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

FORM 10-K

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

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

For the fiscal year ended September 30, 2018

OR

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

For the transition period from _____ to _____

Commission File Number: 001-37759

OUTLOOK THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

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

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

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

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, $0.01 par value per share	**The Nasdaq Capital Market**
Series A warrants to purchase Common Stock	**The Nasdaq Capital Market**

Securities Registered Pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period than the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definition of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

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

The aggregate market value of the registrant's common stock, held by non-affiliates of the registrant as of March 30, 2018 (which is the last business day of registrant's most recently completed second fiscal quarter) based upon the closing market price of such stock on The Nasdaq Capital Market on that date, was approximately $15.6 million.

As of December 14, 2018, the registrant had outstanding 85,091,062 shares of common stock, par value $0.01 per share.

DOCUMENTS INCORPORATED BY REFERENCE

None.

OUTLOOK THERAPEUTICS, INC.
ANNUAL REPORT ON FORM 10-K

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

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 28, 2018, or CHF 0.9813 = $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.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

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

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

PART I

Item 1. Business

Overview

We are a late clinical-stage biopharmaceutical company focused on developing and commercializing ONS-5010, a complex, technically challenging and commercially attractive monoclonal antibody, or mAb, for various ophthalmic indications. Our goal is to launch ONS-5010 as the first, and only, approved bevacizumab in the United States, Europe, Japan and other markets for the treatment of wet age related macular degeneration, or wet AMD, diabetic macular edema, or DME, and branch retinal vein occlusion, or BRVO.

ONS-5010 is an innovative mAb therapeutic product candidate currently enrolling patients in a clinical trial outside the United States designed to serve as the first of two adequate and well controlled studies evaluating ONS-5010 as a treatment for wet AMD. We plan to submit an investigational new drug, or IND, application with the U.S. Food and Drug Administration, or FDA, in the first quarter of calendar 2019. The U.S. portion of the second study is also expected to begin at that time. Our ONS-5010 wet AMD clinical program was reviewed at a successful end of Phase 2 meeting with the FDA conducted in 2018. If the program is successful, it will support our plans to submit for regulatory approval in multiple markets in 2020, including the United States, Europe and Japan. Because there are no approved bevacizumab products for the treatment of retinal diseases in such major markets, we are developing ONS-5010 as an innovative therapy and not using the biosimilar drug development pathway. If approved, we believe ONS-5010 has potential to mitigate risks associated with off-label compounding of Avastin or other drugs. Off-label compounding of Avastin is currently estimated to account for approximately 50% of all wet AMD prescriptions in the United States.

Separately, we have advanced two biosimilar 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 only plan to further advance ONS-3010 and ONS-1045 in major markets, including the United States, upon entering into a license or co-development agreement with a partner in the major markets. The emerging markets rights to these product candidates have been licensed to third parties for development in those markets. At this time, ONS-5010 is our only product candidate in active development.

Our Strategy

Our goal is to launch ONS-5010 as the first, and only, approved bevacizumab for ophthalmic use in the United States, Europe, Japan and other markets. In order to achieve this goal, we have adopted a streamlined clinical and regulatory strategy to quickly and efficiently complete the process required to submit a Biologics License Application, or BLA, with the FDA at the earliest opportunity. The key elements of our strategy include:

- ***Leveraging the recently added ophthalmic drug development and commercialization expertise of our leadership team.*** We recently appointed a Chief Operating Officer and a Chief Commercial Officer with extensive expertise in developing and commercializing treatments for retinal diseases, such as wet AMD. We intend to leverage their collective experience to further the development of, and develop an optimal commercial strategy for, ONS-5010.

- ***Engaging with regulatory agencies to establish clear guidelines for potential approval.*** We have continued our approach to work closely with regulatory authorities to develop and conduct clinical trials that we believe will appropriately support approval of our product candidates if our clinical trials are successful. We conducted a successful end of Phase 2 meeting with the FDA for ONS-5010, and expect to submit an IND in the first quarter of 2019. As an ophthalmic formulation of Avastin, we believe ONS-5010 has a well defined regulatory pathway.

- ***Conducting and efficiently executing adequate and well-controlled clinical trials inside and outside of the United States to support potential approval.*** We have designed our ONS-5010 clinical program

to take advantage of reduced costs for clinical trials conducted outside of the United States. We intend to further this strategy, as appropriate, in a manner that will support a BLA submission in the United States at the earliest opportunity for ONS-5010.

- ***Reducing and managing costs to minimize additional investment to complete our development programs.*** We have made the strategic decision to outsource the commercial manufacturing and future clinical trial supply manufacturing for our product candidates. This decision is expected to significantly reduce future overhead costs not directly related to our ONS-5010 program.

Our Product Candidate Portfolio

Our product candidate portfolio includes our lead product candidate, ONS-5010, which we are actively developing, as well as our biosimilar product candidates, which we only plan to further advance, upon entering into a license or co-development agreement with a partner in the major markets. We refer to these legacy biosimilar product candidates as our inactive development portfolio.

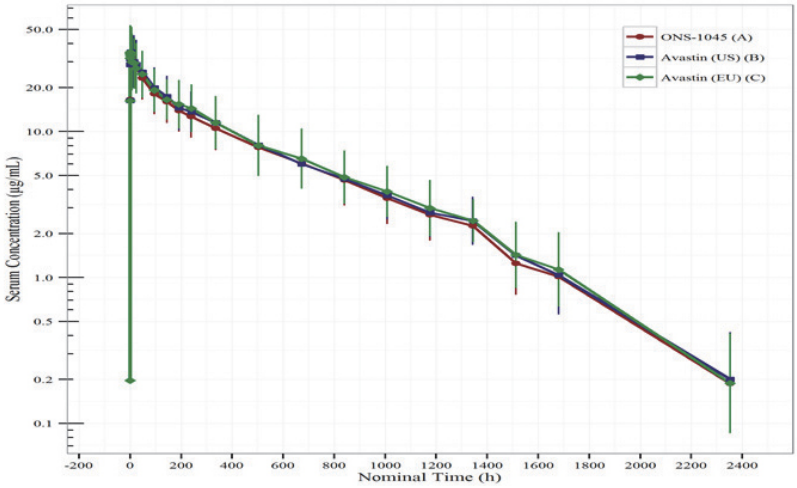
Active Development Portfolio

ONS-5010 — Bevacizumab for Ophthalmic Use

ONS-5010 is a proprietary ophthalmic formulation of bevacizumab to be administered as an intravitreal, or IVT, injection for the treatment of wet AMD and other retina diseases. Bevacizumab is a full length humanized anti-vascular endothelial growth factor, or VEGF, antibody that inhibits VEGF and associated angiogenic activity. Our proprietary ophthalmic bevacizumab product candidate, ONS-5010, is an anti-VEGF recombinant humanized mAb formulated as a single use vial for IVT injection. By inhibiting the VEGF receptor from binding, bevacizumab prevents the growth of abnormal tumor blood vessels beneath the retina.

Previously, ONS-5010 was being developed by us as a biosimilar (ONS-1045) of the cancer drug Avastin for use in oncology indications. In the ONS-1045 program, our bevacizumab met the primary and secondary endpoints in a three-arm single-dose pharmacokinetic, or PK, Phase 1 clinical trial (see "— Inactive Development Portfolio — ONS-1045 — Bevacizumab (Avastin) Biosimilar"). All of the PK endpoints met the bioequivalency criteria of the geometric mean ratios within 90% confidence interval of 80-125% when compared to both U.S.- and E.U.-sourced Avastin reference products. We are developing ONS-5010 as an innovative therapy and not using the biosimilar drug development pathway. The following figure demonstrates the concentration-time profile of ONS-1045, U.S.-licensed Avastin, and E.U.-licensed Avastin as the mean. The vertical line at time zero denotes dosing. These results suggest a high degree of similarity among the three products.

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



Market Opportunity

Age related macular degeneration, or AMD, is a common eye condition and a leading cause of vision loss among people age 50 and older. Wet AMD is a form of "late stage" AMD, and is also called neovascular AMD. In wet AMD, abnormal blood vessels grow underneath the retina. These vessels can leak fluid and blood, which may lead to swelling and damage of the macula causing vision loss. With wet AMD, abnormally high levels of VEGF are secreted in the eyes. VEGF is a protein that promotes the growth of new abnormal blood vessels. Anti-VEGF injection therapy blocks this growth. Since the advent of anti-VEGF therapy, it has become the standard of care treatment option within the retina community, globally. Wet AMD is a significant disease worldwide, with an estimated prevalence of over 2.8 million patients diagnosed in the United States, top five European countries and Japan alone in 2018 (GlobalData). Annual revenue from anti-VEGFs (Avastin, Lucentis, Eylea and Macugen) is estimated to exceed $9.1 billion in wet AMD, DME and BRVO in 2018 (GlobalData). Although bevacizumab is not currently approved by the FDA for use in treating wet AMD, it is believed that bevacizumab currently accounts for approximately 50% of all wet AMD prescriptions in the United States. If approved, we believe ONS-5010 has potential to mitigate risks associated with off-label compounding of Avastin or other drugs. Off-label compounding of Avastin is currently estimated to account for approximately 50% of all wet AMD prescriptions in the United States. If approved, we anticipate seeking to promote use of ONS-5010 rather than compounded Avastin or other drugs.

DME is caused by a complication of diabetes called diabetic retinopathy. Diabetic retinopathy is the most common diabetic eye disease and the leading cause of irreversible blindness in working age Americans. Diabetic retinopathy usually affects both eyes and is caused by ongoing damage to the small blood vessels of the retina. The leakage of fluid into the retina may lead to swelling of the surrounding tissue, including the macula. DME is the most common cause of vision loss in people with diabetic retinopathy. DME can occur at any stage of diabetic retinopathy, although it is more likely to occur in later stages of the disease. There were approximately 1.0 million patients with DME in the United States, top five European countries and Japan alone in 2018 (GlobalData).

In BRVO, retinal vein occlusions occur when there is a blockage of veins carrying blood with needed oxygen and nutrients away from the nerve cells in the retina. A blockage in the main vein of the retina is referred to as a central retinal vein occlusion, or CRVO, while a blockage in a smaller vein is called a branch retinal vein

occlusion, or BRVO. Per the American Academy of Ophthalmology, retinal vein occlusions are the second most common retinal vascular disorder after diabetic retinopathy. There were an estimated 0.3 million patients with BRVO in the United States, top five European countries and Japan alone in 2018 (GlobalData).

Clinical Development Status

ONS-5010 is currently enrolling patients in an ex-U.S. clinical trial for wet AMD. This first clinical study for ONS-5010 is designed to serve as the first of two adequate and well controlled studies for wet AMD. The second adequate and well controlled study is currently being planned and is expected to begin enrolling patients in the United States in the first quarter of 2019 upon the submission of an IND application with the FDA. Our wet AMD clinical program was reviewed at a successful end of Phase 2 meeting held with the FDA earlier in 2018. If the program is successful, it will support our plans to submit for regulatory approval in multiple markets in 2020, including the United States, Europe and Japan. We currently expect to report top line data from the first study in the first quarter of 2020, and top line data from the second study in the third quarter of 2020, and submit a BLA in the fourth quarter of 2020.

In addition to the wet AMD clinical program for ONS-5010, we are also planning to begin enrolling patients in clinical trials for both DME and BRVO in the second half of 2019.

Inactive Development Portfolio

ONS-3010 — Adalimumab (Humira) Biosimilar

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

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 E.U.-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.

Regulatory Status and Development Plan

Prior to commencement of our Phase 1 clinical trial in 2014, we received feedback from both FDA and the European Medicines Agency, or 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, the Swedish Medical Products Agency, and the Canadian regulatory agency, Health Canada to obtain further guidance on the Phase 3 clinical trial design in plaque psoriasis and the general similarity development plan for registration. We have out-licensed all of the emerging markets development rights to third parties. Future development of ONS-3010 as a biosimilar for Humira in the United States and other developed markets will only occur if we secure a development partner or sell those development rights completely.

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 and is approved for use in the United States, Europe and elsewhere for the treatment of various forms of cancer.

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 E.U.-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 E.U.-Avastin. Safety was comparable across all three groups. Immunogenicity was low with only one subject in the E.U.-licensed Avastin arm developing an anti-drug antibody, or ADA, at day 98. No neutralizing antibodies were detected in any arm. The results of the Phase 1 trial (shown in the figure included under "— Active Development Portfolio — ONS-5010 — Bevacizumab for Ophthalmic Use") suggest a high degree of similarity between the three products.

Regulatory Status and Development Plan

Prior to the commencement of the 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 out-licensed all of the emerging markets development rights to third parties. Future development of ONS-1045 as a biosimilar for Avastin in the United States and other developed markets will only occur if we secure a development partner or sell those development rights completely.

Commercialization, Sales and Marketing

We currently own all of the development and commercialization rights to ONS-5010. Our commercialization strategy is to maximize the revenue potential of ONS-5010, which could potentially include marketing it ourselves if approved, as well as seeking and securing licensing opportunities to fund its continued development. If approved, we believe that ONS-5010 will be entitled to 12 years marketing exclusivity against biosimilar competition.

To provide additional resources to fund the ONS-5010 program, we intend to continue to pursue potential strategic collaborations, and partnerships with biotechnology and pharmaceutical companies in the United States and other regions for our clinical stage biosimilar assets, or even the outright sale of the development rights of those assets outside of the emerging markets territories previously licensed. Currently, 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, European Union, or E.U., 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 E.U. and Japan.

For emerging markets opportunities, 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, and in September 2017 we entered into an agreement with BioLexis Pte. Ltd., or BioLexis (formerly GMS Tenshi Holdings Pte. Limited), our controlling stockholder, providing for the license of rights to ONS-3010 and ONS-1045 in emerging markets excluding China, India and Mexico. 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. For many of these emerging market opportunities, our partners may be able to take advantage of differing regulatory requirements that could allow us to begin generating sales as early as 2020, before we begin to generate commercial revenue in regions like the United States, the E.U. and Japan. To date, these agreements have collectively provided an aggregate of $29.0 million in payments as of September 30, 2018.

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 used to research and develop our product

candidates. For product candidates developed using the Selexis technology, we enter into commercial license agreements with Selexis that give us rights to commercialize, file investigational new drugs, or INDs and enter into collaborative arrangements with third parties for the further development and commercialization of such biosimilar product candidates.

MTTR — Strategic Partnership Agreement (ONS-5010)

We entered into a strategic partnership agreement with MTTR, LLC, or MTTR, effective February 15, 2018, to advise on regulatory, clinical and commercial strategy and assist in obtaining approval of ONS-5010, our bevacizumab therapeutic product candidate for ophthalmic indications. Under the terms of the agreement, we currently pay MTTR a $58,333 monthly consulting fee. In March 2018, we amended the MTTR agreement and agreed to pay a one-time fee of $268,553 to MTTR by September 2020 if certain regulatory milestones are achieved earlier than anticipated. Beginning January 2019, the monthly fee increases to $105,208 per month, and then, after launch of ONS-5010 in the United States, to $170,833 per month (the amount of which is reduced by 50% in the event net sales of ONS-5010 are below a certain threshold million per year). We also agreed to pay MTTR a tiered percentage of the net profits of ONS-5010 ranging in the low- to mid-teens, with the ability to credit monthly fees paid to MTTR. Unless earlier terminated, the MTTR Agreement expires, on a country-by-country basis, upon the later of expiration of any regulatory exclusivity in such country and, in certain major market countries, ten years after launch of ONS-5010 in such major market country, and in all other countries in the territory, ten years after launch of ONS-5010 in any country in the territory. Either party may terminate the MTTR Agreement upon the uncured material breach of the agreement by the other party or upon a bankruptcy or insolvency of the other party. Additionally, we are permitted to terminate the MTTR Agreement in the event of certain specified development or commercial failures of ONS-5010 and may terminate either the entire MTTR Agreement or with respect to certain consultants in the event that certain consultants are not able to perform their obligations under the MTTR Agreement and a suitable replacement consultant is not found. Additionally, in the event of a change of control of our company or sale of our rights to ONS-5010, MTTR will be entitled to additional consideration equal to its profit sharing percentage multiplied by the value of the applicable transaction that relates to ONS-5010 (subject to certain adjustments). Our recently appointed Chief Operating Officer has a 16.66% ownership interest in MTTR. For the year ended September 30, 2018, MTTR earned an aggregate of $602,629, which includes monthly consulting fees, expense reimbursement and an initial upfront payment of $75,000.

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

In October 2011, we entered into a research license agreement with 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. A limited scope license was extended for one more year through October 9, 2018, following which, the research license terminated. As such, we are no longer using the Selexis Technology in our research. 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 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, 2018, we have paid Selexis an aggregate of approximately $0.6 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.

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 (a biosimilar to Herceptin that we are no longer developing) 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, 2018, we have paid Selexis an aggregate of approximately $0.4 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 clinical development costs, and proportionately share the revenues from commercialization of ONS-3010 in the United States, Canada, E.U. 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 E.U. or Japan. We currently have collaboration and license agreements for smaller ex-U.S. markets and, collectively, such agreements have provided an aggregate of $29.0 million in payments as of September 30, 2018 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), Huahai (for ONS-3010 and ONS-1045 in China) and BioLexis (for ONS-3010 and ONS-1045 in emerging markets excluding China, India and Mexico). 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, E.U., 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.

In the event Huahai funds its proportionate share of development costs incurred after completion of the “Phase-3 Ready Package,” Huahai would be entitled to retain its 51% value ownership, with us entitled to retain our 49% value ownership, of ONS-3010 in the agreed countries. Similarly, revenues from the commercialization of ONS-3010 in the agreed countries (including major markets such as the United States and the E.U., 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, E.U., 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, 2018, 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,

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 and an aggregate of $5.0 million from BioLexis under our joint development and licensing agreement.

Competition

Competition in the area of pharmaceutical research and development is intense and significantly depends on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain regulatory approval for testing, manufacturing and marketing. Our competitors include major pharmaceutical and specialized biotechnology companies, many of which have financial, technical and marketing resources significantly greater than ours. In addition, many biotechnology companies have formed collaborations with large, established companies to support research, development and commercialization of products that may be competitive with ours. Academic institutions, governmental agencies and other public and private research organizations are also conducting research activities and seeking patent protection and may commercialize products on their own or through joint ventures. We are aware of certain other products manufactured or under development by competitors that are used for the treatment of the health conditions that we have targeted for product development. We can provide no assurance that developments by others will not render our technology obsolete, noncompetitive or harm our development strategy, that we will be able to keep pace with new technological developments or that our technology will be able to supplant established products and methodologies in the therapeutic areas that are targeted by us. The foregoing factors could have a material adverse effect on our business, prospects, financial condition and results of operations. These companies, as well as academic institutions, governmental agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants.

We will encounter competition from existing firms that offer competitive solutions in ocular diseases. These competitive companies could develop products that are superior to, or have greater market acceptance, than the products being developed by us. We will have to compete against other biotechnology and pharmaceutical companies with greater market recognition and greater financial, marketing and other resources.

Wet AMD Market

AMD is a medical condition that usually affects older adults and generally results in a loss of vision. AMD occurs in “dry” (non-exudative) and “wet” (exudative) forms. Wet AMD is the advanced form of macular degeneration that involves the formation of abnormal and leaky blood vessels in the back of the eye behind the retina, through a process known as choroidal neovascularization. While the wet form accounts for approximately 15% of all AMD cases, according to NEI, it is responsible for 90% of severe vision loss associated with AMD. NEI also claims that the prevalence of wet AMD among adults 40 years or older in the United States is estimated at approximately 1.75 million people. In addition, more than 200,000 new cases are diagnosed annually in North America.

Competitive Landscape in Wet AMD

The current FDA approved market leaders for the treatment of wet AMD are VEGF inhibitors, including Lucentis, Eylea and off-label Avastin. Annual revenue (worldwide) is estimated to be approximately $9.1 billion in 2018 for anti-VEGF therapeutics (GlobalData). Off-label use of Avastin is estimated to be approximately 50% of the overall market in the United States. Avastin, Lucentis, and Eylea are administered via frequent intravitreal injections directly into the eye. We are developing ONS-5010 as a replacement for the use of off-label Avastin in the treatment of wet AMD, as well as DME and BRVO.

In addition to the other treatments used in patients with wet AMD, there are various other companies with product candidates in Phase 1, 2 and 3 clinical trials for the treatment of wet AMD. Programs currently in Phase 2 or Phase 3 clinical trials include, but are not limited to:

- Abicipar Pegol, a VEGF targeting DARPin molecule being developed by Allergan plc;
- RTH258, an anti-VEGF agent being developed by Novartis International AG;

- X-82, an oral tyrosine kinase inhibitor being developed by Tyrogenex, Inc.;
- ALG-1001, an integrin targeting peptide being developed by Allegro Ophthalmics LLC;
- Zimura, a C-3 inhibitor being developed by Ophthotech Corporation;
- RG7716, a bispecific antibody to both VEGF-A and Ang2 being developed by F. Hoffman-La Roche AG;
- OPT-302, an inhibitor of VEGF-C and VEGF-D being developed by Opthea Limited; and
- PAN-90806, a selective inhibitor of VEGF being developed by PanOptica Inc.

All of these product candidates in clinical development, with the exception of X-82 and PAN-90806, use an intravitreal route of administration much like the current standards of care. We believe that ONS-5010 has potential competitive advantages through the familiarity of patients and physicians in using off-label Avastin. We also believe we have reduced the risk in our clinical program by leveraging our prior work in developing a biosmilar drug product candidate for Avastin as a treatment for cancer. However, clinical trial data from other clinical programs may negatively impact our ability to garner future financing or business collaborations, combinations or transactions with other pharmaceutical and biotechnology companies.

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 E.U. 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, 2018, we own eight pending U.S. non-provisional applications, and 51 pending international applications that were nationalized from eight Patent Cooperation Treaty, or PCT, applications, and one pending U.S. provisional application, which relate to formulations developed for ONS-3010, ONS-5010/ONS-1045 and ONS-1050, methods of antibody purification, methods for purifying antibodies to separate isoforms, methods of use, methods of reducing high molecular weight species, and modulating afucosylated species as well as efficiently determining the amino acid sequence of antibodies. Our first PCT application was nationalized in April 2016 in Australia, Canada, China, Europe, Hong Kong, India, Japan, Mexico and the United States. If granted, patents issuing from these nine applications are expected to expire in 2034, absent any adjustments or extensions. Our second PCT application was nationalized in July 2017 in Europe and the United States. If granted, patents issuing from these two applications are expected to expire in 2036, absent any adjustments or extensions. Our third PCT application was nationalized in June 2018 in Australia, Canada, China, Europe, India, Japan, Mexico and the United States. If granted, patents issuing from these eight applications are expected to expire in 2036, absent any adjustments or extensions. Our fourth PCT application was nationalized in July 2018 in Australia, Canada, China, Europe, India, Japan, Mexico and the United States. If granted, patents issuing from these eight applications are expected to expire in 2037, absent any adjustments or extensions. Our fifth PCT application was nationalized in July 2018 in Australia, Canada, China, Europe, India, Japan, Mexico and the United States. If granted, patents issuing from these eight applications are expected to expire in 2037, absent any adjustments or extensions. Our sixth PCT application was nationalized in July 2018 in Australia, Canada, China, Europe, India, Japan, Mexico and the United States. If granted, patents issuing from these eight applications are expected to expire in 2037, absent any adjustments or extensions. Our seventh PCT application was nationalized in August 2018 in Australia, Canada, China, Europe, India, Japan, Mexico and the United States. If granted, patents issuing from these eight applications are expected to expire in 2037, absent any adjustments or extensions. Our eighth PCT application was nationalized in August 2018 in Australia, Canada, China, Europe, India, Japan, Mexico and the United States. If granted, patents issuing from these eight applications are expected to expire in 2037, absent any adjustments or extensions. Any patents that may eventually issue claiming priority to our provisional patent application are expected to expire in 2039. 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

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates.

The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices, or GLP, regulation;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with Good Clinical Practices, or GCP; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical and Clinical Development

Prior to beginning the first clinical trial with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA,

within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1 — The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- Phase 2 — The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3 — The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so- called Phase 4 studies may be made a condition to approval of the BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the

FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. The submission of a BLA requires payment of a substantial application user fee to FDA, unless a waiver or exemption applies.

Once a BLA has been submitted, the FDA's goal is to review standard applications within ten months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new

indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later 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 revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. To date, a number of biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered

multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products.

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 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 federal Anti-Kickback Statute is subject to evolving interpretations. In the past, the government has enforced the federal 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, among other things, amends the intent requirement of the federal Anti-Kickback Statute and the criminal statutes governing healthcare fraud. 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 civil False Claims Act or federal civil monetary penalties statute.

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 civil 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. The federal government has used the civil 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 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 their 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 that provide services to the covered entity that involve individually identifiable health information. 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 annual 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.

Certain states also impose restrictions on pharmaceutical manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians. Certain states and local governments require the registration of pharmaceutical sales representatives. 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 significant penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, 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 individual 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, Congressional and executive branch 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. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act such as removing or delaying penalties, starting January 1, 2019, for not complying with the Affordable Care Act's individual mandate to carry health insurance, delaying the implementation of certain Affordable Care Act-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. 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, due to subsequent legislative amendments, will remain in effect through 2027 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 and enacted federal and state legislation 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. For example, the current presidential administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. Although a number of these, and other proposed measures will require authorization through additional legislation to become effective, Congress and the executive branch have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. 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 guidance, 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 the adequacy of reimbursement from third-party payors, including government health administrative authorities, managed care organizations, private health insurers and other organizations. Third-party payors are increasingly examining the medical necessity and cost effectiveness of drug products and services in addition to safety and efficacy and, accordingly, significant uncertainty exists as to the reimbursement status of newly drug products. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, there is no uniform policy for coverage and reimbursement in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As such, 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 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 November 30, 2018, we had 56 full-time employees, 37 of whom were primarily engaged in research and development activities and seven 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 66,000 square feet of office, manufacturing and laboratory space in Cranbury, New Jersey, under a lease, as amended, that expires in February 2028. In September 2018, we terminated the lease for approximately 82,000 square feet of additional office and laboratory space in Cranbury, New Jersey, for approximately $5.8 million in the aggregate.

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. In November 2018, we changed our name to Outlook Therapeutics, Inc. 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.outlooktherapeutics.com. The information contained on, or that can be accessed through, our website is not part of, and is not incorporated by reference into this Annual Report on Form 10-K.

Item 1A. Risk Factors

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

Risks Related to Our Financial Condition and Capital Requirements

We have a limited operating history, have incurred significant losses and negative cash flows from operations since our inception and expect to continue to incur significant losses and negative cash flows from operations for at least the next 12 months.

We are a clinical-stage 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 $30.1 million and $38.8 million for the years ended September 30, 2018 and 2017, 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, IPCA Laboratories Limited, or IPCA, and BioLexis Pte. Ltd., or BioLexis (formerly GMS Tenshi Holdings Pte, Limited). The amount of our future net losses will depend, in part, on our ability to generate revenue from 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 operating losses for at least the next 12 months. We anticipate that our expenses may increase substantially if and as we:

- continue the clinical development of our lead product candidate, ONS-5010;
- advance ONS-5010 into additional clinical trials;
- change or add contract manufacturing providers, clinical research service providers, testing laboratories, device suppliers, legal service providers or other vendors or suppliers;
- seek regulatory and marketing approvals for ONS-5010 in the United States and other markets if we 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 product candidates that may be complementary to ONS-5010;
- 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 respect to our product candidates;
- seek to attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and any 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, 2018 of $216.3 million, $13.5 million of senior secured notes that may become due in fiscal 2019 and $4.6 million of unsecured indebtedness, $1.0 million of which is due on demand, and $3.6 million of which matures December 22, 2018. 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 our company.

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, ONS-5010 for the treatment of wet age related macular degeneration, or wet AMD, and our other targeted indications, and as appropriate, any of our other 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 clinical development of ONS-5010 for the treatment of wet AMD and the other targeted indications, and any other product candidates we may develop in the future;
- obtaining regulatory and marketing approvals for ONS-5010 and any other product candidates for which we or our partners complete clinical trials;
- securing a manufacturing partner for ONS-5010 and any approved product candidates to support clinical development, regulatory requirements and the market demand for any such approved product candidates;
- launching and commercializing ONS-5010 and any other product candidates for which we or our partners obtain regulatory and marketing approval;
- obtaining third-party coverage and adequate reimbursements for our products;
- obtaining market acceptance of ONS-5010 and any other product candidates for which we obtain regulatory and marketing approval as viable treatment options;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- 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 ONS-5010 or one or more of our other 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 competitors in such markets;
- the market acceptance of our products;
- the accepted price for the product;
- the ability to obtain coverage and adequate reimbursement for the product;
- the quality and performance of our products, including the relative safety and efficacy; and
- whether we own, or have partnered, the commercial rights for that territory.

If the market for ONS-5010 or any other product candidates we may develop in the future, 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 ONS-5010, our business will be harmed.

We will need to raise substantial additional funding to complete the 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.

Developing product candidates is an expensive, risky and lengthy process. We are currently advancing ONS-5010 through clinical development, but have decided to secure additional development partners before advancing our biosimilar product candidates into and through clinical trials. Our expenses may 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, ONS-5010.

As of September 30, 2018, our cash balance was $1.7 million. We expect that our current cash resources along with the additional funds from our November 2018 private placement and anticipated proceeds from the sale of New Jersey net operating losses, or NOLs and research and development credits, will be sufficient to fund our operations into June 2019, excluding any unscheduled repayment of debt. We will require substantial additional capital to complete the clinical development of, obtain regulatory approvals for, and commercialize ONS-5010. 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. 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 between December 2016 and May 2017 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 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 highly dependent on the success of ONS-5010, our only product candidate in active development, and if ONS-5010 does not successfully complete clinical development or receive regulatory approval, or is not successfully commercialized, our business may be harmed.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures in the foreseeable future will be devoted to the advancement of ONS-5010, our only product candidate in active development, through clinical trials and the regulatory approval process, as well as the commercialization of ONS-5010 following regulatory approval, if received. We cannot assure you that we will be able to successfully complete the necessary clinical trials and/or obtain regulatory approval and develop sufficient commercial capabilities for ONS-5010. Accordingly, our business currently depends heavily on the successful completion of clinical development and subsequent regulatory approval and commercialization of ONS-5010.

We cannot be certain that ONS-5010 will receive regulatory approval, or be successfully commercialized even if we receive regulatory approval in our targeted markets. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of products are, and will remain, subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market ONS-5010 in the United States until we receive approval from the FDA, or in any foreign country until we receive the requisite approvals from the appropriate authorities in such countries for marketing authorization.

There can be no assurance that our ongoing clinical trial of ONS-5010 for wet AMD will produce results sufficient for us to receive regulatory approval. We have not submitted a biologics license application, or BLA, for any product candidate to the FDA or any comparable application to any other regulatory authority. Obtaining approval from the FDA or similar regulatory approval is an extensive, lengthy, expensive and inherently uncertain process, and the FDA or other foreign regulatory authorities may delay, limit or deny approval of ONS-5010 for many reasons, including:

- we may not be able to demonstrate that ONS-5010 is effective as a treatment for any of our currently targeted indications to the satisfaction of the FDA or other relevant regulatory authorities;
- the relevant regulatory authorities may require additional pre-approval studies or clinical trials, which would increase our costs and prolong our development timelines;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or other relevant regulatory authorities for marketing approval;
- the FDA or other relevant regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA or other relevant regulatory authorities may not find the data from nonclinical studies or clinical trials sufficient to demonstrate that the clinical and other benefits of these products outweigh their safety risks;
- the FDA or other relevant regulatory authorities may disagree with our interpretation of data or significance of results from the nonclinical studies and clinical trials of ONS-5010 and any future product candidate, or may require that we conduct additional trials;
- the FDA or other relevant regulatory authorities may require development of a risk evaluation and mitigation strategy, or REMS, or its equivalent, as a condition of approval;
- the FDA or other relevant regulatory authorities may require additional post-marketing studies, which would be costly;
- the FDA or other relevant regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers; or
- the FDA or other relevant regulatory authorities may change their approval policies or adopt new regulations.

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 focusing only on one active development program, ONS-5010, and are no longer actively developing ONS-3010, ONS-1045 or the other biosimilar product candidates in our pipeline. We currently do not intend to actively develop such biosimilar product candidates absent additional development or licensing partners. 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 pharmaceutical industry, our business, financial condition and results of operations could be harmed.

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.

ONS-5010, our only product candidate in active development, will require extensive clinical testing before we are prepared to submit an application for regulatory approval. 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 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;
- 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 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.

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 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-5010 for the treatment of wet AMD. 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.

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 trials 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 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. In order to market our products in Europe, 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 E.U. This procedure results in a single marketing authorization that is valid in all E.U. 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 Europe, the United States or in other jurisdictions. Failure to obtain these approvals would harm our business, financial condition and results of operations.

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

If ONS-5010, or any other product candidates we may pursue, 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, our current and future manufacturing partners 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. 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.

The development and commercialization of pharmaceutical products is subject to extensive regulation, and we may not obtain regulatory approvals for ONS-5010 in any of the indications for which we plan to develop it, or any future product candidates, on a timely basis or at all.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing, distribution, adverse event reporting, including the submission of safety and other post-marketing information and reports, and other possible activities relating to ONS-5010, as well as any other product candidate that we may develop in the future, are subject to extensive regulation. Marketing approval of biologics in the United States requires the submission of a BLA to the FDA and we are not permitted to market any product candidate in the United States until we obtain approval from the FDA of the BLA for that product. A BLA must be supported by extensive clinical and preclinical data, as well as extensive information regarding pharmacology, chemistry, manufacturing and controls.

FDA approval of a BLA is not guaranteed, and the review and approval process is an expensive and uncertain process that may take several years. The FDA also has substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for BLA approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to treat and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical studies and clinical trials, failure can occur at any stage. The results of preclinical and early clinical trials of ONS-5010 or any future product candidates may not be predictive of the results of our later-stage clinical trials.

Clinical trial failure may result from a multitude of factors including flaws in trial design, dose selection, placebo effect, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits, and failure in clinical trials can occur at any stage. Companies in the biopharmaceutical industry frequently suffer setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from clinical trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may further delay, limit or prevent marketing approval.

The FDA could delay, limit or deny approval of a product candidate for many reasons, including because they:

- may not deem our product candidate to be adequately safe and effective;
- may not agree that the data collected from clinical trials are acceptable or sufficient to support the submission of a BLA or other submission or to obtain regulatory approval, and may impose requirements for additional preclinical studies or clinical trials;
- may determine that adverse events experienced by participants in our clinical trials represents an unacceptable level of risk;
- may determine that population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- may disagree regarding the formulation, labeling and/or the specifications;
- may not approve the manufacturing processes or facilities associated with our product candidate;
- may change approval policies or adopt new regulations; or

- may not accept a submission due to, among other reasons, the content or formatting of the submission.

Generally, public concern regarding the safety of pharmaceutical products could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling, or require us to undertake other activities that may entail additional costs. We have not obtained FDA approval for any product. This lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, for ONS-5010.

If we experience delays in obtaining approval or if we fail to obtain approval of ONS-5010, our commercial prospects will be harmed and our ability to generate revenues will be materially impaired which would adversely affect our business, prospects, financial condition and results of operations.

Any delays in the commencement or completion, or termination or suspension, of our planned or future clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Any delays in the commencement or completion, or termination or suspension, of our planned or future clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects. Before we can initiate clinical trials of ONS-5010 in the United States in any distinct indication, we must submit the results of preclinical and/or other studies to the FDA along with other information, including information about ONS-5010 chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or similar regulatory filing.

Before obtaining marketing approval from the FDA for the sale of ONS-5010 in any indication, we must conduct extensive clinical studies to demonstrate the safety and efficacy of ONS-5010. Clinical testing is expensive, time consuming and uncertain as to outcome. In addition, we expect to rely in part on preclinical, clinical and quality data generated by clinical research organizations, or CROs, and other third parties for regulatory submissions for ONS-5010. While we have or will have agreements governing these third parties' services, we have limited influence over their actual performance. If these third parties do not make data available to us, or, if applicable, make regulatory submissions in a timely manner, in each case pursuant to our agreements with them, our development programs may be significantly delayed and we may need to conduct additional studies or collect additional data independently. In either case, our development costs would increase.

The FDA may require us to conduct additional studies for ONS-5010 or any future product candidate before it allows us to initiate clinical trials under any IND, which may lead to additional delays and increase the costs of our development programs. Any such delays in the commencement or completion of our planned or future clinical trials could significantly affect our product development costs. We do not know whether our planned trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- the FDA disagreeing as to the design or implementation of our clinical studies;
- obtaining FDA authorizations to commence a trial or reaching a consensus with the FDA on trial design;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval from one or more IRBs;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes to clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;
- manufacturing sufficient quantities of product candidate or obtaining sufficient quantities of combination therapies for use in clinical trials;

- subjects failing to enroll or remain in our trial at the rate we expect, or failing to return for post-treatment follow-up;
- subjects choosing an alternative treatment, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- selection of clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing our product candidates or any of their components being ordered by the FDA to temporarily or permanently shut down due to violations of current good manufacturing practice, or cGMP, regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices, or GCP, or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner; or
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a pharmaceutical, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues which may harm our business, financial condition and prospects significantly.

If we experience delays or difficulties in enrolling patients in our planned clinical trials, our receipt of necessary regulatory approval could be delayed or prevented.

We may not be able to initiate or continue our planned clinical trials for ONS-5010 if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA. Some of our competitors may have ongoing clinical trials for product candidates that would treat the same indications as ONS-5010, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Patient enrollment is also affected by other factors, including:

- severity of the disease under investigation;
- our ability to recruit clinical trial investigators of appropriate competencies and experience;

- invasive procedures required to obtain evidence of the product candidate's performance during the clinical trial;
- availability and efficacy of approved medications for the disease under investigation;
- eligibility criteria defined in the protocol for the trial in question;
- the size of the patient population required for analysis of the trial's primary endpoints;
- perceived risks and benefits;
- efforts to facilitate timely enrollment in clinical trials;
- reluctance of physicians to encourage patient participation in clinical trials;
- the ability to monitor patients adequately during and after treatment;
- our ability to obtain and maintain patient consents; and
- proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs, which would cause the value of our company to decline and limit our ability to obtain additional financing.

Adverse side effects or other safety risks associated with ONS-5010 could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon further development, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with ONS-5010 in our planned clinical trials. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by ONS-5010 could result in the delay, suspension or termination of clinical trials by us or the FDA for a number of reasons. If we elect or are required to delay, suspend or terminate any clinical trial, the commercial prospects of ONS-5010 will be harmed and our ability to generate product revenues from this product candidate will be delayed or eliminated. Serious adverse events observed in clinical trials could hinder or prevent market acceptance of ONS-5010. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Moreover, if ONS-5010 is associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon or limit its development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for ONS-5010, if approved. We may also be required to modify our study plans based on findings in our clinical trials. Many biologics that initially showed promise in early stage testing have later been found to cause side effects that prevented further development. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations.

It is possible that as we test ONS-5010 in larger, longer and more extensive clinical trials including for additional indications, or as the use of ONS-5010 become more widespread if it receives regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition and prospects significantly.

In addition, if ONS-5010 receives marketing approval, and we or others later identify undesirable side effects caused by ONS-5010, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approval of ONS-5010;
- we may be required to recall a product or change the way ONS-5010 is administered to patients;

- regulatory authorities may require additional warnings on the label, such as a “black box” warning or a contraindication, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to implement a REMS, or create a medication guide outlining the risks of such side effects for distribution to patients;
- additional restrictions may be imposed on the marketing or promotion of the particular product or the manufacturing processes for the product or any component thereof;
- we could be sued and held liable for harm caused to patients;
- ONS-5010 could become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of ONS-5010, if approved, and could significantly harm our business, results of operations and prospects.

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 products 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, Novartis, which currently markets Lucentis and Regeneron, with their product Eylea, both of which have been approved for use in patients with wet AMD. Furthermore, the cancer drug Avastin, sold by Roche is used in wet AMD patients although it has not been approved for use in these patients. Our ONS-5010 is being developed to replace the use of off-label Avastin. In addition, these companies and other, smaller, biotechnology and pharmaceutical companies are also developing new treatments for wet AMD and are at various stages of pre-clinical and clinical development.

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. Product candidates developed by our competitors may render ONS-5010 and any of our other potential product candidates uneconomical, less desirable or obsolete, and we may not be successful in marketing our product candidates against competitors.

We expect additional companies to seek approval to manufacture and market anti-VEGF therapies for ophthalmic indications. If other anti-VEGF therapies are approved and successfully commercialized before ONS-5010, we may never achieve significant market share for this product, our revenue would be reduced and, as a result, 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 ONS-5010, or any other product candidates we may pursue, 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 in clinical trials, and potential advantages over competing treatments;
- 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;
- 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 our 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 ONS-5010, or any other product candidates we may pursue, if approved;
- our ability to maintain compliance with regulatory requirements; and
- labeling or naming imposed by FDA or other regulatory agencies.

Even if ONS-5010, or any other product candidate we may develop in the future, 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 product candidates. 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 ONS-5010, or any other product candidates we may develop in the future, 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.

Even if ONS-5010 is approved, off-label compounding of Avastin and other drugs may continue, which could have a material adverse effect on our business and financial condition.

It is currently estimated that Avastin accounts for approximately 50% of wet AMD prescriptions in the United States, notwithstanding that such use is off-label and requires preparation at a compounding pharmacy. Even if ONS-5010 is approved for use as a treatment for wet AMD, there is no guarantee that we will be effective in reducing, or stopping, the off-label compounding of Avastin and other drugs in the United States or other major markets where we plan to seek regulatory approval and market ONS-5010 if approved. If we are not successful in replacing off-label compounding of Avastin or other drugs with ONS-5010, our business and financial condition could be adversely affected.

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. We do not yet have any products approved for sale, and we, as a company, have no experience selling and marketing any pharmaceutical products. To successfully commercialize any products, we will need to develop these capabilities, either on our own or with others. If ONS-5010 receives regulatory approval, we may 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 our 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 ONS-5010 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 are a late clinical stage biopharmaceutical company, we have found it necessary to enter into alliances with other companies. For example, we entered into a strategic partnership agreement for consulting services for ONS-5010, pursuant to which we pay a monthly fee and may have to share a portion of net profits, if any. We have also entered into service agreements for clinical trials, and co-development and license agreements for our biosimilar product candidates. 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 the inactive biosimilar product candidates in our pipeline and any other product candidates that we may develop. 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 ONS-5010, or any other product candidates we may develop in the future, 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.

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 ONS-5010, or any other product candidates we may develop in the future,, if approved, may not be adequate to support our commercial infrastructure. Our per-patient prices may not be sufficient to recover our development costs and potentially achieve profitability. The availability of coverage and adequacy of 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 ONS-5010 and any of our other product candidates will be paid for by third-party payors such as health maintenance, managed care organizations, pharmacy benefit and similar healthcare management organizations 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 realize a return on our investment.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors 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 third-party 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 third-party 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 E.U., 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 ONS-5010, or any other product candidates we may develop in the future,. We expect to experience pricing pressures in connection with the sale of ONS-5010, or any other product candidates we may develop in the future, if approved, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes.

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

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

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

Previously, we manufactured bulk drug substance for preclinical and clinical supplies of our product candidates in our in-house facility. Our business could be harmed if we are not able to find a suitable contract manufacturer or we otherwise fail to manufacture our product candidates at the necessary quantity or quality levels.

We no longer have the infrastructure or capability internally to manufacture supplies of ONS-5010, or any other product candidate, for use in clinical development, and we lack the resources and the capability to manufacture any product candidates on a clinical or commercial scale. If we are unable to manufacture or

have manufactured sufficient supplies of ONS-5010 or any other product candidates, our development efforts would be delayed, which would adversely affect our business and prospects. We will rely on third-party manufacturers to manufacture and supply us with our product candidates for clinical development, as well as to establish commercial supplies of our product candidates. Successfully transferring complicated manufacturing techniques to contract manufacturing organizations and scaling up these techniques for commercial quantities is time consuming and we may not be able to achieve such transfer or do so in a timely manner. If our need for contract manufacturing services increases during a period of industry-wide production capacity shortage, we may not be able to produce our product candidates on a timely basis or on commercially viable terms. Any significant delay or discontinuation in the supply of a product candidate for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates, which could harm our business and results of operations.

Reliance on third-party manufacturers entails additional risks, including reliance on the third party for regulatory compliance and quality assurance, the possible breach of the manufacturing agreement by the third party and the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. In addition, third-party manufacturers may not be able to comply with cGMP or similar regulatory requirements outside the United States. Our failure or the failure of our third-party manufacturers 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 adversely affect supplies of ONS-5010 or any other product candidates that we may develop. Any failure or refusal to supply the components for our product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts. If our contract manufacturers were to breach or terminate their manufacturing arrangements with us, the development or commercialization of the affected products or product candidates could be delayed, which could have an adverse effect on our business. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

If ONS-5010 or any of our product candidates are approved, we will need to enter into agreements with a third party for contract manufacturing in order to produce the quantities necessary to meet anticipated market demand. If we are unable to build and stock our product candidates in sufficient quantities to meet the requirements for the launch of these candidates or to meet future demand, our revenue and gross margins could be adversely affected. Although we believe that we will not have any material supply issues, we cannot be certain that we will be able to obtain long-term supply arrangements for our product candidates or materials used to produce them on acceptable terms, if at all. If we are unable to arrange for third-party manufacturing, or to do so on commercially reasonable terms, we may not be able to complete development of our product candidates or market them.

Any adverse developments affecting the manufacture of ONS-5010 could substantially increase our costs and limit supply for such product candidate.

The process of manufacturing our ONS-5010 and our other mAb product candidates is complex, highly regulated and subject to several risks, including but not limited to:

- failure to establish contracts with contract manufacturing organization, or CMOs, and device vendors where applicable;
- product loss due to contamination, equipment failure or improper installation or operation of equipment or vendor or operator error;
- 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 the applicable 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 may depend on third parties for the commercialization of ONS-5010, and failure to commercialize in those markets could harm our business and operating results.

We may 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 E.U. 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 do not have in place any licensing agreements for commercialization of ONS-5010. Our current arrangements are for our inactive biosimilar product candidates, and aside from one U.S. arrangement for ONS-3010, 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 any entity with whom we enter into a commercialization arrangement fails to exercise commercially reasonable efforts to market and sell our approved 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 any product candidates. Further, upon any such termination, our contract counterparties may still have the right to commercialize these product candidates in such markets, which may affect our ability to commercialize in the same markets.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we expect to rely on third parties to manufacture our current and any future product candidates, and we expect to continue to collaborate with third parties on the development of our current and any future product candidates, we must, at times, share trade secrets with them. We also conduct joint research and development programs that may require us to share trade secrets under the terms of our collaboration or similar agreements. For example, under our joint participation arrangement with Huahai, we are obligated to share with Huahai certain information relating to the development of ONS-3010, including reports from nonclinical studies and clinical trials. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, CROs, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we

engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Further, adequate remedies may not exist in the event of unauthorized use or disclosure. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Policing unauthorized use of our or our licensors' intellectual property is difficult, expensive and time-consuming, and we may be unable to determine the extent of any unauthorized use. Moreover, enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

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, E.U., 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, E.U., Japan, Australia and New Zealand and the proportionate sharing of the revenue from commercialization of ONS-3010 in such countries, in the event we were to restart the active development of this program. If so, 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. 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 E.U., 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 currently engage single source suppliers for clinical trial services and multiple source suppliers for fill-finish manufacturing and product testing of ONS-5010. The loss of any of these suppliers, or any future single source suppliers, could harm our business.

Our ONS-5010 product candidate is fill-finished by Ajinomoto Althea, Inc., or Althea. As such, we are heavily dependent on Althea for supplying us with sufficient supply of ONS-5010. 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 ONS-5010. 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 ONS-5010 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.

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.

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. 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 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 E.U., 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 E.U. 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 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. 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 product 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 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 Chief Medical Officer, Kenneth M. Bahrt, M.D. is a former employee of Genentech, which is the reference product sponsor of bevacizumab (Avastin), for which we are developing our own bevacizumab, ONS-5010, for ophthalmic diseases, for which Avastin is currently widely used off label. 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.

We have filed 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 worldwide commercial license agreements with Selexis SA, or Selexis, pertaining to clinical testing and sale of its cell line expression technology and we may enter into additional license agreements in the future. Our commercial license agreements with Selexis impose, 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-5010/ONS-1045 and ONS-3010. 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.

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 current effort will focus on the continued clinical testing, potential approval and commercialization of ONS-5010, the long term 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 able to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in preclinical or clinical testing;
- 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 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 public company, we expect to continue to incur significant legal, accounting and other expenses. 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 Stock Market LLC, or Nasdaq, have imposed various requirements on public companies. Although legislation permits “emerging growth companies” and “smaller reporting companies” such as our company to postpone compliance with certain

requirements for a transition period or for so long as we remain a “smaller reporting company,” we 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 add to our legal and financial compliance costs and make some activities more time-consuming and costly.

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 are required to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report, on the effectiveness of our internal control over financial reporting by Section 404 of the Sarbanes-Oxley Act, or Section 404. Our testing may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 requires us to 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. 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 control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would require additional financial and management resources.

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, 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. 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.

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 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, Congressional and executive branch 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. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act such as removing or delaying penalties, starting January 1, 2019, for not complying with the Affordable Care Act's individual mandate to carry health insurance, delaying the implementation of certain Affordable Care Act-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. We continue to evaluate the potential impact of the Affordable Care Act and its possible repeal or replacement on our business.

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, due to subsequent legislative amendments, will stay in effect through 2027 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 and enacted federal and state legislation 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. For example, the current presidential administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. Although a number of these, and other proposed measures will require authorization through additional legislation to become effective, Congress and the executive branch have each indicated that it will continue to seek new legislative and/or administrative measures to control drug product costs.

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 are subject, directly and 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 are directly and indirectly through our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors subject to various federal and state fraud and abuse laws, including without limitation, the federal Anti-Kickback Statute, the civil 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 can be enforced by private individuals through civil whistleblower or qui tam actions, 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 their 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, known as covered entities, and their business associates that provide services to the covered entity that involve individually identifiable health information;
- 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; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign 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 regulatory 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 significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, individual 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

Our common stock may be delisted from the Nasdaq and begin trading in the over-the-counter markets if we are not successful in regaining compliance with the Nasdaq's continued listing standards, which may negatively impact the price of our common stock and our ability to access the capital markets.

On October 24, 2018, we received written notification from Staff of the Listing Qualifications Department of Nasdaq, indicating that based upon our continued non-compliance with the minimum $1.00 bid price requirement for continued listing on The Nasdaq Capital Market required to maintain continued listing under its rules and regulations, or the Nasdaq Rules, as of October 23, 2018, the Staff determined to delist our securities from Nasdaq unless we timely request a hearing before the Nasdaq Hearing Panel. We timely requested a hearing, which was held on December 6, 2018, at which we requested an extension within which to evidence compliance with all applicable requirements for continued listing on Nasdaq in accordance with Nasdaq Rules. On December 17, 2018, we received formal notification from The Nasdaq that the Nasdaq Hearings Panel had determined to grant our request to extend through April 22, 2019 the period within which we need to evidence compliance with all applicable requirements for continued listing on Nasdaq, including the applicable $1.00 minimum bid price for a period of at least ten consecutive days. We also intend to take definitive steps to evidence compliance with the Nasdaq Rules, including through the implementation of a reverse stock split if deemed advisable by our board of directors. Our securityholders approved the potential action at our 2018 Annual Meeting of Stockholders, which was held on September 21, 2018.

The closing bid price of our securities must be at least $1.00 per share for a minimum of 10 consecutive business days to regain compliance. If we are not successful, or choose not to implement a reverse stock split we anticipate that our securities would begin trading on the over-the-counter market. Delisting from Nasdaq and trading on the over-the-counter market could adversely affect the liquidity of our securities and result in a deemed liquidation event under the terms of our Series A-1 Convertible Preferred Stock, par value $0.01 per share, or Series A-1 Convertible. Securities traded on the over-the-counter market generally have limited trading volume and exhibit a wider spread between the bid/ask quotation, as compared to securities listed on a national securities exchange. Consequently, you may not be able to liquidate your investment in the event of an emergency or for any other reason.

If our securities are delisted from Nasdaq, we could face significant material adverse consequences, including:

- the requirement to redeem the Series A-1 Convertible at (x) 600% of the stated value plus (y) 600% of any unpaid but accrued preferred dividends plus (z) any unpaid participating dividends;

- a limited availability of market quotations for our common stock;
- a reduced amount of news and analyst coverage for us;
- a decreased ability to issue additional securities or obtain additional financing in the future;
- reduced liquidity for our stockholders;
- potential loss of confidence by partners and employees; and
- loss of institutional investor interest and fewer business development opportunities.

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 services, 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 ONS-5010, or any of our product candidates when planned, 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 ONS-5010 or any of our other product candidates;
- failure to successfully develop and commercialize ONS-5010 or any of our other product candidates;
- post-marketing safety issues relating to our product candidates 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;
- 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 our product candidates;

- 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;
- the loss of one or more employees constituting our leadership team;
- changes in 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.

BioLexis has beneficial ownership of a significant percentage of our common stock, has the right to designate a majority of our board of directors, and is able to exert significant control over matters subject to stockholder approval, preventing new investors from influencing significant corporate decisions.

As of November 30, 2018, BioLexis beneficially owns 99,269,168 shares of our common stock, which includes 9,101,717 shares of common stock issuable upon conversion of 60,203 shares of Series A-1 Convertible and 37,262,820 shares of common stock issuable upon exercise of warrants outstanding. Accordingly, BioLexis currently beneficially owns approximately 78.1% of our common stock and controls 69.0% of our outstanding voting power. BioLexis has also agreed to acquire additional shares of our common stock under a November 2018 purchase agreement, which would further increase its ownership and control of our company. Under an investor rights agreement, as amended, with BioLexis, BioLexis also currently has the power to designate a majority of our board of directors, and four of our eight board members were designated by BioLexis. BioLexis' interests may not coincide with the interests of other securityholders. BioLexis has the ability to influence our company through both its ownership position and control of our board of directors, 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-5010 and any other product candidates;
- the cost of clinical development for ONS-5010 and any other product candidates;
- 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 any analysts who cover us in the future 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 from our IPO, 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 $1.07 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 to exercise such warrants.

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

Future sales and issuances of our common stock or rights to purchase securities, including pursuant to our equity incentive plans, exercise of warrants or conversion of outstanding convertible preferred securities, 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, 2018 was 5,558,678 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 (which began in 2017 and will end 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, 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 545,162 shares were available for issuance under the ESPP as of September 30, 2018. 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.

We also currently have issued and outstanding a number of warrants to purchase an aggregate of 45,292,494 shares of our common stock, at prices ranging from $0.01 to $6.60 per share, as well as shares of our convertible preferred stock, which are currently convertible into an aggregate 9,101,717 shares of our common stock.

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 December 2016 through May 2017 restrict our ability to pay dividends, and the terms of our Series A-1 Convertible may also act to limit our ability to pay dividends as we may not declare or pay any dividends on our common stock unless we also concurrently declare and set aside for payment or distribution, as applicable, participating dividends for our Series A-1 Convertible.

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

Our amended and restated certificate of incorporation and our amended and restated bylaws, as amended, provide 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, as amended; 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 or in our amended and restated bylaws, as amended, 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.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our headquarters are located in Cranbury, New Jersey where we occupy approximately 66,000 square feet of office, manufacturing and laboratory space under a lease that expires in February 2028. Additionally, in 2015, we leased approximately 82,000 square feet of unfinished office and laboratory space in Cranbury, New Jersey, with lease payments that commenced in March 2016 and expire in March 2026. However, in August 2018, we entered in to a lease termination agreement effective September 1, 2018, which terminated the 82,000 square feet lease for approximately $5.8 million in the aggregate.

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

Item 3. Legal Proceedings

From time to time, we may become involved in litigation relating to claims arising from the ordinary course of business. Our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which would have a material adverse effect on our results of operations, financial condition or cash flows. We are not currently party to any legal proceedings.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

Our units, which comprised one share of our common stock, one-half of a Series A warrant and one-half of a Series B warrant began trading under the symbol "ONSIU" on The Nasdaq Global Market on May 13, 2016 in connection with our initial public offering. Following separation of the units, on June 13, 2016, our shares of common stock and the Series A warrants and Series B warrants began trading under the symbols "ONS," "ONSIW" and "ONSIZ," respectively, and our units were delisted. On February 13, 2018, the listing of our common stock and the Series A Warrants was transferred to The Nasdaq Capital Market. On February 18, 2018, the Series B warrants expired and were delisted on May 16, 2018. Following our name change to "Outlook Therapeutics, Inc.," effective December 4, 2018, our common stock and the Series A warrants began trading under the symbols "OTLK" and "OTLKW," respectively. Prior to our initial public offering, there was no public market for our securities.

On December 14, 2018, the closing sale price of our common stock was $0.44, and of our Series A warrants was $0.12.

Common Stockholders

As of December 14, 2018, there were approximately 124 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Preferred Stockholders

As of December 14, 2018, there were 60,203 shares of our Series A-1 Convertible Preferred Stock, par value $0.01 per share, or the Series A-1 Convertible, issued and outstanding, all of which were held by one record holder, BioLexis.

Series A Warrant Holders

As of December 14, 2018, there was one holder of record of our Series A warrants. The actual number of warrantholders is greater than this number of record holders, and includes warrantholders who are beneficial owners, but whose warrants are held in street name by brokers and other nominees. This number of holders of record also does not include warrantholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock and do not anticipate paying any cash dividends in the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant. Our outstanding senior secured notes issued in December 2016 restrict our ability to pay dividends. The terms of our Series A-1 Convertible may also act to limit our ability to pay dividends as we may not declare or pay any dividends on our common stock unless we also concurrently declare and set aside for payment or distribution, as applicable, participating dividends for our Series A-1 Convertible.

Securities Authorized for Issuance Under Equity Compensation Plans

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

Recent Sales of Unregistered Equity Securities

None.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during fiscal year ended September 30, 2018.

Item 6. Selected Financial Data

Not applicable.

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

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

Overview

We are a late clinical-stage biopharmaceutical company focused on developing and commercializing ONS-5010, a complex, technically challenging and commercially attractive monoclonal antibody, or mAb, for various ophthalmic indications. Our goal is to launch ONS-5010 as the first, and only, approved bevacizumab in the United States, Europe, Japan and other markets for the treatment of wet age related macular degeneration, or wet AMD, diabetic macular edema, or DME, and branch retinal vein occlusion, or BRVO.

ONS-5010 is an innovative mAb therapeutic product candidate currently enrolling patients in a clinical trial outside the United States designed to serve as the first of two adequate and well controlled studies evaluating ONS-5010 for wet AMD. We plan to submit an investigational new drug, or IND, application with the U.S. Food and Drug Administration, or FDA, in the first quarter of calendar 2019. The U.S. portion of the second study is also expected to begin at that time. Our ONS-5010 wet AMD clinical program was reviewed at a successful end of Phase 2 meeting with the FDA conducted in 2018. If the program is successful, it will support our plans to submit for regulatory approval in multiple markets in 2020 including the United States, Europe and Japan. Because there are no approved bevacizumab products for the treatment of retinal diseases in such major markets, we are developing ONS-5010 as an innovative therapy and not using the biosimilar drug development pathway. If approved, we believe ONS-5010 has potential to mitigate risks associated with off-label compounding of Avastin or other drugs. Off label compounding of Avastin is currently estimated to account for approximately 50% of all wet AMD prescriptions in the United States.

Separately, we have advanced two biosimilar 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 do not plan to further advance ONS-3010 and ONS-1045 in major markets, including the United States, upon entering into a license or co-development agreement with a partner in one or more of the major markets. The emerging markets rights to these drug product candidates have been licensed to third parties for development in those markets. At this time, ONS-5010 is our only product candidate in active development.

Through September 30, 2018, we have funded substantially all of our operations with $195.3 million in proceeds from the sale and issuance of our equity and debt securities. We have also received $29.0 million pursuant to our collaboration and licensing agreements. In September 2017, we closed on the initial sale of 32,628 shares of our newly-created Series A Convertible Preferred Stock, or the Series A Convertible, to BioLexis Holdings Pte. Ltd., or BioLexis (formerly GMS Tenshi Holdings Pte. Limited), our controlling stockholder and strategic partner, for $3.3 million of cash, and entered into an investor rights agreement in connection therewith. In October 2017, following receipt of necessary stockholder approval, we issued an additional 217,372 shares of our Series A Convertible and warrants to acquire 16,750,000 shares of our common stock to BioLexis for $21.7 million of cash. Concurrent with such second closing, we also exchanged an aggregate $1.5 million of outstanding senior secured notes into 1,500,000 shares of our newly-created Series B Convertible Preferred Stock, or the Series B Convertible.

Additionally, as part of the BioLexis transaction, in September 2017, we entered into a joint development and licensing agreement for ONS-3010 and ONS-1045 in all emerging market territories not previously licensed to other development partners.

On May 11, 2018, we entered into a purchase agreement with BioLexis pursuant to which we agreed to sell to BioLexis, and BioLexis agreed to purchase, in a private placement, $15.0 million of our common stock and warrants to acquire that number of shares of common stock having an aggregate exercise price of approximately $20.0 million, to close in two tranches. On May 14, 2018, we closed the sale of the first tranche of the common stock and warrants for aggregate cash proceeds of $7.5 million, issuing to BioLexis an aggregate of 6,377,383 shares of our common stock and warrants to acquire up to 10,256,410 additional shares of our common stock at an exercise price of $0.975 per share, which warrants have a term of eight years from their issuance date. On June 8, 2018, we closed the sale of the second tranche of the common stock and warrants for aggregate cash proceeds of $7.5 million, issuing to BioLexis an aggregate of 6,377,383 shares of our common stock and warrants to acquire up to 10,256,410 additional shares of our common stock at an exercise price of $0.975 per share, which warrants have a term of eight years from their issuance date.

On June 20, 2018, BioLexis converted 208,836 shares of its Series A Convertible into 31,572,617 shares of our common stock. In connection therewith, we agreed in principle to exchange BioLexis's remaining shares of Series A Convertible (along with accrued but unpaid dividends) into a newly created class of preferred stock that was intended to have the same conversion and dividend features as the Series A Convertible, but reflect an increased redemption premium and increased liquidation preference that provides BioLexis with similar redemption premium and liquidation preference as before the June 20, 2018 conversion into common stock. Accordingly, on July 18, 2018, we entered into an exchange agreement with BioLexis pursuant to which we exchanged an aggregate of 58,735 shares of Series A Convertible then held by BioLexis for 58,735 shares of our newly created voting Series A-1 Convertible Preferred Stock, par value $0.01 per share, or the Series A-1 Convertible. Accordingly, all of the issued Series A Convertible have been retired and cancelled and may not be reissued as shares of such series in accordance with their terms.

The Series A-1 Convertible has the same conversion and dividend features as the Series A Convertible (10% per annum, compounded quarterly, payable quarterly at our option in cash or in kind in additional shares of Series A-1 Convertible), but reflects an increased redemption premium (110% to 550%) and increased liquidation preference (120% to 600%) that provides BioLexis with similar redemption premium and liquidation preference for its aggregate Series A Convertible holdings before the conversion.

On November 5, 2018, we entered into a purchase agreement with BioLexis providing for the private placement of $20.0 million of shares of our common stock at $0.9327 per share. The closing of the sale of the first two tranches of this private placement for an aggregate of 12,865,867 shares of our common stock for aggregate cash proceeds of $12.0 million occurred in November and December 2018. The remaining $8.0 million will be funded in two equal tranches on January 3, 2019 and February 1, 2019, subject to customary conditions and achieving certain funding milestones as set forth in the purchase agreement. We intend to use the net proceeds from the private placement primarily for clinical trials for our lead product candidate, ONS-5010, and for working capital and general corporate purposes, including the agreed repayments on the senior secured notes discussed below.

Also on November 5, 2018, we reached an agreement with the holders of our $13.5 million senior secured notes to extend the maturity of the senior secured notes, up to 12 months, or until December 22, 2019, in exchange for making several payments of principal and interest through August 31, 2019, subject to meeting additional capital raising commitments, with an initial payment of $2.2 million paid on November 7, 2018. In addition, we agreed to make the senior secured notes convertible into common stock at a price of $1.11924 per share (120% of the price per share paid by BioLexis under the purchase agreement) and reduced the exercise price of the warrants held by such holders to $1.50 and extended the expiration of these warrants by three years. We also agreed to take such steps as reasonably necessary to amend the outstanding Series A warrants that were issued in our initial public offering, or IPO, to reduce the exercise price to $1.50 and extend the expiration of these warrants by three years.

On November 30, 2018, we received approval from the New Jersey Economic Development Authority's Technology Business Tax Certificate Transfer Program to sell approximately $3.7 million of our unused New Jersey net operating losses, or NOLs, and research and development tax credits, or R&D credits. We expect to receive approximately $3.4 million of proceeds from the sale of the New Jersey NOLs and R&D credits.

As described in their audit report included elsewhere in this Annual Report on Form 10-K, our auditors have included an explanatory paragraph that states that we have incurred recurring losses and negative cash flows from operations since inception and have an accumulated deficit at September 30, 2018 of $216.3 million, $13.5 million of senior secured notes that may become due in fiscal 2019; and $4.6 million of unsecured indebtedness, $1.0 million of which is due on demand, and $3.6 million of which matures December 22, 2018. We will need to raise substantial additional capital to fund our planned future operations, commence clinical trials, receive approval for and commercialize ONS-5010, reactivate the development of ONS-3010 and ONS-1045, or continue to develop our product candidates. We plan to finance our future operations with a combination of proceeds from the issuance of equity securities, and 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-5010 or any other current or future 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 $1.7 million as of September 30, 2018, additional $20.0 million funding from our November BioLexis private placement and anticipated proceeds from the sale of New Jersey NOLs, are expected to fund our operations into June 2019, excluding any unscheduled repayment of debt. 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. If we are not successful in raising additional capital or entering into one or more licensing and/or co-development rights agreements, we may be required to, among other things, make reductions in our workforce, discontinue our development programs, liquidate all or a portion of our assets, and/or seek protection under the provisions of the U.S. Bankruptcy Code.

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, 2018 was $30.1 million. We also had a net loss of $38.8 million for the year ended September 30, 2017. 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 products and/or 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.

MTTR, LLC — ONS 5010

In February 2018, we entered into a strategic partnership agreement with MTTR, LLC, or MTTR, to advise on regulatory, clinical and commercial strategy and assist in obtaining approval of ONS-5010, our bevacizumab therapeutic product candidate for ophthalmic indications. Under the terms of the agreement, we currently pay MTTR a $58,333 monthly consulting fee. In March 2018, we amended the MTTR agreement and agreed to pay a one-time fee of $268,553 to MTTR by September 2020 if certain regulatory milestones are achieved earlier than anticipated. Beginning January 2019, the monthly fee increases to $105,208 per month, and then, after launch of ONS-5010 in the United States, to $170,833 per month (the amount of which is reduced by 50% in the event net sales of ONS-5010 are below a certain threshold million per year). We also agreed to pay MTTR a tiered percentage of the net profits of ONS-5010 ranging in the low- to mid-teens, with the ability to credit monthly fees paid to MTTR. For the year ended September 30, 2018, MTTR earned an aggregate of $602,629, which includes monthly consulting fees, expense reimbursement and an initial upfront payment of $75,000.

Selexis SA

In October 2011, we entered into a research license agreement with Selexis SA, or Selexis, whereby we acquired a non-exclusive license to conduct research internally or in collaboration with third parties to develop recombinant proteins from cell lines created in mammalian cells using the Selexis expression technology, or the Selexis Technology. The original research license had a three-year term, but on October 9, 2014, it was extended for an additional three-year term through October 9, 2017, and then a limited scope license was extended for one more year through October 9, 2018. 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 product candidates in humans, or from filing an investigational new drug, absent a commercial license agreement with Selexis covering the particular 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 license maintenance payments of the same amount for each of the three years that the research license agreement term was extended and for a pro rata amount for the most current one-year license extension that expired on October 9, 2018. As such, we are no longer using the Selexis Technology in our research.

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 (which covers ONS-5010) and ONS-1050 product candidates. We paid an upfront licensing fee to Selexis for each commercial license and also agreed to pay a fixed milestone payment for each licensed product. In addition, we are required to pay a single-digit royalty on a final product-by-final product and country-by-country basis, based on worldwide net sales of such final products by us or any of our affiliates or sub-licensees during the royalty term. At any time during the term, we have the right to terminate our royalty payment obligation by providing written notice to Selexis and paying Selexis a royalty termination fee.

As of September 30, 2018, we have paid Selexis an aggregate of approximately $0.4 million under the commercial license agreements.

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, 2018, 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, 2018, 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, 2018, 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 the event Huahai funds its proportionate share of development costs incurred after completion of the “Phase-3 Ready Packages,” Huahai would be entitled to retain its 51% value ownership, with us entitled to retain our 49% value ownership, of ONS-3010 in the agreed territories. Similarly, revenues from commercialization of ONS-3010 in the agreed countries (including major markets such as the United States and the European Union, 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.

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

On September 7, 2017, in connection with the entry into the BioLexis purchase agreement for the Series A Convertible and warrants, we also entered into a joint development and license agreement providing for the license of rights to ONS-3010 and ONS-1045 in emerging markets, excluding China, India and Mexico, which superseded and replaced a previous strategic licensing agreement dated July 25, 2017. As of September 30, 2018, we have received an aggregate of $5.0 million of payments from BioLexis under our joint development and license agreement.

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 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.

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 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. During the three months ended December 31, 2016, we revised our estimate of the period of completion from December 2019 to December 2021.

Research and Development Expenses

Research and development expense consists of expenses incurred in connection with the discovery and development of our 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 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 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 product candidates or focus on others. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the 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. Product commercialization will take several years and millions of dollars in development costs.

Research and development activities are central to our business model. 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, complexity and duration of later-stage clinical trials.

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 if and when we believe a regulatory approval of a product candidate appears likely, and 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 product.

Interest Expense

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

Income Taxes

During the year ended September 30, 2018, we sold New Jersey NOLs in the amount of $38.5 million resulting in the recognition of income tax benefits of $3.2 million, recorded in our consolidated statement of operations.

Since inception, we have not recorded any U.S. federal or state income tax benefits (excluding the sale of New Jersey 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, 2018, we had federal and state NOL carryforwards of $164.2 million and $67.6 million, respectively, that will begin to expire in 2030 and 2036, respectively. As of September 30, 2018, we had federal foreign tax credit carryforwards of $2.4 million available to reduce future tax liabilities, which begin to expire starting in 2023. As of September 30, 2018, we also had federal research and development tax credit carryforwards of $8.5 million that 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 if we undergo an ownership change in connection with or after our IPO, 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.

Loss on Extinguishment of Debt

We recorded a loss on the extinguishment of debt of $1.3 million during the year ended September 30, 2018 related to the exchange of our senior secured notes for shares of our Series B Convertible.

Change in Fair Value of Warrant Liability

Warrants to purchase our common stock that have been issued in conjunction with our senior secured notes are classified as liabilities and recorded at fair value. The warrants are subject to re-measurement at each balance sheet date and we recognize any change in fair value in our statements of operation.

Results of Operations

Comparison of Years Ended September 30, 2018 and 2017

	Year ended September 30,		
	2018	2017	Change
Collaboration revenues	$ 3,087,560	$ 3,811,519	$ (723,959)
Operating expenses:			
Research and development	18,504,035	23,809,749	(5,305,714)
General and administrative	14,227,828	15,882,033	(1,654,205)
	32,731,863	39,691,782	(6,959,919)
Loss from operations	(29,644,303)	(35,880,263)	6,235,960
Interest expense, net	3,891,250	5,625,833	(1,734,583)
Loss on extinguishment of debt	1,252,353	—	1,252,353
Change in fair value of warrant liability	(1,047,729)	(3,158,469)	2,110,740
Loss before income taxes	(33,740,177)	(38,347,627)	4,607,450
Income tax (benefit) expense	(3,648,216)	501,500	(4,149,716)
Net loss	$(30,091,961)	$(38,849,127)	$ 8,757,166

Collaboration Revenues

The following table sets forth a summary of revenue recognized from our collaboration and licensing agreements for the years ended September 30, 2018 and 2017:

	Year ended September 30,	
	2018	2017
IPCA Collaboration	$ 261,072	$ 261,072
Liomont Collaboration	236,641	236,641
Huahai Collaboration	714,848	714,848
BioLexis	1,874,999	2,598,958
	$3,087,560	$3,811,519

The following table summarizes the milestone payments and recognition of deferred revenues from our collaboration and licensing agreements during the years ended September 30, 2018 and 2017:

	Year ended September 30,	
	2018	2017
Milestone payments	$ —	$2,500,000
Recognition of deferred revenues	3,087,560	1,311,519
	$3,087,560	$3,811,519

Collaboration revenues decreased $0.7 million for the year ended September 30, 2018 compared to the year ended September 30, 2017 due to a $2.5 million decrease in milestone payments offset by a $1.8 million increase in the amortization of deferred revenue as compared to the prior year. There were no milestone payments in 2018 compared to $2.5 million payments received in 2017 under our joint development and licensing agreement with BioLexis. The increase in deferred revenue recognized was primarily due to a full year of amortization of collaboration revenue from BioLexis.

Research and Development Expenses

The following table summarizes our research and development expenses by functional area for the years ended September 30, 2018 and 2017:

	Year ended September 30,	
	2018	2017
Preclinical and clinical development	$ 7,403,015	$ 9,674,633
Settlement of clinical development contract	(3,228,613)	—
Compensation and related benefits	6,911,910	7,460,814
Stock-based compensation	19,450	1,001,022
Other research and development	7,398,273	5,673,280
Total research and development expenses	$18,504,035	$23,809,749

The following table summarizes our research and development expenses by compound for the years ended September 30, 2018 and 2017:

	Year ended September 30,	
	2018	2017
ONS-3010	$ 573,518	$ 5,195,278
ONS-1045	348,596	2,931,414
ONS-5010	6,315,937	—
Early-stage compounds	164,964	1,547,941
Settlement of clinical development contract	(3,228,613)	—
Personnel related and stock-based compensation	6,931,360	8,461,836
Other research and development	7,398,273	5,673,280
Total research and development expenses	$18,504,035	$23,809,749

Research and development expenses for the year ended September 30, 2018 decreased by $5.3 million compared to the year ended September 30, 2017 due to reductions in preclinical and clinical development spending, a related contract settlement and lower personnel related costs as we shifted our focus from our biosimilar product candidates ONS-3010 and ONS-1045 to our innovative therapeutic, ONS-5010. Overall pre-clinical and clinical research and development expenses decreased due to the deprioritization of our biosimilar product candidate development program in favor of the ONS-5010 program. This resulted in a reduction in expenses for ONS-3010, ONS-1045 and our early stage development program of $8.6 million, which was partially offset by $6.3 million in development costs incurred related to our ONS-5010 program as we prepared for the initiation of the ONS-5010 clinical programs in 2018. During the year ended September 30, 2018, we also terminated an agreement related to ONS-3010 and ONS-1045 and were able to favorably settle amounts previously owed under the contract resulting in a reduction to our research and development expenses of $3.2 million. Additionally, we experienced a reduction of $1.5 million in personnel related costs for the year ended September 30, 2018 due to a combination of lower salaries and benefits from reduced employee headcount in the current period as a result of attrition in late 2017 and lower stock-based compensation due to the related forfeitures of equity awards by departing employees and the completion of the vesting period of most pre-IPO equity grants earlier in fiscal 2018.

General and Administrative Expenses

The following table summarizes our general and administrative expenses by type for the years ended September 30, 2018 and 2017:

	Year ended September 30,	
	2018	2017
Professional fees	$ 3,155,658	$ 3,263,523
Compensation and related benefits	2,451,796	2,695,751
Stock-based compensation	1,966,420	7,570,635
Facilities, fees and other related costs	6,653,954	2,352,123
Total general and administrative expenses	$14,227,828	$15,882,033

General and administrative expenses for the year ended September 30, 2018 decreased by $1.7 million compared to the year ended September 30, 2017. The decrease was primarily a result of a decrease in stock-based compensation expenses of $5.6 million related to the completion of the vesting period of most pre-IPO equity grants earlier in fiscal 2018 and a $0.2 million decrease in compensation and related benefits. This was partially offset by an increase in facilities, fees and related costs primarily due to a $4.2 million lease termination charge incurred during the fourth quarter of fiscal 2018.

Interest Expense

Interest expense decreased by $1.7 million to $3.9 million for the year ended September 30, 2018 as compared to $5.6 million for the year ended September 30, 2017 primarily due a $2.4 million decrease in amortization of debt discount and interest expense on the senior secured notes issued December 2016 through May 2017 offset by a $0.8 million increase in interest expense from equipment loans, and capital lease obligations.

Change in Fair Value of Warrant Liability

During the year ended September 30, 2018, we recorded income of $1.0 million related to the decrease in the fair value of our common stock warrant liability as a result of the decrease in the price of our common stock during the period. During the year ended September 30, 2017, we recorded income of $3.2 million related to the decrease in the fair value of our common stock warrant liability as a result of the decrease in the price of our common stock during the period.

Liquidity and Capital Resources

We have not generated any revenue from product sales. Since inception, we have incurred net losses and negative cash flows from our operations. Through September 30, 2018, we have funded substantially all of our operations through the sale and issuance of $195.3 million net proceeds of our equity securities, debt securities and borrowings under debt facilities. We have also received an aggregate of $29.0 million pursuant to our collaboration and licensing agreements.

In September 2017, we closed on the initial sale of 32,628 shares of Series A Convertible to BioLexis for $3.3 million of cash, and entered into an investor rights agreement and joint development and licensing agreement. In October 2017, following receipt of stockholder approval, we issued an additional 217,372 shares of our Series A Convertible and warrants to acquire an aggregate of 16,750,000 shares of our common stock to BioLexis for $21.7 million of cash. All of the issued Series A Convertible was exchanged for Series A-1 Convertible in July 2018. We also converted $1.5 million aggregate principal amount of our senior secured notes into 1,500,000 shares of our Series B Convertible, all of which shares converted into an aggregate of 2,112,675 shares of our common stock in the quarter ended June 30, 2018.

In May 2018 and June 2018, we sold an aggregate of 12,754,766 shares of our common stock and warrants to acquire an aggregate of 20,512,820 shares of our common stock to BioLexis for aggregate cash proceeds of $15.0 million. The warrants have an exercise price of $0.975 per share and a term of eight years from their issuance date.

In November and December 2018, we issued 12,865,872 shares of the common stock to BioLexis in a placement arrangement for an aggregate cash proceeds of $12.0 million. We expect to receive an additional $8.0 in two equal tranches on January 3, 2019 and February 1, 2019, subject to customary closing conditions and meeting certain funding milestones. On November 5, 2018, we reached an agreement with the holders of our $13.5 million senior secured notes to extend the maturity of the senior secured notes, up to 12 months, or until December 22, 2019, in exchange for making several payments of principal and interest through August 31, 2019, subject to meeting additional capital raising commitments, with an initial payment of $2.2 million paid on November 7, 2018.

On November 30, 2018, we received approval from the New Jersey Economic Development Authority's Technology Business Tax Certificate Transfer Program to sell approximately $3.7 million of our unused New Jersey NOLs and R&D credits. We expect to receive approximately $3.4 million of proceeds from the sale of the New Jersey NOLs and R&D credits.

Our current cash resources of $1.7 million as of September 30, 2018, additional $20.0 million funding from our November BioLexis private placement and anticipated proceeds from the sale of New Jersey NOLs and R&D credits are expected to fund our operations into June 2019, excluding any unscheduled repayment of debt. Alternatively, we will be required to, among other things, make reductions in our workforce, scale back our plans and place certain activities on hold, discontinue our development programs, liquidate all or a portion of our assets, and/or seek protection under the provisions of the U.S. Bankruptcy Code.

As of September 30, 2018, we had an accumulated deficit of $216.3 million and a cash balance of $1.7 million. In addition, we have $13.5 million of senior secured notes whose maturity was extended on November 5, 2018 up to 12 months, or until December 22, 2019, in exchange for making several payments of principal and interest through August 31, 2019, subject to customary conditions and achieving certain funding milestones, with an initial payment of $2.2 million paid on November 7, 2018. We also have $4.6 million of unsecured indebtedness, $1.0 million of which is due on demand, and $3.6 million of which matures December 22, 2018. 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 or from receiving fees for contract development and manufacturing services that we plan to provide for other biopharmaceutical companies. 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. There can be no assurance that these future funding efforts will be successful.

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

Cash Flows

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

	Year ended September 30,	
	2018	2017
Net cash used in operating activities	$(33,039,523)	$(15,505,054)
Net cash used in investing activities	(2,781,125)	(292,086)
Net cash provided by financing activities	34,352,520	16,630,772
Net (decrease) increase in cash	$ (1,468,128)	$ 833,632

Operating Activities

During the year ended September 30, 2018, we used $33.0 million of cash in operating activities resulting primarily from our net loss of $30.1 million, as well as an increase in cash outflows from working capital changes primarily due to payments of our outstanding accounts payable and accrued expenses from September 30, 2017 as well as the prepayment of certain research and development expenses. During the year ended September 30, 2017, we used $15.5 million of cash in operating activities, primarily resulting from our net loss of $38.8 million. This use of cash was partially offset by changes in our operating assets and liabilities. Our cash flows are impacted by our underlying results from operations and related timing of cash receipts and cash disbursements.

Investing Activities

During the years ended September 30, 2018 and 2017, we used cash of $2.8 million and $0.3 million, respectively, in investing activities for the purchase of property and equipment.

Financing Activities

During the year ended September 30, 2018, net cash provided by financing activities was $34.4 million, primarily attributable to $20.6 million in net proceeds from our second closing of our Series A Convertible in October 2017 and $14.7 million in net proceeds from the sale of common stock and warrants to BioLexis in May and June 2018. We also had $0.9 million in debt payments.

During the year ended September 30, 2017, net cash provided by financing activities was $16.6 million, primarily attributable to $15.0 million in proceeds from the sale and issuance of our senior secured notes and warrants, $3.3 million from the initial sale and issuance of our Series A Convertible and $1.9 million from the sale and issuance of common stock and exercise of warrants, net of offering costs. These inflows were offset by $3.7 million in debt payments, $2.4 million of which was used to repay senior bank loans in December 2016.

Funding Requirements

We plan to focus in the near term on advancing ONS-5010 through clinical trials to support the filing of a BLA with the FDA to support the generation of commercial revenues. We anticipate we will incur net losses and negative cash flow from operations for the foreseeable future. We may not be able to complete the development and initiate commercialization of ONS-5010 if, among other things, our clinical trials are not successful or if the FDA does not approve our application 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, manufacturing and facility 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 product candidates.

We believe our existing cash as of September 30, 2018, together with the $20.0 million proceeds from the sale and issuance of our common stock to BioLexis in November 2018 and anticipated proceeds from the sale of New Jersey NOLs and R&D credits will provide adequate financial resources to fund our operations

into June 2019, excluding any unscheduled repayment of debt. 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 complete our planned ONS-5010 development program. 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, sale of the development and commercial rights to our drug product candidates 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-5010 or any other current or future 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 pharmaceutical 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 product candidates we pursue;
- the scope, progress, results and costs of researching and developing ONS-5010, and any other product candidates we pursue, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for ONS-5010, and any other product candidates we pursue;
- the cost of manufacturing ONS-5010, and any other product candidates we pursue, and any products 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 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, 2018 were as follows:

	Payments Due by Period				
	Total	Less Than 1 Year	1 – 3 Years	3 – 5 Years	More Than 5 Years
Operating lease commitments[1]	$ 562,500	$ 180,000	$ 382,500	$ —	$ —
Debt obligations[2]	19,942,487	15,587,149	4,355,338	—	—
Capital leases[3]	15,389,496	1,947,199	3,088,359	3,073,538	7,280,400
Lease termination obligation[4]	5,275,750	425,750	4,850,000	—	—
Total[5]	$41,170,233	$18,140,098	$12,676,197	$3,073,538	$7,280,400

(1) Operating lease commitments reflect our obligation to make payments in connection with a lease for our warehouse facility located in Monmouth, New Jersey. See Note 9 to our consolidated financial statements.

(2) Debt obligations reflect outstanding principal and interest obligations due to investors on senior secured debt, stockholder notes payable and institutions and equipment loans.

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

(4) Lease termination obligation reflects our obligation for future lease termination payments.

(5) 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 commercial license agreements 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. Under our third-party agreement for ONS-5010, we are obligated to pay briefly describe royalty obligation.

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

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

Revenue Recognition

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

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

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

sheet. We classify amounts expected to be recognized as revenue in the next twelve months following the balance sheet date as current liabilities. 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

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.

JOBS Act Accounting Election

The JOBS Act permits an “emerging growth company” such as our company 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 Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-09, *Revenue from Contracts with Customers*, or ASU 2014-09, and has subsequently issued a number of amendments to ASU 2014-09. The new standard, as amended, provides a single comprehensive model to be used in the accounting for revenue arising from contracts with customers and supersedes current revenue recognition guidance, including industry-specific guidance. The standard’s stated core principle is that an entity should 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. To achieve this core principle, ASU 2014-09 includes provisions within a five-step model that includes identifying the contract with a customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations, and recognizing revenue when, or as, an entity satisfies a performance obligation. In addition, the standard requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers.

The new standard will be effective for us beginning October 1, 2018 and permits two methods of adoption: the full retrospective method, which requires the standard to be applied to each prior period presented, or the modified retrospective method, which requires the cumulative effect of adoption to be recognized as an adjustment to opening retained earnings in the period of adoption. We will adopt the standard using the modified retrospective method.

Our arrangements fall under Accounting Standards Codification, or ASC, 808, *Collaborations*, and ASC 808 does not address recognition or measurement matters but prescribes that entities look to other GAAP by analogy, namely ASU 2014-09. As such, we have completed an analysis of existing contracts with our collaboration partners and assessed the differences in accounting for such contracts under ASU 2014-09 compared with current revenue accounting standards. Based on our review of current contracts, we expect an adjustment to increase accumulated deficit related to substantive milestones that were previously recognized under current revenue guidance in the period the milestone was achieved. ASU 2014-09 prescribes that those milestones are a form of variable consideration and should be recognized when the performance obligation is satisfied. Although we are still finalizing the impact to the consolidated financial statements as of October 1, 2018, we expect the adjustment to be an increase to accumulated deficit of approximately $3.6 million.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*, or ASC 842. The FASB issued subsequent amendments to the initial guidance in July 2018 with ASU 2018-10 and in August 2018 with ASU 2018-11. ASC 842 supersedes the current accounting for leases. The new standard requires lessees to record a right of use asset and a related liability for the rights and obligations associated with a lease, regardless of lease classification, and 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, however we do not plan to early adopt. The new standard must be adopted using either the modified retrospective approach, which requires application of the new guidance at the beginning of the earliest comparative period presented or the optional alternative approach, which requires application of the new guidance at the beginning of the standard's effective date. We have arrangements currently classified as operating leases, which will be recorded as a right of use asset and corresponding liability on the balance sheet and we are currently evaluating the impact these changes will have on our consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation — Stock Compensation* (Topic 718): *Scope of Modification Accounting*. This new ASU is intended provide clarity and reduce both the diversity in practice of and cost and complexity of applying the guidance in Topic 718, *Compensation — Stock Compensation*, to a change to the terms or conditions of a share-based payment award. This ASU provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. This ASU is effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted. This ASU is not expected to have a material impact on our consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation — Stock Compensation* (Topic 718): *Improvements to Nonemployee Share-Based Payment Accounting*, or Topic 718, which simplifies the accounting for nonemployee share-based payment transactions. The amendments specify that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The standard will be effective for fiscal years beginning after December 15, 2018, although early adoption is permitted (but no sooner than the adoption of Topic 606). This ASU is not expected to have a material impact on our consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement* (Topic 820): *Disclosure Framework — Changes to the Disclosure Requirements for Fair Value Measurement*, which removes and modifies some existing disclosure requirements and adds others. The ASU is effective for all entities for fiscal years beginning after December 15, 2019, including interim periods therein. Early adoption is permitted for any eliminated or modified disclosures upon issuance of this ASU. We are currently evaluating when to adopt this standard.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

Item 8. Consolidated Financial Statements and Supplementary Data

OUTLOOK THERAPEUTICS, INC.
ANNUAL REPORT ON FORM 10-K

INDEX TO AUDITED CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Outlook Therapeutics, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Outlook Therapeutics, Inc. and subsidiaries (the Company) as of September 30, 2018 and 2017, the related consolidated statements of operations, convertible preferred stock and stockholders' equity (deficit), and cash flows for the years then ended and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of September 30, 2018 and 2017, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that 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 and has a stockholders' deficit of $216.3 million, $13.5 million of senior secured notes that may become due in fiscal 2019 and $4.6 million of unsecured indebtedness, $1.0 million of which is due on demand, and $3.6 million of which matures December 22, 2018, that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard 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.

Basis for Opinion

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 are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2015

Philadelphia, Pennsylvania
December 18, 2018

Outlook Therapeutics, Inc.

Consolidated Balance Sheets

	September 30,	
	2018	**2017**
Assets		
Current assets:		
Cash	$ 1,717,391	$ 3,185,519
Prepaid and other current assets	1,585,089	719,087
Total current assets	3,302,480	3,904,606
Property and equipment, net	18,489,976	16,088,902
Other assets	491,039	740,362
Total assets	$ 22,283,495	$ 20,733,870
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Senior secured notes	$ 13,179,449	$ —
Current portion of long-term debt	66,480	52,600
Current portion of capital lease obligations	520,794	341,120
Stockholder notes	4,612,500	4,612,500
Accounts payable	3,609,607	10,954,358
Accrued expenses	6,458,471	7,337,469
Income taxes payable	1,856,129	2,352,129
Deferred revenue	1,738,603	3,087,561
Total current liabilities	32,042,033	28,737,737
Senior secured notes	—	13,231,700
Long-term debt	98,487	151,110
Capital lease obligations	3,453,256	28,067
Warrant liability	1,227,225	2,274,954
Deferred revenue	2,758,262	4,466,865
Other liabilities	3,514,738	2,569,971
Total liabilities	43,094,001	51,460,404
Commitments (Note 9)		
Convertible preferred stock:		
Series A convertible preferred stock, par value $0.01 per share: 1,000,000 shares authorized, no shares issued and outstanding at September 30, 2018 and 32,628 shares issued and outstanding at September 30, 2017	—	2,924,441
Series A-1 convertible preferred stock, par value $100.00 per share: 200,000 shares authorized, 60,203 shares issued and outstanding at September 30, 2018 and no shares issued and outstanding at September 30, 2017	4,734,416	—
Total convertible preferred stock	4,734,416	2,924,441
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; 72,220,351 and 24,933,944 shares issued and outstanding at September 30, 2018 and 2017, respectively	722,204	249,339
Additional paid-in capital	190,040,237	152,315,088
Accumulated deficit	(216,307,363)	(186,215,402)
Total stockholders' equity (deficit)	(25,544,922)	(33,650,975)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 22,283,495	$ 20,733,870

See accompanying notes to consolidated financial statements.

Outlook Therapeutics, Inc.

Consolidated Statements of Operations

	Year Ended September 30,	
	2018	2017
Collaboration revenues	$ 3,087,560	$ 3,811,519
Operating expenses:		
Research and development	18,504,035	23,809,749
General and administrative	14,227,828	15,882,033
	32,731,863	39,691,782
Loss from operations	(29,644,303)	(35,880,263)
Interest expense, net	3,891,250	5,625,833
Loss on extinguishment of debt	1,252,353	—
Change in fair value of warrant liability	(1,047,729)	(3,158,469)
Loss before income taxes	(33,740,177)	(38,347,627)
Income tax (benefit) expense	(3,648,216)	501,500
Net loss	(30,091,961)	(38,849,127)
Recognition of beneficial conversion feature upon issuance of Series A and A-1 convertible preferred stock	(16,022,963)	(1,176,743)
Series A and A-1 convertible preferred stock dividends and related settlement	(1,903,930)	—
Net loss attributable to common stockholders	$(48,018,854)	$(40,025,870)
Per share information:		
Net loss per share of common stock, basic	$ (1.22)	$ (1.67)
Net loss per share of common stock, diluted	$ (1.22)	$ (1.80)
Weighted average shares outstanding, basic	39,457,664	24,022,371
Weighted average shares outstanding, diluted	39,457,664	24,041,789

See accompanying notes to consolidated financial statements.

Outlook Therapeutics, Inc.

Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

	Convertible Preferred Stock				Stockholders' Equity (Deficit)						
	Series A		Series A-1		Series B Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at October 1, 2016	—	$ —	—	$ —	—	$ —	22,802,778	$228,028	$141,965,342	$(147,366,275)	$ (5,172,905)
Proceeds from exercise of common stock warrants	—	—	—	—	—	—	787,018	7,869	305,616	—	313,485
Issuance of vested restricted stock units	—	—	—	—	—	—	483,913	4,840	(4,840)	—	—
Issuance of common stock in connection with equity facility	—	—	—	—	—	—	122,418	1,224	(1,224)	—	—
Sale of common stock, net of issuance costs	—	—	—	—	—	—	737,817	7,378	1,495,749	—	1,503,127
Sale of Series A convertible preferred, net of costs	32,628	2,924,441	—	—	—	—	—	—	—	—	—
Series A convertible preferred stock dividends	—	—	—	—	—	—	—	—	(16,985)	—	(16,985)
Stock-based compensation expense	—	—	—	—	—	—	—	—	8,571,430	—	8,571,430
Net loss	—	—	—	—	—	—	—	—	—	(38,849,127)	(38,849,127)
Balance at September 30, 2017	32,628	2,924,441	—	—	—	—	24,933,944	249,339	152,315,088	(186,215,402)	(33,650,975)
Proceeds from exercise of common stock warrants	—	—	—	—	—	—	3,460	35	(35)	—	—
Issuance of vested restricted stock units	—	—	—	—	—	—	842,889	8,429	(8,429)	—	—
Private placement sale of common stock and common stock warrants, net of costs	—	—	—	—	—	—	12,754,766	127,548	14,567,572	—	14,695,120
Sale of Series A convertible preferred stock and common stock warrants, net of costs	217,372	14,265,861	—	—	—	—	—	—	6,382,181	—	6,382,181
Series A convertible preferred stock dividends and related settlement	17,571	1,757,093	—	—	—	—	—	—	(1,740,108)	—	(1,740,108)
Conversion of Series A convertible preferred stock into common stock	(208,836)	(14,359,816)	—	—	—	—	31,572,617	315,726	14,044,090	—	14,359,816
Conversion of Series A convertible preferred stock into Series A-1 convertible preferred stock	(58,735)	(4,587,579)	58,735	4,587,579	—	—	—	—	—	—	—
Series A-1 convertible preferred stock dividends and related settlement	—	—	1,468	146,837	—	—	—	—	(146,837)	—	(146,837)
Conversion of senior secured notes into Series B convertible preferred stock	—	—	—	—	1,500,000	2,661,972	—	—	—	—	2,661,972
Conversion of Series B convertible preferred stock into common stock	—	—	—	—	(1,500,000)	(2,661,972)	2,112,675	21,127	2,640,845	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	1,985,870	—	1,985,870
Net loss	—	—	—	—	—	—	—	—	—	(30,091,961)	(30,091,961)
Balance at September 30, 2018	—	$ —	60,203	$4,734,416	—	$ —	72,220,351	$722,204	$190,040,237	$(216,307,363)	$(25,544,922)

See accompanying notes to consolidated financial statements.

Outlook Therapeutics, Inc.

Consolidated Statements of Cash Flows

	Year Ended September 30,	
	2018	**2017**
OPERATING ACTIVITIES		
Net loss	$(30,091,961)	$(38,849,127)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,054,352	2,692,100
Loss on extinguishment of debt	1,252,353	—
Non-cash interest expense	1,315,861	4,014,633
Stock-based compensation	1,985,870	8,571,430
Change in fair value of warrant liability	(1,047,729)	(3,158,469)
Loss on disposal of fixed assets	—	61,867
Loss on lease termination	4,173,682	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,419,551)	2,607,520
Other assets	1,554	112,439
Accounts payable	(6,714,137)	5,727,136
Accrued expenses	(1,664,843)	893,526
Income taxes payable	(496,000)	497,500
Deferred revenue	(3,057,561)	1,188,481
Other liabilities	(331,413)	135,910
Net cash used in operating activities	(33,039,523)	(15,505,054)
INVESTING ACTIVITIES		
Purchase of property and equipment	(2,781,125)	(292,086)
Net cash used in investing activities	(2,781,125)	(292,086)
FINANCING ACTIVITIES		
Proceeds from the sale of common stock, net of offering costs	14,695,120	1,607,396
Payment of debt issuance costs	—	(40,000)
Proceeds from issuance of Series A convertible preferred stock	21,737,200	3,262,800
Proceeds from the sale of senior secured notes and detachable warrants	—	15,000,000
Proceeds from exercise of common stock warrants	—	253,289
Change in restricted cash	—	216,086
Payments of capital leases obligations	(862,906)	(991,028)
Repayment of debt	(127,736)	(2,677,771)
Payment of financing costs	(1,089,158)	—
Net cash provided by financing activities	34,352,520	16,630,772
Net (decrease) increase in cash	(1,468,128)	833,632
Cash at beginning of year	3,185,519	2,351,887
Cash at end of year	$ 1,717,391	$ 3,185,519
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 109,979	$ 1,339,644
Cash paid for income taxes	$ —	$ 1,500
Supplemental schedule of noncash investing activities:		
Purchases of property and equipment in accounts payable and accrued expenses	$ 816,501	$ 68,507
Supplemental schedule of noncash financing activities:		
Issuance of Series B convertible preferred stock upon conversion of senior secured notes, net of unamortized debt discount	$ 1,409,619	$ —
Issuance of capital lease obligations and debt in connection with purchase of property and equipment	$ 4,444,095	$ 62,230
Series A and A-1 convertible preferred stock dividends	$ 1,886,945	$ 16,985
Settlement of Series A and A-1 convertible preferred stock dividends upon issuance of Series A and A-1 convertible preferred stock	$ 1,903,930	$ —
Deferred offering costs and common stock issuance costs in accounts payable and accrued expenses	$ —	$ 630,717

See accompanying notes to consolidated financial statements.

OUTLOOK THERAPEUTICS, INC.

Notes to Consolidated Financial Statements

1. Organization and Operations

Description of the Business

Oncobiologics, Inc. was incorporated in New Jersey on January 5, 2010, started operations in July 2011, reincorporated in Delaware by merging with an into a Delaware corporation in October 2015, and in November 2018, changed its name to Outlook Therapeutics, Inc. ("Outlook" or the "Company"). The Company is a late clinical-stage biopharmaceutical company focused on developing and commercializing ONS-5010, a complex monoclonal antibody ("mAb") therapeutic for various ophthalmic indications. The Company is based in Cranbury, New Jersey.

2. Liquidity

The Company has incurred substantial losses and negative cash flows from operations since its inception and has an accumulated deficit of $216.3 million as of September 30, 2018. The Company has substantial indebtedness that includes $13.5 million of senior secured notes that may become due in fiscal 2019 and $4.6 million of unsecured indebtedness, $1.0 million of which is due on demand, and $3.6 million of which matures December 22, 2018. There can be no assurance that the holders of the stockholder notes will not exercise their right to demand repayment. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

On November 5, 2018, the Company entered into a purchase agreement with BioLexis Pte. Ltd. ("BioLexis"), formerly known as GMS Tenshi Holdings Pte. Limited, a Singapore private limited company, and the Company's controlling stockholder and strategic partner, providing for the private placement of $20.0 million of shares of its common stock at $0.9327 per share. The closing of the sale of the first two tranches of this private placement for an aggregate of 12,865,872 shares of the Company's common stock for aggregate cash proceeds of $12.0 million occurred in November and December 2018. The remaining $8.0 is expected to be funded in two equal tranches on January 3, 2019 and February 1, 2019, subject to customary conditions and achieving certain funding milestones as set forth in the purchase agreement. The Company intends to use the net proceeds from the private placement primarily for clinical trials for its lead product candidate, ONS-5010, and for working capital and general corporate purposes, including the agreed repayments on the senior secured notes.

Also on November 5, 2018, the Company reached an agreement with the holders of its $13.5 million senior secured notes to extend the maturity of the senior secured notes, up to 12 months, or until December 22, 2019, in exchange for making several payments of principal and interest through August 31, 2019, subject to meeting additional capital raising commitments, with an initial payment of $2.2 million paid on November 7, 2018. As of September 30, 2018, the senior secured notes remain classified as a current liability because raising additional capital is outside the Company's control. In addition, the Company agreed to make the senior secured notes convertible into common stock at a price of $1.11924 per share (120% of the price per share paid by BioLexis under the purchase agreement) and reduced the exercise price of the warrants held by such holders to $1.50 and extended the expiration of these warrants by three years.

On November 30, 2018, the Company received approval from the New Jersey Economic Development Authority's Technology Business Tax Certificate Transfer Program to sell approximately $3.7 million of its unused New Jersey net operating losses ("NOLs") and research and development tax credits ("R&D credits"). The Company expects to receive approximately $3.4 million of proceeds from the sale of the New Jersey NOLs and R&D credits.

Management believes that the Company's existing cash as of September 30, 2018, additional $20.0 million funding from the November BioLexis private placement and anticipated proceeds from the sale of New Jersey NOLs and R&D credits will be sufficient to fund its operations into June 2019, excluding any

unscheduled repayment of debt. Substantial additional financing will be needed by the Company to fund its operations in the future 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 partners, licensing and/or marketing arrangements with pharmaceutical companies, sale of its development stage product candidates to third parties and public or private 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 accompanying consolidated financial statements include the accounts of the Company and Outlook Therapeutics Pty Ltd, its wholly-owned subsidiary incorporated in Australia (the "Subsidiary"). All intercompany accounts and transactions have been eliminated in consolidation. The Company has determined the functional currency of the Subsidiary to be the U.S. dollar. The Company translates assets and liabilities of its foreign operations at exchange rates in effect at the balance sheet date. The Company records remeasurement gains and losses on monetary assets and liabilities, such as incentive and tax receivables and accounts payables, which are not in the functional currency of the operation. These remeasurement gains and losses are recorded in the consolidated statement of operations as they occur.

Use of estimates

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

Fair value of financial instruments

At September 30, 2018 and 2017, the Company's financial instruments included accounts payable, accrued expenses, equipment loans, stockholder notes and senior secured notes. The carrying amount of accounts payable and accrued expenses approximates fair value due to the short-term maturities of these instruments.

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 for the years ended September 30, 2018 and 2017.

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, on a straight-line basis over the requisite service period, which is generally the vesting period of the respective award.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option pricing model, which is described more fully in Note 12. 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.

Revenue recognition

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

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

The Company typically receives upfront, nonrefundable payments when licensing its intellectual property. For intellectual property licenses that do not have stand-alone value from the other deliverables to be provided, the upfront fee is deferred and revenue is recognized over the contractual or estimated performance period, which is typically the term of the research and development obligations. The periods over which revenue is recognized are subject to estimates by management and may change over the course of the research and development agreement. Such a change could have a material impact on the amount of

revenue the Company records in future periods. Payments or reimbursements resulting from the Company's research and development efforts are recognized as the services are performed. Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue.

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

Incentive and tax receivables

The Subsidiary is eligible to participate in an Australian research and development tax incentive program. As part of this program, the Subsidiary is eligible to receive a cash refund from the Australian Taxation Office for a percentage of the research and development costs expended by the Subsidiary in Australia. The cash refund is available to eligible companies with annual aggregate revenues of less than $20.0 million (Australian) during the reimbursable period. The Company's estimate of the amount of cash refund it expects to receive related to the Australian research and development tax incentive program is included in prepaid and other current assets in the accompanying consolidated balance sheet. As of September 30, 2018, the Company's estimate of the amount of cash refund it expects to receive in 2019 for 2018 eligible spending as part of this incentive program was $0.3 million.

In addition, the Subsidiary incurs Goods and Services Tax ("GST") on services provided by Australian vendors. As an Australian entity, the Subsidiary is entitled to a refund of the GST paid. The Company's estimate of the amount of cash refund it expects to receive related to GST incurred is included in prepaid and other current assets in the accompanying consolidated balance sheet. As of September 30, 2018, prepaid and other current assets included $0.1 million for refundable GST on expenses incurred with Australian vendors.

Research and development

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

Upfront milestone payments made to third parties who perform research and development services on the Company's behalf are expensed as services are rendered. Costs incurred in obtaining technology licenses are charged to research and development expense as acquired in-process research and development if the technology licensed has not reached technological feasibility and has no alternative future use. Research and development expenses are recorded net of expected refunds of eligible research and development costs paid to Australian vendors pursuant to the Australian research and development tax incentive program and GST incurred on services provided by Australian vendors. During the year ended September 30, 2018, the Company recorded $0.3 million in its consolidated results of operations related to the cash refund it expects to receive from the Australian research and development tax incentive program.

OUTLOOK THERAPEUTICS, INC.

Notes to Consolidated Financial Statements

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.

Net loss per share

Basic net loss per common share is determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period.

For purposes of calculating diluted net loss per common share, the denominator includes both the weighted-average common shares outstanding and the number of common stock equivalents if the inclusion of such common stock equivalents would be dilutive. Dilutive common stock equivalents potentially include warrants, stock options and non-vested restricted stock awards using the treasury stock method. The diluted net loss per common share calculation is further affected by an add-back of change in fair value of warrant liability to the numerator under the assumption that the change in fair value of warrant liability would not have been incurred if the warrants had been converted into common stock.

The following table sets forth the computation of basic earnings per share and diluted earnings per share:

	Year Ended September 30,	
	2018	2017
Basic Earnings Per Share		
Net loss attributable to common stockholders	$(48,018,854)	$(40,025,870)
Common stock outstanding (weighted average)	39,457,664	24,022,371
Basic net loss per share	$ (1.22)	$ (1.67)
Diluted Earnings Per Share		
Net loss attributable to common stockholders	$(48,018,854)	$(40,025,870)
Add change in fair value of warrant liability	—	(3,158,469)
Diluted net loss	(48,018,854)	(43,184,339)
Common stock outstanding (weighted average)	39,457,664	24,022,371
Add shares from dilutive warrants	—	19,418
Common stock equivalents	39,457,664	24,041,789
Diluted net loss per share	$ (1.22)	$ (1.80)

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding as of September 30, 2018 and 2017, as they would be antidilutive:

	As of September 30,	
	2018	2017
Series A-1 convertible preferred stock	9,101,717	—
Performance-based stock units	129,095	175,530
Restricted stock units	61,109	939,879
Stock options	1,557,145	—
Common stock warrants	45,292,532	7,484,504

OUTLOOK THERAPEUTICS, INC.

Notes to Consolidated Financial Statements

Recently issued accounting pronouncements

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09) and has subsequently issued a number of amendments to ASU 2014-09. The new standard, as amended, provides a single comprehensive model to be used in the accounting for revenue arising from contracts with customers and supersedes current revenue recognition guidance, including industry-specific guidance. The standard's stated core principle is that an entity should 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. To achieve this core principle, ASU 2014-09 includes provisions within a five-step model that includes identifying the contract with a customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations, and recognizing revenue when, or as, an entity satisfies a performance obligation. In addition, the standard requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers.

The new standard will be effective for the Company beginning October 1, 2018 and permits two methods of adoption: the full retrospective method, which requires the standard to be applied to each prior period presented, or the modified retrospective method, which requires the cumulative effect of adoption to be recognized as an adjustment to opening retained earnings in the period of adoption. The Company will adopt the standard using the modified retrospective method.

The Company's arrangements fall under ASC 808, *Collaborations*, ("ASC 808"). ASC 808 does not address recognition or measurement matters but prescribes that entities look to other GAAP by analogy, namely ASU 2014-09. As such, the Company has completed an analysis of existing contracts with the Company's collaboration partners and assessed the differences in accounting for such contracts under ASU 2014-09 compared with current revenue accounting standards. Based on the review of current contracts, the Company expects an adjustment to increase accumulated deficit related to substantive milestones that were previously recognized under current revenue guidance in the period the milestone was achieved. ASU 2014-09 prescribes that those milestones are a form of variable consideration and should be recognized when the performance obligation is satisfied. Although the Company is still finalizing the impact to the consolidated financial statements as of October 1, 2018, the Company expects the adjustment to be an increase to accumulated deficit of approximately $3.6 million.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* ("ASC 842"). The FASB issued subsequent amendments to the initial guidance in July 2018 with ASU 2018-10 and in August 2018 with ASU 2018-11. ASC 842 supersedes the current accounting for leases. The new standard requires lessees to record a right of use asset and a related liability for the rights and obligations associated with a lease, regardless of lease classification, and 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, however the Company does not plan to early adopt. The new standard must be adopted using either the modified retrospective approach, which requires application of the new guidance at the beginning of the earliest comparative period presented or the optional alternative approach, which requires application of the new guidance at the beginning of the standard's effective date. The Company has arrangements currently classified as operating leases which will be recorded as a right of use asset and corresponding liability on the balance sheet and is currently evaluating the impact these changes will have on the consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation — Stock Compensation* (Topic 718): *Scope of Modification Accounting*. This new ASU is intended provide clarity and reduce both the diversity in practice of and cost and complexity of applying the guidance in Topic 718, *Compensation — Stock Compensation*, to a change to the terms or conditions of a share-based payment award. This ASU provides guidance about which changes to the terms or conditions of a share-based payment award require an entity

to apply modification accounting in Topic 718. This ASU is effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted. This ASU is not expected to have a material impact on the Company's consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation — Stock Compensation* (Topic 718): *Improvements to Nonemployee Share-Based Payment Accounting* ("Topic 718"), which simplifies the accounting for nonemployee share-based payment transactions. The amendments specify that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The standard will be effective for fiscal years beginning after December 15, 2018, although early adoption is permitted (but no sooner than the adoption of Topic 606). This ASU is not expected to have a material impact on the Company's consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement* (Topic 820): *Disclosure Framework — Changes to the Disclosure Requirements for Fair Value Measurement*, which removes and modifies some existing disclosure requirements and adds others. The ASU is effective for all entities for fiscal years beginning after December 15, 2019, including interim periods therein. Early adoption is permitted for any eliminated or modified disclosures upon issuance of this ASU. The Company is currently evaluating when to adopt this standard.

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.

OUTLOOK THERAPEUTICS, INC.

Notes to Consolidated Financial Statements

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

	September 30, 2018		
	(Level 1)	(Level 2)	(Level 3)
Liabilities			
Warrant liability	$ —	$ —	$1,227,225

	September 30, 2017		
	(Level 1)	(Level 2)	(Level 3)
Liabilities			
Warrant liability	$ —	$ —	$2,274,954

The table presented below is a summary of changes in the fair value of the Company's Level 3 valuation for the warrant liability for the years ended September 30, 2018 and 2017:

Balance at October 1, 2016	$ —
Issuance of warrants	5,493,619
Exercise of warrants	(60,196)
Change in fair value	(3,158,469)
Balance at September 30, 2017	2,274,954
Change in fair value	(1,047,729)
Balance at September 30, 2018	$ 1,227,225

The Senior Note Warrants issued in connection with the Notes (see Note 8) are classified as liabilities on the accompanying consolidated balance sheet as the Senior Note Warrants include cash settlement features at the option of the holders under certain circumstances. The warrant liability is revalued each reporting period with the change in fair value recorded in the accompanying consolidated statements of operations until the warrants are exercised or expire. The fair value of the warrant liability is estimated using the Black-Scholes option pricing model using the following assumptions:

	September 30,	
	2018	2017
Risk-free interest rate	2.90%	1.77%
Remaining contractual life of warrant	3.39 years	4.67 years
Expected volatility	82%	82%
Annual dividend yield	0%	0%
Fair value of common stock	$0.98 per share	$1.37 per share

OUTLOOK THERAPEUTICS, INC.

Notes to Consolidated Financial Statements

5. Property and Equipment

Property and equipment, net, consists of:

	September 30,	
	2018	2017
Laboratory equipment	$ 14,333,624	$11,574,473
Leasehold improvements	10,095,100	10,032,640
Computer software and hardware	483,807	472,054
Land and building	3,000,000	—
Construction in progress	2,276,737	2,654,675
	30,189,268	24,733,842
Less: accumulated depreciation and amortization	(11,699,292)	(8,644,940)
	$ 18,489,976	$16,088,902

Depreciation and amortization expense for the years ended September 30, 2018 and 2017 was $3,054,352 and $2,692,100, respectively.

At September 30, 2018, $7,953,856 represents laboratory equipment under capital leases and the Company's corporate office that is classified as a capital lease. At September 30, 2017, $3,692,913 represents laboratory equipment under capital leases. At September 30, 2018 and 2017, $1,619,741 and $1,061,901, respectively, of accumulated amortization related to capital leases. The term of the equipment leases are between 12 and 36 months and qualify as capital leases. The equipment leases bear interest between 4.0% and 19.4% and the effective interest rate on the corporate office lease is 43.9%.

In February 2018, the Company entered into a sixth amendment to its lease for its corporate offices. Pursuant to the amended terms, the Company is now occupying 100% of the corporate facility and has extended the term through February 2028 with two five year renewal options. As a result of this amendment, the lease is now classified as a capital lease. The Company initially recorded the lease obligation and corresponding building asset based on its estimated fair value of $3,000,000. The building is being depreciated over the lease term. Future lease payments will be allocated to interest expense and a pay-down of the lease obligation.

The following is a schedule of future minimum lease payments under capital leases as of September 30, 2018 for the years ending September 30:

2019	$ 1,947,199
2020	1,594,917
2021	1,493,442
2022	1,522,660
2023	1,550,878
Thereafter	7,280,400
	15,389,496
Less: amounts representing interest	(11,415,446)
Less: current portion	(520,794)
Capital lease obligations, excluding current portion	$ 3,453,256

OUTLOOK THERAPEUTICS, INC.

Notes to Consolidated Financial Statements

6. Accrued Expenses

Accrued expenses consists of:

	September 30,	
	2018	2017
Compensation	$2,231,122	$3,688,592
Severance and related costs	396,138	—
Lease termination obligation	395,071	—
Research and development	1,065,169	1,637,657
Interest payable	1,991,044	1,047,122
Professional fees	313,585	521,973
Director fees	59,122	376,695
Other accrued expenses	7,220	65,430
	$6,458,471	$7,337,469

7. Stockholder Notes

	September 30,	
	2018	2017
Restricted stock repurchase notes	$ 800,000	$ 800,000
Common stock repurchase note	2,812,500	2,812,500
Working capital notes	1,000,000	1,000,000
	4,612,500	4,612,500
Less: current portion	(4,612,500)	(4,612,500)
	$ —	$ —

The Company previously repurchased shares of its restricted stock in exchange for notes which bear interest at rates ranging from 0% to 4% per annum.

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

The Company also 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 former chief executive officer. Of the $4.6 million outstanding under these notes, $1.0 million is due on demand, and $3.6 million matures December 22, 2018.

During the years ended September 30, 2018 and 2017, the Company recognized interest expense related to the stockholder notes of $300,000 and $320,000, respectively.

8. Debt

Senior secured notes

	September 30,	
	2018	2017
Senior secured notes	$13,500,000	$15,000,000
Unamortized debt discount	(320,551)	(1,768,300)
	$13,179,449	$13,231,700

OUTLOOK THERAPEUTICS, INC.

Notes to Consolidated Financial Statements

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. The unsecured notes were exchanged for senior secured promissory notes in December 2016 as described below.

In December 2016, the Company entered into a Note and Warrant Purchase Agreement (the "NWPA") 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 "Senior Note 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 Senior Note Warrants in December 2016, issuing $8.35 million aggregate principal amount of Notes and Senior Note Warrants to acquire up to 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 proceeds were first allocated to the warrant liability based on an initial fair value of $3.3 million with a corresponding amount recorded as a debt discount. In addition, the Company incurred $40,000 of debt issuance costs that have been recorded as a debt discount. The debt discount is being amortized into interest expense over the term of the Notes using the effective interest method.

In January 2017, the Company issued additional Notes and Senior Note Warrants for $1.65 million of cash.

In April 2017, the Company entered into the First Amendment to the NWPA (the "Amendment") with the required holders of its Notes named therein, to amend certain terms of the NWPA. The primary purpose of the Amendment was to increase the aggregate principal amount of Notes that may be sold under the NWPA from $10.0 million to $15.0 million, and permit the issuance of additional Senior Note Warrants to acquire an aggregate 1,665,000 shares of the Company's common stock and extend the time that the Company may issue additional Notes and Senior Note Warrants without approval of the holders of existing notes from 90 days to 180 days. Notes sold under the Amendment bear interest at a rate of 5% per annum and were due to mature in December 2017. In September 2017, in connection with the Private Placement, the maturity date of the Notes was extended by one year to December 2018.

During April and May 2017, the Company issued an additional $5.0 million of Notes and Senior Note Warrants to acquire an aggregate of 1,304,500 shares of its common stock. The proceeds were first allocated to the warrant liability based on an initial fair value of $1.4 million with a corresponding amount recorded as a debt discount. In addition, the Company incurred $3,635 of debt issuance costs that have been recorded as a debt discount. The debt discount is being amortized into interest expense over the term of the Notes using effective interest rate method.

Under the NWPA and the Amendment, 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 NWPA, the Notes include customary events of default. In connection with the closing of the initial sale of the Notes and Senior Note 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, as well as a Registration Rights Agreement dated February 3, 2017.

In September 2017, the Company entered into a purchase and exchange agreement (the "Exchange Agreement") with two existing investors and holders of its senior secured notes (the "Noteholders"), pursuant to which the Noteholders exchanged $1.5 million aggregate principal amount of senior secured notes for 1,500,000 shares of Series B convertible preferred stock ("Series B Convertible") and $41,507 of accrued interest on such exchanged senior secured notes in October 2017. The Company recognized a loss on extinguishment of $1,252,353 in connection with the exchange and represents the excess fair value of the Series B Convertible issued over the net carrying amount of the debt and accrued interest. The 1,500,000 shares of Series B Convertible were converted into an aggregate of 2,112,675 shares of common stock in June 2018 and there are no longer any shares of Series B Convertible issued and outstanding.

In connection with the November 2018 purchase agreement with BioLexis providing for the private placement of $20.0 million of shares of the Company's common stock, the Company reached an agreement with the holders of the Notes to further extend the maturity of the Notes up to 12 months, or until December 22, 2019, in exchange for making several payments of principal and interest through August 31, 2019, subject to meeting additional capital raising commitments, of which $2.2 million was paid in November 2018 and $1.17 million was paid in December 2018. At September 30, 2018, the Notes remained classified as a current liability because raising additional capital is outside the Company's control. In addition, the Company agreed to make the Notes convertible into common stock at a price of $1.11924 per share and reduced the exercise price of the Senior Note Warrants to $1.50 and extended the expiration of the Senior Note Warrants by three years.

Interest expense on the Notes for the years ended September 30, 2018 and 2017 was $1,997,231 and $4,441,886, respectively.

Other indebtedness

In addition to the Notes, the Company has other outstanding debt consisting of equipment loans and unsecured notes. Refer to Note 7 for additional information on unsecured notes.

	September 30,	
	2018	2017
Equipment loans	$164,967	$203,710
Less: current portion	(66,480)	(52,600)
Long-term debt	$ 98,487	$151,110

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 collateralized by the related equipment purchased and an unconditional personal guarantee by the founding stockholder and former chief executive officer.

Interest expense on the above loans for the years ended September 30, 2018 and 2017 was $27,660 and $35,608, respectively.

Future maturities of other indebtedness at September 30, 2018 are as follows for the years ending September 30:

2019	$ 66,480
2020	48,204
2021	50,283
	$164,967

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 Laboratories Liomont, S.A. de C.V. ("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 the Company's bankruptcy, insolvency or similar circumstances.

MTTR — Strategic partnership agreement (ONS-5010)

In February 2018, the Company entered into a strategic partnership agreement with MTTR, LLC, or MTTR, to advise on regulatory, clinical and commercial strategy and assist in obtaining approval of ONS-5010, the Company's bevacizumab therapeutic product candidate for ophthalmic indications. Under the terms of the agreement, the Company currently pays MTTR a $58,333 monthly consulting fee. Beginning January 2019, the monthly fee increases to $105,208 per month, and then, after launch of ONS-5010 in the United States, to $170,833 per month (the amount of which is reduced by 50% in the event net sales of ONS-5010 are below a certain threshold million per year). The Company also agreed to pay MTTR a tiered percentage of the net profits of ONS-5010 ranging in the low- to mid-teens, with the ability to credit monthly fees paid to MTTR. In March 2018, the Company amended the MTTR agreement and agreed to pay a one-time fee of $268,553 to MTTR by September 2020 if certain regulatory milestones are achieved earlier than anticipated. For the year ended September 30, 2018, MTTR earned an aggregate of $602,629, which includes monthly consulting fees, expense reimbursement and an initial upfront payment of $75,000.

Technology license

The Company entered into a technology license agreement with Selexis that will require milestone payments of $353,600 (based on an exchange rate on September 30, 2018 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 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 was due to expire in March 2026. Due to the Company's involvement in the construction required to complete the leased facility, the lease was accounted for as a financing arrangement to which the Company recorded the fair value of the asset in property and equipment and a corresponding liability was recorded and amortized over the lease term down to the expected asset value at the end of the lease. During the years ended September 30, 2018 and 2017, the Company recorded interest expense of $390,793 and $421,028, respectively.

OUTLOOK THERAPEUTICS, INC.

Notes to Consolidated Financial Statements

In August 2018, the Company entered into a lease termination agreement effective September 1, 2018, to terminate the lease for office and laboratory space in Cranbury, New Jersey. In consideration for the termination of the lease, the Company agreed to make payments to the landlord totaling up to $5.8 million, which includes (i) $287,615 upon execution of the termination agreement, (ii) $50,000 per month for up to 30 months, commencing September 1, 2018, and (iii) a $4.0 million payment, in any event, on or before February 1, 2021. The Company and landlord agreed that the $174,250 security deposit will be used to pay the 7th, 8th, 9th and a portion of the 10th monthly payments. The Company may pay the final $4.0 million payment at any time, whereupon the Company's obligation to make the remaining monthly payments terminates.

In connection with the lease termination, the Company recorded a $4.2 million liability at September 1, 2018, the cease-use date, that represents the present value of the future termination payments. The Company derecognized the assets and liabilities associated with the financing lease and recorded a charge of $4.2 million to general and administrative expense. At September 30, 2018, the current portion of the lease termination obligation of $395,071 is included in accrued expenses and $3,455,010 is included in other liabilities on the consolidated balance sheets. A rollforward of the charges incurred to general and administrative expense for the year ended September 30, 2018 is as follows:

	Balance October 1, 2017	Expensed/ Accrued Expense	Cash Payments	Non-Cash Items	Balance September 30, 2018
Lease termination payments	$ —	$ 4,187,696	$(337,615)	$ —	$3,850,081
Derecognition of assets and liabilities	—	(14,014)	—	14.014	—
	$ —	$ 4,173,682	$(337,615)	$ 14,014	$3,850,081

Rent expense under operating leases was $854,487 and $1,352,708 for the years ended September 30, 2018 and 2017, 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 payments under noncancelable operating leases at September 30, 2018 are as follows for the years ending September 30:

	Operating Leases
2019	$180,000
2020	187,500
2021	195,000
	$562,500

Employee 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, 2018 and 2017, the expense relating to the matching contribution was $175,693 and $209,782, respectively.

10. Stockholders' Equity (Deficit)

Lincoln Park Capital, LLC transaction

In March 2017, the Company entered into a Purchase Agreement and a registration rights agreement with an accredited investor, Lincoln Park Capital, LLC ("Lincoln Park"), providing for the purchase of up to $15.4 million of the Company's common stock over the 30-month term of the purchase agreement.

In connection with the purchase agreement, the Company issued 113,205 shares of its common stock as initial commitment shares, to Lincoln Park and the Company will issue, pro rata, up to an additional 113,206 shares of its common stock as additional commitment shares to Lincoln Park in connection with any additional purchases.

Under the terms and subject to the conditions of the purchase agreement, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase, up to an additional $15.0 million of shares of the Company's common stock. As contemplated by the purchase agreement, and so long as the closing price of the Company's common stock exceeds $1.50 per share, the Company may direct Lincoln Park, at the Company's sole discretion to purchase up to 30,000 shares of its common stock on any business day. The price per share for such purchases will be equal to the lower of: (i) the lowest sale price on the applicable purchase date and (ii) the arithmetic average of the three (3) lowest closing sale prices for the Company's common stock during the ten (10) consecutive business days ending on the business day immediately preceding such purchase date (in each case, to be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction that occurs on or after the date of the purchase agreement). The maximum amount of shares subject to any single regular purchase increases as the Company's share price increases, subject to a maximum of $1.0 million.

In addition to regular purchases, the Company may also direct Lincoln Park to purchase other amounts as accelerated purchases or as additional purchases if the closing sale price of the common stock exceeds certain threshold prices as set forth in the purchase agreement. In all instances, the Company may not sell shares of its common stock to Lincoln Park under the purchase agreement if it would result in Lincoln Park beneficially owning more than 4.99% of its common stock. There are neither trading volume requirements nor restrictions under the purchase agreement nor upper limits on the price per share that Lincoln Park must pay for shares of common stock.

The purchase agreement and the registration rights agreement contain customary representations, warranties, agreements and conditions to completing future sale transactions, indemnification rights and obligations of the parties. The Company has the right to terminate the purchase agreement at any time, at no cost or penalty. During any "event of default" under the purchase agreement, all of which are outside of Lincoln Park's control, Lincoln Park does not have the right to terminate the purchase agreement; however, the Company may not initiate any regular or other purchase of shares by Lincoln Park, until such event of default is cured. In addition, in the event of bankruptcy proceedings by or against the Company the purchase agreement will automatically terminate.

During the year ended September 30, 2017, the Company sold 737,817 shares of common stock to Lincoln Park for $1,620,931, and incurred $147,540 of issuance costs. In addition, the Company issued 122,418 shares of common stock to Lincoln Park as commitment shares pursuant to the purchase agreement. There were no shares sold to Lincoln Park during the year ended September 30, 2018.

Common stock

In May 2018, the Company entered into a purchase agreement with BioLexis, pursuant to which BioLexis purchased, in a private placement, 12,754,766 shares of common stock and common stock warrants to purchase 20,512,820 shares of common stock for cash proceeds of $15.0 million. The transaction closed in two tranches in May and June 2018. The warrants have an exercise price of $0.975 per share and a term of eight years from their issuance date.

During the years ended September 30, 2018 and 2017, the Company issued 842,889 and 483,913 shares of common stock upon the vesting of RSUs, respectively.

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, 2018.

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Common stock warrants

As of September 30, 2018, the Company had the following warrants outstanding to acquire shares of its common stock:

Outstanding	Exercise Price Per Share	Expiration Date
3,333,333	$ 6.60	February 18, 2019[(i)]
814,378	$ 0.01	November 11, 2019
3,882,001	$ 3.00	December 22, 2021[(ii)]
16,750,000	$ 0.90	October 31, 2025
10,256,410	$0.975	May 10, 2026
10,256,410	$0.975	June 8, 2026
45,292,532		

(i) In connection with the November 2018 purchase agreement with BioLexis providing for the private placement of $20.0 million of shares of the Company's common stock, the Company undertook to take such action as necessary to reduce the exercise price of the Series A warrants to $1.50 and extend the expiration date of such Series A warrants by three years.

(ii) In November 2018, the Company reduced the exercise price of the Senior Note Warrants to $1.50 and extended the expiration of the Senior Note warrants by three years. Such Senior Note Warrants now expire eight years from their initial issuance date.

During the year ended September 30, 2018, warrants to purchase 3,460 shares with an exercise price of $0.01 were exercised. During the year ended September 30, 2017, warrants to purchase 704,019 and 82,999 shares with exercise prices of $0.01 and $3.00 per share respectively, were exercised.

11. Convertible Preferred Stock

Series A Convertible Preferred Stock

In September 2017, the Company entered into a purchase agreement with BioLexis, pursuant to which BioLexis agreed to purchase, in a private placement (the "Initial Private Placement"), $25.0 million of the Company's newly-created voting Series A Convertible Preferred Stock (the "Series A Convertible"), and warrants (the "BioLexis Warrants" and together with the Series A Convertible, the "Securities") to acquire 16,750,000 shares of common stock. In September 2017, the Company completed the initial sale of 32,628 shares of Series A Convertible to BioLexis for $3,262,800 in cash. In October 2017, the Company completed the sale of the remaining 217,372 shares of Series A Convertible and the BioLexis Warrants to BioLexis in the Initial Private Placement, for $21,737,200 in cash.

The Series A Convertible was initially convertible into 37,795,948 shares of the Company's common stock, representing an effective conversion rate of $0.66 per share, which represented a discount to the market value of the Company's common stock as of September 7, 2017 and October 31, 2017 (on which dates, the closing price of the Company's common stock was $0.90 and $1.26 per share, respectively). In connection with the second closing of the Series A Convertible in October 2017, the Company issued the BioLexis Warrants, which have a term of 8-years and an initial exercise price of $0.90 per share. The proceeds from the second closing of the Series A Convertible were allocated among the Series A Convertible and the BioLexis Warrants based on their relative fair values. As a result of the discount to the market value and the allocation of a portion of the proceeds to the BioLexis Warrants, the Company recognized a beneficial conversion charge of $15,355,019, which represents the in-the-money value of the conversion rate as of the date of sale.

The Series A Convertible accrued dividends at a rate of 10% per annum, compounded quarterly, payable quarterly at the Company's option in cash or in kind in additional shares of Series A Convertible, although the initial dividends payable on the shares of Series A Convertible issued in September 2017, while accruing from issuance, was payable in December 2017. The Series A Convertible was also entitled to dividends on an as-if-converted basis in the same form as any dividends actually paid on shares of common stock or other securities. The initial conversion rate was subject to appropriate adjustment in the event of a stock split, stock dividend, combination, reclassification or other recapitalization affecting the common stock.

During the year ended September 30, 2018, the Company issued an additional 17,571 shares of Series A Convertible to settle the related dividends that were due on a quarterly basis. The Company recognized a beneficial conversion charge of $597,255 during the year ended September 30, 2018, which represents the in-the-money value of the conversion rate as of the date of issuance.

In June 2018, BioLexis converted 208,836 shares of Series A Convertible into 31,572,617 shares of common stock, and in July 2018 exchanged its remaining shares of Series A Convertible for newly created Series A-1 (as defined below). As of such exchange, there were no longer any shares of Series A Convertible issued and outstanding.

Series A-1 Convertible Preferred Stock

In July 2018, the Company entered into an exchange agreement (the "Exchange Agreement") with Biolexis, pursuant to which the Company exchanged 58,735 shares of voting Series A Convertible held by BioLexis for 58,735 shares of its newly created series of voting convertible preferred stock, voting Series A-1 Convertible Preferred Stock, (the "Series A-1"). Accordingly, all of the issued Series A Convertible have been retired and cancelled and may not be reissued as shares of such series in accordance with their terms. In connection with the entry into the Exchange Agreement, the Company and BioLexis amended the Investor Rights Agreement dated September 11, 2017, as amended, (the "Second Amendment to Investor Rights Agreement") in order to provide the Investor certain registration and other rights with respect to the shares of Common Stock to be acquired upon conversion of the Series A-1 issued pursuant to the Exchange Agreement.

A total of 200,000 shares of Series A-1 have been authorized for issuance under the Certificate of Designation of Series A-1 Convertible Preferred Stock of the Company. The shares of Series A-1 have a stated value of $100.00 per share, are initially convertible into 8,879,780 shares of the Common Stock and rank senior to all junior securities (as defined in the Certificate of Designation).

The Series A-1 accrue dividends at a rate of 10% per annum, compounded quarterly, payable quarterly at the Company's option in cash or in kind in additional shares of Series A-1. The Series A-1 is also entitled to dividends on an as-if-converted basis in the same form as any dividends actually paid on shares of Common Stock or other securities. The initial conversion rate is subject to appropriate adjustment in the event of a stock split, stock dividend, combination, reclassification or other recapitalization affecting the Common Stock. The holders of the Series A-1 have the right to vote on matters submitted to a vote of the Company's stockholders on an as-converted basis, voting with the Company's other stockholders as a single class. In addition, without the prior written consent of a majority of the outstanding shares of Series A-1, the Company may not take certain actions, including amending its certificate of incorporation or bylaws, or issuing securities ranking pari passu or senior to the Series A-1. During the year ended September 30, 2018, the Company issued 1,468 shares of Series A-1 Convertible to settle the related dividends that are due on a quarterly basis. The Company recognized a beneficial conversion charge of $70,662 during the year ended September 30, 2018, which represents the in-the-money value of the conversion rate as of the date of issuance.

The terms of the Series A-1 distinguish between certain liquidation events (such as a voluntary or involuntary liquidation, dissolution or winding up of the Company) and "deemed" liquidation events (such as a sale of all or substantially all of the Company's assets, various merger and reorganization transactions, being delisted from Nasdaq, and the occurrence of an event of default under the terms of the senior

secured notes), in each case as defined in the Certificate of Designation. In the event of a liquidation (as defined in the Certificate of Designation), the liquidation preference payable equals the sum of (A) 550% of the Series A-1 stated value per share plus (B) an amount equal to (x) 550% of any accrued, but unpaid, preferred dividends (as defined in the Certificate of Designation) plus (y) any unpaid participating dividends (as defined in the Certificate of Designation). In the case of a deemed liquidation event (as defined in the Certificate of Designation), the multiplier is increased to 600%.

The Series A-1 is convertible at any time at the option of the holder based on the then applicable conversion rate. If conversion is in connection with a liquidation, the holder is entitled to receive 550% of the number of shares of common stock issuable based upon the then applicable conversion rate. In the event of a deemed liquidation event, the multiplier is increased to 600%.

Additionally, the holder may irrevocably require the Company to redeem the Series A-1 in the event of a deemed liquidation event for the sum of (A) 600% of the Series A-1 stated value per share plus (B) an amount equal to (x) 600% of any accrued, but unpaid, preferred dividends plus (y) any unpaid participating dividends, although such redemption may not be made without the consent of the senior secured noteholders if such notes are outstanding at the time of any such redemption.

The shares of Series A-1 have not been registered under the Securities Act of 1933, as amended (the “Securities Act”), and may not be offered or sold in the United States without registration or an applicable exemption from the registration requirements of the Securities Act. The exchange of the Series A-1 for the shares of Series A held by the Investor was made in reliance on Sections 3(a)(9) and 4(a)(2) under the Securities Act, without general solicitation or advertising.

Series B Convertible Preferred Stock

Concurrent with completing the sale of Series A Convertible in October 2017, the Noteholders exchanged $1,500,000 in aggregate principal borrowings and $41,507 in accrued interest for 1,500,000 shares of Series B Convertible. The Series B Convertible were convertible into 2,112,675 shares of common stock. The exchange was accounted for as an extinguishment of debt, See Note 8. During May and June 2018, the Noteholders converted all 1,500,000 shares of Series B Convertible into 2,112,675 shares of common stock. Accordingly, there are no longer any shares of Series B Convertible issued and outstanding.

12. 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, 2018, performance-based stock unit awards (“PSUs”) representing 129,095 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. As of September 30, 2018, the maximum number of shares of common stock that may be issued under the 2015 Plan is 8,404,023 shares and 5,558,678 shares remained available for grant under the 2015 Plan.

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The Company recognizes the grant date fair value of each stock-based award over the vesting period of the award. The Company recorded stock-based compensation expense in the following expense categories of its consolidated statements of operations for the years ended September 30, 2018 and 2017:

	Year Ended Ended September 30,	
	2018	2017
Research and development	$ 19,450	$1,001,022
General and administrative	1,966,420	7,570,408
	$1,985,870	$8,571,430

Stock options

The following table summarizes all of the Company's stock option activity for the year ended September 30, 2018:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Balance at October 1, 2017	—	$ —	
Granted	1,667,075	0.93	
Expired/forfeited/cancelled	(209,930)	1.10	
Balance at September 30, 2018	1,457,145	0.93	9.7
Vested and exercisable	30,000	1.32	0.1
Vested and expected to vest at September 30, 2018	1,457,145	$0.90	9.7

As of September 30, 2018, the aggregate intrinsic value of the stock options was $131,442. The aggregate intrinsic value represents the total amount by which the fair value of the common stock subject to options exceeds the exercise price of the related options.

The Company estimated the fair value of each stock option award on the grant date using the Black-Scholes option pricing model, wherein expected volatility is based on historical volatility of the publicly traded common stock of a peer group of companies. The expected term calculation is based on the "simplified" method described in Staff Accounting Bulletin ("SAB") No. 107, *Share-Based Payment*, and SAB No. 110, *Share-Based Payment*, since the simplified method provides a reasonable estimate in comparison to actual experience. The risk-free interest rate is based on the U.S. Treasury yield at the date of grant for an instrument with a maturity that is commensurate with the expected term of the stock options. The dividend yield is zero since the Company has never paid cash dividends on its common stock, and has no present intention to pay cash dividends. Options granted under the 2015 Plan generally vest over two to four years and have a term of 10 years.

The weighted-average grant date fair value of the options awarded to employees for the year ended September 30, 2018 was $0.56 per share. The following table presents the weighted-average assumptions used in the option pricing model for stock options:

	Year Ended September 30, 2018
Risk-free interest rate	2.80%
Expected life	6.0 years
Expected volatility	71%
Expected dividend yield	—

As of September 30, 2018, there was $726,930 of unrecognized compensation expense that is expected to be recognized over a weighted-average period of 3.1 years.

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. Upon exercise, the PSU holder receives common stock or cash at the Company's discretion.

The following table summarizes the activity related to PSUs during the years ended September 30, 2018 and 2017:

	Number of PSUs	Base Price Per PSU
Balance at October 1, 2016	247,309	$6.33
Forfeitures	(71,779)	6.46
Balance at October 1, 2017	175,530	6.27
Forfeitures	(46,435)	6.43
Balance at September 30, 2018	129,095	6.25
Vested and exercisable	128,660	6.23
Vested and expected to vest at September 30, 2018	129,095	$6.25

As of September 30, 2018, there was $1,552 of unamortized expense that will be recognized over a weighted-average period of 0.4 years.

Restricted stock units

The Company has granted RSUs that generally vest over a period of two to four years from the date of grant. The following table summarizes the activity related to RSUs during the years ended September 30, 2018 and 2017:

	Number of RSUs	Weighted Average Grant Date Fair Value
Balance at October 1, 2016	1,094,351	$28.61
Granted	615,000	2.11
Vested and settled	(483,913)	29.05
Forfeitures	(285,559)	3.14
Balance at October 1, 2017	939,879	18.78
Granted	20,000	1.16
Vested and settled	(842,889)	18.40
Forfeitures	(55,881)	17.67
Balance at September 30, 2018	61,109	$19.23

As of September 30, 2018, there was $544,691 of unamortized expense that will be recognized over a weighted-average period of 0.95 years.

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13. Collaboration Arrangements

Huahai Agreement

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

Under the terms of the arrangement, the Company has received $7,500,000 in upfront payments and non-substantive milestones and received $8,500,000 in substantive milestones. The Company determined that the deliverables under the Huahai arrangement were the exclusive license and the research and development services to be completed by the Company. Since the license did not have standalone value, the upfront and non-substantive milestones payments received have been deferred and are being recognized ratably on a straight line basis through December 2021, 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, 2018 and 2017, the Company recognized $714,848 of deferred revenues. As of September 30, 2018 and 2017, deferred revenue included in the Company's consolidated balance sheet related to the Huahai arrangement was $2,323,254 and $3,038,102, 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.

As of September 30, 2018, the Company has received an aggregate of $5.0 million of payments from IPCA under its various agreements. During each of the years ended September 30, 2018 and 2017, the Company recognized deferred revenues of $261,072. As of September 30, 2018 and 2017, deferred revenue included in the Company's consolidated balance sheets was $848,486 and $1,109,558, respectively.

Liomont Agreement

In June 2014, the Company entered into a strategic license agreement with 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.

As of September 30, 2018, the Company has received an aggregate of $3.0 million of upfront and milestone payments from Liomont. During the years ended September 30, 2018 and 2017, the Company recognized deferred revenue of $236,641 for both periods, respectively. As of September 30, 2018 and 2017, deferred revenue included in the Company's consolidated balance sheets was $769,083 and $1,005,724.

BioLexis Agreement

In July 2017, the Company entered into a strategic licensing agreement with BioLexis, under which it granted BioLexis and its affiliates a perpetual, irrevocable, exclusives sublicensable license in the agreed territory for the research, development, manufacture, use or sale of the ONS-1045 biosimilar product candidate in the agreed territory. The agreed territory includes all emerging markets, but specifically excludes major developed markets, such as the United States, Canada, Europe, Japan, Australia and New Zealand, and smaller markets where the Company has existing licensing arrangements, such as Mexico, greater China and India. The Company received an initial upfront payment from BioLexis of $1.25 million, and an additional $1.25 million upon meeting a notice and acknowledgment milestone.

In September 2017 the Company and BioLexis superseded and replaced the strategic license agreement with a Joint Development and License Agreement (the "JDLA") providing for the development and commercialization of the Company's ONS-3010 and ONS-1045 biosimilar product candidates in the same geographic territories. In exchange for granting BioLexis a perpetual, irrevocable, exclusive, sublicensable

license in the agreed territory for the research, development, manufacture, use or sale of the ONS-3010 and ONS-1045 biosimilar product candidates in the agreed territory, BioLexis made an additional payment of $2.5 million in connection with the JDLA. The Company may receive up to an additional $2.5 million milestone payments under the JDLA for each licensed product upon achievement of certain net profit thresholds. The parties agreed to share net profits based on sales of licensed products in the agreed territory, in proportions weighed in BioLexis' favor, subject to adjustment as provided in the agreement.

During the years ended September 30, 2018 and 2017, the Company recognized revenue of $1,874,999 and $2,598,958, respectively, under the BioLexis agreements. As of September 30, 2018 and 2017, deferred revenue included in the Company's consolidated balance sheet was $526,042 and $2,401,042, respectively.

14. Related-Party Transactions

In May 2018, the Company negotiated a contract with Sonnet Biotherapeutics, Inc. ("Sonnet") to provide contract development and manufacturing ("CDMO") services. The maximum contract value is estimated to be approximately $5.1 million, if all milestones are met. Additionally, in order to provide services to Sonnet and other potential CDMO customers, in November 2017, the Company acquired laboratory and office equipment from Sonnet with a value of $115,000 and during the year ended September 30, 2018, assumed leases of $201,000 for equipment necessary for the planned expansion of the Company's development and manufacturing facilities. Such leases were personally guaranteed by Pankaj Mohan, Ph.D., the Company's former chairman and chief executive officer, and current Class III director.

Dr. Mohan and Mr. Donald Griffith, Class II Director, are members of the board of directors of Sonnet, with Dr. Mohan serving as executive chairman of Sonnet. In addition, Dr. Mohan is a significant stockholder of Sonnet and Mr. Griffith is the president, chief executive officer and chief financial officer, of Sonnet.

For other related party transactions during the year ended September 30, 2018 and 2017, refer to the Stockholder Notes (Note 7), Debt (Note 8) and the BioLexis Agreement (Note 13).

15. Income Taxes

Income tax (benefit) expense for the years ended September 30, 2018 and 2017 consists of the following:

	Year Ended September 30,	
	2018	2017
State tax	$(3,148,216)	$ 1,500
Foreign tax	(500,000)	500,000
	$(3,648,216)	$501,500

During the year ended September 30, 2018, the Company sold New Jersey NOLs in the amount of $38,470,278 resulting in the recognition of income tax benefits of $3,150,716.

OUTLOOK THERAPEUTICS, INC.

Notes to Consolidated Financial Statements

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,	
	2018	2017
U.S. federal statutory rate	(24.3)%	(34.0)%
State taxes, net of federal benefit	(6.9)	(6.4)
Sale of New Jersey net operating losses	(7.1)	—
Net operating loss	8.0	—
Change in tax rates	66.6	—
Foreign witholding tax	(1.5)	1.3
Permanent differences	(0.6)	(2.8)
Foreign tax credits	1.5	(1.6)
Research and development credit	(22.9)	—
Change in valuation allowance	(23.7)	44.8
Other	0.1	—
Effective income tax rate	(10.8)%	1.3%

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

	September 30,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	$ 39,532,689	$ 48,828,141
Stock-based compensation	10,227,514	14,098,985
Deferred revenue	1,264,069	3,017,238
Research and development credit carryforward	8,491,452	757,701
Foreign tax credits	2,357,309	2,857,309
Accruals and others	605,173	1,539,943
Gross deferred tax assets	62,478,206	71,099,317
Less: valuation allowance	(61,893,959)	(69,902,446)
	584,247	1,196,871
Deferred tax liability:		
Fixed assets	(584,247)	(1,196,871)
Net deferred tax assets	$ —	$ —

As of September 30, 2018, the Company has approximately $164.7 million and $68.1 million of federal and New Jersey NOLs that will begin to expire in 2030 and 2036, respectively. As of September 30, 2018, the Company has approximately $0.4 million of foreign net operating losses with no expiration. As of September 30, 2018, the Company has federal and state research and development tax credit carryforwards of $6.6 million and $1.9 million available, respectively, to reduce future tax liabilities which will begin to expire in 2032 and 2023 respectively. As of September 30, 2018, the Company has Federal foreign tax credit carryforwards of $2.4 million available to reduce future tax liabilities that will begin to expire starting in 2023, which 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, 2018 and 2017. The valuation allowance decreased $8.0 million during the year ended September 30, 2018 and increased $17.2 million during the year ended September 30, 2017.

OUTLOOK THERAPEUTICS, INC.

Notes to Consolidated Financial Statements

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.

The 2017 Tax Cuts and Jobs Act, which was signed into law on December 22, 2017, has resulted in significant changes to the U.S. corporate income tax system. These changes include a federal statutory rate reduction from 34% to 21%, the elimination or reduction of certain domestic deductions and credits and limitations on the deductibility of interest expense and executive compensation. For the fiscal year ending September 30, 2018, the federal tax rate is 24.3%. The 2017 Tax Cuts and Jobs Act also transitions international taxation from a worldwide system to a modified territorial system and includes base erosion prevention measures on non-U.S. earnings, which has the effect of subjecting certain earnings of the Company's foreign subsidiaries to U.S. taxation as global intangible low-taxed income. These changes are effective beginning in 2018. In regard to the change in the federal tax rate as it relates to the Company's deferred tax assets and liabilities, the Company has decreased its related deferred tax assets by $22.4 million along with a corresponding offset against the valuation allowance for these deferred tax assets.

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

	Year Ended September 30,	
	2018	2017
Balance at beginning of year	$2,352,129	$1,854,629
Changes based on tax positions related to the current year	(496,000)	497,500
Balance at end of year	$1,856,129	$2,352,129

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 2017 remain open for examination by the Internal Revenue Service as well as various states and municipalities.

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 carryforward 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.

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

None

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) prior to the filing of this Annual Report on Form 10-K. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures were, in design and operation, effective as of September 30, 2018.

Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Exchange Act. Our internal control system is designed to provide reasonable assurance regarding the preparation and fair presentation of financial statements for external purposes in accordance with generally accepted account principles. All internal control systems, no matter how well designed, have inherent limitations and can provide only reasonable assurance that the objectives of the internal control system are met.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting, based on criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 2013 *Internal Control-Integrated Framework*. Based on our evaluation, we concluded that our internal control over financial reporting was effective as of September 30, 2018.

As an emerging growth company, as defined under the Terms of the JOBS Act of 2012, the Company's independent registered accounting firm is not required to issue an attestation report on our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitation on the Effectiveness of Internal Control

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

Item 9B. Other Information

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Directors and Executive Officers

The following table sets forth information concerning our current directors and executive officers, including their ages as of November 30, 2018. There are no family relationships among any of our directors or executive officers.

Name	Age	Position(s)
Executive Officers		
Lawrence A. Kenyon	53	President, Chief Executive Officer, Chief Financial Officer, Treasurer, Corporate Secretary and Director
Kenneth M. Bahrt, M.D.	65	Chief Medical Officer
Terry Dagnon	57	Chief Operating Officer
Jeff Evanson	50	Chief Commercial Officer
Non-Employee Directors		
Ralph H. “Randy” Thurman	69	Executive Chairman
Yezan Haddadin	43	Director
Kurt J. Hilzinger	58	Director
Pankaj Mohan, Ph.D.	54	Director
Faisal G. Sukhtian	34	Director
Joe Thomas	61	Director
Joerg Windisch, Ph.D.	48	Director

Executive Officers

Lawrence A. Kenyon. Mr. Kenyon has served as a member of our board of directors, Chief Executive Officer and President since August 2018, as Interim Chief Executive Officer from June 2018 to August 2018, and as our Chief Financial Officer, Treasurer and Corporate 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**.** The Board believes Mr. Kenyon’s experience as our Chief Executive Officer and Chief Financial Officer, combined with his experience in the biopharmaceutical industry qualifies him to serve on our Board.

Kenneth M. Bahrt, M.D. Dr. Bahrt has served as our Chief Medical Officer since June 2015. Prior to joining us, from February 2014 to May 2015, Dr. Bahrt served as the Vice President of U.S. Medical Affairs at NPS Pharmaceuticals, Inc., a biopharmaceutical company. From August 2011 to January 2014, Dr. Bahrt served

as Senior Vice President and Chief Medical Officer at Savient Pharmaceuticals, Inc., a biopharmaceutical company. Prior to that, from September 2009 to August 2011, Dr. Bahrt served as the Therapeutic Head of Immunology Medical Affairs at Genentech, Inc. From July 2007 to September 2009, Dr. Bahrt served as the Global Medical Director for Immunology at Hoffman-La Roche, a Swiss healthcare company. Prior to this, Dr. Bahrt held positions of increasing responsibility at Bristol Myers Squibb, Pfizer, and Daiichi. Prior to joining the pharmaceutical industry, Dr. Bahrt was in clinical practice. Dr. Bahrt is a board-certified Internist and Rheumatologist and a Fellow of the American College of Rheumatology. Dr. Bahrt received an M.D. from Hahnemann University and a Bachelor's degree in Biology from Muhlenberg College.

Terry Dagnon. Mr. Dagnon has served as our Chief Operating Officer since November 2018. From March 2015 through November 2018, Mr. Dagnon was Senior Vice President of Operations at Dohmen Life Science Services, and from March 2014 to March 2015 acted as its Vice President, Regulatory Affairs. From April 2013 through March 2014, Mr. Dagnon provided consulting services through a proprietary company, and prior thereto, held various positions at Alcon, a Novartis Company, where he last served Head of Regulatory Affairs, North America, from October 2012 through April 2013, and prior thereto served a variety of roles with increasing responsibility in regulatory affairs from December 1999 through October 2012. Prior to a career in the life sciences industry, Mr. Dagnon served 11 years on active duty with the United States Army and was a SFC/E-7 Special Forces Green Beret 18D Senior Non-Commissioned Officer. Mr. Dagnon received his Master of Science Regulatory Affairs from San Diego State University, and a B.S. in Health Care Administration from Wayland Baptist University.

Jeff Evanson. Mr. Evanson has served as our Chief Commercial Officer since November 2018. Mr. Evanson has led Scott Three Consulting, LLC as Founder and President since April of 2018, and from September 2014 through April 2018, served as a Managing Director in the Life Science Practice of Navigant. Prior to joining Navigant, Mr. Evanson was a Global Director and then the Vice President and Global Commercial Head of the Pharmaceutical Franchise at Alcon, a Novartis Company from April 2010 to September 2014. Mr. Evanson serves on the Board of Directors of Children's HeartLink and was formerly a two-term Board Member of Gillette Children's Hospital in St. Paul, Minnesota, from 2008 to 2014. Mr. Evanson received his M.B.A. from the University of Minnesota, and a B.A. in Chemistry from the University of St. Thomas in St. Paul Minnesota.

Non-Employee Directors

Ralph H. "Randy" Thurman. Mr. Thurman has served as the Executive Chairman of our board of directors since June 2018 and served as a member of our Board since April 2018. He also currently serves as a senior advisor at BC Partners, a private equity firm, and as the Executive Chairman of the board of directors of Zest Dental, Inc. Mr. Thurman was previously a member of the board of directors of Allscripts, Inc. and the Executive Chairman of Presbia PLC (an Orchard Capital Corporation company), a publicly-traded medical device company. From 2008 until 2011, Mr. Thurman served as Executive Chairman of CardioNet Inc. (now known as BioTelemetry, Inc.), and as its interim Chief Executive Officer from 2008 until 2010. From 2001 until 2007, Mr. Thurman was Founder, Chairman and Chief Executive Officer of VIASYS Healthcare Inc., a diversified healthcare technology company, which was acquired by Cardinal Healthcare Inc. in 2007. Mr. Thurman served as a consultant to Cardinal Healthcare Inc. from the date of acquisition until 2008. From 1997 until 2001, Mr. Thurman served as Chairman and Chief Executive Officer of Strategic Reserves LLC, which provided advisory services to bio-pharmaceutical, genomic, and medical device companies. From 1993 until 1997, Mr. Thurman was Chairman and Chief Executive Officer of Corning Life Sciences, Inc., and from 1984 until 1993, Mr. Thurman held various positions at Rhone-Poulenc Rorer Pharmaceuticals, Inc., a global pharmaceutical company, ultimately as its President. The Board believes Mr. Thurman's expertise in corporate governance, operating and investing as well as extensive expertise in the healthcare industry qualifies him to serve on our Board.

Yezan Haddadin. Mr. Haddadin has served as a member of our board of directors since October 2017. Since July 2017, Mr. Haddadin has served as chief executive officer of GMS Capital Partners LLC, an investment company focused on making direct private equity investments in North America. GMS Capital Partners LLC is a subsidiary of GMS Holdings. From 2014 to 2017, Mr. Haddadin served as the Chief Executive Officer and a member of the board of directors of a regional investment bank based in Amman, Jordan and Dubai, United Arab Emirates. From 2013 to 2014, Mr. Haddadin served as an Advisor at

Ripplewood Holdings LLC, a New York-based private equity firm. Mr. Haddadin also served as a Managing Director at Perella Weinberg Partners in New York from 2007 to 2013 and an Executive Director with J.P. Morgan in its mergers and acquisitions group from 2000 to 2007. Mr. Haddadin currently serves as a member of the board of directors at Sixth of October Development & Investment Company, a publicly listed Egyptian real estate development company. Mr. Haddadin holds a J.D. from Northwestern University Law School and a B.S. in Foreign Service from Georgetown University. The Board believes Mr. Haddadin's managerial and capital raising experience qualifies him to serve on our Board.

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 in 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. The Board believes Mr. Hilzinger's experience and financial expertise in the healthcare sector qualifies him to serve on our Board.

Pankaj Mohan, Ph.D. Dr. Mohan has served as a member of our board of directors since January 2011. From January 2011 to June 2018, he served as our Chairman, President and Chief Executive Officer. 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, and as its Executive Chairman since July 2018. 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. The Board believes Dr. Mohan's experience as our founder, former Chairman and Chief Executive Officer, combined with his experience in the biopharmaceutical industry qualifies him to serve on our Board.

Faisal G. Sukhtian. Mr. Sukhtian has served as a member of our board of directors since September 2017. Mr. Sukhtian has served as a Director of BioLexis Private Limited since 2011, and an Executive Director of GMS Holdings, a diversified investment company, since 2008. In addition to managing operations of GMS Holdings, Mr. Sukhtian oversees a number of investments within the GMS Holdings portfolio and serves as a director of GMS Holdings' board of directors. From 2008 to 2011, Mr. Sukhtian served as Executive Director of Munir Sukhtian International. From 2010 to 2011, he served as Managing Director of Agri Sciences Ltd., an agrochemicals manufacturing business based in Turkey. Mr. Sukhtian has served as a member of the board of directors of Expert Petroleum, an oilfield services company based in Romania, since 2008, Agri Sciences since 2010, MS Pharma, a leading MENA based branded pharmaceutical generics company, since 2011 and Stelis Biopharma Private Limited, a biotherapeutic and biosimilar developer and manufacturer based in India, since 2015. Mr. Sukhtian previously served as a member of the board of directors of Alvogen, a multinational generics pharmaceutical company based in the United States, from 2008 to 2014 and Waterloo Industries, Inc., a manufacturer of tool storage based in the United States, from 2015 to 2017. Prior to joining GMS Holdings, Mr. Sukhtian worked at JP Morgan, in New York, where he

worked primarily on mergers and acquisitions, debt and equity transactions serving clients in the industrials and transportation industries. Mr. Sukhtian received an M.B.A. from Columbia Business School and a B.S. in International Economics from Georgetown University's School of Foreign Service. The Board believes Mr. Sukhtian's managerial and pharmaceutical industry experience qualifies him to serve on our Board.

Joe Thomas. Mr. Thomas has served as a member of our board of directors since September 2017. Since April 2015, Mr. Thomas has served as the Chief Executive Officer and Executive Director of Stelis Biopharma Private Limited, a biotherapeutic and biosimilar developer and manufacturer based in India, and is responsible for managing an integrated organization comprising research and development, manufacturing and commercialization of recombinant biotherapeutics in global markets. From January 2012 until March 2015, Mr. Thomas served as Chief Corporate Development Officer for Strides Shasun Limited, a listed pharmaceutical company based in India, and was responsible for development and deployment of growth strategies across group companies and business of Strides Shasun Limited. Mr. Thomas received both a B.Sc. and M.Sc. in Chemistry from Delhi University and has over 30 years of experience in the pharmaceutical and consumer healthcare industry. Mr. Thomas was appointed to fill a vacancy on the Board, and was designated for such vacancy by BioLexis Private Limited Holdings Pte. Limited pursuant to the Investor Rights Agreement by and between our company and BioLexis Private Limited Holdings Pte. Limited dated September 11, 2017. The Board believes Mr. Thomas's managerial and pharmaceutical industry experience qualifies him to serve on our board of directors.

Joerg Windisch, Ph.D. Dr. Windisch has served as a member of our Board since March 2018. Since July 2017, Dr. Windisch has served as the Chief Operating Officer of Polpharma Biologics (Poland), a division of Polpharma Group. From February 2016 to June 2017, he served as Chief Operating Officer of Affimed N.V., a Nasdaq-listed biotechnology company, which develops novel immune cell engagers for the treatment of cancer. Prior thereto, Dr. Windisch spent 20 years in various managerial roles at Sandoz Biopharmaceuticals, or Sandoz (now part of Novartis AG). While at Sandoz, Dr. Windisch focused on research and development, manufacturing and developed Sandoz's biosimilars program. Dr. Windisch also led the development of Sandoz's Somatropin (Omnitrope ®), the first ever biosimilar, as well as the company's Epoetinalfa (Binocrit ®) and Filgrastim (Zarzio ®) products. Dr. Windisch was educated in Austria, Germany and the United States and received his Ph.D. in Biochemistry and Molecular Biology from the University of Innsbruck. The Board believes Dr. Windisch's managerial and pharmaceutical industry experience qualifies him to serve on our board of directors.

Family Relationships

There are no family relationships among our directors, executive officers or persons nominated to become executive officers or directors.

Section 16(A) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than 10% of a registered class of our equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and other equity securities. Officers, directors and greater than 10% stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file.

To our knowledge, based solely on a review of the copies of such reports furnished to us and written representations that no other reports were required, during the fiscal year ended September 30, 2018, all Section 16(a) filing requirements applicable to our officers, directors and greater than 10% beneficial owners of our capital stock were complied with except that BioLexis failed to timely file five Form 4s during our fiscal year ended September 30, 2018 to report the issuance of quarterly dividends on its Series A Convertible on each of December 31, 2017 and March 31, 2018, the purchase of common stock and warrants on each of May 14, 2018 and June 8, 2018, and the conversion of Series A Convertible on June 20, 2018, all of which were reported on the same Form 4 filed on June 25, 2018.

Certain Corporate Governance Matters

Code of Ethics

We have adopted a Code of Business Conduct and Ethics that applies to all officers, directors and employees. The Code of Business Conduct and Ethics is available on our website at

https://ir.outlooktherapeutics.com/static-files/a7b472e8-e20b-4c13-ac7a-7d879143598d. If we make any substantive amendments to the Code of Business Conduct and Ethics or grant any waiver from a provision of the Code of Business Conduct and Ethics to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website.

Identification of Audit Committee and Financial Expert

Our board of directors has a standing Audit Committee that operates under a written charter approved by our board of directors, which charter reflects the applicable standards and requirements adopted by the SEC and The Nasdaq Stock Market, LLC, or Nasdaq. A copy of the charter can be found on our website at https://ir.outlooktherapeutics.com/static-files/e556395b-ad8e-4bd1-9bc0-1bf2276612e7. Information found on our website is not incorporated by reference into this report.

The Audit Committee is chaired by Kurt J. Hilzinger and also includes Faisal Sukhtian and Joe Thomas. Our Nominating and Corporate Governance Committee will review the Nasdaq listing standards definition of independence for Audit Committee members on an annual basis and our board of directors has determined that all members of our Audit Committee are independent (as independence is currently defined in Rule 5605(c)(2)(A)(i) and (ii) of the Nasdaq listing standards). Our board of directors has also determined that Mr. Hilzinger qualifies as an "audit committee financial expert," as defined in applicable SEC rules.

Item 11. Executive Compensation

For the year ended September 30, 2018, our named executive officers are:

- Pankaj A. Mohan, our former President and Chief Executive Officer and current Director;
- Lawrence A. Kenyon, our President, Chief Executive Officer, Chief Financial Officer, Treasurer, Corporate Secretary and Director;
- Kenneth M. Bahrt, M.D., our Chief Medical Officer; and
- Stephen J. McAndrew, Ph.D., our former Senior Vice President, Business Strategy & Development.

We refer to these executive officers herein as our named executive officers.

Summary Compensation Table

The following table sets forth the information as to compensation awarded to, paid to or earned by our named executive officers. We did not pay any non-equity incentive plan compensation or have any non-qualified deferred compensation earnings and have omitted those columns from the table.

Name and Principal Position	Year	Salary ($)	Bonus ($)[1]	Stock Awards ($)[2]	Option Awards ($)[3]	All Other Compensation ($)[4]	Total ($)
Pankaj Mohan, Ph.D.[5]	2018	350,538	—	—	—	875,172	1,225,710
Director, former Chairman, President and Chief Executive Officer	2017	490,000	—	555,942	—	31,610	1,077,551
Lawrence A. Kenyon[6]	2018	371,635	—	—	326,192	18,305	716,132
Director, Chief Executive Officer, President, Chief Financial Officer, Treasurer and Corporate Secretary	2017	350,000	100,000	128,065	—	16,940	595,005
Kenneth M. Bahrt, M.D.	2018	400,000	—	—	—	29,082	429,082
Chief Medical Officer	2017	400,000	100,000	108,209		21,469	629,678
Stephen J. McAndrew, Ph.D.[7]	2018	300,000	—	—	14,060	12,011	326,071
Former Senior Vice President, Business Strategy & Development							

(1) Discretionary bonus amounts for fiscal year ended September 30, 2018 have not yet been determined.

(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. 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. For a discussion of the assumptions used in determining the fair value of awards of RSUs in the above table and other additional information on the RSUs granted, refer to "Item 8. Financial Statements and Supplementary Data — Notes to the Consolidated Financial Statements — Note 12. Stock-Based Compensation.

(3) In accordance with SEC rules, this column reflects the aggregate grant date fair value of the stock option awards granted computed in accordance with ASC 718, for stock-based compensation transactions. These amounts do not reflect the actual economic value that would be realized by the named executive officer upon the exercise of the stock options. For a discussion of the assumptions used in determining the fair value of stock option awards in the above table and other additional information on the stock options granted, refer to "Item 8. Financial Statements and Supplementary Data — Notes to the Consolidated Financial Statements — Note 12. Stock-Based Compensation

(4) 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. We also reimbursed Dr. Mohan for cell phone expenses. For Dr. Mohan, all other compensation also includes benefits to which Dr. Mohan became entitled under his employment agreement in connection with his cessation of service as President and Chief Executive Officer in June 2018 comprised of (i) $735,000 of cash severance (including $490,000 of salary and $245,000 of cash bonus) and (ii) $25,428 of projected COBRA coverage costs for himself and his eligible dependents for which he is entitled to reimbursement for up to a 12-month period beginning July 1, 2018.

(5) Dr. Mohan resigned as Chairman, President and Chief Executive Officer in June 2018.

(6) Mr. Kenyon was appointed Interim Chief Executive Officer in June 2018 and later appointed Director, Chief Executive Officer and President in August 2018. Salary reflects Mr. Kenyon's salary adjustment approved in August 2018, which was retroactive to June 2018 when he began acting as Interim Chief Executive Officer.

(7) Dr. McAndrew was terminated as Senior Vice President, Business Strategy & Development in November 2018 when we eliminated his position.

Agreements with our Named Executive Officers

Below are written descriptions of our employment arrangements with our named executive officers.

Dr. Mohan. In February 2016, we entered into a new employment agreement with Dr. Mohan that took effect in connection with our initial public offering, or IPO. Under Dr. Mohan's new employment agreement, Dr. Mohan was entitled to an initial annual base salary of $490,000, was eligible to receive an annual performance bonus of up to 50% of his annual base salary as determined by our board of directors, and was 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, which was contingent upon the closing of our initial public offering. Dr. Mohan was employed by and performing services for us on a full-time basis through his June 2018 resignation. His employment agreement did not have a specified term and his employment could have been terminated by us or by Dr. Mohan at any time, with or without cause. Dr. Mohan was also entitled to certain severance and change in control benefits pursuant to his employment agreement, the terms of which are described below under "— Potential Payments upon Termination or Change of Control." Dr. Mohan resigned as Chairman and Chief Executive Officer in June 2018, and entered into a separation and release agreement and a consulting agreement in July 2018 in connection therewith. The terms of his separation and release agreement are described below under "— Potential Payments upon Termination or Change of Control." The terms of his consulting agreement are described under "Transactions with Related Persons — Certain Related-Person Transactions."

Mr. Kenyon. In February 2016, we entered into a new employment agreement with Mr. Kenyon that took effect in connection with our IPO. Under Mr. Kenyon's February 2016 employment agreement, Mr. Kenyon was entitled to an annual base salary and was eligible to receive an annual performance bonus as determined by our board of directors. These amounts were initially $350,000 and 40%, however, in connection with his August 2018 appointment as our Chief Executive Officer and President, our Compensation Committee increased his base salary to $425,000 and set his annual performance bonus at up to 50% of his base salary as determined by our board, with such increases having retroactive effect to June 18, 2018 when he was appointed Interim Chief Executive Officer. Mr. Kenyon was also granted stock

options to acquire 500,000 shares of our common stock under our 2015 Equity Incentive Plan, or the 2015 Plan, which options are non-qualified stock options that vest annually over four years, and may be accelerated in the event of a "change in control" (as defined in the 2015 Plan) and achievement of a pre-defined objective. Mr. Kenyon is also eligible for additional stock option grants under the 2015 Plan for up to an aggregate of 1.7 million shares of our common stock, which grants are subject to, and will be made effective upon, achievement of certain pre-defined corporate objectives, with four-year vesting and subject to acceleration in the event of a "change in control."

In October 2018, following review of Mr. Kenyon's severance and change in control benefits, which were not modified in August 2018, the Compensation Committee recommended, and our board of directors approved, the amendment of Mr. Kenyon's executive employment agreement to reflect the prior compensation determinations regarding his salary, target bonus and equity incentives, as well as reflect certain modifications to his severance and change in control benefits.

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

Dr. McAndrew. In February 2016, we entered into a new employment agreement with Dr. McAndrew that took effect in connection with our IPO. Under Dr. McAndrew's new employment agreement, Dr. McAndrew was entitled to an initial annual base salary of $300,000, was eligible to receive an annual performance bonus of up to 40% of his annual base salary as determined by our board of directors. Dr. McAndrew was employed by and performing services for us on a full-time basis through November 2018, when we eliminated his position in connection with our change in focus to ophthalmic indications. His employment agreement did not have a specified term and his employment could have been terminated by us or by Dr. McAndrew at any time, with or without cause. Dr. McAndrew was 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." In connection with the elimination of Dr. McAndrew's position as Senior Vice President, Business Strategy & Development in November 2018, we entered into a separation and release agreement in November 2018. The terms of his separation and release agreement 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 connection with our IPO, if he had been terminated without cause or if he resigned 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 would have been 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 was 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 resigned 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 would have been 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 would have become fully vested.

Dr. Mohan resigned in June 2018 and in connection therewith, he entered into a separation and release agreement, effective on July 10, 2018, providing for, as severance, his current base salary ($490,000). Pursuant to the agreement, he will also receive a target cash bonus of $245,000, payable in two installments, 50% within 10 business days of effectiveness of the agreement and 50% no later than January 4, 2019. Dr. Mohan will receive 12 months of COBRA reimbursement. He also agreed to non-solicit and non-compete covenants, as well as executed a general release of claims in connection therewith. In July 2018, Dr. Mohan received the first installment related to his separation and release agreement totaling $367,500.

Mr. Kenyon. Pursuant to Mr. Kenyon's current executive employment agreement, 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, 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 his current executive 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 18 months, 150% of his annual target bonus for the calendar year of termination paid in a lump sum, employee benefit coverage for up to 18 months, and reimbursement of expenses owed to him through the date of his termination. Additionally, 100% of his then unvested equity awards shall become fully vested.

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

Pursuant to the employment agreement, if Dr. Bahrt's employment is terminated by us or any successor entity (provided such successor entity either assumes Dr. Bahrt's equity awards or substitutes similar equity awards) without cause or if he resigns for good reason within two months prior to or within 12 months following a change in control (as defined in the 2015 Plan), subject to his execution of a separation agreement with an effective release of claims in favor of us and continued compliance with certain restrictive covenants set forth in such employment agreement and the PIIA, he is entitled to continued

payment of his base salary for 12 months, 100% of his annual target bonus for the calendar year of termination paid in a lump sum, employee benefit coverage for up to 12 months, and reimbursement of expenses owed to him through the date of his termination. Additionally, 100% of his then unvested equity awards shall become fully vested.

Dr. McAndrew. We eliminated Dr. McAndrew's position in November 2018 in connection with our change in focus to ophthalmic indications. In connection therewith, he entered into a separation and release agreement, effective on November 9, 2018, providing for, as severance, his current base salary for the equivalent of nine months, or a total of $225,000. Dr. McAndrew will receive nine months of COBRA reimbursement. He also agreed to non-solicit and non-compete covenants, as well as executed a general release of claims in connection therewith.

For purposes of our named executive officers' 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, 2018.

		Option awards[1]					*Stock awards*[1]			
Name	**Grant date**	**Number of securities underlying unexercised options (#) exercisable**	**Number of securities underlying unexercised options (#) unexercisable**	**Equity incentive plan awards: Number of securities underlying unexercised unearned options (#)**	**Option exercise price ($)**	**Option expiration date**	**Number of shares or units of stock that have not vested (#)**	**Market value of shares or units of stock that have not vested ($)**	**Equity incentive plan awards: Number of unearned shares, units or other rights that have not vested (#)**	**Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested ($)**
Lawrence A. Kenyon	8/1/2018	—	500,000[2]	—	0.86	8/1/2028	—	—	—	—
Lawrence A. Kenyon	12/31/2015	—	—	—	—	—	21,739[3]	21,304	—	—
Kenneth M. Bahrt, M.D.	06/22/2015	—	—	—	—	—	14,493[4]	14,203	—	—
Stephen J. McAndrew, Ph.D.	06/15/2018	—	30,000[5]	—	0.90	06/15/2028	—	—	—	—

(1) The outstanding equity awards as of September 30, 2018 are RSUs and stock options that were granted under and subject to the terms of the 2015 Equity Incentive Plan, or the 2015 Plan. Except as otherwise indicated, each RSU or stock option is subject to vesting, subject to the executive's continuous service with us through the vesting dates and the potential vesting acceleration of the time-based vesting conditions upon a change in control and certain terminations of employment. Each RSU represents the right to receive, at settlement one share of our common stock.

(2) The shares underlying the option shall vest in four equal installments beginning on August 1, 2019 such that the option shall be vested in full on August 1, 2022, subject to Mr. Kenyon providing continuous service on each such date. Vesting may be accelerated in the event of (a) a change in control as defined in the 2015 Plan and (b) the achievement of certain predefined corporate objectives, in each case subject to Mr. Kenyon providing continuous service through such event.

(3) The RSUs satisfied the performance-based vesting restrictions on the date that was six months following the effective date of the registration statement on Form S-1 (File No. 333-209011). Of these RSUs, 50% of the time-based vesting restrictions was satisfied on September 15, 2018 and the remaining 50% will vest on September 15, 2019, subject to Mr. Kenyon's continuous service with us through such dates; provided that 100% of the shares underlying the RSU will satisfy the time-based vesting restrictions upon the occurrence of a change in control, subject to Mr. Kenyon's continuous service with us through such date.

(4) The RSUs satisfied the performance-based vesting restrictions on the date that was six months following the effective date of the registration statement on Form S-1 (File No. 333-209011). Of these RSUs, 50% of the time-based vesting restrictions was satisfied on June 22, 2018 and the remaining 50% will vest on June 22, 2019, subject to Dr. Bahrt's continuous service with us through such dates; provided that 100% of the shares underlying the RSU will satisfy the time-based vesting restrictions upon the occurrence of a change in control, subject to Dr. Bahrt's continuous service with us through such date.

(5) 15,000 shares, or 50% of the underlying the option vested as of November 9, 2018, upon Dr. McAndrew's termination as Senior Vice President, Business Strategy & Development. Dr. McAndrew forfeited the remaining 15,000 shares underlying the grant.

Director Compensation

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, 2018. Mr. Kenyon's and Dr. Mohan's compensation as executive officers is set forth under "Executive Compensation — Summary Compensation Table." Mr. Kenyon does not receive any additional compensation for service as a director. None of our directors received any compensation other than cash fees or stock option awards under the 2015 Plan during the fiscal year ended September 30, 2018, accordingly, we have omitted all other columns from the table below.

Name	Fees Earned or Paid in Cash[1] ($)	Option Awards[2] ($)	All Other Compensation[3] ($)	Total ($)
Claudio Albrecht[4]	—	—	—	—
Todd C. Brady, M.D., Ph.D.[5]	6,339	5,292	—	11,631
Scott Canute[4]	28,447	—	—	28,447
Albert Dyrness[5]	4,198	5,292	—	9,490
Yezan Haddadin[6]	—	—	—	—
Kurt Hilzinger	62,500	21,421	—	83,921
Pankaj Mohan, Ph.D.[7]	9,997	9,837	61,250	81,084
Faisal G. Sukhtian[6]	—	—	—	—
Joe Thomas[6]	—	—	—	—
Randy Thurman[8]	59,494	73,454	—	132,948
Joerg Windisch, Ph.D.	20,986	23,327	—	44,313

(1) Represents the annual cash fees pursuant to our non-employee director compensation policy, which took effect in connection with IPO.

(2) Reflects the aggregate grant date fair value of the stock option awards granted computed in accordance with ASC 718, for stock-based compensation transactions. These amounts do not reflect the actual economic value that would be realized by the director upon exercise of the stock options. For a discussion of the assumptions used in determining the fair value of awards of stock options in the above table and other additional information on stock options granted, refer to "Item 8. Financial Statements and Supplementary Data — Notes to the Consolidated Financial Statements — Note 12. Stock-Based Compensation.

(3) Represents consulting fees paid to Dr. Mohan pursuant to a six-month consulting arrangement effective July 2, 2018 focused on the ONS-5010 development program.

(4) Messrs. Albrecht and Canute resigned from our Board effective April 13, 2018.

(5) Dr. Brady and Mr. Dyrness each resigned from our Board effective October 30, 2017.

(6) Board service commenced effective September 11, 2017, and no fees were paid during the fiscal year ended September 30, 2018. Messrs. Sukhtian and Thomas have waived their right to cash and equity compensation for their services as directors of our company. Both Messrs. Albrecht and Haddadin, who joined our Board effective October 30, 2017, did not receive any fees during the fiscal year ended September 30, 2018 and have similarly waived their right to cash and equity compensation for services as directors of our company. Mr. Haddadin resigned from our Board in March 2018 and was reappointed to our Board in April 2018.

(7) Dr. Mohan resigned as Chairman, President and Chief Executive Officer effective June 18, 2018, but remains a director. While employed, Dr. Mohan did not receive any additional compensation for service as a director.

(8) Mr. Thurman was appointed Executive Chairman of the Board in June 2018.

Non-Employee Director Compensation Policy

We have adopted a non-employee director compensation policy 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, which took effect in connection with our IPO.

Equity Compensation

Initial Grant

Under the non-employee director compensation policy, each new non-employee director who joins our board of directors is granted a non-statutory stock option to purchase 25,000 shares of common stock under the 2015 Plan, which option vests annually over three years from the grant date, subject to continued service as a director through the applicable vesting date. Messrs. Albrecht, Haddadin, Sukhtian and Thomas waived their initial equity grants. In addition, in connection with his appointment as Executive Chairman, Mr. Thurman received a one-time grant of a non-statutory stock option to purchase 100,000 shares of common stock under the 2015 Plan, which vests annually in three equal installments.

Annual Grant

Under the non-employee director compensation policy, on the date of each annual meeting of our stockholders, each current non-employee director is granted an annual non-statutory stock option to purchase 15,000 shares of common stock under the 2015 Plan, which option vests on the first anniversary of the grant date, subject to continued service as a director though the applicable vesting date. Messrs. Haddadin, Sukhtian and Thomas have waived their annual equity grants.

Cash Compensation

Under the non-employee director compensation policy, 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. In the event that the chairperson is an employee and the board of directors appoints a Lead Independent Director, that person will receive the additional annual cash retainer otherwise payable to the chairperson. In addition, as Executive Chairman, Mr. Thurman is entitled to an annual retainer of $120,000 payable in equal monthly installments.

The chairperson and members of the three principal standing committees of our board of directors are generally entitled to the following annual cash retainers under our non-employee director compensation policy:

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

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

In November 2018, to reduce cash expenses, the Compensation Committee of our Board revised our non-employee director compensation policy and suspended cash payments and authorized a one-time equity grant of immediately vested options equal in value to two-years of cash fees. Accordingly, effective November 9, 2018, all non-employee directors who did not previously waive their cash fees received the following equity grants.

The following reflects the stock options that were granted to non-employee directors on November 9, 2018.

		Option awards				
Name	**Grant date**	**Number of securities underlying unexercised options (#) exercisable**	**Number of securities underlying unexercised options (#) unexercisable**	**Equity incentive plan awards: Number of securities underlying unexercised unearned options (#)**	**Option exercise price ($)**	**Option expiration date**
Randy Thurman	11/09/2018	567,522	—	—	0.89	11/09/2018
Kurt Hilzinger	11/09/2018	203,851	—	—	0.89	11/09/2018
Joerg Windisch, Ph.D.	11/09/2018	130,465	—	—	0.89	11/09/2018
Pankaj Mohan, Ph.D.	11/09/2018	114,157	—	—	0.89	11/09/2018

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

Security Ownership Of Certain Beneficial Owners And Management

The following table sets forth certain information relating to the beneficial ownership of our common stock as of November 30, 2018, 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.

Beneficial ownership determined in accordance with the rules of the SEC and includes any shares over which a person exercises sole or shared voting or investment power. Applicable percentage ownership and total voting power are based on 80,798,031 shares of our common stock and 60,203 shares of our voting Series A-1 convertible preferred stock outstanding as of November 30, 2018. Unless otherwise indicated, the persons or entities identified in this, or Series A-1 Convertible, table have sole voting and investment power with respect to all shares shown beneficially owned by them, subject to applicable community property laws. Shares of common stock issuable upon vesting, exercise or conversion of outstanding equity awards or preferred stock that are exercisable, subject to vesting or convertible within 60 days after November 30, 2018 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 Outlook Therapeutics, Inc., 7 Clarke Drive, Cranbury, New Jersey 08512.

	Common Stock		**Series A-1 Convertible**		
Name of Beneficial Owner	**Number of Shares Beneficially Owned**	**%**	**Number of Shares Beneficially Owned**	**%**	**% of Total Voting Power**
Five Percent Stockholders (other than directors and officers):					
BioLexis Pte. Ltd[(1)]	99,269,168	78.1%	60,203	100.0%	69.0%

Name of Beneficial Owner	Common Stock		Series A-1 Convertible		% of Total Voting Power
	Number of Shares Beneficially Owned	%	Number of Shares Beneficially Owned	%	
Named Executive Officers and Directors:					
Lawrence A. Kenyon, *Director, Chief Executive Officer, Chief Financial Officer, Treasurer and Corporate Secretary*	35,474	*	—	—	†
Kenneth M. Bahrt, Chief Medical Office[2]	33,627	*	—	—	†
Ralph H. "Randy" Thurman, Executive Chairman[3]	576,522	*	—	—	†
Yezan Haddadin, Director	—	—	—	—	—
Pankaj Mohan, Ph.D., Director[4]	8,383,714	10.4%			
Kurt J. Hilzinger, Director[5]	256,621	*	—	—	†
Faisal G. Sukhtian, Director	—	—	—	—	—
Joe Thomas, Director	—	—	—	—	—
Joerg Windisch, Ph.D., Director[6]	130,465	*			†
All executive officers and directors as a group (11 persons)	9,416,423	11.5%	—	—	9.3%

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

† Represents voting power of less than one percent (1%) of the outstanding common stock.

(1) Includes (a) 9,101,717 shares of common stock issuable upon conversion of 60,203 shares of Series A-1 Convertible and (b) 37,262820 shares of common stock issuable upon exercise of warrants. The Series A-1 Convertible (which votes on an as-converted basis) and warrants are held directly by BioLexis Pte. Ltd. (formerly known as GMS Tenshi Private Limited Holdings Pte. Limited), or BioLexis. Tenshi Life Sciences Private Limited, or Tenshi, a private investment vehicle controlled by Arun Kumar Pillai, or Kumar, and GMS Pharma (Singapore) Pte. Limited, or GMS Pharma, a private investment company and wholly-owned subsidiary of GMS Holdings, a private investment company, or GMS Holdings, are the 50:50 beneficial owners of BioLexis, in which each of Tenshi and GMS Pharma owns 50% of the outstanding voting shares. Kumar, a natural person, is the holder of a controlling interest in Tenshi. Ghiath M. Sukhtian, or Sukhtian, a natural person, is the holder of a controlling interest in GMS Holdings, which is the holder of a controlling interest in GMS Pharma. The principal office address of Kumar is #30, "Galaxy", 1st Main, J.P. Nagar, 3rd Phase, Bangalore, India 560078. The principal office address of Sukhtian is Zahran Street, 7th Circle Zahran Plaza Building, 4th Floor P.O. Box 142904, Amman, Jordan 11844.

(2) Includes warrants to acquire 1,000 shares held by Dr. Bahrt.

(3) Represents vested options held by Mr. Thurman.

(4) Includes (i) 39,405 shares held directly by Dr. Mohan's child, (ii) 492,753 shares held directly by Dr. Mohan's spouse, (iii) 86,956 shares held in a family trust for which Dr. Mohan's spouse serves as trustee, and (iv) 114,157 vested options.

(5) Includes (i) 218,851 vested options and (ii) 2,416 RSUs held directly by Mr. Hilzinger.

(6) Represents vested options held directly by Dr. Windisch.

Equity Compensation Plan Information

The following table provides certain information with respect to all of our equity compensation plans in effect as of September 30, 2018.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders:			
2011 Stock Incentive Plan	129,095	$6.25[1]	—[2]
2015 Equity Incentive Plan	1,518,254	[3]	5,558,678[4]
2016 Employee Stock Purchase Plan	—	—	545,162[5]
Equity compensation plans not approved by security holders:			
None	—	—	—
Total	1,647,349		6,103,840

(1) Represents the base price per outstanding performance stock unit, or PSU, awards at September 30, 2018.

(2) Effective upon approval of the 2015 Equity Incentive Plan, no additional options or awards may be granted under the 2011 Stock Incentive Plan; all outstanding stock awards will continue to be governed by their existing terms.

(3) Number of securities to be issued upon exercise of outstanding options, warrants and rights outstanding at September 30, 2018 is comprised of 1,457,145 option awards with a weighted average exercise price of $0.90, and 61,109 restricted stock units with a weighted average grant date fair value of $19.23.

(4) The number of shares of our common stock reserved for issuance under the 2015 Equity Incentive Plan automatically increases on January 1st of each year continuing through January 1, 2026, in an amount equal to the lesser of (A) 3% of the total number of shares of our common stock outstanding on December 31st of the immediately preceding calendar year and (B) a number determined by our board of directors.

(5) The number of shares of our common stock reserved for issuance under the 2016 Employee Stock Purchase Plan automatically increases on January 1st each year continuing through January 1, 2026, by the lesser of (i) one percent (1%) of the total number of shares of our common stock outstanding on December 31st of the preceding calendar year, (ii) 1,760,000 shares of our common stock and (iii) a number determined by our board of directors.

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

Certain Related-Person Transactions

The following is a summary of transactions since October 1, 2015 to which we have been a party, in which the amount involved exceeded or will exceed the lesser of (x) $120,000 or (y) 1% of our total assets at September 30, 2017 or 2018, 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 sections titled “Executive Compensation” and “Director Compensation.” We also describe below certain other transactions with our directors, executive officers and stockholders.

Financings

Common Stock

Mezzanine Financings

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 an investors’ rights agreement, as amended, and a co-sale agreement, as amended, which have since terminated.

The foregoing mezzanine financings included 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 members of our board, current director, Mr. Hilzinger, and former directors, Mr. Canute and Ms. Hoke, invested an aggregate of $2.0 million in our company through investments in these funds. Following the completion of our IPO and pursuant to the documents governing such funds, these individuals 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

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 a share buyback conducted in June 2014 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

At the time of the above transactions, Mr. Canute and Dr. Brady were on our board of directors, Mr. Gangloff was an executive officer, and Mr. Griffith was on our board of directors and an executive officer.

Loans and Guarantees

In March 2015, Mr. Canute, a former 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 the 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 former Chairman, President and Chief Executive Officer, current director, 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, 2015, amounts owed to Dr. Mohan amounted to $117,506. 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. Former directors, Messrs. Canute and Dyrness and one of our, at the time, significant stockholders, Sabby Healthcare Master Fund, Ltd., or Sabby, 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 named therein, which included former directors, Messrs. Canute and Dyrness, and Sabby 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 initially matured December 22, 2017 and warrants to acquire an aggregate 2.3 million shares of our common stock. The warrants initially had 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 Sabby. We closed the sale of the remaining $1.65 million of additional notes and warrants to acquire up to an additional 379,500 shares of our common stock in January 2017. 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.

On April 13, 2017, we entered into the First Amendment to the Note and Warrant Purchase Agreement, or the Amendment, with the required holders of our outstanding senior secured promissory notes named

therein. The primary purpose of the Amendment was to increase the amount of notes, which bear interest at a rate of 5% per annum and mature on December 22, 2017, from $10.0 million to $15.0 million, permit the issuance of additional warrants (which have a five-year term and an exercise price of $3.00 per share) to acquire an aggregate 1,665,000 shares of its common stock in connection therewith. In connection with the Amendment, we issued an additional $3.5 million in note principal and warrants to acquire an aggregate 1,165,000 shares of common stock. On May 31, 2017, we issued the remaining $1.5 million in note principal and warrants to acquire 499,500 shares of common stock.

In connection with the September 2017 private placement to BioLexis, described in more detail below, on September 11, 2017, we entered into a Note, Warrant and Registration Rights Amendment and Waiver, pursuant to which the senior secured noteholders agreed to, among other items, waive certain events of default that may be deemed to have occurred and waive past non-compliance with certain registration rights of the senior secured noteholders, as well as extend the maturity date of the senior secured notes to the later to occur of (x) December 22, 2018 and (y) one year following the second closing under the BioLexis Purchase Agreement, as defined below.

In connection with the November 2018 private placement to BioLexis, described in more detail below, we entered into a Second Note and Warrant Amendment and Waiver, pursuant to which the senior secured noteholders agreed to, among other items, further extend the maturity date of the senior secured notes and provide that such notes may be converted into common stock at an initial conversion price of $1.11924 per share (120% of the price per share paid by BioLexis in the private placement). Under this amendment, the maturity date of such senior secured notes may be extended up to December 22, 2019 in exchange for us making several payments of principal and interest through August 31, 2019, and raising no less than $20.0 million of additional equity capital on or prior to June 30, 2019.

In November 2018, following the initial sale to BioLexis, we paid the holders an aggregate of approximately $2.2 million of principal and interest. We agreed to make additional scheduled payments of an aggregate of $3.7 million of principal and interest on these senior secured notes as follows: (i) approximately $1.2 million of principal and interest on or prior to December 7, 2018; (ii) approximately $1.0 million of interest on or prior to December 22, 2018; and (iii) approximately $1.5 million of principal and interest on or prior to February 15, 2019. Additionally, we have raised $20.0 million of additional equity capital on or prior to June 30, 2019, then we agreed to (i) pay an additional aggregate of $3.0 million of principal and interest; and (ii) make additional payments of $1.0 million of principal and interest on or prior to each of July 31, 2019 and August 31, 2019. If we make the payments of an aggregate of $4.4 million on or prior to December 22, 2018 as contemplated, then the maturity date of the senior notes will be automatically extended to June 30, 2019. If we raise no less than $20.0 million of additional equity capital on or prior to June 30, 2019, and pays the additional aggregate of $3.0 million of principal and interest, then the maturity date will be automatically extended to December 22, 2019.

In addition, we and the holders mutually agreed to reduce the exercise price of the warrants held by them to acquire an aggregate of 3,792,500 shares of our common stock to $1.50 per share, and extend the expiration of such warrants by three years.

We also agreed to take such steps as may be reasonably necessary to amend the exercise price to $1.50 and further extend the expiration date of our outstanding Series A warrants (Nasdaq: OTLKW) by three years. Such Series A warrants currently have an exercise price of $6.60 per share and expire on the earlier to occur of (a) the date that is 20 business days after the date on which the closing sales price of our common stock is greater than or equal to $7.25 per share and (b) February 18, 2019.

Employment and Other Compensation Arrangements and 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 — 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.

Performance Stock Units

We previously granted our employees PSUs. The PSUs as issued were 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. 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, current officers, Drs. Bahrt and McAndrew, and former officers, Ms. Yamashita and Mr. Gangloff and our former director, Mr. Griffith, forfeited their PSUs and were granted RSUs under our 2015 Plan. The RSUs granted to Messrs. Gangloff and Griffith satisfied the performance-based vesting restrictions six months following the effective date of the registration statement for our initial public offering. The RSUs granted to Drs. Bahrt and 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 our company, provided the executive remains in continuous service with us through such date.

Mohan Consulting Agreement

Following Dr. Mohan's resignation as Chairman of our board of directors and as our Company's Chief Executive Officer, on July 2, 2018, we entered into a consultant agreement with Dr. Mohan. Under the agreement, Dr. Mohan agreed to a six-month consulting arrangement, pursuant to which he will be paid at 50% of his base salary prior to his resignation, and will be focused on the ONS-5010 development program. Such consultant arrangement may be extended as mutually agreed between us and Dr. Mohan or terminated early in accordance with the terms.

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, a former director of our company. 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.

In October 2015, our former subsidiary that we spun-off in April 2015, Sonnet Biotherapeutics, Inc., or 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.

During the three months ended June 30, 2018, we negotiated a contract with Sonnet to provide contract development and manufacturing, or CDMO, services for a fee. The gross contract value is estimated to be approximately $5.14 million, if all milestones are met. Additionally, in order to provide services to Sonnet and other potential CDMO customers, in November 2017, we acquired additional laboratory and office equipment from Sonnet with a value of approximately $115,000 and during the nine months ended June 30, 2018, assumed leases of approximately $201,000 for equipment necessary for the then planned expansion of our development and manufacturing facilities. Such leases were personally guaranteed by Dr. Mohan, our former Chairman and Chief Executive Officer and current Class III director.

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

Concurrent Private Placement

Sabby, a then significant stockholder, purchased approximately $5.0 million of our units at the initial public offering price (or 833,332 units based on the initial public offering price of $6.00 per unit) in a private placement that closed concurrently with our initial public offering. The units sold in the proposed concurrent private placement were not registered under the Securities Act. We paid the underwriters as placement agents in the private placement an aggregate cash fee equal to 7.0% of the gross sales price of the units sold. The closing of the private placement was contingent upon, and occurred concurrently with, the closing of our initial public offering.

Pre-IPO Investors' Rights Agreement

In connection with our common stock financings, we entered into a pre-IPO investors' rights agreement containing registration rights, among other things, with certain holders of our common stock. On April 26, 2016, we amended the pre-IPO investors' rights agreement and agreed, under certain circumstances, to issue certain of the investors, upon the closing of our IPO, three-year warrants to purchase an aggregate of 1,520,268 shares of our common stock at $0.01 per share. The registration rights granted under the pre-IPO 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.

BioLexis Private Placement

Private Placement — September 2017

In September 2017, we entered into a purchase agreement with BioLexis pursuant to which BioLexis agreed to purchase, in a private placement, 250,000 shares of our newly created Series A Convertible Preferred Stock, or the Series A Convertible, for $25.0 million and warrants to acquire an aggregate 16,750,000 shares of our common stock. The Series A Convertible was initially convertible into 37,795,948 shares of our common stock. We completed the initial sale of 32,628 shares of Series A Convertible for $3.3 million in September 2017, and in October 2017, we consummated the sale of the remaining 217,372 shares of Series A Convertible for $21.7 million.

In connection with the September 2017 private placement to BioLexis, we entered into an investor rights agreement with BioLexis pursuant to which BioLexis received certain demand and piggyback registration rights with respect to the shares of our common stock issuable upon the conversion of the Series A Convertible and the warrants. Additionally, we agreed to appoint up to four new directors to be designated by BioLexis, such that BioLexis's designees represent a majority of our board of directors. So long as BioLexis maintains beneficial ownership of at least 5% of our company's outstanding common stock, it shall be entitled to nominate directors to our board of directors in proportion its ownership stake in our company. So long as BioLexis maintains beneficial ownership of at least 50% but less than or equal to 57% of our company, it shall be entitled to nominate a majority of the directors for election to our board of directors.

Also in connection with the September 2017 private placement to BioLexis, we entered into a joint development and licensing agreement with BioLexis providing for the development and commercialization of ONS-3010 and ONS-1045 biosimilar product candidates in emerging markets, but explicitly excluding

major developed markets, such as the United States, Canada, Europe, Japan, Australia and New Zealand and smaller markets where we have existing licensing agreements, including Mexico, greater China and India. In exchange for granting BioLexis a perpetual, irrevocable, exclusive, sublicensable license in the agreed territory for research, development, manufacture, use or sale of ONS-3010 and ONS-1045 biosimilar product candidates, BioLexis made a signing payment of $50,000, and an additional payment of $2.45 million upon the initial sale of the Series A Convertible under the purchase agreement. We may receive up to an additional $2.5 million milestone payments under the agreement for each licensed product upon achievement of certain net profit thresholds. We agreed with BioLexis to share net profits based on sales of licensed products in the agreed territory, in proportions weighed in BioLexis' favor, subject to adjustment as provided in the agreement. The agreement superseded and replaced a strategic licensing agreement dated July 25, 2017 by and between our company and BioLexis pursuant to which we received an aggregate $2.5 million in payments.

May 2018 Private Placement Offering

In May 2018, we entered into a purchase agreement with BioLexis pursuant to which BioLexis agreed to purchase, in a private placement, 12,754,767 shares of common stock and warrants to acquire an aggregate 20,512,820 shares of our common stock for $15.0 million in two tranches. We completed the sale of the first tranche of 6,377,383 shares of common stock and warrants to acquire an aggregate 10,256,410 shares of our common stock for $7.5 million in May 2018. In June 2018, we consummated the sale of the remaining 6,377,383 shares of common stock and warrants to acquire an aggregate 10,256,410 shares of our common stock for $7.5 million. We also amended the BioLexis investor rights agreement to clarify that the securities issued in this private placement had the same rights as shares issued in the initial September 2017 investment.

Conversion of Series A Convertible and Exchange for Series A-1 Convertible

In June 2018, BioLexis converted 208,836 shares of its Series A Convertible into 31,572,617 shares of common stock. In connection therewith, we reached an agreement in principle with BioLexis to exchange the remaining 52,209 shares of Series A Convertible held by BioLexis (along with accrued but unpaid dividends) for shares of our newly-created Series A-1 Convertible.

In July 2018, our Board declared a dividend-in-kind on the Series A Convertible, issuing BioLexis 6,526 additional shares of Series A Convertible. Thereafter, we entered into an exchange agreement with BioLexis pursuant to which we exchanged 58,735 shares of Series A Convertible held by BioLexis for 58,735 shares of newly created Series A-1 Convertible. The Series A-1 Convertible has the same conversion and dividend features as the Series A Convertible (10% per annum, compounded quarterly, payable quarterly at our option in cash or in kind in additional shares of Series A-1 Convertible), but reflects an increased redemption premium (110% to 550%) and increased liquidation preference (120% to 600%) that provides BioLexis with similar redemption premium and liquidation preference for its aggregate Series A Convertible holdings before the conversion. Accordingly, there are no longer any shares of Series A Convertible outstanding.

In connection with the exchange, we amended the BioLexis investor rights agreement to clarify that the shares of Series A-1 Convertible issued in the exchange had the same rights as shares issued in the initial September 2017 investment.

November 2018 Private Placement Offering

In November 2018, we entered into a purchase agreement with BioLexis pursuant to which BioLexis agreed to purchase, in a private placement, up to $20.0 million of shares of common stock in four tranches, subject to customary closing conditions and meeting certain pre-agreed funding milestones. We completed the sale of the first tranche of 8,577,248 shares of common stock for $8.0 million in November 2018, and the second tranche of 4,288,624 shares of common stock for $4.0 million in December 2018. We agreed to close the remaining two tranches of $4.0 million each (or 4,288,624 shares each) in January 2019 and February 2019, subject, in each case, to customary closing conditions and achievement of certain funding milestones. We also amended the BioLexis investor rights agreement to clarify that the shares issued in this private placement had the same rights as shares issued in the initial September 2017 investment.

Sabby Senior Secured Note Exchange

In connection with the September 2017 private placement to BioLexis, we entered into a purchase and exchange agreement with Sabby pursuant to which Sabby exchanged $1.5 million in aggregate principal amount of senior secured notes for 1,500,000 shares of our newly-created Series B Convertible Preferred Stock, or the Series B Convertible. The Series B Convertible was initially convertible into 2,112,676 shares of our common stock. We closed the exchange on October 30, 2017. The Series B Convertible was not able to be converted into shares of our common stock if conversion would result in Sabby (together with its affiliates and any other persons acting as a group together) beneficially owning in excess of 9.99% (or, if during the 6-month period immediately following the exchange, 7.5%).

In June 2018, following the conversion of the Series A Convertible by BioLexis, the Series B Convertible was converted into an aggregate into 2,112,676 shares of our common stock in accordance with its terms. Accordingly, there are no longer any shares of Series B Convertible outstanding.

MTTR, LLC — ONS-5010 Strategic Partnership Agreement

In February 2018, we entered into a strategic partnership agreement with MTTR, LLC, or MTTR, to advise on regulatory, clinical and commercial strategy and assist in obtaining approval of ONS-5010, our bevacizumab therapeutic product candidate for ophthalmic indications. Under the terms of the agreement, we currently pay MTTR a $58,333 monthly consulting fee. Beginning January 2019, the monthly fee increases to $105,208 per month, and then, after launch of ONS-5010 in the United States, to $170,833 per month (the amount of which is reduced by 50% in the event net sales of ONS-5010 are below a certain threshold million per year). We also agreed to pay MTTR a tiered percentage of the net profits of ONS-5010 ranging in the low- to mid-teens, with the ability to credit monthly fees paid to MTTR. In March 2018, we amended the MTTR agreement and agreed to pay a one-time fee of $268,553 to MTTR by September 2020 if certain regulatory milestones are achieved earlier than anticipated. For the year ended September 30, 2018, MTTR earned an aggregate of $602,629, which includes such monthly consulting fees, expense reimbursement and an initial upfront payment of $75,000.

Indemnification Agreements

Our amended and restated certificate of incorporation, as amended, contains provisions limiting the liability of directors, and our amended and restated bylaws, as amended, provide that we will indemnify each of our directors and officers to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws, each as amended, also provide our board of directors with discretion to indemnify our employees and other agents when determined appropriate by our board of directors. 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.

Related-Party Transaction Policy

In 2016, we 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.

Independence of the Board of Directors

As required under The Nasdaq Stock Market, LLC, or Nasdaq, listing standards, a majority of the members of a listed company's board of directors must qualify as "independent," as affirmatively

determined by the board. Our board of directors consults with our counsel to ensure that its determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent listing standards of Nasdaq, as in effect from time to time.

Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of his or her family members, and us, our senior management and our independent auditors, our board of directors has affirmatively determined that the following six directors are independent directors within the meaning of the applicable Nasdaq listing standards: Messrs. Thurman, Haddadin, Hilzinger, Sukhtian, Thomas and Dr. Windisch. In making this determination, our board of directors found that none of these directors had a material or other disqualifying relationship with our company.

In making those independence determinations, our board of directors took into account certain relationships and transactions that occurred in the ordinary course of business between us and entities with which some of our directors are or have been affiliated, including the relationships and transactions described in the section of this report captioned "Certain Related-Person Transactions," and all other facts and circumstances that our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each director.

Item 14. Principal Accounting Fees and Services

The following table represents aggregate fees billed to us for the fiscal years ended September 30, 2018 and 2017 by KPMG LLP, our principal accountant.

	Fiscal Year Ended	
	2018	2017
Audit Fees	$350,000	$350,000
Audit-related Fees	32,500	27,500
Tax Fees	139,986	31,504
Total Fees	$522,486	$409,004

Audit Fees. This category consists of the annual audit of our consolidated financial statements and the interim reviews of the quarterly consolidated financial statements.

Audit-Related Fees. This category consists of fees related to our initial public offering and services rendered in connection with our registration statements.

Tax Fees. This category includes all fees associated with tax compliance, tax advice and tax planning work.

All Other Fees. None.

Pre-Approval Policies and Procedures.

Our Audit Committee charter provides that the Audit Committee will approve the fees and other significant compensation to be paid to our independent auditors, and pre-approve all audit services and all non-audit services of independent auditors permitted under applicable law. The charter also provides that the Audit Committee may establish other pre-approval policies and procedures for the engagement of independent auditors to render services to us, including without limitation policies that would allow the delegation of pre-approval authority to one or more members of the Audit Committee, provided that any pre-approval decision is reported to the Audit Committee at its next scheduled meeting. The Audit Committee has approved all audit and audit-related work covered by the audit fees, audit-related fees, and tax fees.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) (1) The financial statements required by Item 15(a) are filed in Item 8 of this Annual Report on Form10-K.

(2) The financial statement schedules required by Item 15(a) are omitted because they are not applicable, not required or the required information is included in the financial statements or notes thereto as filed in Item 8 of this Annual Report on Form 10-K.

EXHIBITS

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed with the SEC on May 19, 2016).
3.2	Certificate of Designation of Series A-1 Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed with the SEC on July 19, 2018).
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed with the SEC on December 6, 2018).
3.4	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Registrant's current report on Form 8-K filed with the SEC on May 19, 2016).
3.5	Amendment to the Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed with the SEC on November 29, 2016).
10.1#	2011 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.2#	Form of Amended and Restated Performance Stock Unit Agreement for 2011 Stock Incentive Plan (incorporated by reference to Exhibit 10.29 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on April 27, 2016).
10.3#	2015 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 99.1 to the Registrant's current report on Form 8-K filed with the SEC on September 24, 2018).
10.4#	Forms of agreements and award grant notices for 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.5#	2016 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.5 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on February 12, 2016).
10.6#	Form of Indemnity Agreement, by and between the Registrant and each of its directors and executive officers (incorporated by reference to Exhibit 10.12 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.7#	Employment Agreement between the Registrant and Pankaj Mohan, Ph.D. dated February 22, 2016 (incorporated by reference to Exhibit 10.25 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on April 27, 2016).
10.8#	Separation Agreement and Release by and between the Registrant and Pankaj Mohan, Ph.D., dated July 2, 2018 (incorporated by reference to Exhibit 10.5 to the Registrant's quarterly report on Form 10-Q filed with the SEC on August 14, 2018).

Exhibit Number	Description
10.9#	Consulting Agreement and Release by and between the Registrant and Pankaj Mohan, Ph.D., dated July 2, 2018 (incorporated by reference to Exhibit 10.6 to the Registrant's quarterly report on Form 10-Q filed with the SEC on August 14, 2018).
10.10#	Executive Employment Agreement between the Registrant and Lawrence A. Kenyon, dated October 22, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on October 26, 2018).
10.11#	Employment Agreement between the Registrant and Kenneth Bahrt, M.D., dated February 22, 2016 (incorporated by reference to Exhibit 10.26 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on April 27, 2016).
10.12#+	Separation Agreement and Release by and between the Registrant and Stephen J. McAndrew, Ph.D., effective as of November 26, 2018.
10.13†	Research License Agreement by and between the Registrant and Selexis SA, effective as of October 3, 2011, as amended by Amendment No. 1 dated as of October 9, 2014 (incorporated by reference to Exhibit 10.13 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on February 26, 2016).
10.14†	ONS-3010 Commercial License Agreement by and between the Registrant and Selexis SA effective as of April 11, 2013, as amended effective as of May 21, 2014 (incorporated by reference to Exhibit 10.14 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.15†	ONS-1045 Commercial License Agreement by and between the Registrant and Selexis SA effective as of April 11, 2013, as amended effective as of May 21, 2014 (incorporated by reference to Exhibit 10.15 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.16†	ONS-1050 Commercial License Agreement by and between the Registrant and Selexis SA effective as of April 11, 2013, as amended effective as of May 21, 2014 (incorporated by reference to Exhibit 10.16 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.17	Joint Participation Agreement by and between the Registrant and Zhejiang Huahai Pharmaceutical Co., Ltd., effective as of May 6, 2013, as amended by that Amendment No. 1 and Mutual Termination Agreement re: Joint Participation Agreement, dated December 23, 2014 (incorporated by reference to Exhibit 10.17 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.18*+	Strategic Partnership Agreement by and between the Registrant and MTTR, LLC, effective as of February 15, 2018, as amended by the Letter Addendum dated March 2, 2018.
10.19	Lease Agreement by and between the Registrant and Cedar Brook 7 Corporate Center, LP, dated as of March 18, 2011 (incorporated by reference to Exhibit 10.18 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.20	First Amendment to Lease Agreement by and between the Registrant and Cedar Brook 7 Corporate Center, LP, dated as of December 2013 (incorporated by reference to Exhibit 10.19 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.21	Second Amendment to Lease Agreement by and between the Registrant and Cedar Brook 7 Corporate Center, LP, dated as of July 18, 2014 (incorporated by reference to Exhibit 10.20 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).

Exhibit Number	Description
10.22	Third Amendment to Lease Agreement by and between the Registrant and Cedar Brook 7 Corporate Center, LP, dated as of January 16, 2015 (incorporated by reference to Exhibit 10.21 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.23	Fourth Amendment to Lease Agreement by and between the Registrant and Cedar Brook 7 Corporate Center, LP, dated as of February 9, 2015 (incorporated by reference to Exhibit 10.22 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.24	Fifth Amendment to Lease Agreement by and between the Registrant and Cedar Brook 7 Corporate Center, LP, dated as of September 26, 2015 (incorporated by reference to Exhibit 10.23 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).
10.25	Sixth Amendment to Lease Agreement by and between the Registrant and Cedar Brook 7 Corporate Center, LP, dated as of February 1, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on February 7, 2018).
10.26+	Lease Termination Agreement by and between the Registrant and Cedar Brook East Corporate Center, LP, dated as of August 28, 2018.
10.27	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 10.30 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on May 11, 2016).
10.28	Securities Purchase Agreement between the Registrant and Sabby Healthcare Master Fund Ltd., dated May 11, 2016 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on May 19, 2016).
10.29	Warrant Agreement by and between the Registrant and American Stock Transfer & Trust Company LLC, as Warrant Agent dated May 18, 2016 (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on June 27, 2016).
10.30	Amendment to the Warrant Agreement dated May 18, 2016 by the Registrant and American Stock Transfer & Trust Company LLC, as Warrant Agent, dated February 6, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on February 6, 2017).
10.31	Amendment #2 to the Warrant Agreement dated May 18, 2016 by and between the Registrant and American Stock Transfer & Trust Company LLC, as Warrant Agent, dated February 9, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on February 9, 2018).
10.32	Form of Series A warrant certificate (included in Exhibit A to Exhibit 10.29).
10.33	Note and Warrant Purchase Agreement by and between the Registrant 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).
10.34	First Amendment to Note and Warrant Purchase Agreement by and the Registrant and the Noteholders named therein, dated April 13, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on April 17, 2017).
10.35	Note, Warrant and Registration Rights Amendment and Waiver, dated September 7, 2017 (incorporated by reference to Exhibit 10.9 to the Registrant's current report on Form 8-K filed with the SEC on September 11, 2017).

Exhibit Number	Description
10.36	Second Note and Warrant Amendment and Waiver, dated November 5, 2018 (incorporated by reference to Exhibit 10.3 to the Registrant's current report on Form 8-K filed with the SEC on November 9, 2018).
10.37	Form of Senior Secured Promissory Note (included as Exhibit A to the Note and Warrant Purchase Agreement filed as Exhibit 10.33).
10.38	Form of Warrant (included as Exhibit B to the Note and Warrant Purchase Agreement filed as Exhibit 10.33).
10.39	Security Agreement by and between the Registrant 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).
10.40	Intellectual Property Security Agreement by and between the Registrant 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).
10.41	Registration Rights Agreement by and among the Registrant and the Investors named therein, dated February 3, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on February 3, 2017).
10.42	Purchase and Exchange Agreement by and between the Registrant and the Noteholders named therein, dated September 7, 2017 (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K filed with the SEC on September 11, 2017).
10.43	Purchase Agreement by and between the Registrant. and Lincoln Park Capital Fund, LLC, dated March 8, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on March 9, 2017).
10.44	Registration Rights Agreement by and between the Registrant and Lincoln Park Capital Fund, LLC, dated March 8, 2017 (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K filed with the SEC on March 9, 2017).
10.45	Purchase Agreement by and between the Registrant and BioLexis Pte. Ltd. (formerly GMS Tenshi Holdings Pte. Limited), dated September 7, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on September 11, 2017).
10.46	Form of Warrant to Purchase Common Stock of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's current report on Form 8-K filed with the SEC on September 11, 2017).
10.47	Investor Rights Agreement by and between the Registrant and BioLexis Pte. Ltd. (formerly GMS Tenshi Holdings Pte. Limited), dated September 11, 2017 (incorporated by reference to Exhibit 10.3 to the Registrant's current report on Form 8-K filed with the SEC on September 11, 2017).
10.48	Amendment to Investor Rights Agreement by and between the Registrant and BioLexis Pte. Ltd. (formerly GMS Tenshi Holdings Pte. Limited), dated May 11, 2018 (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K filed with the SEC on May 15, 2018).
10.49	Second Amendment to Investor Rights Agreement by and between the Registrant, and BioLexis Pte. Ltd. (formerly GMS Tenshi Holdings Pte. Limited), dated July 18, 2018 (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K filed with the SEC on July 19, 2018).
10.50	Third Amendment to Investor Rights Agreement by and between the Registrant and BioLexis Pte. Ltd., dated November 5, 2018 (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K filed with the SEC on November 9, 2018).

Exhibit Number	Description
10.51	Purchase Agreement by and between the Registrant and BioLexis Pte. Ltd. (formerly GMS Tenshi Holdings Pte. Limited), dated May 11, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on May 15, 2018).
10.52	Form of Warrant to Purchase Common Stock of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's current report on Form 8-K filed with the SEC on May 15, 2018).
10.53	Term Sheet, Convertible Preferred Equity Investment in the Registrant by and between the Registrant and BioLexis Pte. Ltd. (formerly GMS Tenshi Holdings Pte. Limited), dated June 20, 2018 (incorporated by reference to Exhibit 10.4 to the Registrant's quarterly report on Form 10-Q filed with the SEC on August 14, 2018).
10.54	Exchange Agreement by and between the Registrant and BioLexis Pte. Ltd. (formerly GMS Tenshi Holdings Pte. Limited), dated July 18, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on July 19, 2018).
10.55	Purchase Agreement by and between the Registrant and BioLexis Pte. Ltd. (formerly GMS Tenshi Holdings Pte. Limited), dated November 5, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on November 9, 2018).
23.1+	Consent of independent registered public accounting firm.
31.1+	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1+	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

+ Filed herewith.

† Confidential treatment has been granted for certain information contained in this document pursuant to an order of the SEC. Such information (indicated by asterisks) has been omitted and been filed separately with the SEC.

* 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.

# Indicates management contract or compensatory plan.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: December 18, 2018

By: /s/ Lawrence A. Kenyon

Name: Lawrence A. Kenyon
Title: President, Chief Executive Officer and Chief Financial Officer

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

/s/ Ralph H. Thurman Ralph H. Thurman	Executive Chairman	December 18, 2018
/s/ Lawrence A. Kenyon Lawrence A. Kenyon	President, Chief Executive Officer, Chief Financial Officer, Treasurer, Secretary and Director *(Principal Executive, Financial and Accounting Officer)*	December 18, 2018
/s/ Yezan Haddadin Yezan Haddadin	Director	December 18, 2018
/s/ Kurt J. Hilzinger Kurt J. Hilzinger	Director	December 18, 2018
/s/ Pankaj Mohan, Ph.D. Pankaj Mohan, Ph.D.	Director	December 18, 2018
/s/ Faisal G. Sukhtian Faisal G. Sukhtian	Director	December 18, 2018
/s/ Joe Thomas Joe Thomas	Director	December 18, 2018
/s/ Joerg Windisch, Ph.D. Joerg Windisch, Ph.D.	Director	December 18, 2018

SEPARATION AGREEMENT AND RELEASE

This Separation Agreement and Release ("Agreement") is made by and between Stephen J. McAndrew, Ph.D. ("Employee") and Oncobiologics, Inc. (the "Company") (collectively referred to as the "Parties" or individually referred to as a "Party").

RECITALS

WHEREAS, Employee was employed by the Company;

WHEREAS, Employee signed an Executive Employment Agreement with the Company on or about February 19, 2016 (the "Employment Agreement");

WHEREAS, Employee signed an Employee Proprietary Information, Inventions, Non-Competition and Non-Solicitation Agreement with the Company on February 26, 2016 (the "Confidentiality Agreement");

WHEREAS, Employee is separating from employment with the Company effective November 9, 2018 (the "Separation Date");

WHEREAS, the Parties wish to resolve any and all disputes, claims, complaints, grievances, charges, actions, petitions, and demands that the Employee may have against the Company and any of the Releasees as defined below, including, but not limited to, any and all claims arising out of or in any way related to Employee's employment with or separation from the Company;

NOW, THEREFORE, in consideration of the mutual promises made herein, the Company and Employee hereby agree as follows:

COVENANTS

1. Consideration. In consideration of Employee's execution of this Agreement and Employee's fulfillment of all of its terms and conditions, and provided that Employee does not revoke the Agreement under Section 5 below, the Company agrees as follows:

a. Cash Consideration. The Company will make severance payments to Employee in the form of continuation of Employee's base salary in effect on the Separation Date for the equivalent of nine (9) months following the Separation Date (the "Salary Continuation"). These payments will be subject to standard payroll deductions and withholdings and will be made on the Company's ordinary payroll dates, provided that the first payment shall be made on the date that is sixty (60) days following the Separation Date (the "Severance Pay Commencement Date"), provided the Company has received the executed Agreement from Employee on or before that date. On the Severance Pay Commencement Date, the Company will pay in a lump sum the aggregate amount of the Salary Continuation under this Section 1(a) that the Company would have paid Employee through such date had the payments commenced on the Separation Date through the Severance Pay Commencement Date, with the balance paid thereafter on the applicable schedule described above.

b. COBRA. If Employee timely elects continued coverage under COBRA for himself and his covered dependents under the Company's group health plans following the Separation Date, then the Company will pay, as and when due to the insurance carrier or COBRA administrator (as applicable), Employee's COBRA premiums until the earliest of (A) nine (9) months after the Separation Date (B) the expiration of Employee's eligibility for the continuation coverage under COBRA, or (C) the date when Employee becomes eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment (such period from the termination date through the earliest of (A) through (C), the "COBRA Payment Period"). Notwithstanding the foregoing, if at any time the Company determines, in its sole discretion, that the payment of the COBRA premiums would result in a violation of the nondiscrimination rules of Section 105(h)(2) of the Code or any statute or regulation of similar effect (including but not limited to the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then provided Employee remains eligible for reimbursement in accordance with this Section 1(b), in lieu of providing the COBRA premiums, the Company will instead pay Employee on the last day of each remaining month of the COBRA Payment Period, a fully taxable cash payment equal to the COBRA premiums for that month, subject to applicable tax withholdings for the remainder of the COBRA Payment Period. If Employee becomes eligible for coverage under another employer's group health plan through self-employment or otherwise ceases to be eligible for COBRA during the period provided in this clause, Employee must immediately notify the Company of such event, and all payments and obligations under this clause will cease.

c. Equity Award Acceleration. You were issued stock options with respect to common stock of the Company pursuant to the Company's 2015 Equity Incentive Plan (the "Plan") and stock option grant notices and agreements (the "Grant Agreements") that remain outstanding as of the Separation Date as set forth on **Exhibit A** (the "Equity Awards"). Fifty percent (50%) of the shares of Company common stock subject to the Equity Awards outstanding as of the Separation Date that were subject to time-based vesting requirements that have not otherwise vested as of the Separation Date will be deemed vested as of the Separation Date as set forth on **Exhibit A**. Vesting of the Equity Awards will otherwise cease as of the Separation Date, and you will forfeit the Equity Awards with respect to any unvested shares. The Equity Awards will continue to be governed by the terms of the Plan and the Grant Agreements governing the Equity Awards.

d. General. Employee acknowledges and agrees that without this Agreement, Employee is otherwise not entitled to the consideration listed in this Section 1.

2. Benefits. Employee's health insurance benefits shall cease on the Separation Date, unless otherwise stated in the Company's health insurance plan documents and subject to Employee's right to continue Employee's health insurance under COBRA. Employee's participation in all benefits and incidents of employment, including, but not limited to, vesting in equity awards, and the accrual of bonuses, vacation, and paid time off, ceased as of the Separation Date.

3. Payment of Salary and Receipt of All Benefits. Employee acknowledges and represents that, other than the consideration set forth in this Agreement, the Company and its agents have paid or provided all salary, wages, bonuses, accrued vacation/paid time off, notice periods, premiums, leaves, housing allowances, relocation costs, interest, severance, outplacement costs, fees, reimbursable expenses, commissions, stock, stock options, vesting, and any and all other benefits and compensation due to Employee.

4. Release of Claims. Employee agrees that the foregoing consideration represents settlement in full of all outstanding obligations owed to Employee by the Company and its current and former officers, directors, employees, agents, investors, attorneys, shareholders, administrators, affiliates, benefit plans, plan administrators, professional employer organization or co-employer, insurers, trustees, divisions, and subsidiaries, and predecessor and successor corporations and assigns (collectively, the "Releasees"). Employee, on Employee's own behalf and on behalf of Employee's respective heirs, family members, executors, agents, and assigns, hereby and forever releases the Releasees from, and agrees not to sue concerning, or in any manner to institute, prosecute, or pursue, any claim, complaint, charge, duty, obligation, demand, or cause of action relating to any matters of any kind, whether presently known or unknown, suspected or unsuspected, that Employee may possess against any of the Releasees arising from any omissions, acts, facts, or damages that have occurred up until and including the Effective Date of this Agreement, including, without limitation:

a. any and all claims relating to or arising from Employee's employment relationship with the Company and the termination of that relationship;

b. any and all claims relating to, or arising from, Employee's right to purchase, or actual purchase of equity in the Company, including, without limitation, any claims for fraud, misrepresentation, breach of fiduciary duty, breach of duty under applicable state corporate law, and securities fraud under any state or federal law;

c. any and all claims for wrongful discharge of employment; termination in violation of public policy; discrimination; harassment; retaliation; breach of contract, both express and implied; breach of covenant of good faith and fair dealing, both express and implied; promissory estoppel; negligent or intentional infliction of emotional distress; fraud; negligent or intentional misrepresentation; negligent or intentional interference with contract or prospective economic advantage; unfair business practices; defamation; libel; slander; negligence; personal injury; assault; battery; invasion of privacy; false imprisonment; conversion; and disability benefits;

d. any and all claims for violation of any federal, state, or municipal statute, including, but not limited to, Title VII of the Civil Rights Act of 1964; the Civil Rights Act of 1991; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990; the Equal Pay Act; the Fair Labor Standards Act; the Fair Credit Reporting Act; the Age Discrimination in Employment Act of 1967; the Older Workers Benefit Protection Act; the Employee Retirement Income Security Act of 1974; the Worker Adjustment and Retraining Notification Act; the Family and Medical Leave Act; the Uniformed Services Employment and Reemployment Rights Act; the New Jersey Law Against Discrimination; the New Jersey Equal Pay Act; the New Jersey Conscientious Employee Protection Act; the New Jersey Civil Rights Act; the New Jersey Family Leave Act; the New Jersey State Wage and Hour Law; and the New Jersey Wage Withholding Protection Law.

e. any and all claims for violation of the federal or any state constitution;

f. any and all claims arising out of any other laws and regulations relating to employment or employment discrimination;

g. any claim for any loss, cost, damage, or expense arising out of any dispute over the nonwithholding or other tax treatment of any of the proceeds received by Employee as a result of this Agreement; and

h. any and all claims for attorneys' fees and costs.

Employee agrees that the release set forth in this section shall be and remain in effect in all respects as a complete general release as to the matters released. This release does not extend to any obligations incurred under this Agreement. This release does not release claims that cannot be released as a matter of law, including any Protected Activity (as defined below). This release does not extend to any right Employee may have to unemployment compensation benefits or workers' compensation benefits. Employee represents that Employee has made no assignment or transfer of any right, claim, complaint, charge, duty, obligation, demand, cause of action, or other matter waived or released by this Section.

5. Acknowledgment of Waiver of Claims under ADEA. Employee acknowledges that Employee is waiving and releasing any rights Employee may have under the Age Discrimination in Employment Act of 1967 ("ADEA"), and that this waiver and release is knowing and voluntary. Employee agrees that this waiver and release does not apply to any rights or claims that may arise under the ADEA after the Effective Date of this Agreement. Employee acknowledges that the consideration given for this waiver and release is in addition to anything of value to which Employee was already entitled. Employee further acknowledges that Employee has been advised by this writing that: (a) Employee should consult with an attorney prior to executing this Agreement; (b) Employee has forty-five (45) days within which to consider this Agreement; (c) Employee has seven (7) days following Employee's execution of this Agreement to revoke this Agreement; (d) this Agreement shall not be effective until after the revocation period has expired; and (e) nothing in this Agreement prevents or precludes Employee from challenging or seeking a determination in good faith of the validity of this waiver under the ADEA, nor does it impose any condition precedent, penalties, or costs for doing so, unless specifically authorized by federal law. In the event Employee signs this Agreement and returns it to the Company in less than the 45-day period identified above, Employee hereby acknowledges that Employee has freely and voluntarily chosen to waive the time period allotted for considering this Agreement. Employee acknowledges and understands that revocation must be accomplished by a written notification to the undersigned Company representative that is received prior to the Effective Date. The Parties agree that changes, whether material or immaterial, do not restart the running of the 45-day period. You further acknowledge that you have received (as Exhibit B hereto) the disclosure statement required under the ADEA which provides you with additional information regarding the group layoff of which you are a part (the "ADEA Disclosure Schedule").

6. No Pending or Future Lawsuits. Employee represents that Employee has no lawsuits, claims, or actions pending in Employee's name, or on behalf of any other person or entity, against the Company or any of the other Releasees. Employee also represents that Employee does not intend to bring any claims on Employee's own behalf or on behalf of any other person or entity against the Company or any of the other Releasees.

7. Application for Employment. Employee understands and agrees that, as a condition of this Agreement, Employee shall not be entitled to any employment with the Company, and Employee hereby waives any right, or alleged right, of employment or re-employment with the Company. Employee further agrees not to apply for employment with the Company and not otherwise pursue an independent contractor or vendor relationship with the Company.

8. Confidentiality. Employee agrees to maintain in complete confidence the existence of this Agreement, the contents and terms of this Agreement, and the consideration for this Agreement (hereinafter collectively referred to as "Separation Information"). Except as required by law, Employee may disclose Separation Information only to Employee's immediate family members, the Court in any proceedings to enforce the terms of this Agreement, Employee's counsel, and Employee's accountant and any professional tax advisor to the extent that they need to know the Separation Information in order to provide advice on tax treatment or to prepare tax returns, and must prevent disclosure of any Separation Information to all other third parties. Employee agrees that Employee will not publicize, directly or indirectly, any Separation Information.

9. Trade Secrets and Confidential Information/Company Property. Employee reaffirms and agrees to observe and abide by the terms of the Confidentiality Agreement, specifically including the provisions therein regarding nondisclosure of the Company's trade secrets and confidential and proprietary information and certain restrictions on solicitations and competitive activity. Employee agrees that the above reaffirmation and agreement with the Confidentiality Agreement shall constitute a new and separately enforceable agreement to abide by the terms of the Confidentiality Agreement, entered and effective as of the Effective Date. Employee specifically acknowledges and agrees that any violation of the restrictive covenants in the Confidentiality Agreement and/or this Agreement shall constitute a material breach of this Agreement. Employee's signature below constitutes Employee's certification under penalty of perjury that Employee has returned all documents and other items provided to Employee by the Company, developed or obtained by Employee in connection with Employee's employment with the Company, or otherwise belonging to the Company, including, but not limited to, all passwords to any software or other programs or data that Employee used in performing services for the Company.

10. No Cooperation. Employee agrees that Employee will not knowingly encourage, counsel, or assist any attorneys or their clients in the presentation or prosecution of any disputes, differences, grievances, claims, charges, or complaints by any third party against any of the Releasees, unless under a subpoena or other court order to do so or as related directly to the ADEA waiver in this Agreement. Employee agrees both to immediately notify the Company upon receipt of any such subpoena or court order, and to furnish, within three (3) business days of its receipt, a copy of such subpoena or other court order. If approached by anyone for counsel or assistance in the presentation or prosecution of any disputes, differences, grievances, claims, charges, or complaints against any of the Releasees, Employee shall state no more than that Employee cannot provide counsel or assistance.

11. Nondisparagement. Employee agrees to refrain from any disparagement, defamation, libel, or slander of any of the Releasees, and agrees to refrain from any tortious interference with the contracts and relationships of any of the Releasees. The Company agrees to refrain from any disparagement, defamation, libel, or slander of Employee, and agrees to refrain from any tortious interference with the contracts and relationships of Employee. The Parties understand and agree that the Company's obligations under this Agreement apply to its officers and only for so long as each remains employed by the Company. Employee shall direct any inquiries by potential future employers to the Company's human resources department, which shall provide only the Employee's last position and dates of employment. Employee's violation of this provision shall be a material breach of this Agreement.

12. Breach. In addition to the rights provided in the "Attorneys' Fees" section below, Employee acknowledges and agrees that any material breach of this Agreement, unless such breach constitutes a legal action by Employee challenging or seeking a determination in good faith of the validity of the waiver herein under the ADEA, or of any provision of the Confidentiality Agreement shall entitle the Company immediately to recover and/or cease providing the consideration provided to Employee under this Agreement and to obtain damages, except as provided by law, provided, however, that the Company shall not recover One Hundred Dollars ($100.00) of the consideration already paid pursuant to this Agreement and such amount shall serve as full and complete consideration for the promises and obligations assumed by Employee under this Agreement and the Confidentiality Agreement.

13. No Admission of Liability. Employee understands and acknowledges that this Agreement constitutes a compromise and settlement of any and all actual or potential disputed claims by Employee. No action taken by the Company hereto, either previously or in connection with this Agreement, shall be deemed or construed to be (a) an admission of the truth or falsity of any actual or potential claims or (b) an acknowledgment or admission by the Company of any fault or liability whatsoever to Employee or to any third party.

14. Costs. The Parties shall each bear their own costs, attorneys' fees, and other fees incurred in connection with the preparation of this Agreement.

15. ARBITRATION. THE PARTIES AGREE THAT ANY AND ALL DISPUTES ARISING OUT OF THE TERMS OF THIS AGREEMENT, THEIR INTERPRETATION, AND ANY OF THE MATTERS HEREIN RELEASED, SHALL BE SUBJECT TO ARBITRATION IN MIDDLESEX COUNTY, BEFORE THE JUDICIAL ARBITRATION AND MEDIATION SERVICE ("JAMS") UNDER ITS COMPREHENSIVE ARBITRATION RULES ("JAMS RULES") AND NEW JERSEY LAW. THE ARBITRATOR MAY GRANT INJUNCTIONS AND OTHER RELIEF IN SUCH DISPUTES. THE ARBITRATOR SHALL ADMINISTER AND CONDUCT ANY ARBITRATION IN ACCORDANCE WITH NEW JERSEY LAW, AND THE ARBITRATOR SHALL APPLY SUBSTANTIVE AND PROCEDURAL NEW JERSEY LAW TO ANY DISPUTE OR CLAIM, WITHOUT REFERENCE TO ANY CONFLICT-OF-LAW PROVISIONS OF ANY JURISDICTION. TO THE EXTENT THAT THE JAMS RULES CONFLICT WITH NEW JERSEY LAW, NEW JERSEY LAW SHALL TAKE PRECEDENCE. THE DECISION OF THE ARBITRATOR SHALL BE FINAL, CONCLUSIVE, AND BINDING ON THE PARTIES TO THE ARBITRATION. THE PARTIES AGREE THAT THE PREVAILING PARTY IN ANY ARBITRATION SHALL BE ENTITLED TO INJUNCTIVE RELIEF IN ANY COURT OF COMPETENT JURISDICTION TO ENFORCE THE ARBITRATION AWARD. THE PARTIES TO THE ARBITRATION SHALL EACH PAY HALF THE COSTS AND EXPENSES OF SUCH ARBITRATION, AND EACH PARTY SHALL SEPARATELY PAY FOR ITS RESPECTIVE COUNSEL FEES AND EXPENSES; PROVIDED, HOWEVER, THAT THE ARBITRATOR SHALL AWARD ATTORNEYS' FEES AND COSTS TO THE PREVAILING PARTY, EXCEPT AS PROHIBITED BY LAW. THE PARTIES AGREE THAT PUNITIVE DAMAGES SHALL BE UNAVAILABLE IN ARBITRATION. THE PARTIES HEREBY AGREE TO WAIVE THEIR RIGHT TO HAVE ANY DISPUTE BETWEEN THEM RESOLVED IN A COURT OF LAW BY A JUDGE OR JURY. NOTWITHSTANDING THE FOREGOING, THIS SECTION WILL NOT PREVENT EITHER PARTY FROM SEEKING INJUNCTIVE RELIEF (OR ANY OTHER PROVISIONAL REMEDY) FROM ANY COURT HAVING JURISDICTION OVER THE PARTIES AND THE SUBJECT MATTER OF THEIR DISPUTE RELATING TO THIS AGREEMENT AND THE AGREEMENTS INCORPORATED HEREIN BY REFERENCE. SHOULD ANY PART OF THE ARBITRATION AGREEMENT CONTAINED IN THIS PARAGRAPH CONFLICT WITH ANY OTHER ARBITRATION AGREEMENT BETWEEN THE PARTIES, THE PARTIES AGREE THAT THIS ARBITRATION AGREEMENT SHALL GOVERN.

16. Authority. The Company represents and warrants that the undersigned has the authority to act on behalf of the Company and to bind the Company and all who may claim through it to the terms and conditions of this Agreement. Employee represents and warrants that Employee has the capacity to act on Employee's own behalf and on behalf of all who might claim through Employee to bind them to the terms and conditions of this Agreement. Each Party warrants and represents that there are no liens or claims of lien or assignments in law or equity or otherwise of or against any of the claims or causes of action released herein.

17. Protected Activity. Employee understands that nothing in this Agreement shall in any way limit or prohibit Employee from engaging for a lawful purpose in any Protected Activity, provided, however, that Employee agrees not to seek or accept any monetary award from such a proceeding (except with respect to proceedings before the Securities and Exchange Commission). For purposes of this Agreement, "Protected Activity" shall mean filing a charge, complaint, or report with, or otherwise communicating with, cooperating with or participating in any investigation or proceeding that may be conducted by, any federal, state or local government agency or commission, including the Securities and Exchange Commission, the Equal Employment Opportunity Commission, the Occupational Safety and Health Administration, and the National Labor Relations Board ("Government Agencies"). Employee understands that in connection with such Protected Activity, Employee is permitted to disclose documents or other information as permitted by law, and without giving notice to, or receiving authorization from, the Company. Notwithstanding the foregoing, Employee agrees to take all reasonable precautions to prevent any unauthorized use or disclosure of any information that may constitute Company confidential information under the Confidentiality Agreement to any parties other than the relevant Government Agencies. Employee further understands that "Protected Activity" does not include the disclosure of any Company attorney-client privileged communications, and that any such disclosure without the Company's written consent shall constitute a material breach of this Agreement. In addition, pursuant to the Defend Trade Secrets Act of 2016, Employee is notified that an individual will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that (i) is made in confidence to a federal, state, or local government official (directly or indirectly) or to an attorney *solely* for the purpose of reporting or investigating a suspected violation of law, or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding, if (and only if) such filing is made under seal. In addition, an individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the individual's attorney and use the trade secret information in the court proceeding, if the individual files any document containing the trade secret under seal and does not disclose the trade secret, except pursuant to court order.

18. No Representations. Employee represents that Employee has had an opportunity to consult with an attorney, and has carefully read and understands the scope and effect of the provisions of this Agreement. Employee has not relied upon any representations or statements made by the Company that are not specifically set forth in this Agreement.

19. Severability. In the event that any provision or any portion of any provision hereof or any surviving agreement made a part hereof becomes or is declared by a court of competent jurisdiction or arbitrator to be illegal, unenforceable, or void, this Agreement shall continue in full force and effect without said provision or portion of provision.

20. Attorneys' Fees. Except with regard to a legal action challenging or seeking a determination in good faith of the validity of the waiver herein under the ADEA, in the event that either Party brings an action to enforce or effect its rights under this Agreement, the prevailing Party shall be entitled to recover its costs and expenses, including the costs of mediation, arbitration, litigation, court fees, and reasonable attorneys' fees incurred in connection with such an action.

21. Entire Agreement. This Agreement represents the entire agreement and understanding between the Company and Employee concerning the subject matter of this Agreement and Employee's employment with and separation from the Company and the events leading thereto and associated therewith, and supersedes and replaces any and all prior agreements and understandings concerning the subject matter of this Agreement and Employee's relationship with the Company, including the Employment Agreement, with the exception of the dispute resolution and cooperation provisions in the Employment Agreement, the Confidentiality Agreement, and any agreements between the Company and Employee relating to stock, stock options, or restricted stock units.

22. No Oral Modification. This Agreement may only be amended in a writing signed by Employee and the Company's Chief Executive Officer.

23. Governing Law. This Agreement shall be governed by the laws of the State of New Jersey, without regard for choice-of-law provisions. Employee consents to personal and exclusive jurisdiction and venue in the State of New Jersey.

24. Effective Date. Employee understands that this Agreement shall be null and void if not executed by Employee, and returned to the Company, within the forty-five (45) day period set forth above. Each Party has seven (7) days after that Party signs this Agreement to revoke it. This Agreement will become effective on the eighth (8th) day after Employee signed this Agreement, so long as it has been signed by the Parties and has not been revoked by either Party before that date (the "Effective Date").

25. Counterparts. This Agreement may be executed in counterparts and each counterpart shall be deemed an original and all of which counterparts taken together shall have the same force and effect as an original and shall constitute an effective, binding agreement on the part of each of the undersigned. The counterparts of this Agreement may be executed and delivered by facsimile, photo, email PDF, Docusign/Echosign or a similarly accredited secure signature service, or other electronic transmission or signature. This Agreement may be executed in one or more counterparts, and counterparts may be exchanged by electronic transmission (including by email), each of which will be deemed an original, but all of which together constitute one and the same instrument.

26. Voluntary Execution of Agreement. Employee understands and agrees that Employee executed this Agreement voluntarily, without any duress or undue influence on the part or behalf of the Company or any third party, with the full intent of releasing all of Employee's claims against the Company and any of the other Releasees. Employee acknowledges that:

(a) Employee has read this Agreement;

(b) Employee has been represented in the preparation, negotiation, and execution of this Agreement by legal counsel of Employee's own choice or has elected not to retain legal counsel;

(c) Employee understands the terms and consequences of this Agreement and of the releases it contains; and

(d) Employee is fully aware of the legal and binding effect of this Agreement.

IN WITNESS WHEREOF, the Parties have executed this Agreement on the respective dates set forth below.

STEPHEN J. MCANDREW, an individual

Dated: November 18, 2018

/s/ Stephen J. McAndrew, Ph.D.
Stephen J. McAndrew, Ph.D.

ONCOBIOLOGICS, INC.

Dated: November 9, 2018

By /s/ Lawrence A. Kenyon
Lawrence A. Kenyon
President, Chief Executive Officer & Chief Financial Officer

Exhibit A – Equity Interests

Exhibit B – ADEA Disclosure Schedule

Exhibit A

Equity Awards Outstanding as of Separation Date

Type of Equity Award	Date of Issuance	Number of Shares subject to Equity Award Outstanding as of Separation Date	Number of Shares Vested as of Separation Date (inclusive of accelerated vesting under Section 1(c) of the Agreement)	Number of Shares Unvested as of Separation Date
Stock Option	6/15/2018	30,000	15,000	15,000
Stock Option	10/22/2018	200,000	100,000	100,000

Exhibit B
ADE Disclosure Schedule

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

CONFIDENTIAL Execution Version

STRATEGIC PARTNERSHIP AGREEMENT

THIS STRATEGIC PARTNERSHIP AGREEMENT (the "**Agreement**") by and between Oncobiologics, Inc., a Delaware corporation with a principal place of business at 7 Clarke Drive, Cranbury, New Jersey 08512 USA ("**Oncobiologics**"), and MTTR, LLC, a Delaware limited liability company, with a principal place of business at [***] ("**MTTR**"), is effective as of February 15, 2018 (the "**Effective Date**"). Oncobiologics and MTTR are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**".

RECITALS

WHEREAS, Oncobiologics is a clinical-stage biopharmaceutical company focused on identifying, developing, manufacturing, and commercializing complex biosimilar therapeutics in immunology and oncology disease areas;

WHEREAS, MTTR is controlled by a group of Consultants (as defined below) that are physicians and/or executives with professional expertise in ophthalmology, including scientific, medical and regulatory affairs, as well as commercial operations and strategic planning;

WHEREAS, Oncobiologics is developing a biosimilar product of bevacizumab; and

WHEREAS, the Parties desire for Oncobiologics to engage MTTR as a consulting company to perform, through its Consultants, the Services (as defined below), and for MTTR to provide such Services; all on the terms and conditions described herein.

NOW THEREFORE, in consideration of the promises and mutual agreements contained herein, the Parties hereto, intending to be legally bound, agree as follows:

1. Definitions

1.1 "Actual Deductible Costs" means the aggregate amount of the following costs incurred after the Effective Date:

(a) the aggregate amount of all costs and expenses incurred by Oncobiologics or its Affiliates for the pre-clinical or clinical Development of Products [***], including all costs identified in Exhibit D as "Development Costs", in each case, [***], (**"Development Costs"**);

(b) the aggregate amount of all costs and expenses incurred by Oncobiologics or its Affiliates in connection with the manufacture or Commercialization of Products [***];

(c) the aggregate amount of all costs and expenses incurred by Oncobiologics or its Affiliates in bringing an appropriate suit or other action against any person or entity engaged in any existing or threatened infringement of any patent right owned or controlled by Oncobiologics or its Affiliates that Covers the Development, Commercialization, manufacture, making, having made, use, offering for sale, sale, having sold, importation or exportation of a Product in the Field in the Territory [***]; and

(d) to the extent Oncobiologics reasonably believes that it is required to obtain a license or similar right under any Third Party IP to make, have made, use, offer for sale, sell, have sold, import or export any Product in the Field in the Territory, the aggregate amount of all any royalties, milestones, upfront fees or other payments payable by Oncobiologics or its Affiliates during the Term for such license or similar right pursuant to an agreement with a Third Party (and including, for clarity, any such licenses or similar rights obtained by Oncobiologics prior to the Effective Date for the exercise of similar rights during the Term [***]) (each such agreement with a Third Party, a "**Third Party IP Agreement**"). For the purposes of this Agreement, **"Third Party IP"** means any patent right that is owned or controlled by a Third Party and to the extent it Covers the making, having made, using, offering for sale, selling, having sold, importing or exporting a Product in the Field in the Territory.

Notwithstanding the foregoing, Actual Deductible Costs shall not include any such costs, expenses or other amounts for which Oncobiologics or its Affiliates have received prepayment or reimbursement from any Third Party, including in connection with the grant of a license or other right with respect to Product(s) for the Field in the Territory. For clarity, any amounts excluded from the definition of Other Income under subsections (a) – (c) of Section 1.33 shall not be Actual Deductible Costs.

1.2 "**Adjusted Deductible Cost**" means, for purposes of the calculation of Net Profits for a Calendar Year, the cumulative Actual Deductible Costs for a given Product that do not exceed (i) [***] percent ([***]%) of the gross revenues received by Oncobiologics or its Affiliates in such Calendar Year, for the [***] period after First Commercial Sale of such Product, and (ii) [***] ([***]%) of the gross revenues received by Oncobiologics or its Affiliates in such Calendar Year, for any other Calendar Year.

1.3 **"Affiliate"** means, with respect to a Party, any entity which controls, is controlled by or is under common control with such Party. For purposes of this definition only, "control" means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of fifty percent (50%) or more of the securities entitled to be voted generally or in the election of directors of such entity, or by contract or otherwise. For clarity, once an entity ceases to be an Affiliate of a Party, then, without any further action, such entity shall cease to have any rights under this Agreement by reason of being an Affiliate of such Party.

1.4 **"Anti-Corruption Laws"** means laws, regulations, or orders prohibiting the provision of a financial or other advantage for a corrupt purpose or otherwise in connection with the improper performance of a relevant function, including without limitation, the US Foreign Corrupt Practices Act (FCPA), and similar laws governing corruption and bribery, whether public, commercial or both, to the extent applicable.

1.5 "Applicable Laws" means, individually and collectively, any federal, state, local, national and supra-national laws, treaties, statutes, ordinances, rules and regulations, that are in effect from time to time during the Term and applicable to a particular activity hereunder.

1.6 "Approved Indication(s)" means any Indication for which a Product has received Regulatory Approval (whether in the United States or in any other country in the Territory).

1.7 "Biosimilar" means a biological product that: [***] .

1.8 "BPCI Act" means the Biologics Price Competition and Innovation Act of 2009 within the Patient Protection and Affordable Care Act, as set forth in Section 351(k) of the PHS Act (42 U.S.C. 262), which was signed into law in the United States in March 2010, and as may be subsequently amended.

1.9 "Business Day" means a day other than Saturday, Sunday or any day that banks in the U.S. are required or permitted to be closed.

1.10 "Calendar Quarter" means the period beginning on the Effective Date and ending on the last day of the calendar quarter in which the Effective Date falls, and thereafter each successive period of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31; provided, that, the final Calendar Quarter shall end on the last day of the Term.

1.11 "Calendar Year" means the period beginning on the Effective Date and ending on December 31 of the calendar year in which the Effective Date falls, and thereafter each successive period of twelve (12) months commencing on January 1 and ending on December 31; provided, that, the final Calendar Year shall end on the last day of the Term.

1.12 "Change of Control" means, with respect to Oncobiologics: (a) the sale of all or substantially all of Oncobiologics's assets or business; (b) a merger, reorganization or consolidation involving Oncobiologics in which the voting securities of Oncobiologics outstanding immediately prior thereto cease to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (c) a person or entity, or group of persons or entities, acting in concert acquire more than fifty percent (50%) of the voting equity securities or management control of Oncobiologics.

1.13 "**Cost of Goods Sold**" or "**COGS**" means the fully burdened costs incurred by Oncobiologics or its Affiliates, in U.S. Dollars (as defined by Oncobiologics's consistent application of GAAP), in manufacturing or having manufactured Products.

1.14 "Commercially Reasonable Efforts" means, with respect to a Party's obligations under this Agreement, the carrying out of such obligations with a level of efforts and resources consistent with the commercially reasonable practices of a similarly situated company in the pharmaceutical industry for developing or seeking Regulatory Approval of a similarly situated branded pharmaceutical product as the Product at a similar stage of development, taking into account efficacy, safety, patent and regulatory exclusivity, anticipated or approved labeling, present and future market potential, competitive market conditions, the profitability of the product in light of pricing and reimbursement issues, and all other relevant factors.

1.15 "Commercialization" or "**Commercialize"** means all activities directed to marketing, promotion, distribution, detailing or selling a Product (including supply chain, importing and exporting activities in connection therewith).

1.16 "Confidential Information" of a Party means any and all Information of a Party (the "**Disclosing Party**") that is disclosed to the other Party (the "**Receiving Party**") related to activities conducted pursuant to this Agreement, whether in oral, written, graphic, or electronic form, provided that any information that is disclosed in writing shall be marked as "Confidential" and any information not disclosed in writing shall be designated by the Disclosing Party as confidential at the time of its initial disclosure and reduced to a written summary by the Disclosing Party that is marked in a manner to indicate its confidential nature and delivered to the Receiving Party within [***] after its initial disclosure (provided, however, that such requirement to summarize in writing non-written disclosures shall not apply to information that pertains to the Product that the Receiving Party knew, or reasonably should have known, was the Confidential Information of the Disclosing Party). In addition all Information disclosed by a Party pursuant to the Confidentiality Agreement between the Parties dated February 2, 2018 (the "**Confidentiality Agreement**") shall be deemed to be Confidential Information of such Party disclosed hereunder; provided, however, that any use or disclosure of any such Information that is authorized under Article 13 shall not be restricted by, or be deemed a violation of, the Confidentiality Agreement.

1.17 "Consultant" (or, collectively, "**Consultants**") means each of (a) [***], an individual and citizen of the U.S. residing, as of the Effective Date, in the state of [***] ("**[***]**"); (b) [***], an individual and citizen of the U.S. residing, as of the Effective Date, in the state of [***] ("**[***]**"); (c) Mr. Terry Dagnon, an individual and citizen of the U.S. residing, as of the Effective Date, in the state of [***] ("**Mr. Dagnon**"); and (d) [***], an individual and citizen of the U.S. residing, as of the Effective Date, in the state of [***] ("**[***]**").

1.18 "Cover," "Covering" or "Covered" means, with respect to any Product, that the manufacture, use, offer for sale, sale, import or export of such Product in the Field in a particular country in the Territory by a party who has not been granted a license or similar right under patent rights owned or controlled by another party would infringe a valid claim of such other party's patent rights.

1.19 "Development" (with a correlative meaning for "**Develop**" and "**Developing**") means all activities relating to preclinical and clinical trials, toxicology testing, statistical analysis, publication and presentation of study results and reporting, preparation and submission of applications for obtaining and maintaining Regulatory Approval of Products.

1.20 **"FDA"** means the United States Food and Drug Administration or any successor entity thereto.

1.21 **"Field"** means the treatment, prevention or cure of any ophthalmic indication, including wet macular degeneration ("**Wet AMD**"), diabetic macular edema ("**DME**") or diabetic retinopathy ("**DR**") (together with retinal vein occlusions, myopic choroidal neovascularization and all other ophthalmic indication, collectively, "**Indications**").

1.22 **"First Commercial Sale"** means, with respect to each country in the Territory, the first sale for end use or consumption of the Product in such country in the Territory after Marketing Approval has been granted in such country in the Territory.

1.23 **"GAAP"** means the then-current generally accepted accounting principles in the United States as established by the Financial Accounting Standards Board or any successor entity or other entity generally recognized as having the right to establish such principles in the United States, in each case consistently applied.

1.24 **"Governmental Authority"** means any multi-national, national, federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

1.25 **"IND"** means an Investigational New Drug application filed with the FDA, or an equivalent filing outside of the U.S.

1.26 **"Information"** means any data, results, technology, business or financial information or information of any type whatsoever, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulae, software, algorithms, marketing reports, expertise, technology, test data (including pharmacological, biological, chemical, biochemical, clinical test data and data resulting from non-clinical studies), CMC information, stability data or other study data and procedures.

1.27 [***].

1.28 [***].

1.29 **"Marketing Authorization Application"** or **"MAA"** means an application to the appropriate Regulatory Authority for approval to market a Product in any particular jurisdiction and all amendments and supplements thereto.

1.30 **"Marketing Approval"** means an approval for a Product from a Regulatory Authority necessary for the distribution, marketing and sale of such Product, including where necessary to initiate marketing and sales, pricing and reimbursement approval(s).

1.31 "Net Profits" means, with respect to a given Calendar Year, the Other Income and Net Revenue received by Oncobiologics and its Affiliates in the Field in the Territory, minus Adjusted Deductible Costs, accounted for in accordance with Oncobiologics's standard accounting practices consistent with GAAP. Any Actual Deductible Costs that are not accounted for in the definition of "Net Profits" due to the limitations set forth in the definition of "**Adjusted Deductible Costs**", below, may be carried forward to the calculation of Net Profits in subsequent Calendar Years until such Actual Deductible Costs have been fully offset. [***]. Additionally, in calculating Net Profits with respect to sales of Products to Third Parties in the Field in the Territory by a Third Party sublicensee of Oncobiologics only the cash consideration received by the Oncobiologics or its Affiliates in connection with such sale from such Third Party sublicensee will be included in the calculation of Net Revenues, provided that no other material consideration is received by Oncobiologics in connection therewith.

1.32 "**Net Revenues**" means, with respect to any Product, the gross sales price of such Product sold by Oncobiologics or its Affiliates (the "**Selling Party**") to Third Parties, less:

[***]

Net Revenues will be determined in accordance with GAAP, consistently applied throughout the organization and across all products of the Selling Party whose sales of Products are giving rise to Net Revenues.

[***]

Where a Product is sold in combination with other pharmaceutical products, diagnostic products, or active ingredients (collectively, "**Combination Components**") the Net Revenues applicable to such transaction shall be calculated by multiplying the total Net Revenues of such combined product by the fraction A/(A+B), where A is the actual price of the Product in the same formulation and dosage amount or quantities in the applicable country during the applicable quarter if sold separately, and B is the sum of the actual prices of all Combination Components with which the Product is combined, in the same formulation and dosage amount or quantities in the applicable country during the applicable quarter if sold separately. If A or B cannot be determined because values for the Product or Combination Components with which the Product is combined are not available separately in a particular country, then [***].

Sales of Product(s) between or among Oncobiologics and its Affiliates shall be excluded from the computation of Net Revenues and no payments shall be payable on such sales except where such Affiliates are end users.

1.33 "**Other Income**" means any consideration received by Oncobiologics or its Affiliates from a Third Party that is attributable to Product(s) for the Field in the Territory, including any consideration received in connection with the grant of a license or other right with respect to Product(s) for the Field in the Territory, including the grant of an option to obtain such license or other right, but excluding in all cases: (a) payments received from such Third Party for the purposes of funding and/or reimbursing expenses incurred by Oncobiologics or any of its Affiliates for [***] research and development activities related to Products in the Field in the Territory, (b) payments and reimbursements by such Third Party of patent costs incurred by Oncobiologics or its Affiliates in connection with Products in the Field in the Territory, (c) payments received from such Third Party for the supply of Products by Oncobiologics or its Affiliates (to the extent not in excess of Oncobiologics's COGS for such Products), and (d) payments made by such Third Party as consideration for the issuance of equity or debt securities of Oncobiologics or its Affiliates at fair market value (excluding amounts in excess of the fair market value of such securities).

1.34 "**PDUFA Fees**" means any fees owed to the FDA pursuant to the Prescription Drug User Fee Act.

1.35 **"Phase 3 Clinical Study"** means a human clinical trial that would satisfy the requirements for a Phase 3 study as defined in 21 CFR § 312.21(c) (or any amended or successor regulations), regardless of where such clinical trial is conducted.

1.36 **"Pilot Study"** means a human clinical experience study (as defined in FDA guidance) of a Product for use in the Field in the Territory, which study shall initially be designed for [***].

1.37 **"Pivotal Study"** means: (a) a Phase 3 Clinical Study; or (b) any other human clinical study that the applicable Regulatory Authority has agreed is sufficient to form the primary basis of an efficacy claim in an MAA submission, including any such study that is determined to have become pivotal after its commencement, in each case of (a) and (b), which clinical study shall initially be designed for approximately [***].

1.38 **"Primary End Point"** means the primary end points set forth in Exhibit F attached hereto.

1.39 **"Product"** means any Biosimilar of bevacizumab controlled by Oncobiologics, as such compound shall be developed by the Parties under this Agreement (including all pharmaceutical products and formulations thereof), sold alone or in combination with one or more other therapeutically active ingredients.

1.40 **"Regulatory Approval"** means an approval, clearance or authorization for the Product from a Regulatory Authority necessary for the research, Development, manufacture, distribution, pricing, reimbursement, marketing or sale of the Product, including any Marketing Approval.

1.41 **"Regulatory Authority(ies)"** means any Governmental Authority or other authority responsible for granting Regulatory Approvals for the Product, including the FDA and any corresponding national or regional regulatory authorities.

1.42 **"Regulatory Exclusivity"** means, with respect to a Product and country, the rights conferred by any Regulatory Authority in such country with respect to such Product, including the rights conferred in the United States under 42 U.S.C. §262 or comparable rights outside of the United States.

1.43 "Successful First FDA Interaction" means written approval by the FDA (after discussions with the FDA) to conduct a Pilot Study requiring no more than [***], and written guidance from the FDA that a Pivotal Study will not require more than [***].

1.44 "Territory" means all countries or territories in the world, excluding Mexico.

1.45 "Third Party" means any Person that is not a Party, or an Affiliate of a Party.

1.46 "United States" or **"U.S."** means the United States of America and its territories and possessions.

2. Performance of Services; Records; Deliverables

2.1 Services. The Parties agree that, among other things, MTTR will provide to Oncobiologics strategic advice for the Development, seeking and obtaining Regulatory Approval and Commercialization, of the Product in the Field in the Territory as agreed upon in writing by the Parties during the Term, including such services set forth in Exhibit A, attached hereto (the "**Services**"; the description and/or list of such Services, the "**Services Schedule**"). The Services Schedule can only be amended in a writing signed by the Parties. MTTR agrees to exercise the professionalism consistent with industry standard for the performance of similar services and utilize its collective expertise and creative talents in performing the Services. In addition to any JSC (as defined below) meetings agreed upon by the Parties, MTTR agrees to make the Consultants reasonably available to meet with Oncobiologics (in person or by teleconference), as reasonably requested by Oncobiologics from time to time, consistent with such Consultant's time commitment set forth in Section 2.2(b). This Agreement will take precedence over any contrary or inconsistent terms or conditions appearing in or referred to in any exhibit, unless the exhibit expressly refers to the Parties' intent to alter the terms of this Agreement with respect to such exhibit.

2.2 Expertise; Time Commitments; Replacement.

(a) The Consultants have the respective expertise ascribed to their names in Exhibit B. MTTR agrees to inform Oncobiologics in the event that any of the Consultants is no longer qualified to represent itself as an expert in accordance with Exhibit B.

(b) MTTR shall ensure that each Consultant commits to dedicate a percentage of his time on a full-time equivalent basis, which shall constitute [***] hours ("**FTE**"), to the performance of Services under this Agreement, in accordance with the respective Development Stage (as defined below) of the Product and determined on a Calendar Quarter basis, pursuant to the schedule set forth in Exhibit B.

(c) MTTR shall not replace [***] with any person during the Term; provided that, if [***] dies, becomes incapacitated or voluntarily resigns from employment at MTTR (through no fault of MTTR), MTTR shall have the right to suggest a replacement consultant by notifying Oncobiologics promptly (but in any event no later than [***]) after the occurrence of such trigger event; provided that, Oncobiologics may withhold consent to such replacement consultant, in Oncobiologics's sole discretion; provided further, that if Oncobiologics does not approve of such replacement consultant, then this Agreement will terminate in its entirety in accordance with Section 15.5(a).

(d) MTTR shall have the right to replace each of [***] with another person with similar qualifications, solely with the prior written approval of Oncobiologics ([***]). If Oncobiologics does not approve any such replacement consultant for [***], then Oncobiologics shall provide its basis for non-approval. Notwithstanding the foregoing, if Oncobiologics does not approve of such replacement consultant after good faith consideration, then this Agreement will terminate with respect to such Consultant in accordance with Section 15.5(b).

(e) Upon any approval of a replacement consultant in accordance with subsection (c) or (d) above, any and all references in this Agreement to the applicable replaced Consultant shall be deemed to refer to the replacement consultant, without any further modification of the terms and conditions of this Agreement, unless otherwise agreed by the Parties in writing.

2.3 Records.

(a) MTTR shall ensure that the Consultants shall maintain complete and accurate records of the status and progress of the Services, and all materials, information, data or other know-how generated, authored, conceived or reduced to practice by the Consultants in the course of performing the Services, in accordance with Applicable Law (collectively, the "**Records**"). MTTR shall maintain the Records in sufficient detail to properly reflect, in a reasonable manner, all significant Services performed and the results of such Services, at a level of detail appropriate for patent and regulatory purposes.

(b) Upon expiration or termination of this Agreement, and upon such other times as requested by Oncobiologics during the Term, MTTR shall (i) provide to Oncobiologics copies of the Records and (ii) allow Oncobiologics to access, review and copy the Records (including access to relevant databases). At no time shall MTTR dispose of any Records without first giving Oncobiologics [***] prior written notice of its intent to dispose such Records.

2.4 Deliverables. MTTR will deliver to Oncobiologics all Records, reasonable descriptions of Inventions, reports, documentation, data, information or materials as set forth in the Services Schedule or otherwise generated in the course of performing the Services (collectively, "**Deliverables**"), within [***] of the completion of the Services, or as otherwise set forth in the Services Schedule. Any failure by MTTR to deliver such Deliverables to Oncobiologics within such time period [***]. The Parties acknowledge that (a) all information regarding regulatory pathway and strategy with respect to the Product for the Field in the Territory disclosed by MTTR to Oncobiologics ("**MTTR Regulatory Strategy**") shall be MTTR's Confidential Information (which, for avoidance of doubt, may be used by Oncobiologics in accordance with the license grant to Oncobiologics under Section 10.3 and the non-use and non-confidentiality obligations under Article 13) and (b) all Deliverables, other than MTTR Regulatory Strategy, shall be deemed Oncobiologics's Confidential Information.

3. Governance

3.1 JSC Formation and Role. The Parties hereby establish a joint steering committee (the "**Joint Steering Committee**" or "**JSC**"). The JSC shall have the following responsibilities:

(a) to serve as a forum for the Consultants to discuss and share updates with respect to their performance of the Services, including strategies for the Development and/or Commercialization of the Product (including presentation of the then-current Development Plan and/or Commercialization Plan), regulatory updates and marketing materials;

(b) to serve as a forum for Oncobiologics to discuss and share updates with respect to its Development, regulatory and Commercialization efforts under this Agreement and/or to review and approve any material updates to the Development Plan, the Commercialization Plan (including any material updates thereto), drafts of regulatory filings or communications and marketing materials, with respect to Products for the Field in the Territory;

(c) to discuss the Development of Products for use in the Field in the Territory in the First Indication, Second Indication and any Additional Indications, including the order and prioritization of such Development activities in the respective Indications in accordance with Section 4.3(a);

(d) to discuss, coordinate and share updates and information with respect to the Parties' respective interactions with Regulatory Authorities, with respect to Products for the Field in the Territory; and

(e) to perform such other functions as appropriate to further the purposes of this Agreement, as expressly set forth in this Agreement or as agreed by the Parties in writing.

3.2 Members. The JSC shall be comprised of (a) at least two (2) of the Consultants (provided that, at all times after commencement of Development Stage 2 with respect to a Product in the Field in the Territory, all four (4) Consultants shall be present at the JSC); and (b) four (4) representatives from Oncobiologics (with each representative of Oncobiologics being an officer, employee or consultant of Oncobiologics or its Affiliate having sufficient seniority to make decisions arising within the scope of the JSC's responsibilities). The initial members of the JSC from Oncobiologics and MTTR are as set forth on Exhibit G attached hereto; provided that, Oncobiologics may replace its representatives with an officer, employee or consultant of Oncobiologics or its Affiliates at any time upon written notice to MTTR. For purposes of any particular JSC meeting, MTTR may substitute an "Initial JSC Member" with an "Initial Alternate JSC Member", each as described in Exhibit G attached hereto. The JSC may change its size from time to time by mutual consent of the Parties. Oncobiologics shall appoint one (1) of its representatives to act as the chairperson of the JSC. The role of the chairperson shall be to convene and preside at the JSC meeting, to ensure the circulation of meeting agendas in advance of JSC meetings and to prepare meeting minutes and circulate to all of the JSC members such minutes that reflect all material decisions made at such meetings.

3.3 Meetings. The JSC shall meet at least once per calendar month during the Term, unless the Parties mutually agree in writing to a different frequency for such meetings. Either Party may also call a special meeting of the JSC (by videoconference or teleconference) upon at least [***] prior written notice to the other Party in the event such Party reasonably believes that a significant matter must be addressed prior to the next regularly scheduled meeting. The JSC may meet in person, by videoconference or by teleconference (provided, however, that, unless the Parties otherwise mutually agree, at least [***] JSC meetings per [***] shall be in person until commencement of Development Stage 3 with respect to a Product in the Field in the Territory, after which at least [***] JSC meeting per [***] shall be in person, and MTTR shall have the right to select the location of the first in-person meeting (and, thereafter, the location shall be selected by the Parties on an alternating basis). [***]. The participation at JSC meetings by the Consultants, in accordance with Section 3.2(a), shall be mandatory. Oncobiologics may have additional employee representatives and consultants of Oncobiologics attend JSC meetings as non-voting participants, including one employee to act as secretary of the meeting. MTTR may have additional employee representatives and consultants of MTTR attend JSC meetings as non-voting participants. All JSC meetings shall be conducted in English and all communications under this Agreement shall be in English. The chairperson shall send draft meeting minutes to each representative of the JSC for review and approval within [***] after the applicable meeting. Such minutes shall be deemed approved when signed by the chairperson from Oncobiologics and a JSC member from MTTR; such sign off should not be delayed and be provided within [***] after receipt thereof unless one or more JSC representatives object to the accuracy of such minutes within said [***] period.

3.4 Decision Making. The JSC shall be primarily a forum for information exchange and discussion; provided that, to the extent that any decisions need to be made pursuant to this Agreement, the JSC shall strive to seek consensus in its actions and decision making process, with each Party having collectively one (1) vote in all decisions. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before the JSC, the representatives of the Parties cannot reach an agreement as to such matter within the course of such JSC meeting, then, and subject to Section 3.5, Oncobiologics shall have the final decision-making authority with respect to such matter, including with respect to matters regarding the Development, manufacture, seeking Regulatory Approval or Commercialization of Products under this Agreement; [***].

3.5 Limitation of JSC Authority. The JSC shall only have the powers expressly assigned to it in this Article 3 and elsewhere in this Agreement and shall not have the authority to: (a) modify or amend the terms and conditions of this Agreement (including any material alteration to the terms of the Services or time commitments of any Consultant); (b) waive or determine either Party's compliance with the terms and conditions of under this Agreement; or (c) decide any issue in a manner that would conflict with the express terms and conditions of this Agreement.

4. Development Program

4.1 Conduct of Development Activities. Except as expressly set forth in Exhibit A or otherwise in this Agreement with respect to Development-related Services to be conducted by MTTR, Oncobiologics shall have the sole right and responsibility, at its sole cost and expense, in each case in accordance with the Development Plan, for the conduct of all Development activities applicable to Products in the Field in the Territory. At all times during the Term, MTTR shall, through the Consultants, provide Services to Oncobiologics with respect to the Development of Products in the Field for all Indications for which Oncobiologics intends to pursue Regulatory Approval in the Territory.

4.2 Preparation of Development Plans. MTTR will prepare the non-clinical safety and clinical development plan for the Development of Products in the Field in the Territory (which plan shall include, for clarity, any MTTR Regulatory Strategy existing as of such date with respect to the Development of such Products in the Field in the Territory) (collectively, the "**Development Plan**"), including any updates thereto, in accordance with this Section 4.2. The Development Plan shall reflect at least the use of Commercially Reasonable Efforts to obtain Regulatory Approval of the Product in the Field for [***]. The initial Development timeline is attached hereto as Exhibit E. Subject to the remainder of this Section 4.2, MTTR shall submit any non-material updates to the Development Plan to Oncobiologics for review and approval by Oncobiologics. MTTR will incorporate all feedback provided by Oncobiologics (after any reasonable discussion requested by MTTR) with respect to the Development Plan, and the Parties will communicate, cooperate and share information with each other on an ongoing basis during the Term in order to keep each other informed as to the Development of the Product and enable MTTR to revise the Development Plan to reflect the then-current plans for Oncobiologics's Development of Products in the Field in the Territory. MTTR shall provide any material updates to the Development Plan to the JSC at least [***] for review and approval by the JSC in accordance with Article 3. The Development Plan and updates thereto shall contain a reasonably detailed summary of (a) all major Development activities (including all clinical studies) conducted under this Agreement since the last Development Plan and (b) all major Development activities proposed to be conducted under this Agreement, including the anticipated timelines for achieving such activities.

4.3 Initial Development Activities.

(a) Oncobiologics will initially Develop and submit for Regulatory Approval Products in the following Indications: (i) intravitreal injection of Product for the treatment of Wet AMD (the "**First Indication**"), and (ii) intravitreal injection of Product for the treatment of DME (the "**Second Indication**"). The Parties shall jointly discuss and evaluate, through the JSC, the Development of Products for treatment of Indications other than the First Indication and Second Indication (each, an "**Additional Indication**"). For clarity, the terms "First Indication", "Second Indication" and "Additional Indications" may not track the actual temporal order of Development of the Product (*i.e.*, Oncobiologics may Develop the Product in the Field for the Second Indication or an Additional Indication prior to the First Indication), as discussed by the Parties through the JSC and without limiting Section 4.3(b).

(b) Oncobiologics will use Commercially Reasonable Efforts to Develop and seek Marketing Approval of a Product in the Field for the First Indication, the Second Indication, or an Additional Indication (whichever Indication is the lead Indication at such time). Oncobiologics will not delay filing for Marketing Approval in the U.S. of a Product in the Field for the lead Indication by more than one (1) Calendar Quarter as a result of insufficient funding of the program. For clarity, in the event that Development Costs incurred specifically for (i) conducting the Pilot Study and Pivotal Study (but excluding costs incurred in manufacturing and/or supplying Products for use in such studies), and (ii) obtaining Regulatory Approval of Products in the Field in the U.S. (but excluding any PDUFA Fees and all other Development or Commercialization costs incurred by Oncobiologics) either exceed or are reasonably likely to exceed [***] U.S. Dollars ($[***]) ([***]), then Oncobiologics termination of the Development of Products shall not be considered a failure to use Commercially Reasonable Efforts.

4.4 Development Stages. The development stages for Development of the Products under this Agreement shall be as set forth below (each, a "**Development Stage**").

(a) Development Stage 1A: commences on the Effective Date and ends upon the first Successful First FDA Interaction;

(b) Development Stage 1B: commences upon the first Successful First FDA Interaction and ends upon the first completion (*i.e.*, last patient completion of follow-up) of a Pilot Study;

(c) Development Stage 2: commences upon the first completion of a Pilot Study and ends upon the first achievement of the Primary End Point in a Pivotal Study;

(d) Development Stage 3: commences upon the first achievement of the Primary End Point in a Pivotal Study and ends upon the First Commercial Sale of a Product for use in any Approved Indication in the U.S.; and

(e) Development Stage 4: commences upon the First Commercial Sale of a Product for use in any Approved Indication in the U.S.

5. Exclusivity; ROFN; Limitations

5.1 Exclusivity. During the Term, MTTR shall cause each Consultant not to work for, assist or enable in any way, directly or indirectly, any Third Party with respect to the development or commercialization of any Biosimilar of bevacizumab in the Field; so long as Oncobiologics is using Commercially Reasonable Efforts to Develop and/or Commercialize a Product in the Field in the Territory and making all undisputed payments owed to MTTR in connection therewith, in accordance with Article 9. MTTR shall ensure that each Consultant acknowledges and abides by the obligations of exclusivity owed to Oncobiologics pursuant to this Section 5.1.

5.2 Right of First Negotiation. [***]

5.3 Limitations.

(a) Except as expressly set forth in Section 5.2, Oncobiologics reserves the right to engage other Third Party contractors to perform any of its Development, manufacturing, regulatory or Commercialization activities under this Agreement ("**Oncobiologics Service Providers**"), subject to binding such Third Party contractor to confidentiality and non-use restrictions that are consistent with the provisions of Article 13 with respect to any Confidential Information of MTTR disclosed to such Third Party contractor. Oncobiologics shall permit Oncobiologics Service Providers to disclose Confidential Information of Oncobiologics to MTTR for the sole purpose of MTTR performing its obligations under this Agreement, including the performance of Services, and shall, at MTTR's request, promptly inform such Third Party contractor of such permission. Notwithstanding anything to the contrary herein, with respect to any such Confidential Information of Oncobiologics disclosed to MTTR by an Oncobiologics Service Provider, Oncobiologics shall be deemed the "Disclosing Party" of such Confidential Information and the provisions of Article 13 shall apply with equal force and effect to protect the confidentiality, non-use and non-disclosure of such Confidential Information by MTTR. Subject to the terms and conditions of this Agreement, MTTR shall have the right to discuss with any Oncobiologics Service Provider the performance of any of its obligations under this Agreement but not to engage or solicit any Oncobiologics Service Provider to work directly for MTTR to perform such obligations without obtaining prior written consent from Oncobiologics (which consent may not be unreasonably withheld, conditioned or delayed). For clarity, as long as MTTR is complying with its obligations under this Agreement, Oncobiologics shall not prohibit any Oncobiologics Service Provider from working with MTTR pursuant to the immediately preceding sentence. For avoidance of doubt, MTTR may discuss, engage or solicit any Oncobiologics Service Provider for the performance of any activities outside the scope of this Agreement that are not in violation of MTTR's obligations under Section 5.1. Upon termination or expiration of this Agreement, MTTR shall not require Oncobiologics's approval in order to work with any Oncobiologics Service Provider.

(b) Subject to Section 5.1, MTTR and each Consultant reserves the right to perform services for other persons, provided that the performance of such services do not conflict or interfere with the Services or MTTR's obligations under this Agreement.

6. Regulatory Responsibilities

6.1 Regulatory Activities. Except as expressly set forth in Exhibit A or otherwise in this Agreement with respect to regulatory-related Services to be conducted by MTTR, Oncobiologics will have the sole right and responsibility, at its sole cost and expense, for all regulatory activities with respect to Products in the Field in the Territory, and Oncobiologics shall have final decision-making authority with respect thereto, taking into good faith consideration MTTR's perspective as provided through the JSC and provided that Oncobiologics shall exercise such final decision-making authority in a manner that does not delay, and is consistent with the exercise of Commercially Reasonable Efforts with respect to, the conduct of regulatory activities with respect to Products in the Field in the Territory.

6.2 Responsibility for Regulatory Filings. Oncobiologics shall have the sole right and responsibility, at its sole expense, to prepare, file, prosecute and maintain all regulatory filings for Products in the Territory in Oncobiologics's own name; provided that, MTTR shall provide such regulatory-related Services as set forth in Exhibit A, including providing Oncobiologics with drafts of all regulatory filings as provided therein within a reasonable time prior to submission for Oncobiologics's review, comment and approval, and timely incorporating any feedback provided by Oncobiologics with respect to such regulatory filings. The Parties will communicate, cooperate and share information with each other on an ongoing basis during the Term in order to enable MTTR to prepare and update all applicable regulatory filings.

6.3 Interactions with Regulatory Authorities. Oncobiologics will oversee, monitor and manage all regulatory interactions and communications with Regulatory Authorities with respect to Products in the Territory; provided that, MTTR shall assist Oncobiologics as reasonably requested by Oncobiologics in drafting (including any amendments or revisions to such drafts) or responding to any such regulatory communications and providing such other regulatory-related Services as set forth in Exhibit A. As between the Parties, Oncobiologics shall be responsible for all reporting to Regulatory Authorities with respect to any adverse events occurring with respect to any Product in the Field in the Territory, in accordance with Applicable Law. MTTR shall, through the JSC, keep Oncobiologics reasonably informed of regulatory developments related to Products in the Field in the Territory for which MTTR is responsible pursuant to this Agreement and shall notify Oncobiologics in writing of any decision by any Regulatory Authority in the Territory regarding Products in the Field of which it is aware. Oncobiologics shall keep MTTR reasonably informed of regulatory developments and regulatory activities conducted by or on behalf of Oncobiologics with respect to the Product (in and outside the Field) that are relevant to the Field, including with respect to the biosimilar approval process and the biosimilar patent dance for the Product, and shall notify MTTR in writing of any decision by any Regulatory Authority in the Territory regarding Products that is relevant to the Field of which it is aware.

6.4 Regulatory Meetings. Oncobiologics shall provide MTTR with at least [***] prior written notice (or, to the extent such meeting or discussion is scheduled in less than [***], immediate notice) of any material meeting or discussion with any Regulatory Authority in the Territory related to Products in the Field. One (1) or more of the Consultants shall attend such meetings; provided that, with respect to meetings for which Oncobiologics has given less than [***] prior written notice, the Consultants shall, upon Oncobiologics's request, attend such meeting by teleconference if in-person attendance is not practicable. Oncobiologics shall reimburse Consultants for reasonable, documented travel, meal and lodging costs for such attendance to the extent in accordance with the MTTR Travel Policy in Exhibit H attached hereto.

6.5 Remedial Actions. Each Party shall notify the other immediately, and promptly confirm such notice in writing, if it obtains information indicating that any Product may be subject to any recall, corrective action or other regulatory action by any Governmental Authority or Regulatory Authority (a "**Remedial Action**"). The Parties shall assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action. Oncobiologics shall have sole discretion with respect to any matters relating to any Remedial Action in the Territory, including the decision to commence such Remedial Action and the control over such Remedial Action. The cost and expenses of any Remedial Action in the Territory shall be borne solely by Oncobiologics.

7. Commercialization

7.1 Responsibility for Commercialization of Products. Except as expressly set forth in Exhibit A or otherwise in this Agreement with respect to Commercialization-related Services to be conducted by MTTR, Oncobiologics will have the sole right and responsibility for, and final decision-making authority with respect to, the Commercialization of Products in the Field in the Territory, including (a) the conduct of all pre-marketing, marketing, promotion, sales, distribution, import and export activities (including the securing of reimbursement, sales and marketing and any post-marketing trials or databases and post-marketing safety surveillance); (b) the submission of applications for reimbursement with respect to any Product in any country in the Territory; (c) the identification and registration of all tradenames for any Product in the Field in the Territory; (d) the out-licensing of intellectual property owned or controlled by Oncobiologics that Covers any Product in the Field in the Territory; and (e) the booking of all sales of Products in the Field in the Territory, in each case in accordance with the Commercialization Plan. During the Term, MTTR shall, through the Consultants, provide Services to Oncobiologics with respect to the Commercialization of Products in the Field in the Territory for all Approved Indications. Any promotion of the Product by any Active HCP shall be subject to the prior approval of Oncobiologics. [***].

7.2 Preparation of Commercialization Plan. MTTR will prepare the plan for the Commercialization of each Product in the Field in the Territory ("**Commercialization Plan**") and any updates thereto, in accordance with this Section 7.2. MTTR shall submit the initial Commercialization Plan to the JSC for review and approval by the JSC, no later than [***] prior to the expected date of First Commercial Sale of such Product. MTTR will incorporate all feedback provided by Oncobiologics (after any reasonable discussion requested by MTTR) with respect to such Commercialization Plan, and the Parties will communicate, cooperate and share information with each other on an ongoing basis through the Term to keep each other informed as to the Commercialization of the Product and in order to enable MTTR to revise the Commercialization Plan to reflect Oncobiologics's then-current plans for Commercialization of Products in the Field in the Territory. The Commercialization Plan shall reflect at least the use of Commercially Reasonable Efforts to market and sell the Product in the Field [***]. MTTR shall provide any material updates to the Commercialization Plan to the JSC at least [***] each [***] for review and approval by the JSC in accordance with Article 3. The Commercialization Plan and updates thereto shall contain a reasonably detailed summary of (a) all major Commercialization activities conducted with respect to Products in the Field in the Territory since the last Commercialization Plan and (b) and all major Commercialization activities proposed to be conducted with respect to Products in the Feld in the Territory, including the anticipated timelines for achieving such activities. Subject to Section 4.3(b), Oncobiologics will use Commercially Reasonable Efforts to execute the Commercialization Plan and maximize sales of Products for the Field in the Territory.

8. Manufacturing

8.1 Responsibility. Oncobiologics will have the sole right and responsibility, at its sole cost and expense, to manufacture clinical and commercial supply of Products to support the Development and Commercialization of the Products for the Field in the Territory, and shall have final decision-making authority with respect thereto, taking into good faith consideration MTTR's perspective as provided through the JSC and provided that Oncobiologics shall exercise such final decision-making authority in a manner that does not materially delay, and is consistent with the exercise of Commercially Reasonable Efforts with respect to, the manufacture of Products for Development and Commercialization. Oncobiologics shall keep MTTR reasonably informed of the manufacturing activities for the Products (in and outside the Field) by or on behalf of Oncobiologics that are relevant to manufacture of the Products for the Field.

9. Compensation

9.1 Retainer Fees.

(a) **Monthly Retainer Fee**. In partial consideration for the Services rendered pursuant to this Agreement and for the assignment of MTTR's right, title and interest in Inventions pursuant to this Agreement, Oncobiologics will pay MTTR a monthly retainer fee ("**Monthly Retainer Fee**") in the amount and pursuant to the schedule set forth in the table below (subject to Section 9.3). For clarity, MTTR shall provide a single invoice per month setting forth in an itemized fashion the costs attributable to work performed by each Consultant and the aggregate amount payable for such month. Oncobiologics shall pay all undisputed amounts of such invoice monthly, in arrears, within [***] after receipt of such invoice from MTTR. MTTR shall be solely responsible for all payments to be made to the Consultants.

Timeframe	Consulting Fee ($)
(i) Commencing on the Effective Date, until one year after the Effective Date	monthly installments of US$58,333
(ii) Commencing one year after the Effective Date until the First Commercial Sale of a Product in the Field in the U.S.	monthly installments of $105,208
(iii) Commencing after First Commercial Sale of a Product in the Field in the U.S.	monthly installments of $170,833

(b) **Offset of Retainer Fee; Reduction in Retainer Fee**. The payment of the Monthly Retainer Fee set forth in Section 9.1(a)(iii) shall be offset against any Profit Share payable to MTTR under Section 9.2. In any Calendar Year (commencing one year after a J code has been obtained pursuant to the Health Care Procedure Coding System processes for a Product in the U.S. in an Approved Indication, a "**J Code**")) in which the Net Revenues for Products in the U.S. in all Approved Indications is less than [***] Dollars ([***]), the Monthly Retainer Fee set forth in Section 9.1(a)(iii) shall be reduced by fifty percent (50%).

(c) **Reconciliation of Payments**. Within [***] after the end of each Calendar Quarter, Oncobiologics shall conduct a reconciliation and determine if any reconciliation payment is due from one Party to another for Monthly Retainer Fees paid by Oncobiologics to MTTR in the prior Calendar Quarter and, if so, the amount of such reconciliation payment period. If any such payment is owed, the applicable Party shall make such payment to the other Party within [***] after the reconciliation.

9.2 Profit Share.

(a) **Profit Sharing**. Subject to Section 9.3, following the First Commercial Sale of any Product in the Field in the U.S., Oncobiologics shall pay to MTTR an initial percentage of the Net Profits (if any), in accordance with Exhibit C ("**Profit Sharing Percentage**"; such profit share, the "**Profit Share**"); [***]. For clarity, the Profit Sharing Percentage shall reset to the initial Profit Sharing Percentage on a Calendar Year-by-Calendar Year basis.

(b) **Profit Reports**. Within [***] after the end of each [***] following the First Commercial Sale of a Product in the Field in the Territory, Oncobiologics shall submit to MTTR a report setting forth, with respect to the previous [***]: (i) an itemized calculation of the Net Profits for each Product, (ii) the amount of each Actual Deductible Cost deducted from such Net Profits, along with a reasonable basis and explanation for the inclusion of any such costs and expenses that are not specific to use of Products in the Field, the sum of the aggregate Actual Deductible Costs and the calculation for the Adjusted Deductible Cost (if different from the Actual Deductible Cost) and (iii) a calculation of the amount of Net Profits, if any (the "**Net Profit Report**"). MTTR shall have the right to review and submit any reasonable objection to the calculation of Net Profits within [***] following its receipt of the Net Profit Report from Oncobiologics. Reasonably prior to the delivery of the first Net Profit Report, the Parties, along with their respective accountants, shall discuss and agree on financial accounting matters with respect to the determination and reporting of Net Profits, Actual Deductible Costs and Adjusted Deductible Costs, including any procedures, allocation mechanisms and reporting requirements. In the event that the Parties are not able to agree on such financial accounting matters (after good faith discussions of at least [***]), then such disagreement shall be referred to an independent certified public accounting firm for binding resolution (the cost of which shall be shared by the Parties).

(c) **Payments**. Oncobiologics shall pay all undisputed amounts owed to MTTR pursuant to this Section 9.2, if any, at the time of submission of the Net Profit Report.

9.3 Limitations.

(a) The payment of Monthly Retainer Fees and Net Profits to MTTR shall be contingent upon the performance by each Consultant of the obligations assigned to such Consultant under the Services Schedule or otherwise under this Agreement in accordance with the terms and conditions of this Agreement.

(b) In the event that a Consultant performs fewer hours of work, on an FTE basis (as described in Section 2.2(b)) for a particular Calendar Quarter than such Consultant should perform pursuant to the agreed-upon time commitment for such Consultant for the relevant Development Stage of the Product, as set forth in Exhibit B (e.g., if, during a given Calendar Quarter, [***] performs work at a [***]% FTE level rather than [***]% during Development Stage 1), then Oncobiologics shall have the right to offset future payments owed to MTTR under Sections 9.1 and 9.2 by the pro rata amount overpaid to MTTR for such Consultant (on the basis of an hourly rate for such Consultant determined by the anticipated total of Monthly Retainer Fees for the Calendar Quarter, the hours required to be performed by such Consultant during the applicable Calendar Quarter and such Consultant's share of the Profit Sharing Percentage specified in Exhibit C). In the event that there is no possibility of a future payment owed to MTTR, MTTR shall refund the amount of such overpayment within [***] after receipt of any invoice from Oncobiologics. If a Consultant needs to perform more hours of work during any Calendar Quarter than agreed upon in Exhibit B, then MTTR will notify Oncobiologics in writing and shall obtain written approval of Oncobiologics prior to incurring any expenses. In the event that Oncobiologics approves of such overtime expenses, Oncobiologics shall pay a pro rata amount for such hours (on the basis of an hourly rate determined as set forth above in this Section 9.3(b)). Notwithstanding anything to the contrary in this Agreement, unless any such additional hours are pre-approved by Oncobiologics, no Consultant shall, with respect to a given Calendar Quarter, be obligated to perform more hours of work under this Agreement than as set forth in Exhibit B.

9.4 Change of Control. In the event of (x) a Change of Control of Oncobiologics; (y) an acquisition by a Third Party of Oncobiologics's rights to the Product in its entirety, through the sale and/or exclusive out-license by Oncobiologics of all or substantially all of Oncobiologics's assets relating to the Product, including all intellectual property owned or controlled by Oncobiologics that Covers the Product, for use in all fields on a worldwide basis; or (z) an acquisition by a Third Party of Oncobiologics's rights to the Product for use in the Field on a worldwide basis, through the sale and/or exclusive out-license by Oncobiologics of all or substantially all of Oncobiologics's assets primarily relating to the Product, including all intellectual property owned or controlled by Oncobiologics that Covers the Product, for use in the Field on a worldwide basis, (each of (x)-(z), an "**Acquisition Event**") the following will apply:

(a) Oncobiologics will have the right to assign this Agreement in connection with such Acquisition Event in accordance with the terms of Section 16.1;

(b) In each case of (x), (y) and (z), MTTR shall be entitled to receive, within [***] after Oncobiologics's receipt thereof, an amount as follows (such amount as described below, the "**Shared Acquisition Consideration**"):

(1) in each case of (x), MTTR shall be entitled to receive an amount equal to [***];

(2) in each case of (y), MTTR shall be entitled to receive an amount equal to [***];

(3) in the case of (z), MTTR shall be entitled to receive an amount equal to [***]; and

(4) in the event that an Acquisition Event occurs prior to the first effective IND filing for the Product in the Field, then in each of (x), (y) and (z), [***].

(c) Following such Acquisition Event, [***].

(d) [***], the terms of this Agreement shall continue as between MTTR and Oncobiologics's assignee on the same terms as between MTTR and Oncobiologics, provided that if this Agreement is terminated in its entirety pursuant to Sections 15.5(a) or for any termination with respect to any Consultant pursuant to Section 15.5(b), then MTTR shall pay to Oncobiologics a percentage of the Shared Acquisition Consideration received by MTTR that is allocated to the applicable terminated Consultant as follows:

Date of Applicable Termination	Applicable Percentage
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

In no event shall Oncobiologics structure the acquisition consideration received pursuant to subsections (x), (y) or (z) above with the intent to evade payment obligations owed to MTTR. Any dispute with respect to payments owed to MTTR pursuant to this Section 9.4 [***] shall be resolved by referring such dispute to an independent valuation firm mutually selected by the Parties; each Party shall provide the valuation firm with all information and materials in its possession or control as requested by the valuation firm in connection with such valuation.

9.5 Payments; Withholding Tax.

(a) **Payments in Dollars**. All payments owed by Oncobiologics under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by MTTR. For clarity, all payments made pursuant to this Agreement shall be in U.S. dollars.

(b) **Withholding Taxes**. If Applicable Law requires withholding of income or other taxes due by Oncobiologics and imposed upon any payments made by Oncobiologics to MTTR under this Agreement, Oncobiologics shall (i) make such withholding payments as may be required, (ii) subtract such withholding payments from such payments, (iii) submit appropriate proof of payment of the withholding taxes to MTTR within a reasonable period of time, and (iv) promptly provide MTTR with all official receipts with respect thereto.

(c) **Foreign Currency Exchange**. If, in any Calendar Quarter, Net Profits are received by Oncobiologics in any currency other than U.S. dollars, such Net Profits shall be converted into U.S. dollars as follows: (A/B), where: "A" = foreign "Net Profits" in such Calendar Quarter expressed in such foreign currency; and "B" = the applicable foreign exchange conversion rate, expressed in local currency of the foreign country per U.S. dollar (using, as the applicable foreign exchange rate, the average of the daily closing rates published in the eastern edition of *The Wall Street Journal* under the heading "Money Rates," or any other mutually agreed upon source, for such Calendar Quarter).

(d) **Disputes**. If, following the applicable due date for a payment owed under this Agreement by one Party to the other Party, the Parties disagree with respect to the calculation of such payment, any undisputed portion shall be paid within [***] of the Parties' agreement with respect to such undisputed portion and the remaining, disputed portion shall be paid within [***] after the date on which the Parties resolve the dispute in accordance with Section 16.4.

9.6 Interest on Late Payments. If either Party does not receive payment of any sum due to it on or before the due date, interest shall thereafter accrue on the sum due to the such Party until the date of payment at the per annum rate of [***] percent ([***]%) over the then-current [***] reported in *The Wall Street Journal* or the maximum rate allowable by Applicable Law, whichever is lower.

9.7 Audit Rights. Each Party shall maintain complete and accurate records in sufficient detail to permit the other Party to verify the accuracy of the payment obligations hereunder. For clarity, (a) with respect to Oncobiologics as the auditing Party, MTTR shall maintain records of the number of hours worked by each Consultant during the Term in order for Oncobiologics to verify payment amounts due under Sections 9.1 and 9.2, and (b) with respect to MTTR as the auditing Party, Oncobiologics shall maintain records of Actual Deductible Costs, Adjusted Deductible Costs, Net Revenues and Net Profits in order for MTTR to verify the accuracy of the Net Profit Report furnished by Oncobiologics pursuant to Section 9.2(b) and the amount of Profit Share and other payments due under this Agreement. All payments and other amounts under this Agreement shall be accounted for in accordance with GAAP. Upon reasonable prior notice, such records shall be available for examination during regular business hours for a period of [***] to which they pertain, and not more often than once each Calendar Year, by an independent certified public accountant selected by the auditing Party and reasonably acceptable to the other Party. Any such auditor shall not disclose Confidential Information of the Party being audited, except to the extent such disclosure is necessary to verify the accuracy of the payment obligations hereunder. Any amounts shown to be owed but unpaid shall be paid within [***] from the accountant's report, plus interest (as set forth in Section 9.6) from the original due date. Oncobiologics shall bear the full cost of any audit conducted by or on behalf of Oncobiologics unless such audit discloses an overpayment by Oncobiologics of more than [***] percent ([***]%) of the amount due for the audited period, in which case MTTR shall bear the full cost of such audit. MTTR shall bear the full cost of any audit conducted by or on behalf of MTTR unless such audit discloses an underpayment by Oncobiologics of more than [***] percent ([***]%) of the amount due for the audited period, in which case Oncobiologics shall bear the full cost of such audit.

10. Intellectual Property

10.1 Ownership of Inventions. Other than with respect to MTTR Regulatory Strategy, MTTR and each of the Consultants hereby irrevocably assigns, grants and conveys to Oncobiologics all of its right, title and interest now existing or that may exist in the future in and to any Deliverable, document, development, invention, know-how, design, process, technique, trade secret, or idea, and all intellectual property rights related thereto, that is created, generated, authored, conceived or reduced to practice by each Consultant, in the course of performing Services and to the extent related to a Product under this Agreement (the "**Inventions**"), including all copyrights, trademarks, patents or other intellectual property rights relating thereto. MTTR agrees that any and all Inventions shall be and remain the property of Oncobiologics. MTTR will use Commercially Reasonable Efforts to promptly disclose to Oncobiologics all Inventions, and in any event will promptly disclose to Oncobiologics any material Inventions. MTTR agrees to execute, at Oncobiologics's request and expense, all documents and other instruments necessary or desirable to confirm such assignment with respect to the Inventions. In the event that MTTR does not, for any reason, execute such documents within a reasonable time of Oncobiologics's request, MTTR and each of the Consultants hereby irrevocably appoints Oncobiologics as MTTR's or such Consultant's attorney-in-fact solely for the purpose of executing such documents on MTTR's (or such Consultant's) behalf, which appointment is coupled with an interest. MTTR shall not attempt to register any works created by MTTR pursuant to this Agreement that pertain to Products at the U.S. Copyright Office, the U.S. Patent & Trademark Office, or any foreign copyright, patent, or trademark registry. MTTR retains no rights in the Inventions and agrees not to challenge Oncobiologics's ownership of the rights embodied in the Inventions. MTTR and each of the Consultants further agrees, at Oncobiologics request and expense, to assist Oncobiologics in every proper way to enforce Oncobiologics's rights relating to the Inventions in any and all countries, including, but not limited to, executing, verifying and delivering such documents and performing such other acts (including appearing as a witness) as Oncobiologics may reasonably request for use in obtaining, perfecting, evidencing, sustaining and enforcing Oncobiologics's rights to the Inventions.

10.2 Artist's, Moral, and Other Rights. If MTTR has any rights, including without limitation "artist's rights" or "moral rights," in any Invention which cannot be assigned (the "**Non-Assignable Rights**"), MTTR agrees to waive enforcement worldwide of such rights against Oncobiologics. In the event that MTTR has any such rights that cannot be assigned or waived, MTTR, on behalf of itself and each of the Consultants, hereby grants to Oncobiologics a royalty-free, paid-up, exclusive, worldwide, irrevocable, sublicenseable, transferable perpetual license under the Non-Assignable Rights to (a) use, make, have made, sell, have sold, offer to sell, import, export or otherwise exploit and (b) reproduce, distribute, create derivative works of, publicly perform and publicly display, the Invention in any medium or format, whether now known or later developed.

10.3 License to MTTR Regulatory Strategy. Effective upon termination or expiration of this Agreement and subject to the terms of Section 15.7, MTTR hereby grants, and agrees to grant, to Oncobiologics a non-exclusive sublicenseable, transferable (in accordance with Section 16.1) license, under the MTTR Regulatory Strategy, to use, make, have made, sell, have sold, offer for sale, import, export or otherwise exploit Products in the Field in the Territory.

10.4 No Conflicts. MTTR represents that [***] is, as of the Effective Date, a full time employee and faculty member of the [***] and may become, in the future, employed by another academic or research institution (such academic or research institution, an "**Institution**"). Nothing in this Agreement shall be construed to conflict with his obligations and duties as such, including his duties (a) to protect information that is confidential and/or proprietary to [***] or any Institution, (b) to not disclose such protected information to either MTTR or Oncobiologics, or any Third Party, or (c) to fully comply with [***] or any Institution's patent policy and other applicable policies and regulations, including with respect to conflicts of interest and disclosure of this Agreement to [***] or any Institution as required to comply with such policies and regulations.

11. Representations, Warranties and Covenants

11.1 Mutual Representations, Warranties and Covenants. Each Party hereby represents, warrants and covenants, as applicable, to the other Party as follows:

(a) **Corporate Existence**. As of the Effective Date, it is a company or corporation duly organized, validly existing, and in good standing under the Applicable Laws of the jurisdiction in which it is incorporated.

(b) **Corporate Power, Authority and Binding Agreement**. As of the Effective Date, (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium and similar Applicable Laws affecting creditors' rights and remedies generally; and (iv) the execution, delivery and performance of this Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any Applicable Laws.

(c) **Compliance.**

(i) In the performance of its obligations under this Agreement, each Party shall comply, and shall cause its and its Affiliates' employees and contractors to comply, with Anti-Corruption Laws and all Applicable Laws. Without limiting the foregoing, each Party, and its and its Affiliates' employees and contractors, shall not, in connection with the performance of this Agreement, directly or indirectly through Third Parties, pay, promise, or offer to pay, or authorize the payment of, any money or give any promise or offer to give, or authorize the giving of anything of value to any public official or other person or entity for the purpose of obtaining or retaining business for or with, or directing business to, any person, including, without limitation, either Party.

(ii) Each Party shall immediately notify the other Party if it has any information or suspicion that there may be a violation of any Applicable Laws (including Anti-Corruption Laws) in connection with its performance under this Agreement. In the event that either Party has violated or been suspected of violating any of its obligations, representations, warranties or covenants in this Section 11.1(c), such Party will take reasonable actions to remedy such breach and to prevent further such breaches from occurring.

(iii) Notwithstanding the foregoing, each Party will have the right, upon reasonable prior written notice and during the other Party's regular business hours, to audit the other Party's books and records in the event that a suspected violation of any Anti-Corruption Law needs to be investigated (in such Party's reasonable, good-faith discretion). Such audit shall be conducted by such Party's audit team comprised of qualified auditors who have received anticorruption training. For clarity, a credible finding, after a reasonable investigation, of any breach of subsections (i) or (ii) above with respect to any Anti-Corruption Law, shall be deemed a material breach of this Agreement and allow the non-breaching Party to terminate this Agreement in accordance with Section 15.2.

11.2 MTTR Representations and Warranties. MTTR hereby represents, warrants and covenants to Oncobiologics that:

(a) MTTR has the right and unrestricted ability to assign all Inventions to Oncobiologics in accordance with Article 10, and each of the Consultants is bound by an enforceable written agreement pursuant to which such Consultant assigns to MTTR all of its right, title and interest in all Inventions;

(b) MTTR shall (and shall ensure that each of its Consultants shall) use Commercially Reasonable Efforts, and shall devote the time necessary on an ongoing basis, to perform the Services in accordance with the Services Schedule and all other terms of this Agreement. MTTR shall (and shall ensure that each of its Consultants shall) use Commercially Reasonable Efforts to complete the Services in a timely manner and in accordance with timelines mutually agreed by Oncobiologics and MTTR, including as set forth in the Services Schedule. The Services, and the results thereof, will be performed with, and be the product of, the professional skill and expertise consistent with industry standards for the performance of similar services; and

(c) [***].

11.3 Oncobiologics Representations and Warranties.

(a) Oncobiologics hereby represents, warrants and covenants to MTTR that, as of the Effective Date, there are no Third Party IP Agreements [***].

(b) [***].

11.4 No Other Representations or Warranties. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY OR ITS AFFILIATE, AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED. For avoidance of doubt, neither Party guarantees any outcome with respect to the activities conducted under this Agreement.

12. Independent Contractor Relationship

12.1 Independent Contractor. MTTR (and each Consultant) is an independent contractor and not an employee of the Oncobiologics. Nothing in this Agreement is intended to, or should be construed to, create a partnership, agency, joint venture or employment relationship. MTTR is not authorized to represent that it or any Consultant is an agent, employee, or legal representative of Oncobiologics. MTTR is not authorized to make any representation, contract, or commitment on behalf of Oncobiologics or incur any liabilities or obligations of any kind in the name of or on behalf of the Oncobiologics.

12.2 Tax Treatment. MTTR and Oncobiologics agree that Oncobiologics will treat MTTR as an independent contractor for purposes of all tax laws (local, state and federal) and file forms consistent with that status. MTTR agrees, as an independent contractor, that neither it nor its employees are entitled to unemployment benefits in the event this Agreement terminates, or workers' compensation benefits in the event that MTTR, or any employee of MTTR, is injured in any manner while performing obligations under this Agreement. MTTR will be solely responsible to pay any and all local, state, and/or federal income, social security and unemployment taxes for MTTR and its employees. Oncobiologics will not withhold any taxes or prepare W-2 Forms for MTTR, but will provide MTTR with a Form 1099, if required by Applicable Law. MTTR is solely responsible for, and will timely file all tax returns and payments required to be filed with, or made to, any Governmental Authority with respect to the performance of Services and receipt of fees under this Agreement. MTTR is solely responsible for, and must maintain adequate records of, expenses incurred in the course of performing Services under this Agreement, except as provided herein. No part of MTTR's compensation will be subject to withholding by Oncobiologics for the payment of any social security, federal, state or any other employee payroll taxes. Oncobiologics will regularly report amounts paid to MTTR with the appropriate taxing authorities, as required by Applicable Law.

12.3 No Employee Benefits. MTTR acknowledges and agrees that neither it nor anyone acting on its behalf shall receive any employee benefits of any kind from Oncobiologics. MTTR (and MTTR's agents, employees, and subcontractors) is excluded from participating in any fringe benefit plans or programs as a result of the performance of Services under this Agreement, without regard to MTTR's independent contractor status. In addition, MTTR (and MTTR's agents, employees, and contractors) waives any and all rights, if any, to participation in any of Oncobiologics's fringe benefit plans or programs including, but not limited to, health, sickness, accident or dental coverage, life insurance, disability benefits, severance, accidental death and dismemberment coverage, unemployment insurance coverage, workers' compensation coverage, and pension or 401(k) benefit(s) provided by Oncobiologics to its employees.

12.4 Expenses and Liabilities. MTTR agrees that as an independent contractor, it is solely responsible for all expenses (and profits/losses) it incurs in connection with the performance of Services. MTTR understands that it will not be reimbursed for any supplies, equipment, or operating costs, nor will the costs of doing business be defrayed in any way by Oncobiologics except as set forth in this Agreement; provided however, that MTTR will be reimbursed for reasonable travel and other business expenses in accordance with the travel policy attached hereto as Exhibit H, to the extent pre-approved by a senior executive of Oncobiologics.

13. Confidentiality

13.1 Confidentiality Obligations. Each of Oncobiologics and MTTR, as a Receiving Party, hereby agrees that, during the Term and for an additional [***] after termination or expiration of this Agreement, it will (and in the case of MTTR, will ensure that Consultants will): (a) maintain in confidence such Confidential Information of the Disclosing Party using not less than the efforts such Receiving Party uses to maintain in confidence its own proprietary information of similar kind and value, but in no event less than a reasonable degree of efforts, (b) not disclose such Confidential Information of the Disclosing Party to any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted under this Article 13; and (c) it will not use any Confidential Information of the Disclosing Party, except as expressly permitted in this Agreement, including in connection with the exercise of any rights or licenses granted hereunder. Notwithstanding the foregoing, with respect to any Confidential Information that constitutes a trade secret, the foregoing obligations of confidentiality, non-use and non-disclosure shall continue for as long as such Confidential Information remains a trade secret. Notwithstanding the definition of Confidential Information in Section 1.16, Confidential Information of a Receiving Party will not be deemed to include:

(a) any information that is or becomes generally available to the public other than as a direct or indirect result of the disclosure of any of such information by the Receiving Party in violation of this Agreement;

(b) any information that was in the Receiving Party's possession without obligations of confidentiality with respect thereto prior to the time it was first made available to the Receiving Party by the Disclosing Party, provided that the source of such information was not and is not known to the Receiving Party to be bound by any contractual or other obligation of confidentiality to the Disclosing Party or to any other entity with respect to any of such information;

(c) any information that becomes available to the Receiving Party on a non-confidential basis from a source other than the Disclosing Party, provided that such source is not known to the Receiving Party to be bound by any contractual or other obligation of confidentiality to the Disclosing Party or to any other entity with respect to any of such information; or

(d) any information that is developed by or on behalf of the Receiving Party independently of the Disclosing Party's Confidential Information and without reference to or use of such Confidential Information.

13.2 Permitted Disclosures.

(a) MTTR hereby agrees, as a Disclosing Party, that Oncobiologics, as a Receiving Party, may disclose MTTR's Confidential Information: (i) to any Affiliate, or to its or its Affiliate's employee, consultant, contractor, subcontractor, agent or sublicensee on a need-to-know basis in order to enable such person to exercise its rights, or to carry out its responsibilities, under this Agreement; (ii) on a need-to-know basis to Oncobiologics's professional, legal or financial advisors; (iii) as reasonably necessary to any bona fide actual or potential (A) permitted sublicensee of Oncobiologics's rights hereunder, or (B) investor, financer or commercial partner of Oncobiologics for purposes of evaluating or carrying out an actual or potential investment, merger, acquisition, consolidation, share exchange or other similar transaction involving Oncobiologics and such Third Party; (iv) as reasonably necessary to file, prosecute or maintain patent rights, or to file, prosecute or defend litigation related to patent rights, in accordance with this Agreement; (v) as reasonably required to obtain Regulatory Approvals; or (vi) as required by Applicable Laws, including regulations promulgated by court orders, administrative subpoenas and security exchanges; provided, that, in the case of any disclosure under subsections (iv)-(vi), Oncobiologics shall (x) if practicable, provide MTTR with reasonable advance notice of and an opportunity to comment on any such required disclosure and (y) if requested by MTTR, cooperate in all reasonable respects with the MTTR's efforts to obtain confidential treatment or a protective order with respect to any such disclosure, at MTTR's expense. Notwithstanding the foregoing in this Section 13.2(a), Oncobiologics shall not disclose any of MTTR's Confidential Information that is MTTR Regulatory Strategy to any Third Party during the Term and for an additional [***] after the termination or expiration of this Agreement without the prior written consent of MTTR, not to be unreasonably withheld, conditioned or delayed, provided that Oncobiologics may disclose such MTTR Regulatory Strategy without MTTR's prior consent (AA) as reasonably required to be disclosed to regulatory authorities for the purpose of obtaining or maintaining Regulatory Approval of a Product in the Field in the Territory, in which case the foregoing provisions of subsections (x) and (y) shall apply to such disclosure and (BB) to a sublicensee of Oncobiologics under the license granted to Oncobiologics under Section 10.3, to the extent reasonably necessary for such sublicensee to exercise such sublicense.

(b) Oncobiologics hereby agrees, as a Disclosing Party, that MTTR, as a Receiving Party, may disclose Oncobiologics's Confidential Information (i) to any of its or Oncobiologics's or Oncobiologics's Affiliates' consultants, contractors, subcontractors, agents or sublicensees on a need-to-know basis in order to exercise its rights or carry out its responsibilities under this Agreement, including the performance of the Services; or (ii) to the extent required by Applicable Laws, including regulations promulgated by court orders, administrative subpoenas and security exchanges; provided, that, in the case of any such disclosure, MTTR shall (x) if practicable, provide Oncobiologics with reasonable advance notice of and an opportunity to comment on any such required disclosure and (y) if requested by Oncobiologics, cooperate in all reasonable respects with the Oncobiologics's efforts to obtain confidential treatment or a protective order with respect to any such disclosure, at Oncobiologics's expense.

13.3 Covenants of Receiving Party. Each of Oncobiologics and MTTR hereby covenants and agrees, as a Receiving Party that any person or entity who is granted access by such Receiving Party to Confidential Information of the Disclosing Party will, prior to having such access, be bound by written obligations of confidentiality and non-use no less stringent than the obligations set forth in Section 13.1. Each Receiving Party will be liable to the other Party for any disclosure or misuse by such person or entity of Confidential Information of the Disclosing Party.

14. Indemnification; Insurance; Liability Limitations

14.1 Indemnification by MTTR. MTTR shall defend (solely upon Oncobiologics's request), indemnify, and hold Oncobiologics and its Affiliates and their respective officers, directors, employees, and agents (the "**Oncobiologics Indemnitees**") harmless from and against any and all Third Party claims, suits, proceedings, damages, expenses (including court costs and reasonable attorneys' fees and expenses) and recoveries (collectively, "**Claims**") arising out of, based on, or resulting from (a) gross negligence or willful misconduct of any MTTR Indemnitee in the performance of Services under this Agreement; or (b) the breach of any of MTTR's obligations under this Agreement, including MTTR's representations, warranties or covenants set forth herein. The foregoing indemnity obligation shall not apply to the extent that (i) the Oncobiologics Indemnitees fail to comply with the indemnification procedures set forth in Section 14.3 and MTTR's defense of the relevant Claim is prejudiced by such failure, or (ii) any Claim arises from, is based on, or results from any activity or occurrence for which Oncobiologics is obligated to indemnify the MTTR Indemnitees under Section 14.2. Notwithstanding anything to the contrary herein, the foregoing indemnification obligations of MTTR shall not apply to any Claims that are based on, or resulting from, activities by MTTR Indemnitees that were expressly authorized in writing by Oncobiologics.

14.2 Indemnification by Oncobiologics. Oncobiologics shall defend, indemnify, and hold MTTR and each of the Consultants (the "**MTTR Indemnitees**") harmless from and against any and all Third Party Claims arising out of, based on, or resulting from (a) the Development, manufacture or Commercialization of the Product in the Field in the Territory by or on behalf of Oncobiologics or any of its Affiliates; (b) the breach of any of Oncobiologics's obligations under this Agreement, including Oncobiologics's representations, warranties or covenants set forth herein; or (c) the negligence or willful misconduct of any Oncobiologics Indemnitee. The foregoing indemnity obligation shall not apply to the extent that (i) the MTTR Indemnitees fail to comply with the indemnification procedures set forth in Section 14.3 and Oncobiologics's defense of the relevant Claim is prejudiced by such failure, or (ii) any Claim arises from, is based on, or results from any activity or occurrence for which MTTR is obligated to indemnify the Oncobiologics Indemnitees under Section 14.1.

14.3 Indemnification Procedures. The Party claiming indemnity under this Article 14 (the "**Indemnified Party**") shall give written notice to the Party from whom indemnity is being sought (the "**Indemnifying Party**") promptly after learning of such Claim and shall offer control of the defense of such Claim to the Indemnifying Party. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the Claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; provided, however, the Indemnifying Party shall have the right to assume and conduct the defense of the Claim with counsel of its choice. The Indemnifying Party shall not settle any Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, unless the settlement involves only the payment of money. So long as the Indemnifying Party is actively defending the Claim in good faith, the Indemnified Party shall not settle or compromise any such Claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (a) the Indemnified Party may defend against, consent to the entry of any judgment, or enter into any settlement with respect to such Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnifying Party shall remain responsible to indemnify the Indemnified Party as provided in this Article 14.

14.4 Insurance. Each Party shall procure and maintain insurance, including product liability insurance, adequate to cover its obligations hereunder and consistent with normal business practices of prudent companies similarly situated; provided that, MTTR shall have no obligation to obtain product liability insurance. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 14. Each Party shall provide the other Party with written evidence of such insurance upon request. Each Party shall provide the other Party with written notice at least [***] prior to the cancellation, non-renewal or material change in such insurance.

15. Term and Termination

15.1 Term. The term of this Agreement is from the Effective Date until the later of (a) (i) for each country in the Major Market Countries on a country-by-country basis, ten (10) years after the First Commercial Sale of a Product in the Field for an Approved Indication in such country and (ii) for each country in the Territory outside of the Major Market Countries, ten (10) years after the First Commercial Sale of a Product in the Field for an Approved Indication in the Territory and (b) on a country-by-country basis, the expiration of any Regulatory Exclusivity associated with the applicable Product in such country, unless earlier terminated as provided in this Agreement (the "**Term**").

15.2 Termination for Material Breach.

(a) Each Party shall have the right to terminate this Agreement in its entirety immediately upon written notice to the other Party if the other Party materially breaches its obligations under this Agreement and, after receiving written notice identifying such material breach in reasonable detail, fails to cure such material breach within [***] from the date of such notice. For clarity, the failure of [***] to materially perform his obligations under this Agreement in accordance with the terms herein shall be deemed to be a material breach of this Agreement by MTTR.

(b) Oncobiologics shall have the right to terminate this Agreement on a Consultant-by-Consultant basis, immediately upon written notice to MTTR if (i) the applicable Consultant materially breaches his obligations under this Agreement and, after receiving written notice identifying such material breach in reasonable detail, fails to cure such material breach within [***] from the date of such notice, or (ii) the applicable Consultant materially fails to meet the time commitment for such Consultant for the relevant Development Stage of the Product, as set forth in Exhibit B and determined on a Calendar Quarter basis and fails to materially perform the underlying Service, as applicable, within [***] of the date of notice thereof.

15.3 Termination Due to Bankruptcy. Either Party may terminate this Agreement if, at any time, the other Party files in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of that Party or of its assets, or if the other Party proposes a written agreement of composition or extension of its debts, or if the other Party is served with an involuntary petition against it, filed in any insolvency proceeding, and such petition is not dismissed within [***] after the filing thereof, or if the other Party proposes or becomes a Party to any dissolution or liquidation, or if the other Party makes an assignment for the benefit of its creditors.

15.4 Termination for Development Failure. Oncobiologics shall have the right to terminate this Agreement immediately, upon [***] prior written notice to MTTR, in the event that: (i) Oncobiologics fails to achieve any of the milestones set forth for the Development Stages in Section 4.4 (as such Development Stages may be modified by mutual written agreement of the Parties) in the timeframe outlined in the initial Development timeline; provided that, Oncobiologics has exercised Commercially Reasonable Efforts to achieve such milestones, to the extent set forth in Section 4.3(b); or (ii) after the [***] after obtaining the first J Code for a Product in the U.S., the annual revenue in the U.S. from sales of Products in the Field in the Territory is less than [***] Dollars ($[***]). For avoidance of doubt, any such failure to achieve such milestones within such timeframes shall not in and of itself provide the basis for termination by Oncobiologics under Section 15.2 of this Agreement.

15.5 Termination for Failure to Replace Consultant.

(a) If Oncobiologics does not approve any replacement consultant for [***] pursuant to Section 2.2(c) within [***] of MTTR's proposal of such replacement, then, unless the Parties agree otherwise in writing, this Agreement will terminate in its entirety immediately. For avoidance of doubt, any failure to approve any replacement consultant for [***] pursuant to Section 2.2(c) shall not provide basis for termination by Oncobiologics under Section 15.2 of this Agreement.

(b) If Oncobiologics does not approve any replacement consultant for [***] pursuant to Section 2.2(d) within [***] of MTTR's proposal of such replacement, then, unless the Parties agree otherwise in writing, this Agreement shall terminate with respect to such Consultant immediately. For avoidance of doubt, any failure to approve any replacement consultant for the foregoing Consultants pursuant to Section 2.2(d) shall not provide basis for termination by Oncobiologics under Section 15.2 of this Agreement.

15.6 [***].

15.7 Effects of Termination.

(a) Upon any termination or expiration of this Agreement in its entirety, each Party shall return to the other Party, or at such other Party's option, destroy, all copies of such Confidential Information then in such Party's possession; provided that, each Party may retain a copy of the other Party's Confidential Information for legal archival purposes; provided, however, that with respect to a termination by Oncobiologics pursuant to Section 15.2(b), the foregoing shall apply only with respect to such terminated Consultant.

(b) Upon any termination or expiration of this Agreement in its entirety, MTTR shall promptly furnish to Oncobiologics all Inventions in MTTR's possession as of the date of termination or expiration. Oncobiologics shall not perform any additional Services or incur any additional expenses with respect to this Agreement without Oncobiologics's prior written approval; provided, however, that with respect to a termination by Oncobiologics pursuant to Section 15.2(b), the foregoing shall apply only with respect to such terminated Consultant.

(c) [***]

(d) [***]

(e) With respect to a termination of this Agreement with respect to a Consultant by Oncobiologics pursuant to Section 15.2(b) or as set forth in Section 15.5(b), the Monthly Retainer Fee and Profit Sharing Percentage shall be reduced in accordance with the applicable Consultant's share of the Profit Sharing Percentage specified in Exhibit C as of the date of delivery of written notice of termination.

15.8 Survival. Termination or expiration of this Agreement shall not affect rights or obligations of the Parties under this Agreement that have accrued prior to the date of termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement. Notwithstanding anything to the contrary, the following provisions shall survive any expiration or termination of this Agreement: [***], together with any other provisions needed to effectuate the intent of the foregoing. If this Agreement is terminated with respect to a Consultant but not in its entirety, then the foregoing provisions of this Agreement shall remain in effect with respect to the terminated Consultant (to the extent such provisions would survive and apply in the event this Agreement expires or is terminated in its entirety), and all provisions not surviving in accordance with the foregoing to the extent applicable to the terminated Consultant shall terminate upon termination of this Agreement and be of no further force and effect (and, for purposes of clarity, all provisions of this Agreement shall remain in effect with respect to the remaining Consultants that are not terminated).

16. Miscellaneous

16.1 Successors and Assigns. MTTR may not assign, transfer or delegate this Agreement or any of its obligations hereunder without Oncobiologics's prior written consent (which may be withheld, conditioned or delayed, in Oncobiologics's sole discretion). Oncobiologics may not assign, transfer or delegate this Agreement or any of its obligations hereunder without MTTR's prior written consent (which may be withheld, conditioned or delayed, in MTTR's sole discretion), except that Oncobiologics may assign this Agreement without MTTR's prior written consent (a) to an Affiliate of Oncobiologics, so long as Oncobiologics remains responsible for the activities of such Affiliate and all of such Affiliate's obligations under this Agreement, (b) to a successor of Oncobiologics in the event of a Change of Control of Oncobiologics or (c) to an exclusive sublicensee of all of Oncobiologics's rights to the Products for use (i) in the Field in the Territory or (ii) in all fields on a worldwide basis.

16.2 Notices. Any notice required or permitted by this Agreement shall be in writing and shall be delivered as follows with notice deemed given as indicated: (a) by overnight courier upon written verification of receipt; or (b) by email or facsimile transmission with confirmation of receipt of transmission. Notice shall be sent to the addresses set forth below or such other address as either Party may specify in writing.

If to Oncobiologics:
7 Clarke Drive
Cranbury, New Jersey 08512
Attn: [***]
Tel: [***]
Email: [***]
Facsimile: [***]

If to MTTR:
[***]
Attn: [***]
Tel: [***]
Email: [***]
Facsimile: [***]

16.3 Governing Law. This Agreement shall be governed in all respects by the laws of the State of Delaware, without regard to the application of principles of conflicts of law.

16.4 Arbitration. Either Party may submit any dispute arising hereunder to binding arbitration pursuant to the [***]. The arbitration shall be conducted in [***]. In any arbitration under this Section 16.4, the arbitrator and the Parties shall use their best efforts to resolve such dispute within [***] after the selection of the arbitrator, or as soon thereafter as is practicable. The decision of the arbitrator or shall be final and binding upon the Parties and shall be enforceable by any court of competent jurisdiction. By agreeing to arbitration, the Parties do not intend to deprive any competent court of such court's jurisdiction to issue a pre-arbitral injunction, pre-arbitral attachment or other order in aid of the arbitration proceedings and the enforcement of any award or judgment. Without prejudice to such provisional remedies in aid of arbitration as may be available under the jurisdiction of a national court, the arbitrator shall have full authority to grant provisional remedies and to award damages for failure of any Party to respect the court of arbitration's order to that effect. The expenses of any arbitration shall be borne equally by the Parties, except as otherwise allocated by the arbitrator. Each Party shall bear the expenses of its counsel and other experts in connection with any arbitration proceedings.

16.5 Severability. Should any provisions of this Agreement be held by a court of law to be illegal, invalid or unenforceable, the legality, validity and enforceability of the remaining provisions of this Agreement shall not be affected or impaired thereby.

16.6 Waiver. The waiver by either Party of a breach of any provision of this Agreement by the other Party shall not operate or be construed as a waiver of any other or subsequent breach by such other Party.

16.7 Entire Agreement. This Agreement constitutes the entire understanding of the Parties relating to the subject matter and supersedes any previous oral or written communications, representations, understanding, or agreement between the Parties concerning such subject matter, including the Confidentiality Agreement. This Agreement may not be changed, modified, supplemented or amended except by express written agreement signed by an authorized representative of each of the Parties.

16.8 Construction. Except where the context otherwise requires, (a) wherever used, the singular shall include the plural, the plural shall include the singular; (b) the terms "including," "include," "includes" or "e.g.," shall be deemed to mean "including, without limitation"; (c) the word "or" has the inclusive meaning that is typically associated with the phrase "and/or"; and (d) the word "will" means "shall"; (f) "Dollar" or "$" means U.S. Dollars. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof.

16.9 Equitable Relief. Each Party acknowledges that its breach of Article 13 (and in the case of MTTR, its breach of Section 5.1) may cause irreparable harm to the other Party, which cannot be reasonably or adequately compensated in damages in an action at law. By reasons thereof, each Party agrees that the other Party shall be entitled, in addition to any other remedies it may have under this Agreement or otherwise, to seek preliminary and permanent injunctive and other equitable relief to prevent or curtail any actual or threatened breach of such obligations.

16.10 Force Majeure. A Party shall be excused from the performance of its obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the reasonable control of the applicable Party, including an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, and failure of plant or machinery. Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a force majeure affecting such Party. If a force majeure persists for more than [***], then the Parties will discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such force majeure. If a force majeure persists for more than [***], then either Party shall have the right to terminate this Agreement in its entirety upon written notice to the other Party.

16.11 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 16.11 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 14.1 OR 14.2, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 13 OR ITS OBLIGATIONS UNDER SECTIONS 5.1 AND 5.2 OR THAT RESULT FROM THE INTENTIONAL BREACH OF THIS AGREEMENT.

In Witness Whereof, the Parties have executed this Agreement as of the date first written above.

Oncobiologics, Inc.	**MTTR, LLC**
By: /s/ Pankaj Mohan	By: /s/ [***]
Pankaj Mohan, Ph.D.	Name: [***]
Chairman and CEO	Title: [***]

EXHIBIT A
Services Schedule

Description of Services (including applicable Deliverables and timelines for completion)

The following activities and deliverables with respect to the Product in the Field in the Territory:

[***]

AGREED TO:
MTTR, LLC

Date: _____

AGREED TO:
Oncobiologics, Inc.

_____ Date: _____

EXHIBIT B
Consultant Expertise & Time Commitments

A. Consultant Expertise

(1) [***]

(2) [***]

(3) Mr. Dagnon is a senior executive with regulatory, operations, quality and compliance experience.

(4) [***]

B. Consultant Time Commitments (as a percentage of FTE and pro-rated based on the actual number of days during the applicable Development Stage)

(1) **Development Stage 1:**

(a) [***]
(b) [***]
(c) Mr. Dagnon – 25%
(d) [***]

(2) **Development Stage 2:**

(a) [***]
(b) [***]
(c) Mr. Dagnon – 75%
(d) [***]

(3) **Development Stage 3:**

(a) [***]
(b) [***]
(c) Mr. Dagnon – 100%
(d) [***]

(4) **Development Stage 4:**

(a) [***]
(b) [***]
(c) Mr. Dagnon – 100%
(d) [***]

EXHIBIT C
Profit Sharing Percentage

Subject to the terms and conditions of this Agreement, including the adjustment pursuant to Section 9.2(a), Oncobiologics shall pay MTTR [***] of Net Profits.

[***] share of such amount paid to MTTR shall be [***] and each of the other three (3) Consultants share of such amount shall be [***].

EXHIBIT D
Development Costs

[***]

EXHIBIT E
Initial Development Timelines

[***]

EXHIBIT F
Primary End Points

[***]

EXHIBIT G

Oncobiologics's Initial JSC Members

[***]

MTTR's Initial JSC Members

[***]

MTTR's Initial Alternate JSC Members

[***]

EXHIBIT H
Travel Policy

[***]

EXHIBIT I
[***]

[***]

MTTR, LLC
[***]
Attention: [***]
Email: [***]

March 2, 2018

Oncobiologics, Inc.
7 Clarke Drive
Cranbury, NJ 08512
Attention: Pankaj Mohan, Ph.D.
Email: [***]

Re: Monthly retainer payment schedule adjustment, additional one-time fee, and MTTR consultant time commitment

Dear Pankaj:

This letter is to confirm our understanding with respect to certain changes to the Strategic Partnership Agreement between Oncobiologics, Inc. ("**Oncobiologics**") and MTTR, LLC ("**MTTR**") dated February 15, 2018 (the "**Agreement**"). Such changes are as set forth below:

1. The table set forth in Section 9.1(a) of the Agreement is not changed in terms of monthly retainer installments but hereby is amended in terms of timing by the following table:

Timeframe	**Consulting Fee ($) (prorated as needed)**
(i) Commencing on the Effective Date until December 31, 2018	monthly installments of US$58,333
(ii) Commencing January 1, 2019 until First Commercial Sale of a Product in the Field in the U.S.	monthly installments of $105,208
(iii) Commencing after First Commercial Sale of a Product in the Field in the U.S.	monthly installments of $170,833

2. In consideration of [***], as reflected by the [***] within [***] (as compared to [***] listed in Exhibit E), Oncobiologics agrees to pay a one-time [***] fee of $268,553 to MTTR by September 11, 2020. The amount paid by Oncobiologics to MTTR pursuant to this Paragraph 2 as well as all and any retainer payments shall be excluded from the determination of Development Costs under Section 4.3(b) of the Agreement.

3. Subsection B of Exhibit B is hereby also amended as follows:

B. Consultant Time Commitments (as a percentage of FTE and pro-rated based on the actual number of days during the applicable period)

(1) Effective Date until December 31, 2018:
(a) [***]
(b) [***]
(c) Mr. Dagnon – 25%
(d) [***]

(2) January 1, 2019 until December 31, 2019:
(a) [***]
(b) [***]
(c) Mr. Dagnon – 70%
(d) [***]

(3) January 1, 2020 until First Commercial Sale of a Product in the Field in the U.S.:
(a) [***]
(b) [***]
(c) Mr. Dagnon – 70%
(d) [***]

(4) After First Commercial Sale of a Product in the Field in the U.S.:
(a) [***]
(b) [***]
(c) Mr. Dagnon – 100%
(d) [***]

Please confirm Oncobiologics's agreement with the changes as set forth in this letter by signing this letter and returning a countersigned copy to me at [***]. I look forward to receiving your agreement, and thank you for your assistance in this matter.

Sincerely,
MTTR, LLC

By: /s/ [***]
[***]

Agreed by Oncobiologics, Inc.:

By: /s/ Pankaj Mohan, Ph.D.
Name: Pankaj Mohan, Ph.D.
Title: Chairman and CEO

Exhibit 10.26

LEASE TERMINATION AGREEMENT

THIS LEASE TERMINATION AGREEMENT is made as of the 28th day of August, 2018, by and between **CEDAR BROOK EAST CORPORATE CENTER, LP**, a New Jersey limited partnership, whose address is 4A Cedar Brook Drive, Cranbury, New Jersey 08512 (hereinafter referred to as "**Landlord**"); and **ONCOBIOLOGICS, INC.,** a Delaware corporation, whose address is 7 Clarke Drive, Cranbury, New Jersey 08512 (hereinafter referred to as "**Tenant**").

RECITALS:

A. Landlord and Tenant have entered into that certain Lease for certain real property and improvements located at 9 Cedar Brook Drive, Cranbury, New Jersey, constituting a portion of the office/industrial park known as Cedar Brook Corporate Center, dated August 31, 2015 (the "**Lease**")·

B. Landlord and Tenant have agreed to terminate the Lease subject to the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants and conditions herein contained and for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Landlord and Tenant hereby agree as follows:

1. **Recitals**. The Recitals set forth above are incorporated and shall be deemed a part of this Agreement.

2. **Defined Terms**. All defined terms not defined herein shall have the same meaning herein as set forth in the Lease.

3. **Termination**. Landlord and Tenant agree that the Lease is hereby terminated as of September 1, 2018 ("**Lease Termination Date**") and, as of such date, Tenant shall have no further rights to occupancy or possession of the Demised Premises under the Lease and, except as expressly provided in this Agreement, each party hereby releases each other, their respective successors and assigns of and from any and all claims, damages, obligations, liabilities, actions and causes of action, of every kind and nature whatsoever arising out of the Lease from and after the Lease Termination Date. Except as expressly set forth herein, from and after the Lease Termination Date, neither Landlord nor Tenant shall have any further rights or obligations under the Lease. Landlord and Tenant shall execute a separate certificate (the "**Lease Termination Certificate**", attached hereto and made a part hereof as Exhibit A) evidencing the termination of the Lease which shall be subject to the terms set forth herein.

4. **Representations**. Landlord and Tenant each represent and warrant to the other that (i) Tenant has vacated the Demised Premises in full compliance with all the terms and provisions of the Lease, and (ii) each has the full power and authority to enter into this Agreement and to perform its obligations hereunder without the consent or approval of any other person or entity which has not already been obtained. Tenant represents and warrants that it has not assigned the Lease or sublet its interest in the Lease.

5. **Releases**.

(a) Effective as of the Lease Termination Date, Landlord does hereby remise, release and forever discharge Tenant, its successors and assigns, from all obligations and liability under the Lease except as expressly set forth in this Agreement and Landlord hereby agrees that, as of the Lease Termination Date, the Lease is hereby cancelled, null and void and of no further force or effect.

(b) Effective as of the Lease Termination Date, Tenant does hereby remise, release and forever discharge Landlord, its successors and assigns, from all obligations and liability under the Lease, and Tenant hereby agrees that, as of the Lease Termination Date, the Lease is hereby cancelled, null and void and of no further force or effect.

The foregoing releases shall not affect the terms and provisions of this Agreement which shall remain in full force and effect in accordance with the terms set forth herein.

6. **Consideration Payable to Landlord for Lease Termination.** In consideration of and as a condition to Landlord's agreement to terminate the Lease and all obligations thereunder other than as provided herein, Tenant shall, and covenants and agrees to, pay to Landlord: (i) upon execution of this Lease Termination Agreement, the sum of Two Hundred Eighty Seven Thousand Six Hundred Fifteen Dollars ($287,615.00), constituting the unamortized balance of the broker fee paid by the Landlord for the Lease, as indicated on Exhibit B attached hereto and made a part hereof, (ii) on a monthly basis, commencing on September 1, 2018 and on the first day of each of the twenty-nine (29) months thereafter, the sum of Fifty Thousand Dollars ($50,000) (the "**Monthly Lease Termination Payments**") and, together with the thirtieth (30th) Monthly Lease Termination Payment, and, in any event, on or before February 1, 2021, the sum of Four Million Dollars ($4,000,000.00) (the "**Final Lease Termination Payment**"). Landlord and Tenant agree that the amount of the security deposit held by the Landlord under the Lease is One Hundred Seventy Four Thousand Two Hundred Fifty Dollars ($174,250.00), and that such amount shall be retained by the Landlord as payment of the seventh, eighth and ninth Monthly Lease Termination Payments and partial payment of the tenth Monthly Lease Termination Payment (leaving a balance of $25,750). Notwithstanding the foregoing, Tenant shall have the right, at any time, to pay the Final Lease Termination Payment, whereupon Tenant's obligation to make any further Monthly Lease Termination Payments shall terminate. All payments hereunder shall be paid to Landlord by wire transfer of immediately available funds in accordance with Landlord's wire transfer instructions. There shall be no further payments or adjustments between the parties. In the event Tenant shall fail to pay any Monthly Lease Termination Payment, or the Final Lease Termination Payment, within ten (10) days of receiving notice from Landlord of such failure to make any such payment when due, Landlord shall have the right, in addition to all other rights available at law or in equity for such breach, to accelerate the remaining balance of payments hereunder, whereupon the same shall immediately become due and payable in full.

7. **No Subsequent Adjustments**. Landlord and Tenant acknowledge that Tenant's payment of the Monthly Lease Termination Payments and the Final Lease Termination Fee shall be made without offset or claim and the same shall satisfy all of Tenant's obligations to pay Fixed Annual Rent, Additional Rent and all other charges accrued and outstanding for the period up to and including the Expiration Date.

8. **Captions**. The captions preceding the various paragraphs of this Agreement have been inserted solely for convenience of reference and shall not be used in construing this Agreement.

9. **Choice of Law**. This Agreement shall be governed by the laws of the State of New Jersey.

10. **Successors and Assigns**. This Agreement shall be binding upon the parties hereto, their successors and permitted assigns, and may not be altered, amended, terminated or modified except by written instrument executed by the parties hereto.

11. **Counterparts**. This Agreement may be executed in several counterparts, which shall constitute one and the same instrument. Execution of this Agreement by PDF or facsimile shall bind the parties.

12. **Construction**. This Termination Agreement has been drafted by Landlord as a matter of convenience and shall not, on such account, be interpreted against or for either party, it being understood that each of the parties has had an opportunity to submit revisions to the text hereof.

[SIGNATURES APPEAR ON THE FOLLOWING PAGE]

IN WITNESS WHEREOF the parties have hereunto set their hands and seal the day and year first above written.

Cedar Brook East Corporate Center, LP, Landlord

By: /s/ Joe Stern
Name: Joe Stern
Title:

OncoBiologics, Inc., Tenant

By: /s/ Lawrence A. Kenyon
Name: Lawrence A. Kenyon
Title: President and CEO

EXHIBIT A

LEASE TERMINATION CERTIFICATE

THIS LEASE TERMINATION CERTIFICATE is made as of the 28th day of August, 2018, by and between CEDAR BROOK EAST CORPORATE CENTER, LP, a New Jersey limited partnership, whose address is 4A Cedar Brook Drive, Cranbury, New Jersey 08512 (hereinafter referred to as "**Landlord**"); and ONCOBIOLOGICS, INC., a Delaware corporation, whose address is 7 Clarke Drive, Cranbury, New Jersey 08512 (hereinafter referred to as "**Tenant**").

Landlord and Tenant have entered into that certain Lease for certain real property and improvements located at 9 Cedar Brook Drive, Cranbury, New Jersey, (the "**Demised Premises**") constituting a portion of the office/industrial park known as Cedar Brook Corporate Center, dated August 31, 2015 (the "**Lease**")·

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant hereby agree that, pursuant to the Lease Termination Agreement executed simultaneously herewith, the Lease is hereby terminated as of September 1, 2018 (the "**Lease Termination Date**") and, as of such date, Tenant shall have no further rights to occupancy or possession of the Demised Premises under the Lease and, except as provided in the Lease Termination Agreement, the parties to the Lease release each other, their respective successors and assigns of and from any and all claims, damages, obligations, liabilities, actions and causes of action, of every kind and nature whatsoever arising out of the Lease from and after the Lease Termination Date.

This Certificate may be executed in several PDF counterparts, which shall constitute one and the same instrument.

[SIGNATURES APPEAR ON THE FOLLOWING PAGE]

IN WITNESS WHEREOF the parties have hereunto set their hands and seal the day and year first above written.

Cedar Brook East Corporate Center, LP, Landlord

By: /s/ Joe Stern
Name: Joe Stern
Title:

OncoBiologics, Inc., Tenant

By: /s/ Lawrence A. Kenyon
Name: Lawrence A. Kenyon
Title: President and CEO

EXHIBIT B

UNAMORTIZED COMMISSION FROM 9/1/2018

9/1/18-2/28/21		
30 months' rent: month is	$	58,083.33
Rent for 30 months:	$	1,742,500
3/1/21-2/28/26		
60 months' rent: per month is	$	66,830
Rent for 60 months:	$	4,009,800
Total rent:	$	5,752,300
Commission at 5%	$	287,615.00

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Outlook Therapeutics, Inc.:

We consent to the incorporation by reference in the Registration Statements (Nos. 333-211362, 333-216081 and 333-223064) on Form S-8, (Nos. 333-223063 and 333-212351) on Form S-3 and (No. 333-216610) on Form S-1 of Outlook Therapeutics, Inc. of our report dated December 18, 2018, with respect to the consolidated balance sheets of Outlook Therapeutics, Inc. as of September 30, 2018 and 2017, and the related consolidated statements of operations, convertible preferred stock and stockholders' equity (deficit), and cash flows for the years then ended and related notes (collectively, the consolidated financial statements), which report appears in the September 30, 2018 annual report on Form 10-K of Outlook Therapeutics, Inc.

Our report dated December 18, 2018 contains an explanatory paragraph that states that Outlook Therapeutics, Inc. has incurred recurring losses and negative cash flows from operations since inception and has an accumulated deficit at September 30, 2018 of $216.3 million, $13.5 million of senior secured notes that may become due in fiscal 2019 and $4.6 million of unsecured indebtedness, $1.0 million of which is due on demand, and $3.6 million of which matures December 22, 2018, which raises substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KPMG LLP

Philadelphia, Pennsylvania
December 18, 2018

Exhibit 31.1

CERTIFICATIONS

I, Lawrence A. Kenyon, certify that:

1. I have reviewed this Annual Report on Form 10-K of Outlook Therapeutics, Inc. (the "registrant"); and

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: December 18, 2018

/s/ Lawrence A. Kenyon
Lawrence A. Kenyon
Chief Executive Officer and Chief Financial Officer
(Principal Executive, Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Outlook Therapeutics, Inc. (the "Registrant") certifies that the Annual Report of Outlook Therapeutics, Inc. on Form 10-K for the year ended September 30, 2018 (the " Report") fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that information contained in the Report fairly presents in all material respects the financial condition and results of operations of the Registrant.

Date: December 18, 2018

By: /s/ Lawrence A. Kenyon
Name: Lawrence A. Kenyon
Title: Chief Executive Officer and Chief Financial Officer
(Principal Executive, Financial and Accounting Officer)

A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350 has been provided to the Registrant and will be retained by the Registrant and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.