions with affiliates. In addition to the negative covenants in the Note and Warrant Purchase Agreement, the Notes include customary events of default.

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

**1,666,664 Shares of Common Stock**  
**416,666 Series A Warrants**  
**416,666 Series B Warrants**



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**PRELIMINARY PROSPECTUS**

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, 2017

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## PART II

## INFORMATION NOT REQUIRED IN PROSPECTUS

**Item 13. Other Expenses of Issuance and Distribution.**

The following table sets forth the costs and expenses payable by the registrant in connection with the sale of our securities being registered. All amounts are estimates.

Item	Amount to be paid
Legal fees and expenses	\$ 25,000
Accounting fees and expenses	8,500
Printing and miscellaneous expenses	40,000
Total	\$ 73,500

**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 amended and restated certificate of incorporation and bylaws which are filed as Exhibits 3.1 and 3.2, 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 agreements 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.

**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 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.
- (b) 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.
- (c) 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.
- (d) 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.
- (e) 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.
- (f) In December 2015, we issued 1,066,193 restricted stock unit awards under our 2015 Equity Incentive Plan.
- (g) 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, Arlight 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.
- (h) In April 2016, we issued 30,421 restricted stock unit awards under our 2015 Equity Incentive Plan.
- (i) In May 2016, we issued certain of the accredited investors party to that certain investors' rights agreement dated March 10, 2014, as amended, three-year warrants to purchase an aggregate of 1,520,268 shares of our common stock.
- (j) In May 2016, concurrent with the closing of our initial public offering, we sold to an accredited investor in a concurrent private placement 833,332 shares of our common stock, 416,666 of our Series A warrants and 416,666 of our Series B warrants, for an aggregate purchase price of approximately \$5.0 million. The underwriters of our initial public offering served as placement agents for the private placement and receive a placement agent fee of approximately \$350,000.
- (k) In December 2016, we entered into a Note and Warrant Purchase Agreement with the accredited investors named therein providing for the issuance and sale of up to \$10.0 million of senior secured promissory notes, which bear interest at a rate of 5% per year and mature December 22, 2017 and warrants to acquire up to an aggregate 2,300,000 shares of our common stock at an exercise price of \$3.00 per share, which have a five-year term.

We claimed exemption from registration under the Securities Act for the sale and issuance of securities in the transactions described in paragraphs (a), (c)-(e), (g) and (i)-(k) 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 (b), (f) and (h) 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.**

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, each prospectus filed pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of

such securities at that time shall be deemed to be the initial *bona fide* offering thereof. *Provided, however,* that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.



**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this Post-Effective Amendment No. 1 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 January 4, 2017.

**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 Post-Effective Amendment No. 1 to the Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Pankaj Mohan</u> Pankaj Mohan, Ph.D.	Chairman, President and Chief Executive Officer <i>(Principal Executive Officer)</i>	January 4, 2017
<u>/s/ Lawrence A. Kenyon</u> Lawrence A. Kenyon	Chief Financial Officer <i>(Principal Accounting and Financial Officer)</i>	January 4, 2017
<u>*</u> Todd C. Brady, M.D., Ph.D.	Director	January 4, 2017
<u>*</u> Scott Canute	Director	January 4, 2017
<u>*</u> Albert D. Dyrness	Director	January 4, 2017
<u>*</u> Donald J. Griffith	Director	January 4, 2017
<u>*</u> Kurt J. Hilzinger	Director	January 4, 2017
<u>*</u> Robin Smith Hoke	Director	January 4, 2017

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

## EXHIBIT INDEX

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of Oncobiologics, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed on May 19, 2016).
3.2	Amended and Restated Bylaws of Oncobiologics, Inc. (incorporated by reference to Exhibit 3.2 to the Registrant's current report on Form 8-K filed on May 19, 2016).
3.3	Amendment to the Amended and Restated Bylaws of Oncobiologics, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed with the SEC on November 29, 2016).
5.1	Opinion of Cooley LLP (incorporated by reference to Exhibit 5.1 to the Registrant's registration statement on Form S-1 filed on June 30, 2016).
10.1	Investors' Rights Agreement by and among Oncobiologics, Inc. and certain of its stockholders, dated March 10, 2014, as amended (incorporated by reference to Exhibit 10.1 to the Registrant's registration statement on Form S-1 filed on May 11, 2016).
10.2	2011 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's registration statement on Form S-1 filed on January 15, 2016).
10.3	Form of Amended and Restated Performance Stock Unit Agreement for 2011 Stock Incentive Plan (incorporated by reference to Exhibit 10.29 to the Registrant's registration statement on Form S-1 filed on April 27, 2016).
10.4	2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's registration statement on Form S-1 filed on January 15, 2016).
10.5	Forms of agreements and award grant notices for 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's registration statement on Form S-1 filed on January 15, 2016).
10.6	2016 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.5 to the Registrant's registration statement on Form S-1 filed on February 12, 2016).
10.7	Form of Indemnity Agreement, by and between Oncobiologics, Inc. and each of its directors and executive officers (incorporated by reference to Exhibit 10.12 to the Registrant's registration statement on Form S-1 filed on January 15, 2016).
10.8†	Research License Agreement by and between Oncobiologics, Inc. and Selexis SA, effective as of October 3, 2011, as amended by Amendment No. 1 dated as of October 9, 2014 (incorporated by reference to Exhibit 10.13 to the Registrant's registration statement on Form S-1 filed on February 26, 2016).
10.9†	ONS-3010 Commercial License Agreement by and between Oncobiologics, Inc. and Selexis SA effective as of April 11, 2013, as amended effective as of May 21, 2014 (incorporated by reference to Exhibit 10.14 to the Registrant's registration statement on Form S-1 filed on January 15, 2016).
10.10†	ONS-1045 Commercial License Agreement by and between Oncobiologics, Inc. and Selexis SA effective as of April 11, 2013, as amended effective as of May 21, 2014 (incorporated by reference to Exhibit 10.15 to the Registrant's registration statement on Form S-1 filed on January 15, 2016).
10.11†	ONS-1050 Commercial License Agreement by and between Oncobiologics, Inc. and Selexis SA effective as of April 11, 2013, as amended effective as of May 21, 2014 (incorporated by reference to Exhibit 10.16 to the Registrant's registration statement on Form S-1 filed on January 15, 2016).
10.12	Joint Participation Agreement by and between Oncobiologics, Inc. and Zhejiang Huahai Pharmaceutical Co., Ltd., effective as of May 6, 2013, as amended by that Amendment No. 1 and Mutual Termination Agreement re: Joint Participation Agreement, dated December 23, 2014 (incorporated by reference to Exhibit 10.17 to the Registrant's registration statement on Form S-1 filed on January 15, 2016).
10.13	Lease Agreement by and between Oncobiologics, Inc. and Cedar Brook 7 Corporate Center, LP, dated as of March 18, 2011 (incorporated by reference to Exhibit 10.18 to the Registrant's registration statement on Form S-1 filed on January 15, 2016).
10.14	First Amendment to Lease Agreement by and between Oncobiologics, Inc. and Cedar Brook 7 Corporate Center, LP, dated as of December 2013 (incorporated by reference to Exhibit 10.19 to the Registrant's registration statement on Form S-1 filed on January 15, 2016).
10.15	Second Amendment to Lease Agreement by and between Oncobiologics, Inc. and Cedar Brook 7 Corporate Center, LP, dated as of July 18, 2014 (incorporated by reference to Exhibit 10.20 to the Registrant's registration statement on Form S-1 filed on January 15, 2016).
10.16	Third Amendment to Lease Agreement by and between Oncobiologics, Inc. and Cedar Brook 7 Corporate Center, LP, dated as of January 16, 2015 (incorporated by reference to Exhibit 10.21 to the Registrant's registration statement on Form S-1 filed on January 15, 2016).

Exhibit Number	Description
10.17	Fourth Amendment to Lease Agreement by and between Oncobiologics, Inc. and Cedar Brook 7 Corporate Center, LP, dated as of February 9, 2015 (incorporated by reference to Exhibit 10.22 to the Registrant's registration statement on Form S-1 filed on January 15, 2016).
10.18	Fifth Amendment to Lease Agreement by and between Oncobiologics, Inc. and Cedar Brook 7 Corporate Center, LP, dated as of September 26, 2015 (incorporated by reference to Exhibit 10.23 to the Registrant's registration statement on Form S-1 filed on January 15, 2016).
10.19	Lease Agreement by and between Cedar Brook East Corporate Center, LP and Oncobiologics, Inc., dated as of August 31, 2015 (incorporated by reference to Exhibit 10.24 to the Registrant's registration statement on Form S-1 filed on January 15, 2016).
10.20	Employment Agreement between Oncobiologics, Inc. and Pankaj Mohan, Ph.D., dated February 22, 2016 (incorporated by reference to Exhibit 10.25 to the Registrant's registration statement on Form S-1 filed on April 27, 2016).
10.21	Employment Agreement between Oncobiologics, Inc. and Lawrence A. Kenyon, dated February 18, 2016 (incorporated by reference to Exhibit 10.28 to the Registrant's registration statement on Form S-1 filed on April 27, 2016).
10.22	Employment Agreement between Oncobiologics, Inc. and Kogan Bao, Ph.D., dated February 22, 2016 (incorporated by reference to Exhibit 10.22 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed on January 4, 2017).
10.23	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 10.30 to the Registrant's registration statement on Form S-1 filed on May 11, 2016).
10.24	Securities Purchase Agreement between Oncobiologics, Inc. and Sabby Healthcare Master Fund Ltd., dated May 11, 2016 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed on May 19, 2016).
10.25	Warrant Agreement by and between Oncobiologics, Inc. and American Stock Transfer & Trust Company LLC, as Warrant Agent dated May 18, 2016 (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed on June 27, 2016).
10.26	Form of Series A warrant certificate (included in Exhibit 10.25).
10.27	Form of Series B warrant certificate (included in Exhibit 10.25).
10.28	Note and Warrant Purchase Agreement by and between Oncobiologics, Inc. and the Purchasers named therein dated December 22, 2016 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on December 23, 2016).
10.29	Form of Senior Secured Promissory Note (included as Exhibit A to the Note and Warrant Purchase Agreement filed as Exhibit 10.28).
10.30	Form of Warrant (included as Exhibit B to the Note Purchase Agreement filed as Exhibit 10.28).
10.31	Security Agreement by and between Oncobiologics, Inc. and the Secured Parties named therein dated December 22, 2016 (incorporated by reference to Exhibit 10.4 to the Registrant's current report on Form 8-K filed with the SEC on December 23, 2016).
10.32	Intellectual Property Security Agreement by and between Oncobiologics, Inc. and the Secured Parties named therein dated December 22, 2016 (incorporated by reference to Exhibit 10.5 to the Registrant's current report on Form 8-K filed with the SEC on December 23, 2016).
23.1	Consent of independent registered public accounting firm.
23.2	Consent of Cooley LLP (included in Exhibit 5.1).
24.1	Power of Attorney (included on signature page to the Registrant's registration statement on Form S-1 (File No. 333-212351) filed on June 30, 2016).
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been filed separately with the SEC.

**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 December 29, 2016 contains an explanatory paragraph that states that Oncobiologics, Inc. has incurred recurring losses and negative cash flows from operations since inception and has an accumulated deficit at September 30, 2016 of \$147.4 million and \$4.6 million of indebtedness that is due on demand, which raises substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KPMG LLP

Philadelphia, Pennsylvania  
January 4, 2017

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