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**

For the fiscal year ended September 30, 2019

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**
(Address of principal executive offices)	**(Zip Code)**

(609) 619-3990
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	OTLK	The Nasdaq Stock Market LLC
Series A Warrants	OTLKW	The Nasdaq Stock Market LLC

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ 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 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 29, 2019 (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 $18.9 million.

As of December 16, 2019, the registrant had outstanding 30,103,173 shares of common stock, par value $0.01 per share.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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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 30, 2019, or CHF 0.99045 = $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 in Item 1A under the heading "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

We are a late clinical-stage biopharmaceutical company working to develop the first U.S. Food and Drug Administration, or FDA, -approved ophthalmic formulation of bevacizumab for use in retinal 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 investigational ophthalmic formulation of bevacizumab under development to be administered as an intravitreal injection for the treatment of wet AMD and other retinal diseases. Bevacizumab is a full-length, humanized anti-VEGF (Vascular Endothelial Growth Factor) recombinant monoclonal antibody, or mAb, that inhibits VEGF and associated angiogenic activity. The study design for our Phase 3 clinical program to evaluate ONS-5010 as an ophthalmic formulation of bevacizumab was reviewed at an end of Phase 2 meeting with the FDA in April 2018, and we filed our investigational new drug application, or IND, with the FDA in the first quarter of calendar 2019.

Our Phase 3 program for ONS-5010 in wet AMD involves two clinical trials, which we refer to as NORSE 1 and NORSE 2, evaluating ONS-5010 against ranibizumab (LUCENTIS). Enrollment in the NORSE 1 study is complete with 61 patients enrolled, all in Australia. The NORSE 2 study has been initiated and began enrolling wet AMD patients in July 2019. The NORSE 2 study is expected to enroll a total of at least 220 patients and is being conducted in the United States. The endpoint for both studies is a mean increase in baseline visual acuity at 11 months for ONS-5010 dosed on a monthly basis compared to LUCENTIS dosed using the alternative PIER clinical trial dosing regimen of three-monthly doses followed by quarterly dosing.

Currently, the cancer drug Avastin (bevacizumab) is used off-label for the treatment of wet AMD and other retinal diseases such as DME and BRVO even though Avastin has not been approved by regulatory authorities for use in these diseases. If the ONS-5010 clinical program is successful, it will support our plans to submit for regulatory approval in multiple markets in 2021 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 a novel biologic and not using the biosimilar drug development pathway that would be required if Avastin were an approved drug for the targeted diseases. If approved, we believe ONS-5010 has potential to mitigate risks associated with off-label use of bevacizumab. Off-label use of bevacizumab is currently estimated to account for at least 50% of all wet AMD prescriptions in the United States.

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 ophthalmic drug development and commercialization expertise of our leadership team.*** Members of our executive team have 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 execute 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. As an ophthalmic formulation of bevacizumab, we believe ONS-5010 has a well-defined regulatory pathway.

- ***Conducting and efficiently executing 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, as appropriate. We intend to further this strategy, 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. We believe this will 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

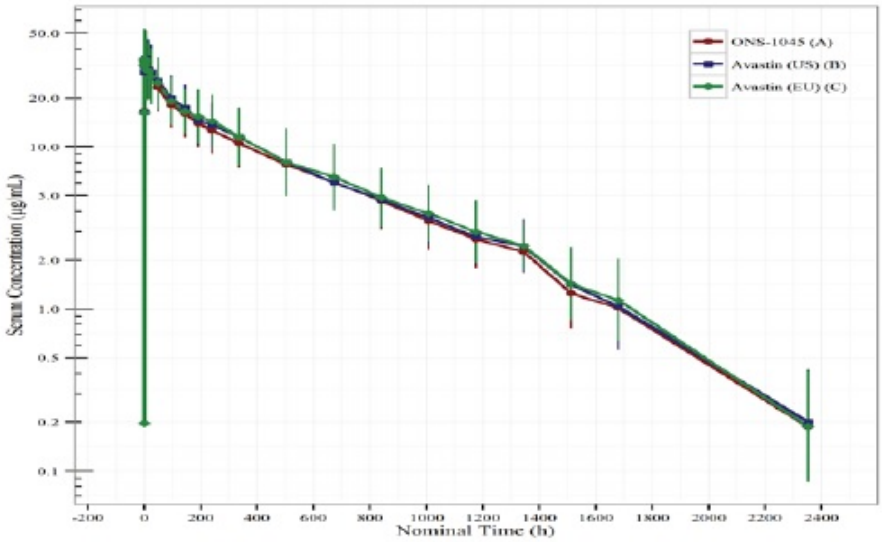
ONS-5010 — Bevacizumab for Ophthalmic Use

ONS-5010 is an investigational ophthalmic formulation of bevacizumab under development to be administered as an intravitreal injection for the treatment of wet AMD and other retinal diseases. We currently intend to commercialize both vial and pre-filled syringe formulations if approved.

Bevacizumab is a full-length, humanized anti-VEGF recombinant mAb that inhibits VEGF and associated angiogenic (the growth of new blood vessels) activity. With wet AMD, abnormally high levels of VEGF are secreted in the eye. 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.

Previously, we were developing ONS-5010 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 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 ophthalmic formulation of bevacizumab for a BLA filing 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 LUCENTIS and EYLEA (two approved anti-VEGF therapies) was approximately $9.0 billion in 2018. Although bevacizumab is not currently FDA-approved for use in treating wet AMD, it is believed that bevacizumab currently accounts for at least 50% of all wet AMD prescriptions in the United States, where Avastin is repackaged through compounding pharmacies and prescribed off-label. If approved, we believe ONS-5010 has potential to mitigate risks associated with off-label repackaging of bevacizumab.

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

The study design for our Phase 3 clinical program to evaluate ONS-5010 as an ophthalmic formulation of bevacizumab was reviewed with the FDA at an end of Phase 2 meeting in April 2018. We began enrolling patients in the NORSE 2 study in July 2019. NORSE 2 is the second study in the Phase 3 clinical program for ONS-5010 for the treatment of wet AMD. We are conducting the NORSE 2 study in the United States. The NORSE 1 study, the first clinical study in the Phase 3 clinical trial program for ONS-5010, completed enrollment in Australia in August 2019. If the program is successful, it will support our plans to submit for regulatory approval in multiple markets in 2021, including the United States, Europe and Japan. Because enrollment completed in August 2019, we currently expect to report top line data from NORSE 1 in the third quarter of calendar 2020. For NORSE 2, we expect to report top line data and submit a BLA in the first calendar quarter of 2021.

We have also received agreement from the FDA on three Special Protocol Assessments, or SPAs, for three additional registration clinical trials for our ongoing Phase 3 program for ONS-5010. The agreements reached with the FDA on these SPAs cover the protocols for NORSE 4, a registration clinical trial to treat BRVO, and NORSE 5 and NORSE 6, two registration clinical trials to treat DME. We intend to initiate NORSE 4, 5 and 6 in 2020 after completion of enrollment in NORSE 2.

NORSE 1

NORSE 1 completed enrollment in August 2019 with a total of 61 patients at nine sites in Australia. The study is the first of two ongoing, clinical trials evaluating ONS-5010 against ranibizumab for wet AMD. The endpoint for the study is a mean change in baseline visual acuity at 11 months for ONS-5010 dosed on a monthly basis compared to ranibizumab dosed using the PIER alternative dosing regimen of three monthly doses followed by quarterly dosing. We currently expect to announce a readout of the topline results from NORSE 1 in the third quarter of calendar year 2020.

NORSE 2

NORSE 2 is the second of our two required clinical trials evaluating ONS-5010 against ranibizumab for wet AMD. We began enrolling patients in July 2019, and the study is expected to enroll a total of at least 220 patients at sites in the United States. Patients enrolled in the ONS-5010-002 study will be treated for 11 months. The endpoint for the study is a mean increase in baseline visual acuity of at least five letters at 11 months for ONS-5010 dosed on a monthly basis compared to ranibizumab dosed using the approved PIER alternative dosing regimen of three-monthly doses followed by quarterly dosing. We currently anticipate full enrollment for NORSE 2 in the first quarter of calendar year 2020.

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 40mg 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 outlicensed 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.

For many years, anti-VEGF therapy has been the standard of care for many ophthalmic diseases, including wet AMD, DME and BRVO. However, although multiple branded drugs have been approved for these indications (*e.g.,* LUCENTIS, EYLEA and BEOVU), they are very expensive. Doctors who wish to treat their retinal patients with a less expensive anti-VEGF drug often use bevacizumab. But because there is no FDA-approved ophthalmic formulation of bevacizumab, doctors must use repackaged bevacizumab (Avastin) provided by compounding pharmacists. Despite clinicians' widespread acceptance and use of bevacizumab to treat ophthalmic diseases such as wet AMD, DME and BRVO, no manufacturer has previously sought approval from FDA of bevacizumab for these purposes.

The repackaged bevacizumab for ophthalmic use that is provided by compounding pharmacies can carry known risks of contamination (including silicone oil droplet contamination from syringes) and inconsistent potency, with potentially severe consequences, as leading retinal societies have reported. For these reasons, the retina community and payors have shown interest in the development of an ophthalmic formulation of bevacizumab that could be an on-label alternative to repackaged bevacizumab from compounding pharmacists.

To meet this retinal market need, we are developing ONS-5010 as an investigational ophthalmic formulation of bevacizumab. If approved, it will provide an FDA-approved and European Agency-approved, viable treatment option across the spectrum of anti-VEGF ophthalmic drugs that treat wet AMD, DME and BRVO. Additionally, if approved, it would avoid the safety, sterility, potency, availability and syringe drawbacks that can occur with repackaged bevacizumab from compounding pharmacies.

Additionally, if ONS-5010 is approved and commercialized, we expect to price it responsibly to help mitigate the high cost of on-label treatment for retinal diseases. Both in the U.S. and globally, the high cost of treating retinal diseases such as wet AMD, DME and BRVO can result in patients receiving an insufficient number of treatments, or potentially no treatment at all. Our commercial strategy includes a focus on becoming the step therapy of choice for retinal diseases for branded and long acting options. where an anti-VEGF therapy is indicated. Step therapy is a type of prior authorization for drugs that begins treatment for a medical condition with the most preferred drug therapy and progresses to other therapies only if necessary.

By ensuring the consistent availability of safe, sterile and fully potent on-label bevacizumab for intravitreal injection, at a responsible price, ONS-5010, if approved, has the potential to become the anti-VEGF cornerstone of care for retinal diseases. It may also provide synergies with future long-acting agents and adjunct therapies for advanced treatment of wet AMD, DME and BRVO. ONS-5010 has the potential, if approved and commercialized with a responsible pricing strategy, to help lower the aggregate costs of treating retinal diseases for the overall healthcare system.

To provide additional resources to fund the ONS-5010 program, in addition to pursuing potential strategic collaborations and partnerships for ONS-5010, we also 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 these 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, our controlling stockholder, providing for the license of rights to ONS-3010 and ONS-1045 in emerging markets excluding China, India and Mexico. To date, these agreements have collectively provided an aggregate of $29.0 million in payments as of September 30, 2019.

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)

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 paid MTTR a $58,333 monthly consulting fee through December 2018. Beginning January 2019, the monthly fee increased to $105,208 per month, and then, after launch of ONS-5010 in the United States, will increase 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. In June 2019, we entered into a further amendment of our strategic partnership agreement with MTTR pursuant to which we increased the aggregate monthly payments to MTTR under the existing agreement from $105,208 to $170,724 through December 2019 by adding an additional monthly retainer of $115,516, and an offset of $50,000 to the existing monthly retainer while the additional monthly retainer is in effect. MTTR earned an aggregate $1,744,933 and $602,629 during the years ended September 30, 2019 and 2018, respectively, which includes monthly consulting fees and expense reimbursement.

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).

In November 2018 we appointed Terry Dagnon as our Chief Operating Officer and Jeff Evanson as our Chief Commercial Officer. Although each is an executive officer of our company, they are providing services to us pursuant to our strategic partnership agreement with MTTR, are compensated by MTTR, and each has an ownership interest in MTTR. See also Item 13 “Certain Relationships and Related Transactions, and Director Independence—MTTR LLC - ONS 5010 Strategic Partnership Agreement.”

Selexis — Humira (ONS-3010), Avastin (ONS-5010 and ONS-1045) and Herceptin (ONS-1050)

In October 2011, we entered into a research license agreement with 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 research license expired on October 9, 2018, and accordingly, 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.

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). The initiation of our Phase 3 clinical program for ONS-5010 in fiscal 2019 triggered a CHF 65,000 (approximately $0.1 million) milestone payment to Selexis under the commercial license agreement, which we paid in November, 2019. As of September 30, 2019, 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, 2019 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, 2019, 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 the National Eye Institute, it is responsible for 90% of severe vision loss associated with AMD. The National Eye Institute also estimates that the prevalence of wet AMD among adults 40 years or older in the United States is approximately 1.75 million people. In addition, more than 200,000 new cases are diagnosed annually in North America.

Competitive Landscape in Wet-AMD

Off-label use of bevacizumab (Avastin) is estimated to be at least 50% of the overall market in the United States. The current FDA approved market leaders for the treatment of wet AMD are VEGF inhibitors, including LUCENTIS and EYLEA. Annual revenue (worldwide) was approximately $9.0 billion in 2018 for the approved anti-VEGF therapeutics LUCENTIS and EYLEA alone. Additionally, in 2019, BEOVU (brolucizumbab-dbll) was approved by the FDA as another anti-VEGF for the treatment of wet AMD. Bevacizumab, LUCENTIS, EYLEA and BEOVU are all administered via frequent intravitreal injections directly into the eye. We are developing ONS-5010 as an approved bevacizumab for 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;
- 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 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, 2019, we own one U.S. patent, one foreign patent, seven pending U.S. non-provisional applications, and 50 pending international applications that were nationalized from eight Patent Cooperation Treaty, or PCT, applications, and one pending PCT 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 or otherwise restrict payments that may be made to healthcare providers or other potential referral sources. In addition, certain states require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures or drug pricing. In addition, state and local laws may require the registration of pharmaceutical sales representatives. We may also be subject to, 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 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. Additionally, on December 15, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the individual mandate was repealed by Congress. While the Texas U.S. District Court Judge, as well as the current presidential administration and the Centers for Medicare & Medicaid Services, or CMS, have stated that the ruling will have no immediate effect pending appeal of the decision. 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 2029 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. At the federal level, the Trump administration's budget proposals for fiscal years 2019 and 2020 contain further drug price control measures that could be enacted during the budget process or in other future legislation. In addition, 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. The Department of Health and Human Services, or HHS, has started soliciting feedback on some of these measures and, at the same, is implementing others under its existing authority. While some of these measures may require additional authorization to become effective, U.S. Congress and the Trump administration have indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. Although a number of these, and other measures may require authorization 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. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. 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 September 30, 2019, we had 14 full-time employees, two of whom were primarily engaged in research and development activities and two of whom have a Ph.D. degree. We also have two full-time consultants, who act as executive officers. 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. Most of this space is no longer being used by us and we are in the process of attempting to sublease all or part of the facility to reduce expenses.

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 our 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 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 late clinical-stage biopharmaceutical company and we have incurred net losses in each year since our inception in January 5, 2010, including net losses of $34.5 million and $30.1 million for the years ended September 30, 2019 and 2018, 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, none of our product candidates have been approved for sale and 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. The amount of our future net losses will depend, in part, on our ability to generate revenue from product sales, 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 our value and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in our value 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 and have a stockholders' deficit at September 30, 2019 of $16.1 million, $6.7 million of convertible senior secured notes that become due on December 22, 2019, $3.6 million unsecured indebtedness due on demand, and $1.0 million of unsecured notes also due on demand, but subject to a forbearance agreement through March 2020. 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, 2019, our cash balance was $8.0 million. We expect that our current cash resources 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 March 2020, excluding any 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. For example, we only completed enrollment in the NORSE 1 pivotal study in August 2019, which was delayed from our original expectation of March 2019. 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;
- further 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 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 off-label in wet AMD patients although it has not been approved for use in these patients. Our ONS-5010 is being developed as an approved alternative to the use of off-label Avastin as well as the much more expensive approved therapies. 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. Even though we expect to be able to price ONS-5010 responsibly, if approved, there is no guarantee that ONS-5010 or any other product that we bring to the market will 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 repackaging of Avastin at compounding pharmacies may continue, which could have a material adverse effect on our business and financial condition.

It is currently estimated that Avastin accounts for at least 50% of wet AMD prescriptions in the United States, notwithstanding that such use is off-label and requires repackaging 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, the off-label use 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 reducing off-label use 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 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 our new contract manufacturer is unable 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 have selected FUJIFILM Diosynth Biotechnologies to manufacture and supply us with our product candidates for future 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 may need to enter into agreements with another 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 future drug substance manufacturing, f ill-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 Bio-Pharma Services, Inc., or Ajinomoto. As such, we are heavily dependent on Ajinomoto for supplying us with sufficient supply of ONS-5010. Additionally, we no longer plan to manufacture ONS-5010 bulk drug substance at our facilities and have selected FUJIFILM Diosynth Biotechnologies to conduct all future manufacturing of ONS-5010 bulk drug substance. Although we believe that there are alternate sources for these services, 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 our lead product candidate, and are not 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. 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.

We have one issued patent and when and if we do obtain additional issued patents, we may discover that competitors are infringing these 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. 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 one issued patent. 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.

In addition to our one issued patent, we have filed over 50 patent applications in the U.S. and other jurisdictions, 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. Additionally, on December 15, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the individual mandate was repealed by Congress. While the Texas U.S. District Court Judge, as well as the current presidential administration and the Centers for Medicare & Medicaid Services, or CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business. 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 2029 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. At the federal level, the Trump administration's budget proposals for fiscal years 2019 and 2020 contain further drug price control measures that could be enacted during the budget process or in other future legislation. In addition, 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. The Department of Health and Human Services, or HHS, has started soliciting feedback on some of these measures and, at the same, is implementing others under its existing authority. Although a number of these, and other measures may 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. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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 or drug pricing; 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

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 September 30, 2019, BioLexis beneficially owns 23,589,499 shares of our common stock, which includes 1,225,789 shares of common stock issuable upon conversion of 66,451 shares of our voting Series A-1 convertible preferred stock and 8,294,216 shares of common stock issuable upon exercise of warrants outstanding. Accordingly, BioLexis currently beneficially owns approximately 61.8% of our common stock and controls 51.2% of our outstanding voting power. 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 two of our five 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 initial public offering, 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, 2019 was 1,309,950 shares, and our stockholders approved an increase of an additional 1,500,000 shares at our 2019 annual meeting of stockholders held on September 12, 2019. The number of shares available for future grant under the 2015 Plan also provides for an "evergreen" increase on an annual basis unless our board of directors determines otherwise. In addition, we have reserved shares for issuance under our 2016 Employee Stock Purchase Plan, or the ESPP, which similarly provides for an annual "evergreen" increase unless determined otherwise 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 15,968,013 shares of our common stock, at prices ranging from $2.90 to $12.00 per share, as well as shares of our Series A-1 convertible preferred stock, which are currently convertible into an aggregate 1,225,789 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 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. Recently enacted U.S. tax legislation has also impacted the ability to fully utilize NOL carryforwards generated in periods after December 31, 2017. 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 preferred stock 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 preferred stock.

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 the following types of actions or proceedings under Delaware statutory or common law: 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. This provision would not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended, or any other claim for which the U.S. federal courts have exclusive jurisdiction.

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. Our current needs do not require the amount of space in our existing facilities and we are in the process of attempting to sublease all or part of the facility to reduce expenses.

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 16, 2019, the closing sale price of our common stock was $1.21, and of our Series A warrants was $0.17.

Common Stockholders

As of December 16, 2019, there were approximately 107 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 16, 2019, there were 66,451 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 16, 2019, 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. Each Series A warrant has an exercise price of $12.00 and is exercisable until February 18, 2022. The exercise price and number of shares issuable upon exercise of the Series A warrants may be adjusted upon the occurrence of certain events, including but not limited to any stock split, stock dividend, extraordinary dividend, recapitalization, reorganization, merger or consolidation. The Series A warrant holders do not have rights or privileges of holders of common stock or any voting rights until they exercise their warrants and receive common stock.

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 preferred stock 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 preferred stock.

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, 2019.

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 Item 1A "Risk Factors" in 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 working to develop the first U.S. Food and Drug Administration, or FDA,-approved ophthalmic formulation of bevacizumab for use in retinal 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 investigational ophthalmic formulation of bevacizumab under development to be administered as an intravitreal injection for the treatment of wet AMD and other retinal diseases. Bevacizumab is a full-length, humanized anti-VEGF (Vascular Endothelial Growth Factor) recombinant monoclonal antibody, or mAb, that inhibits VEGF and associated angiogenic activity. The study design for our Phase 3 clinical program to evaluate ONS-5010 as an ophthalmic formulation of bevacizumab was reviewed at an end of Phase 2 meeting with the FDA in April 2018, and we filed our investigational new drug application, or IND, with the FDA in the first quarter of calendar 2019.

Our Phase 3 program for ONS-5010 in wet AMD involves two clinical trials, which we refer to as NORSE 1 and NORSE 2, evaluating ONS-5010 against ranibizumab (LUCENTIS). Enrollment in the NORSE 1 study is complete with 61 patients enrolled, all in Australia. The NORSE 2 study has been initiated and began enrolling wet AMD patients in July 2019. The NORSE 2 study is expected to enroll a total of at least 220 patients and will be conducted in the United States. The endpoint for both studies is a mean increase in baseline visual acuity at 11 months for ONS-5010 dosed on a monthly basis compared to LUCENTIS dosed using the alternative PIER clinical trial dosing regimen of three-monthly doses followed by quarterly dosing. Currently, the cancer drug Avastin (bevacizumab) is used off-label for the treatment of wet AMD and other retinal diseases such as DME and BRVO even though Avastin has not been approved by regulatory authorities for use in these diseases. If the ONS-5010 clinical program is successful, it will support our plans to submit for regulatory approval in multiple markets in 2021 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 a standard Biologics License Application, or BLA and not using the biosimilar drug development pathway that would be required if Avastin were an approved drug for the targeted diseases. If approved, we believe ONS-5010 has potential to mitigate risks associated with off-label use of bevacizumab. Off-label use of bevacizumab is currently estimated to account for at least 50% of all wet AMD prescriptions in the United States.

Through September 30, 2019, we have funded substantially all of our operations with $241.4 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 April 2019, we completed an underwritten public offering of 10,340,000 shares of our common stock, 15-month warrants to purchase up to an aggregate of 10,340,000 shares of our common stock and five-year warrants to purchase up to an aggregate of 10,340,000 shares of our common stock at a combined public offering price of $2.75 per share and accompanying warrants. The shares of common stock and the warrants were immediately separable and were issued separately. The warrants were exercisable immediately at an exercise price of $2.90 per share. We received approximately $26.2 million in net proceeds from the public offering after payment of fees, expenses and underwriting discounts and commissions.

In June 2019, we redeemed approximately $1.8 million outstanding aggregate principal amount of our senior secured notes and entered into a third note amendment with the holders of the remaining $6.7 million outstanding aggregate principal amount of such notes. Under the third amendment, we amended the maturity date of the senior secured notes to December 22, 2019 and removed the scheduled payments of principal and interest of approximately $5.0 million that were previously to have occurred in June, July and August 2019. We also agreed to increase the interest rate payable on such senior secured notes to 12.0% per annum from 5.0% per annum.

In September 2019, the holder of $1.0 million outstanding principal and interest of our unsecured notes began exchanging the outstanding principal and interest from those notes for our common stock per the terms of a forbearance and exchange agreement dated March 7, 2019. During September 2019, a total of $0.5 million of principal and accrued interest on these notes was exchanged for an aggregate 372,888 shares of our common stock. Subsequently, the holder exchanged the remaining approximately $1.5 million of accrued interest and principal for an aggregate 1,475,258 shares of our common stock between October 1, 2019 and December 5, 2019 and such notes are no longer outstanding.

On December 11, 2019, we received approval from the New Jersey Economic Development Authority's Technology Business Tax Certificate Transfer Program to sell approximately $3.6 million of our unused New Jersey net operating losses, or NOLs, and research and development tax credits, or R&D credits. We anticipate proceeds from the sale of these New Jersey NOLs and R&D credits in the first calendar quarter of calendar year 2020. We received $3.4 million of proceeds from the sale of the New Jersey NOLs and R&D credits during fiscal 2019.

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 and have a stockholders' deficit at September 30, 2019 of $16.1 million, $6.7 million of senior secured notes that mature on December 22, 2019, $3.6 million unsecured notes that are due on demand, and $1.0 million of unsecured notes that are due on demand, but are subject to a forbearance agreement through March 7, 2020. We will need to raise substantial additional capital to fund our planned future operations, commence clinical trials, receive approval for and commercialize ONS-5010, or to develop other product candidates. We plan to finance our future operations with a combination of proceeds from potential licensing and/or marketing arrangements with pharmaceutical companies, 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 $8.0 million as of September 30, 2019 and anticipated proceeds from the sale of New Jersey NOLs and R&D credits are expected to fund our operations into March 2020, excluding any 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 ONS-5010. 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, modify our clinical trial plans for ONS-5010 in additional indications, 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, 2019 was $34.5 million. We also had a net loss of $30.1 million for the year ended September 30, 2018. 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 paid MTTR a $58,333 monthly consulting fee through December 2018. Beginning January 2019, the monthly fee increased to $105,208 per month, and then, after launch of ONS-5010 in the United States, will increase 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.

In June 2019, we entered into a further amendment of our strategic partnership agreement with MTTR pursuant to which we increased the aggregate monthly payments to MTTR under the existing agreement from $105,208 to $170,724 through December 2019 by adding an additional monthly retainer of $115,516, and an offset of $50,000 to the existing monthly retainer while the additional monthly retainer is in effect. MTTR earned an aggregate $1,744,933 and $602,629 during the years ended September 30, 2019 and 2018, respectively, which includes monthly consulting fees and expense reimbursement.

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).

In November 2018 we appointed Terry Dagnon as our Chief Operating Officer and Jeff Evanson as our Chief Commercial Officer. Although each is an executive officer of our company, they are providing services to us pursuant to our strategic partnership agreement with MTTR, are compensated by MTTR, and each has an ownership interest in MTTR. See also Item 13 “Certain Relationships and Related Transactions, and Director Independence—MTTR LLC - ONS 5010 Strategic Partnership Agreement.”

Selexis SA

In October 2011, we entered into a research license agreement with 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 research license expired on October 9, 2018 and accordingly, 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. The initiation of our Phase 3 clinical program for ONS-5010 triggered a CHF 65,000 (approximately $0.1 million) a milestone payment under the commercial license agreement, which we paid in November 2019.

Components of Our Results of Operations

Collaboration Revenue

To date, we have derived revenue only from activities pursuant to our emerging market collaboration and licensing agreements related to our inactive biosimilar development program. 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 was considered to be a multiple-element arrangement for accounting purposes. We determined that there were two deliverables; specifically, the license to our product candidate and the related research and development services that we were obligated to provide. We concluded that these deliverables should be accounted for as a single unit of accounting and revenue was being recognized on a straight-line basis through the estimated period of completion of our obligations under the agreement. As of September 30, 2019, all future development will be completed by our partners without any further assistance by us. As a result, we recognized all remaining deferred revenue under our collaboration agreements as of September 30, 2019.

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;
- expenses incurred by us directly, as well as under agreements with contract manufacturing organizations, or CMOs, for 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, and unsecured notes with current and former stockholders, equipment loans, capital lease and other finance obligations.

Loss on Extinguishment of Debt

We recorded a loss on extinguishment of debt of $0.6 million during the year ended September 30, 2019 in connection with a March 2019 forbearance and exchange agreement in respect of two previously issued unsecured stockholder notes having an aggregate original principal amount of $1.0 million and outstanding balance of $1.9 million including accrued interest; and the June 2019 third note amendment of our $6.7 million outstanding aggregate principal amount of senior secured notes in which (i) the maturity date of the senior secured notes was amended to December 22, 2019, (ii) the scheduled payments of principal and interest on or prior to each of June 30, 2019; July 31, 2019; and August 31, 2019 were removed, and (iii) the interest rate payable on such senior secured notes was increased to 12.0% per annum from 5.0% per annum.

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 $1.5 million aggregate principal amount of our senior secured notes for shares of our Series B Convertible preferred stock.

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 operations as other (income) expense.

Income Taxes

During the years ended September 30, 2019 and 2018, we sold New Jersey State net operating losses in the amount of $31.2 million and $38.5, respectively, and in the year ended September 30, 2019, unused R&D tax credits in the amount of $0.9 million, resulting in the recognition of income tax benefits of $3.4 million and $3.2 million respectively, recorded in the Company's statement of operations.

Since inception, we have not recorded any U.S. federal or state income tax benefits (excluding the sale of New Jersey state NOLs and research credits) for the net losses we have incurred in each year or on our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. As of September 30, 2019, we had federal and state NOL carryforwards of $202.7 million and $71.8 million, respectively that will begin to expire in 2030 and 2037, respectively. As of September 30, 2019, 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, 2019, we also had federal research and development tax credit carryforwards of $7.0 million which begin to expire in 2032.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its NOLs to offset future taxable income. We have not completed a study to assess whether an ownership change has occurred in the past. Our existing NOLs may be subject to limitations arising from previous ownership changes, and 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.

Results of Operations

Comparison of Years Ended September 30, 2019 and 2018

	Year ended September 30,		
	2019	**2018**	**Change**
Collaboration revenues	$ 8,146,123	$ 3,087,560	$ 5,058,563
Operating expenses:			
Research and development	23,805,251	18,504,035	5,301,216
General and administrative	9,369,823	14,227,828	(4,858,005)
Impairment of property and equipment	11,270,110	-	11,270,110
	44,445,184	32,731,863	11,713,321
Loss from operations	(36,299,061)	(29,644,303)	(6,654,758)
Interest expense, net	3,466,688	3,891,250	(424,562)
Loss on extinguishment of debt	607,240	1,252,353	(645,113)
Change in fair value of warrant liability	(2,438,201)	(1,047,729)	(1,390,472)
Loss before income taxes	(37,934,788)	(33,740,177)	(4,194,611)
Income tax benefit	(3,411,001)	(3,648,216)	237,215
Net loss	$ (34,523,787)	$ (30,091,961)	$ (4,431,826)

Collaboration Revenues

The following table sets forth a summary of revenue recognized from our collaboration and licensing agreements for the years ended September 30, 2019 and 2018:

	Year ended September 30,	
	2019	**2018**
IPCA Collaboration	$ 1,664,085	$ 261,072
Liomont Collaboration	1,097,412	236,641
Huahai Collaboration	4,828,584	714,848
BioLexis Collaboration	556,042	1,874,999
	$ 8,146,123	$ 3,087,560

Collaboration revenues increased $5.1 million for the year ended September 30, 2019 compared to the year ended September 30, 2018. The increase was primarily due to the full recognition of IPCA, Liomont, and Huahai deferred revenue during the fourth quarter of fiscal 2019 after we had assessed that we did not have any further performance obligations on these collaboration arrangements. During fourth quarter of fiscal year 2019, we substantially completed our efforts to outsource the commercial manufacturing and remaining development for the ONS-5010 program, resulting in the termination of the majority of manufacturing and development personnel and initiation of efforts to sell or transfer excess manufacturing, laboratory and related computer equipment no longer required for the development of ONS-5010. As a result, we no longer have the internal capability to support our inactive development programs for ONS-3010 (biosimilar for Humira) and ONS-1045 (biosimilar for Avastin) and do not intend to complete the development of these assets in the United States and other developed markets. All future development for the biosimilar programs, if any, will be completed by our existing, or potential future, partners without further assistance from us. The increase in IPCA, Liomont, and Huahai revenue was offset by a $1.3 million decrease from the BioLexis collaboration revenue due to the full recognition of related milestones in the second quarter of fiscal 2019.

Research and Development Expenses

The following table summarizes our research and development expenses by functional area for the years ended September 30, 2019 and 2018:

	Year ended September 30,	
	2019	**2018**
ONS-5010 development	$ 11,163,383	$ 6,540,433
Settlement of clinical development contract	-	(3,228,613)
Compensation and related benefits	5,618,375	6,911,910
Stock-based compensation	37,053	19,450
Other research and development	6,986,440	8,260,855
Total research and development expenses	$ 23,805,251	$ 18,504,035

Research and development expenses for the year ended September 30, 2019 increased by $5.3 million compared to the year ended September 30, 2018. The increase was primarily due to increased ONS-5010 development costs of $4.6 million as we progressed into Phase 3 clinical trials near the end of fiscal year 2018. In addition, 2018 reflects a $3.2 million favorable settlement of a contract related to our inactive biosimilar product candidates. The increase was offset by a $1.3 million decrease in compensation and related benefits and a $1.3 million decrease in other research and development expenses due to reduction in headcount and closure of our manufacturing and laboratory facilities resulting from our decision to outsource the commercial manufacturing and remaining development for the ONS-5010 program.

General and Administrative Expenses

The following table summarizes our general and administrative expenses by type for the years ended September 30, 2019 and 2018:

	Year ended September 30,	
	2019	**2018**
Professional fees	$ 4,028,104	$ 3,155,658
Compensation and related benefits	1,281,442	2,451,796
Stock-based compensation	1,276,282	1,966,420
Facilities, fees and other related costs	2,783,995	6,653,954
Total general and administrative expenses	$ 9,369,823	$ 14,227,828

General and administrative expenses for the year ended September 30, 2019 decreased by $4.9 million compared to the year ended September 30, 2018. The decrease was primarily due to a $4.2 million lease termination charge incurred during the fourth quarter of fiscal 2018, reduction in compensation and related benefits of $1.2 million and stock-based compensation expense of $0.7 million, resulting from staff reductions connected with the closure of our manufacturing facility and laboratory facilities. These decreases were offset by an increase in professional fees of $0.9 million and $0.5 million increase in lease termination obligation accretion costs.

Impairment of property and equipment

We recognized a loss on impairment of property and equipment of $11.3 million for the year ended September 30, 2019. The impairment was recognized due to the substantial completion of our efforts to outsource the commercial manufacturing and remaining development for the ONS-5010 program during the fourth quarter of fiscal 2019. As a result, we are no longer using the manufacturing or development areas of our facility and have been engaged in an effort to sublease all or a portion of the facility and sell or transfer excess manufacturing, laboratory and related computer equipment no longer required for the development of ONS-5010. For a discussion of the impairment analysis, refer to Item 8 “Consolidated Financial Statements and Supplementary Data - Notes to the Consolidated Financial Statements – Note 5 - Property and Equipment.”

Interest Expense, Net

Interest expense, net decreased by $0.4 million to $3.5 million for the year ended September 30, 2019 as compared to $3.9 million for the year ended September 30, 2018. The decrease was primarily due to; (i) decreased amortization of debt discount and interest expense on the senior secured notes issued due to the modification of the interest rate made to the notes, (ii) decrease in interest on equipment leases to expiration of lease terms, (iii) increase in interest income during the year ended September 30, 2019.

Change in Fair Value of Warrant Liability

During the years ended September 30, 2019 and 2018, we recorded income of $2.4 and $1.0 million, respectively, 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, 2019, we have funded substantially all of our operations through the sale and issuance of $241.4 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 emerging markets collaboration and licensing agreements for our inactive biosimilar development programs.

In November 2018 through February 2019, we issued an aggregate of 2,680,390 shares of our common stock for gross cash proceeds of $20.0 million ($19.8 million net of issuance costs) pursuant to the November 5, 2018 BioLexis private placement agreement.

In April 2019, we completed an underwritten public offering of 10,340,000 shares of our common stock, 15-month warrants to purchase up to an aggregate of 10,340,000 shares of our common stock and five-year warrants to purchase up to an aggregate of 10,340,000 shares of our common stock at a combined public offering price of $2.75 per share and accompanying warrants. The shares of common stock and the warrants were immediately separable and were issued separately. The warrants were exercisable immediately at an exercise price of $2.90 per share. We received approximately $26.2 million in net proceeds from the public offering after payment of fees, expenses and underwriting discounts and commissions.

In June 2019, we redeemed approximately $1.8 million outstanding aggregate principal amount of our senior secured notes and entered into a third note amendment with the holders of the remaining $6.7 million outstanding aggregate principal amount of such notes. Under the third note amendment, we amended the maturity date of the senior secured notes to December 22, 2019 and removed the scheduled payments of principal and interest of approximately $5.0 million that were previously to have occurred in June, July and August 2019. We also agreed to increase the interest rate payable on such senior secured notes to 12.0% per annum from 5.0% per annum. We paid $7.7 million of principal and interest on the senior secured notes through September 30, 2019.

In September 2019, the holder of $1.0 million outstanding principal and interest of our unsecured notes began exchanging the outstanding principal and interest from those notes for our common stock per the terms of a forbearance agreement dated March 7, 2019. During September 2019, a total of $0.5 million of principal and accrued interest on these notes was exchanged for 372,888 shares of our common stock. Subsequently, the holder exchanged the remaining approximately $1.5 million of accrued interest and principal for an aggregate 1,475,258 shares of our common stock between October 1, 2019 and December 5, 2019 and such notes are no longer outstanding.

On December 11, 2019, we received approval from the New Jersey Economic Development Authority's Technology Business Tax Certificate Transfer Program to sell approximately $3.6 million of its unused New Jersey NOLs and R&D credits. We expect to receive approximately $3.3 million of proceeds from the sale of the New Jersey NOLs and R&D credits.

Our current cash resources of $8.0 as of September 30, 2019 and anticipated proceeds from the sale of New Jersey NOLs and R&D credits are expected to fund our operations into March 2020, excluding any debt repayment. Alternatively, we will be required to, among other things, make further 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, 2019, we had a stockholders' deficit of $16.1 million and a cash balance of $8.0 million. In addition, we have $6.7 million of senior secured notes that become due in December 2019, $3.6 million unsecured notes, which are due on demand as of such date, and $1.0 million of unsecured notes that were due on demand but were subject to a forbearance agreement through March 7, 2020. These matters raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. We anticipate incurring additional losses until such time, if ever, that we can generate significant sales of our product candidates currently in development. We will need substantial additional financing to fund our operations and to commercially develop our product candidates. Management is currently evaluating various strategic opportunities to obtain the required funding for future operations. These strategies may include but are not limited to payments from potential strategic research and development, licensing and/or marketing arrangements with pharmaceutical companies, private placements and/or public offerings of equity and/or debt securities. There can be no assurance that these future funding efforts will be successful.

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

Cash Flows

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

	Year ended September 30,	
	2019	**2018**
Net cash used in operating activities	$ (32,289,988)	$ (33,039,523)
Net cash used in investing activities	(437,307)	(2,781,125)
Net cash provided by financing activities	39,025,432	34,352,520

Operating Activities

During the year ended September 30, 2019, we used $32.3 million of cash in operating activities resulting primarily from our net loss of $34.5 million and the change in our operating assets and liabilities of $13.2 million. This use of cash was partially offset was partially offset by $15.4 million of noncash items such as non-cash interest expense, stock-based compensation, change in fair value of warrant liability, impairment of property and equipment, loss on extinguishment of debt and depreciation and amortization expense. The change in our operating assets and liabilities was primarily due (i) to prepayments associated with our clinical trials and ONS 5010 development costs; (ii) payments of our accounts payable and accrued expenses from September 30, 2018; and (iii) full recognition of our deferred revenues balances from collaborations as September 30, 2019.

During the year ended September 30, 2018, we used $33.0 million of cash in operating activities resulting from our net loss of $30.1 million and the change in our operating assets and liabilities of $13.6 million. This use of cash was partially offset by $10.7 million of non-cash items such as non-cash interest expense, stock-based compensation, change in fair value of warrant liability, loss on extinguishment of debt, loss on lease termination and depreciation and amortization expense. The change in our operating assets and liabilities was 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 and the amortization of our deferred revenues from collaborations.

Investing Activities

During the years ended September 30, 2019 and 2018, we used cash of $0.4 million and $2.8 million, respectively, in investing activities for the purchase of property and equipment.

Financing Activities

During the year ended September 30, 2019, net cash provided by financing activities was $39.0 million, primarily attributable to $19.8 million in net proceeds from the November 2018 BioLexis private placement, and $26.2 million in net proceeds from the April 2019 public offering. We also paid $6.9 million in debt and capital lease obligations payments.

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.

Funding Requirements

We plan to focus in the near term on advancing ONS-5010 through clinical trials to support the filing of a Biologics License Application 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 lead product candidate.

We believe our existing cash as of September 30, 2019 and anticipated proceeds from the sale of New Jersey NOLs and R&D credits will provide adequate financial resources to fund our operations into March 2020, excluding any 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 potential strategic collaborations, sale of the development and commercial rights to our drug product candidates, the issuance of equity securities, the issuance of additional debt, 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. Alternatively, we will be required to, among other things, modify our clinical trial plans for ONS-5010 in additional indications, 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.

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

See Item 1A “Risk Factors” for additional risks associated with our substantial capital requirements.

Contractual Obligations and Commitments

Our future contractual obligations as of September 30, 2019 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)	$ 382,500	$ 187,500	$ 195,000	$ -	$ -
Debt obligations (2)	12,571,659	12,518,135	53,524	-	-
Capital leases (3)	13,499,278	1,608,067	3,042,401	3,157,318	5,691,492
Lease termination obligation (4)	4,850,000	600,000	4,250,000	-	-
Total (5)	$ 31,303,437	$ 14,913,702	$ 7,540,925	$ 3,157,318	$ 5,691,492

(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 obligations due to investors on senior secured debt, stockholder notes payable and institutions and equipment loans.
(3) Capital lease obligations reflect our outstanding principal 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 license agreement with Selexis, we are obligated to pay milestone payments, as well as a royalty at a single-digit percentage of net sales of any covered product we successfully commercialize. Under our agreement with MTTR, we are also agreed to pay 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.

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

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

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Significant Judgments and Estimates

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

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

Revenue Recognition

On October 1, 2018, we adopted ASU No. 2014-09, *Revenue from Contracts with Customers,* and changed our revenue recognition policies accordingly. 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. This guidance also requires an entity to disclose sufficient information to enable users of financial statements to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. Qualitative and quantitative information is required about:

- *Contracts with customers* – including revenue and impairments recognized, disaggregation of revenue and information about contract balances and performance obligations (including the transaction price allocated to the remaining performance obligations).
- *Significant judgments and changes in judgments* – determining the timing of satisfaction of performance obligations (over time or at a point in time) and determining the transaction price and amounts allocated to performance obligations.
- *Certain assets* – assets recognized from the costs to obtain or fulfill a contract.

Our arrangements fall under Accounting Standards Codification, or ASC, Topic 808, *Collaborative Arrangements* ("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, we 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. We previously recognized substantive milestones in the period the milestones were achieved, but ASU 2014-09 prescribes that those milestones are a form of variable consideration that results in such amounts being recognized over the estimated performance period. During the fiscal year ended September 30, 2019, we would have recognized $4.5 million of collaboration revenues under revenue recognition guidance in effect during fiscal 2018 prior to the adoption of ASU 2014-09.

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 make adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

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

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.

We estimate the fair value of stock options as of the date of grant and warrant liability at the end of each reporting period using the Black-Scholes option pricing model, which requires management to apply judgment and make estimates including the volatility of our common stock, the expected term of our stock options, the expected dividend yield and the fair value of our common stock on the date of grant. We estimate the fair value of restricted stock based on the closing price of our common stock on the date of grant.

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 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. We will adopt the new standard on October 1, 2019 using a modified retrospective approach, the transition method that allows for application of the standard at the adoption date rather than at the beginning of the earliest comparative period presented in the financial statements. We also elected available practical expedients. While we are still finalizing the adoption procedures, we estimate the primary impact to the consolidated financial position upon adoption will be the recognition, on a discounted basis, of the minimum commitments under noncancelable operating leases on the consolidated balance sheets resulting in the recording of lease obligations for approximately $0.4 million.

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* ("ASU 2018-13"), which removes and modifies some existing disclosure requirements and adds others. ASU 2018-13 modifies the disclosure requirements for fair value measurements and removes the requirement to disclose (1) the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, (2) the policy for timing of transfers between levels, and (3) the valuation processes for Level 3 fair value measurements. ASU 2018-13 requires disclosure of changes in unrealized gains and losses for the period included in other comprehensive income (loss) for recurring Level 3 fair value measurements held at the end of the reporting period and the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. 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 the impact of the adoption of 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, 2019 and 2018, 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, 2019 and 2018, 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 $16.1 million, $6.7 million of convertible senior secured notes that become due on December 22, 2019, $3.6 million of unsecured indebtedness due on demand and $1.0 million of unsecured indebtedness also due on demand, but subject to a forbearance agreement through March 2020, 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 19, 2019

Outlook Therapeutics, Inc.
Consolidated Balance Sheets

	September 30,	
	2019	**2018**
Assets		
Current assets:		
Cash	$ 8,015,528	$ 1,717,391
Prepaid and other current assets	4,986,033	1,585,089
Assets held for sale	500,000	-
Total current assets	13,501,561	3,302,480
Property and equipment, net	3,175,960	18,489,976
Other assets	457,476	491,039
Total assets	$ 17,134,997	$ 22,283,495
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Convertible senior secured notes	$ 6,699,000	$ 13,179,449
Current portion of long-term debt	1,026,168	66,480
Current portion of capital lease obligations	192,290	520,794
Stockholder notes	3,612,500	4,612,500
Accounts payable	2,277,817	3,609,607
Accrued expenses	4,622,988	6,458,471
Income taxes payable	1,859,434	1,856,129
Deferred revenue	-	1,738,603
Total current liabilities	20,290,197	32,042,033
Long-term debt	50,285	98,487
Capital lease obligations	3,365,790	3,453,256
Warrant liability	255,734	1,227,225
Deferred revenue	-	2,758,262
Other liabilities	3,942,948	3,514,738
Total liabilities	27,904,954	43,094,001
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	-	-
Series A-1 convertible preferred stock, par value $0.01 per share: 200,000 shares authorized, 66,451 and 60,203 shares issued and outstanding at September 30, 2019 and 2018, respectively	5,359,404	4,734,416
Total convertible preferred stock	5,359,404	4,734,416
Stockholders' equity (deficit):		
Preferred stock, par value $0.01 per share: 7,300,000 shares authorized, no shares issued and outstanding	-	-
Series B convertible preferred stock, par value $0.01 per share: 1,500,000 shares authorized, no shares issued and outstanding	-	-
Common stock, par value $0.01 per share; 200,000,000 shares authorized; 28,609,995 and 9,027,491 shares issued and outstanding at September 30, 2019 and 2018, respectively	286,100	90,275
Additional paid-in capital	238,064,947	190,672,166
Accumulated deficit	(254,480,408)	(216,307,363)
Total stockholders' equity (deficit)	(16,129,361)	(25,544,922)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 17,134,997	$ 22,283,495

See accompanying notes to consolidated financial statements

Outlook Therapeutics, Inc.
Consolidated Statements of Operations

	Year ended September 30,	
	2019	**2018**
Collaboration revenues	$ 8,146,123	$ 3,087,560
Operating expenses:		
Research and development	23,805,251	18,504,035
General and administrative	9,369,823	14,227,828
Impairment of property and equipment	11,270,110	-
	44,445,184	32,731,863
Loss from operations	(36,299,061)	(29,644,303)
Interest expense, net	3,466,688	3,891,250
Loss on extinguishment of debt	607,240	1,252,353
Change in fair value of warrant liability	(2,438,201)	(1,047,729)
Loss before income taxes	(37,934,788)	(33,740,177)
Income tax benefit	(3,411,001)	(3,648,216)
Net loss	(34,523,787)	(30,091,961)
Recognition of beneficial conversion feature upon issuance of Series A and A-1 convertible preferred stock	(61,365)	(16,022,963)
Series A and A-1 convertible preferred stock dividends and related settlement	(624,988)	(1,903,930)
Deemed dividend upon modification of warrants	(829,530)	-
Net loss attributable to common stockholders	$ (36,039,670)	$ (48,018,854)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (1.98)	$ (9.74)
Weighted average shares outstanding, basic and diluted	18,191,827	4,932,202

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	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance at October 1, 2017	32,628	$ 2,924,441	-	$ -	-	$ -	3,116,692	$ 31,167	$ 152,533,260	$ (186,215,402)	$ (33,650,975)
Proceeds from exercise of common stock warrants	-	-	-	-	-	-	432	4	(4)	-	-
Issuance of vested restricted stock units	-	-	-	-	-	-	105,361	1,054	(1,054)	-	-
Private placement sale of common stock and common stock warrants, net of costs	-	-	-	-	-	-	1,594,345	15,943	14,679,177	-	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)	-	-	-	-	3,946,577	39,466	14,320,350	-	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)	264,084	2,641	2,659,331	-	-
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	-	-	9,027,491	90,275	190,672,166	(216,307,363)	(25,544,922)
Cumulative effect of adoption of ASU 2014-09 (Topic 606)	-	-	-	-	-	-	-	-	-	(3,649,258)	(3,649,258)
Issuance of common stock in connection with exercise of warrants	-	-	-	-	-	-	6,134,763	61,348	(56,998)	-	4,350
Issuance of common stock in connection with public offering, net of costs	-	-	-	-			10,340,000	103,400	26,053,103	-	26,156,503
Private placement sale of common stock, net of costs	-	-	-	-	-	-	2,680,390	26,804	19,781,514	-	19,808,318
Issuance of vested restricted stock units	-	-	-	-	-	-	4,069	41	(41)	-	-
Issuance of common stock in connection with conversion of senior secured notes	-	-	-	-	-	-	50,394	503	401,464	-	401,967
Issuance of common stock in connection with conversion of stockholder notes	-	-	-	-	-	-	372,888	3,729	476,271	-	480,000
Series A-1 convertible preferred stock dividends and related settlement	-	-	6,248	624,988	-	-	-	-	(624,988)	-	(624,988)
Stock-based compensation expense	-	-	-	-	-	-	-	-	1,313,335	-	1,313,335
Accrued directors fees settled in fully vested stock options	-	-	-	-	-	-	-	-	49,121	-	49,121
Net loss	-	-	-	-	-	-	-	-	-	(34,523,787)	(34,523,787)
Balance at September 30, 2019	-	$ -	66,451	$ 5,359,404	-	$ -	28,609,995	$ 286,100	$ 238,064,947	$ (254,480,408)	$ (16,129,361)

See accompanying notes to consolidated financial statements.

Outlook Therapeutics, Inc.
Consolidated Statements of Cash Flows

	Year ended September 30,	
	2019	**2018**
OPERATING ACTIVITIES		
Net loss	$ (34,523,787)	$ (30,091,961)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,361,873	3,054,352
Loss on extinguishment of debt	607,240	1,252,353
Non-cash interest expense	1,314,321	1,315,861
Stock-based compensation	1,313,335	1,985,870
Change in fair value of warrant liability	(2,438,201)	(1,047,729)
Impairment of property and equipment	11,270,110	-
Loss on lease termination	-	4,173,682
Changes in operating assets and liabilities:		
Prepaid and other current assets	(3,245,146)	(1,419,551)
Other assets	(87,182)	1,554
Accounts payable	(1,331,640)	(6,714,137)
Accrued expenses	(482,665)	(1,664,843)
Income taxes payable	3,305	(496,000)
Deferred revenue	(8,146,123)	(3,057,561)
Other liabilities	94,572	(331,413)
Net cash used in operating activities	(32,289,988)	(33,039,523)
INVESTING ACTIVITIES		
Purchase of property and equipment	(437,307)	(2,781,125)
Net cash used in investing activities	(437,307)	(2,781,125)
FINANCING ACTIVITIES		
Proceeds from issuance of common stock through private placement and public offering, net	45,964,821	14,695,120
Proceeds from issuance of Series A convertible preferred stock	-	21,737,200
Proceeds from exercise of common stock warrants	4,350	-
Payments of capital lease obligations	(526,087)	(862,906)
Repayment of debt	(6,417,652)	(127,736)
Payment of financing costs	-	(1,089,158)
Net cash provided by financing activities	39,025,432	34,352,520
Net increase (decrease) in cash	6,298,137	(1,468,128)
Cash at beginning of year	1,717,391	3,185,519
Cash at end of year	$ 8,015,528	$ 1,717,391
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 2,794,572	$ 109,979
Supplemental schedule of noncash investing activities:		
Purchases of property and equipment in accounts payable and accrued expenses	$ -	$ 816,501
Supplemental schedule of noncash financing activities:		
Senior secured notes and accrued interest converted into common stock	$ 401,967	$ -
Unsecured notes and accrued interest converted into common stock	$ 480,000	$ -
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 in connection with purchase of property and equipment	$ 48,683	$ 4,444,095
Change in fair value of convertible senior secured notes warrants capitalized as deferred financing costs	$ 1,466,710	$ -
Series A and A-1 convertible preferred stock dividends	$ 624,988	$ 1,886,945
Settlement of Series A and A-1 convertible preferred stock dividends upon issuance of Series A and A-1 convertible preferred stock	$ 624,988	$ 1,903,930
Accrued directors fees settled in fully vested stock options	$ 49,121	$ -

See accompanying notes to consolidated financial statements.

1. Organization and Operations

Description of the Business

Outlook Therapeutics, Inc., (formerly Oncobiologics, Inc.), ("Outlook" or the "Company") was incorporated in New Jersey on January 5, 2010, started operations in July 2011, reincorporated in Delaware by merging with and into a Delaware corporation in October 2015 and changed its name to "Outlook Therapeutics, Inc." in November 2018. The Company is a late clinical-stage biopharmaceutical company focused on developing and commercializing ONS-5010, an ophthalmic formulation of bevacizumab for use in retinal 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 a stockholders' deficit of $16.1 million as of September 30, 2019. As of September 30, 2019, the Company had substantial indebtedness that included $6.7 million of convertible senior secured notes that mature on December 22, 2019, $3.6 million of unsecured notes that are due on demand, and $1.0 million of unsecured notes that were due on demand, but which are subject to a forbearance agreement through March 7, 2020. 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.

In September 2019, the holder of $1.0 million of outstanding principal and accrued interest of the Company's unsecured notes began exchanging the outstanding principal and accrued interest from those notes for the Company's common stock per the terms of a forbearance agreement dated March 7, 2019. The holder exchanged the remaining $1.5 million of accrued interest and principal for an aggregate 1,475,258 shares of the Company's common stock between October 1, 2019 and December 5, 2019.

On December 11, 2019, the Company received approval from the New Jersey Economic Development Authority's Technology Business Tax Certificate Transfer Program to sell approximately $3.6 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 $3.3 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, 2019 and anticipated proceeds from the sale of New Jersey NOLs and R&D credits will be sufficient to fund its operations into March 2020, excluding any 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: payments from potential strategic research and development partners, licensing and/or marketing arrangements with pharmaceutical companies, private placements of equity and/or debt securities, sale of its development stage product candidates to third parties and public offerings of equity and/or debt securities. There can be no assurance that these future funding efforts will be successful.

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

3. Basis of Presentation and Summary of Significant Accounting Policies

Basis of presentation

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

Reverse stock-split

On March 15, 2019, the Company amended its amended and restated certificate of incorporation to implement a one-for-eight reverse stock split of its common stock. As a result of the reverse stock split, the Company adjusted the share amounts under its employee incentive plans, outstanding options, restricted stock units and common stock warrant agreements with third parties. The disclosure of common shares and per common share data in the accompanying consolidated financial statements and related notes reflect the reverse stock split for all periods presented.

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, 2019 and 2018, the Company's financial instruments included cash, accounts payable, accrued expenses, equipment loans, stockholder notes and senior secured debt. 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 recognized an impairment loss of $11.3 million for the year ended September 30, 2019 which is described more fully in Note 5. There was no impairment charge recognized during the year ended September 30, 2018.

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. The Company accounts for forfeitures of stock option awards as they occur.

Revenue recognition

On October 1, 2018, the Company adopted ASU No. 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09") and changed its revenue recognition policies accordingly. 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. This guidance also requires an entity to disclose sufficient information to enable users of financial statements to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. Qualitative and quantitative information is required about:

- *Contracts with customers* – including revenue and impairments recognized, disaggregation of revenue and information about contract balances and performance obligations (including the transaction price allocated to the remaining performance obligations).
- *Significant judgments and changes in judgments* – determining the timing of satisfaction of performance obligations (over time or at a point in time) and determining the transaction price and amounts allocated to performance obligations.
- *Certain assets* – assets recognized from the costs to obtain or fulfill a contract.

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 typically receives upfront, nonrefundable payments when licensing its intellectual property.

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 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. Under the ASU 2014-09, the Company treat substantive milestones as forms of variable consideration which is recognized over the estimated performance period. Payments or reimbursements resulting from the Company's research and development efforts are recognized as the services are performed.

The Company adopted the new accounting standard utilizing the modified retrospective method, and, therefore, no adjustments were made to amounts in its prior period financial statements. The Company recorded the cumulative effect of adopting the standard as an adjustment to increase accumulated deficit by $3.6 million. During the fiscal year ended September 30, 2019, we would have recognized $4.5 million of collaboration revenues under revenue recognition guidance in effect during fiscal 2018 prior to the adoption of ASU 2014-09.

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 sheets. As of September 30, 2019, the Company's estimate of the amount of cash refund it expects to receive in 2020 for 2019 eligible spending as part of this incentive program was $1.1 million. As of September 30, 2018, the Company had a receivable of $0.3 million which was received in 2019 as part of this incentive program.

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, 2019, and 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 years ended September 30, 2019 and 2018, the Company recorded $1.2 million and $0.3 million, respectively, in its consolidated statements of operations related to the cash refund it expected to receive from the Australian research and development tax incentive program.

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 attributable to common stockholders by the weighted-average number of shares of common stock 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 unit ("RSU") awards using the treasury stock method. For all periods presented, there is no difference in the number of shares used to compute basic and diluted shares due to the Company's loss.

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding as of September 30, 2019 and 2018, as they would be antidilutive:

	September 30,	
	2019	**2018**
Series A-1 convertible preferred stock	1,255,789	1,137,714
Convertible senior secured notes	767,605	-
Convertible unsecured notes	149,573	-
Performance-based stock units	15,691	16,131
Restricted stock units	109	7,638
Stock options	1,389,999	182,120
Common stock warrants	16,067,948	5,661,506

Recently issued accounting pronouncements

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. The Company adopted the new standard on October 1, 2019 using a modified retrospective approach, the transition method that allows for application of the standard at the adoption date rather than at the beginning of the earliest comparative period presented in the financial statements. The Company also elected available practical expedients. While the Company is still finalizing its adoption procedures, the Company estimates the primary impact to the consolidated financial position upon adoption will be the recognition, on a discounted basis, of the minimum commitments under noncancelable operating leases on the consolidated balance sheets resulting in the recording of lease obligations for approximately $0.4 million. The adoption of the guidance will not impact the Company's consolidated statements of operations or cash flows.

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* ("ASU 2018-13"), which removes and modifies some existing disclosure requirements and adds others. ASU 2018-13 modifies the disclosure requirements for fair value measurements and removes the requirement to disclose (1) the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, (2) the policy for timing of transfers between levels, and (3) the valuation processes for Level 3 fair value measurements. ASU 2018-13 requires disclosure of changes in unrealized gains and losses for the period included in other comprehensive income (loss) for recurring Level 3 fair value measurements held at the end of the reporting period and the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. 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 the impact of the adoption of 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.

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

	September 30, 2019		
	(Level 1)	(Level 2)	(Level 3)
Liabilities			
Warrant liability	$ -	$ -	$ 255,734

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

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, 2019 and 2018:

Balance at October 1, 2017	$ 2,274,954
Change in fair value	(1,047,729)
Balance at September 30, 2018	1,227,225
Senior note warrants modification	1,466,710(i)
Change in fair value	(2,438,201)
Balance at September 30, 2019	$ 255,734

(i) In connection with the November 2018 private placement to BioLexis Pte. Ltd. ("BioLexis"), the Company reduced the exercise price of the warrants issued in connection with the senior secured notes (the "Senior Note Warrants") from $24.00 to $12.00 and extended the expiration of the Senior Note Warrants by three years. Such Senior Note Warrants now expire eight years from their initial exercise date.

The Senior Note Warrants issued in connection with the senior secured notes (see Note 8) are classified as liabilities on the accompanying consolidated balance sheets 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,	
	2019	2018
Risk-free interest rate	1.56%	2.90%
Remaining contractual life of warrant	5.38 years	3.39 years
Expected volatility	89%	82%
Annual dividend yield	0%	0%
Fair value of common stock	$ 1.49 per share	$7.84 per share

5. Property and Equipment

Property and equipment, net, consists of:

	September 30,	
	2019	2018
Laboratory equipment	$ 1,067,351	$ 14,333,624
Leasehold improvements	160,086	10,095,100
Computer software and hardware	-	483,807
Land and building	3,000,000	3,000,000
Construction in progress	-	2,276,737
	4,227,437	30,189,268
Less: accumulated depreciation and amortization	(1,051,477)	(11,699,292)
	$ 3,175,960	$ 18,489,976

Depreciation and amortization expense for the years ended September 30, 2019 and 2018 was $3,361,873 and $3,054,351, respectively.

At September 30, 2019, $3,000,000 and 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, 2019 and September 30, 2018, $475,000 and $1,619,741, respectively, of accumulated amortization related to capital leases. The term of the equipment leases were between 22 and 36 months and qualify as capital leases. The equipment leases bear interest between 5.0% and 19.4% and the effective interest rate on the corporate office lease is 43.9%.

Impairment Charge

During the year ended September 30, 2019, the Company wrote off certain construction in progress and laboratory equipment with a carrying amount of $1,913,798 due to the Company changing its operations to focus solely on developing and commercializing ONS-5010. The Company determined that the carrying amount of these assets was not recoverable.

In the fourth quarter of fiscal year 2019, as a result of management's decision to outsource the commercial manufacturing and remaining development for the Company's ONS-5010 program, the Company decided to vacate and sublease the Company's manufacturing and corporate offices and sell or transfer excess laboratory and related computer equipment no longer required for the development of the Company's ONS-5010 program. These events qualified as indicators of impairment in accordance with ASC 360, *Property, Plant and Equipment* ("ASC 360") and required an impairment analysis. As a result of the analysis, management determined that the Company's long-lived assets with a carrying amount of $13,032,320 were no longer recoverable and were impaired and wrote the assets down to their estimated fair value of $3,676,008. The estimated fair value for the Company's land and building and leasehold improvement assets was based on discounted expected future cash flows using Level 3 inputs under ASC 820, *Fair Value Measurements* ("ASC 820"). The estimated fair value for the Company's laboratory and related computer equipment was based on offers the Company received from unrelated third parties to purchase the assets which is classified as a Level 3 measurement under ASC 820's fair value hierarchy.

Management determined that $500,000 of laboratory equipment met the definition of "held for sale" under ASC 360 as it was probable that a sale of the laboratory equipment could be completed within one year as of September 30, 2019.

The Company recorded an impairment charge totaling $11,270,110 for the year ended September 30, 2019 in the consolidated statements of operations associated with the above items.

Corporate Office Lease

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 became 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. During the years ended September 30, 2019 and 2018, the Company recorded interest expense of $1,425,913 and $823,592, respectively.

The following is a schedule of future minimum lease payments under capital leases as of September 30, 2019 for the years ending September 30:

2020	$ 1,608,067
2021	1,506,592
2022	1,535,809
2023	1,564,027
2024	1,593,291
Thereafter	5,691,492
	13,499,278
Less: amounts representing interest	(9,941,198)
Less: current portion	(192,290)
Capital lease obligations, excluding current portion	$ 3,365,790

6. Accrued Expenses

Accrued expenses consists of:

	September 30,	
	2019	**2018**
Compensation	$ 919,394	$ 2,231,122
Severance and related costs	505,570	396,138
Research and development	1,692,040	1,065,169
Interest payable	934,145	1,991,044
Professional fees	419,216	313,585
Director fees	-	59,122
Other accrued expenses	152,623	402,291
	$ 4,622,988	$ 6,458,471

7. Stockholder Notes

	September 30,	
	2019	2018
Restricted stock repurchase notes	$ 800,000	$ 800,000
Common stock repurchase note	2,812,500	2,812,500
Working capital notes	-	1,000,000
	3,612,500	4,612,500
Less: current portion	(3,612,500)	(4,612,500)
	$ -	$ -

The Company previously repurchased shares of its restricted stock in exchange for notes that bear interest at rates ranging from 0% to 4% per annum and are due on demand.

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

The Company also borrowed from stockholders for working capital purposes and had outstanding two unsecured stockholder notes having an original aggregate principal amount of $1,000,000 and which bear interest from 0% to 30% per annum. The notes are due on demand but are currently subject to a forbearance through March 7, 2020 pursuant to a forbearance and exchange agreement dated March 7, 2019 with a different lender. The holder of these notes agreed to refrain and forbear from bringing any action to collect under the stockholder notes until March 7, 2020 and to reduce the interest rates currently in effect to 12.0% per annum simple interest during such forbearance period. The Company also agreed to repay or exchange the unsecured stockholder notes (or portions thereof) during the forbearance period for shares of the Company's common stock at an exchange rate of $13.44 per share or, beginning September 2019, at 95% of the average of the two lowest closing bid prices in the prior twenty trading days, as applicable. The forbearance and exchange agreement was accounted for as an extinguishment of debt and the Company recorded a loss of $183,554 during the year ended September 30, 2019.

During the year ended September 30, 2019, unsecured notes with a carrying amount of $ $22,034 and accrued interest of $457,966 were exchanged for 372,888 shares of the Company's common stock at weighted average exchange price of $1.29. As of September 30, 2019, the unsecured stockholder notes are included in the current portion of long-term debt on consolidated balance sheets.

During the years ended September 30, 2019 and 2018, the Company recognized interest expense related to the stockholder notes of $105,357 and $300,000, respectively.

8. Debt

Senior secured notes

	September 30,	
	2019	2018
Convertible senior secured notes	$ 6,699,000	$ 13,500,000
Unamortized debt discount	-	(320,551)
	$ 6,699,000	$ 13,179,449

In October 2017, the Company exchanged $1.5 million aggregate principal amount of senior secured notes and $41,507 of accrued interest for 1,500,000 shares of Series B convertible preferred stock ("Series B Convertible"). 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.

In November 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 until December 22, 2019, in exchange for making several payments of principal and interest during 2019, as well as subject to meeting additional capital raising commitments that the Company met in April 2019 through the completed public offering. In addition, the Company agreed to make the senior secured notes convertible into common stock at a price of $8.9539 per share and reduced the exercise price of warrants to purchase 485,245 shares of common stock held by the senior secured noteholders from $24.00 per share to $12.00 per share. The increase in the fair value of the warrants of $1.5 million due to the modification was recorded as additional debt discount and amortized over the remaining term of the senior secured notes using the effective interest rate method. The total amortization of the debt discount for the year ended September 30, 2019 was $1,314,321.

During the year ended September 30, 2019, convertible senior secured notes with a carrying amount of $400,575 and accrued interest of $1,393 were converted into 50,394 shares of the Company's common stock. During the year ended September 30, 2019, the Company repaid a total of $6.4 million of principal and $1.3 million of accrued interest of such notes.

In June 2019, the Company entered into a Third Note Amendment (the "Third Amendment") with the holders of the remaining $6.7 million outstanding aggregate principal amount of senior secured notes. Under the Third Amendment, the maturity date of the convertible senior secured notes was amended to December 22, 2019 and eliminated the scheduled payments of certain principal and interest payments on or prior to December 22, 2019. The Company also agreed to increase the interest rate payable on such convertible senior secured notes to 12.0% per annum from 5.0% per annum. The Third Amendment was accounted for as an extinguishment of debt. Loss on extinguishment of convertible senior secured notes recognized during the year ended September 30, 2019 was $423,686.

Interest expense on the convertible senior secured notes for the years ended September 30, 2019 and 2018 was $1,892,155 and $1,997,231, 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 (working capital notes).

	September 30,	
	2019	**2018**
Unsecured notes	$ 977,966	$ -
Equipment loans	98,487	164,967
	1,076,453	164,967
Less: current portion	(1,026,168)	(66,480)
Long-term debt	$ 50,285	$ 98,487

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 unsecured notes and equipment loans for the years ended September 30, 2019 and 2018 was $83,963 and $27,660, respectively.

Future maturities of other indebtedness at September 30, 2019 are as follows for the years ending September 30:

2020	$ 1,026,168
2021	50,285
	$ 1,076,453

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.

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, 2019 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 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 which was due to expire in March 2026. 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, 2019 and 2018, the lease termination obligation is included in other liabilities on the consolidated balance sheet. A rollforward of the charges incurred to general and administrative expense for the years ended September 30, 2019 and 2018 is as follows:

	Balance October 1, 2018	Expensed / Accrued Expense	Cash Payments	Balance September 30, 2019
Lease termination payments	$ 3,850,081	$ 485,117	$ (425,750)	$ 3,909,448

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

Rent expense under operating leases was $1,139,714 and $854,487 for the years ended September 30, 2019 and 2018, 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, 2019 are as follows for the years ending September 30:

	Operating Leases
2020	$ 187,500
2021	195,000
	$ 382,500

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, 2019 and 2018, the expense relating to the matching contribution was $125,828 and $175,693, respectively.

10. Stockholders' Equity (Deficit)

Common stock

During the year ended September 30, 2019, the Company issued an aggregate of 2,680,390 shares of the Company's common stock for gross cash proceeds of $20.0 million ($19.8 million net of issuance costs) pursuant to the November 5, 2018 BioLexis private placement agreement.

In April 2019, the Company issued an aggregate of 10,340,000 shares of its common stock, 15-month warrants to purchase up to an aggregate of 10,340,000 shares of common stock and five-year warrants to purchase up to an aggregate of 10,340,000 shares of common stock for $26.2 million in net proceeds after payment of fees, expenses and underwriting discounts and commissions. The shares of common stock and the warrants were immediately separable and were issued separately. The warrants are exercisable immediately at an exercise price of $2.90 per share.

During the year ended September 30, 2019 and 2018, the Company issued 4,069 and 105,361 shares of common stock, respectively, upon the vesting of RSUs.

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, 2019.

Common stock warrants

As of September 30, 2019, the Company had the following warrants outstanding to acquire shares of its common stock:

Expiration Date	Shares of common stock issuable upon exercise of warrants	Exercise Price Per Share
November 11, 2019	99,935	$ 0.08
July 12, 2020	68,250	$ 2.90
February 18, 2022	416,666	$ 12.00(i)
April 24, 2024	10,340,000	$ 2.90
December 22, 2024	277,122	$ 12.00(ii)
April 13, 2025	145,686	$ 12.00(ii)
May 31, 2025	62,437	$ 12.00(ii)
October 31, 2025	2,093,750	$ 7.20
May 10, 2026	1,282,051	$ 7.80
June 8, 2026	1,282,051	$ 7.80
	16,067,948	

(i) In January 2019, the Company reduced the exercise price of these warrants from $52.80 to $12.00 and further extended the exercise period from February 18, 2019 to February 18, 2022.

(ii) In November 2018, the Company reduced the exercise price of the warrants issued in connection with its senior secured notes from $24.00 to $12.00 and extended the expiration of the Senior Note Warrants by three years.

During the year ended September 30, 2019, warrants to purchase an aggregate of 10,273,558 shares of common stock with a weighted averaged exercise price of $2.90 were exercised resulting in the issuance of an aggregate 6,134,763 shares of the Company's common stock. Of these exercised warrants, 10,270,250 of them were 15-month warrants issued in the Company's April 2019 public offering that were exercised pursuant to the net exercise provisions therein.

During the year ended September 30, 2018, warrants to purchase 432 shares with exercise prices of $0.08 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") to acquire 2,093,750 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 4,724,493 shares of the Company's common stock, representing an effective conversion rate of $5.28 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 $7.20 and $10.08 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 $7.20 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 3,946,577 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 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 years ended September 30, 2019 and 2018, the Company issued an additional 6,248 and 1,468 shares, respectively, of Series A-1 to settle the related dividends that were due on a quarterly basis. The Company recognized a beneficial conversion charge of $61,365 and $70,662, respectively, during the years ended September 30, 2019 and 2018, which represents the in-the-money value of the conversion rate as of the date of issuance.

At September 30, 2019, 66,451 shares of Series A-1 were convertible into 1,255,789 shares of common stock.

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.

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, RSUs, performance-based awards ("PSUs"), 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 106,490. As of September 30, 2019, PSUs representing 16,131 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, (the "2015 Plan") no future awards under the 2011 Plan will be granted.

2015 Equity Incentive Plan

In December 2015, the Company adopted the 2015 Plan. The 2015 Plan provides for the grant of stock options, stock appreciation rights, restricted stock awards, RSU awards, performance stock awards and other forms of equity compensation to Company employees, directors and consultants. The aggregate number of shares of common stock authorized for issuance pursuant to the Company's 2015 Plan is 2,869,598. As of September 30, 2019, 1,309,950 shares remained available for grant under the 2015 Plan.

Stock options and RSUs granted under the Company's 2015 Plan generally vest over a period of two to four years from the date of grant and, in the case of stock options, have a term of 10 years. The Company recognizes the grant date fair value of each option and share of RSU over its vesting period.

	Year ended September 30,	
	2019	**2018**
Research and development	$ 37,053	$ 19,450
General and administrative	1,276,282	1,966,420
	$ 1,313,335	$ 1,985,870

Stock options

The following table summarizes all of the Company's stock option activity for the years ended September 30, 2018 and 2019:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Balance at October 1, 2017	-	$ -	
Granted	208,357	7.19	
Forfeited	(26,237)	8.80	
Balance at September 30, 2018	182,120	7.22	
Granted	1,449,498	3.80	
Expired	(19,077)	7.86	
Forfeited	(222,542)	8.34	
Balance at September 30, 2019	1,389,999	3.46	9.7
Vested and exercisable	172,405	7.19	8.6
Vested and expected to vest at September 30, 2019	1,389,999	$ 3.46	9.7

As of September 30, 2019, the aggregate intrinsic value of the stock options was zero. 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 years ended September 30, 2019 and 2018 was $2.86 and $4.48 per option, respectively. The fair value of the options was estimated on the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions:

	Year ended September 30,	
	2019	2018
Risk-free interest rate	2.02%	2.80%
Expected life (years)	6.14	6.00
Expected volatility	92.7%	71.0%
Expected dividend yield	-	-

As of September 30, 2019, there was $2,493,119 of unrecognized compensation expense that is expected to be recognized over a weighted-average period of 3.6 years.

Performance-Based stock units

The Company has issued PSUs, which generally have a ten-year life from the date of grant. 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, 2019 and 2018:

	Number of PSUs	Base Price Per PSU	Weighted Average Remaining Contractual Term (Years)
Balance at October 1, 2017	21,933	$ 50.16	
Forfeitures	(5,802)	51.44	
Balance at September 30, 2018	16,131	49.99	
Forfeitures	(440)	50.60	
Balance at September 30, 2019	15,691	49.97	4.7
Vested and exercisable at September 30, 2019	15,691	49.97	4.7
Vested and expected to vest at September 30, 2019	15,691	$ 49.97	4.7

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, 2019 and 2018:

	Number of RSUs	Weighted Average Grant Date Fair Value
Balance at October 1, 2017	117,485	$ 150.24
Granted	2,500	9.28
Vested and settled	(105,361)	147.20
Forfeitures	(6,986)	3.14
Balance at September 30, 2018	7,638	153.88
Vested and settled	(4,069)	227.57
Forfeitures	(3,460)	69.06
Balance at September 30, 2019	109	$ 96.00

As of September 30, 2019, there was $1,021 of unamortized expense that will be recognized over a weighted-average period of 0.2 years.

13. Collaboration Arrangements

During fourth quarter of fiscal year 2019, the Company substantially completed its efforts to outsource the commercial manufacturing and remaining development for the ONS-5010 program, resulting in the termination of the majority of manufacturing and development personnel and initiation of efforts to sell or transfer excess manufacturing, laboratory and related computer equipment no longer required for the development of ONS-5010 program. As a result, the Company no longer has the internal capability to support its inactive development programs for ONS-3010 (biosimilar for Humira) and ONS-1045 (biosimilar for Avastin) and does not intend to complete the development of these assets in the United States and other developed markets. All future development for the biosimilar programs, if any, will be completed by the Company's existing, or potential future, partners without further assistance from the Company. As a result, the Company recognized all remaining deferred revenues as of September 30, 2019 for each of its collaboration agreements.

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 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 a standalone value, the upfront milestones payments received had been deferred and were being recognized ratably on a straight line basis through December 2021, the expected date in which the research and development would be completed prior to the Company's decision in the fourth quarter of fiscal 2019 to stop developing its biosimilar assets as described fully above.

During years ended September 30, 2019 and 2018, the Company recognized $4,828,584 and $714,848, respectively, of deferred revenues. As of September 30, 2018, deferred revenue included in the Company's consolidated balance sheet related to the Huahai arrangement was $2,323,254.

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 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 milestones payments received had been deferred and were being recognized ratably on a straight line basis through December 2021 the expected date in which the research and development would be completed prior to the Company's decision in the fourth quarter of fiscal 2019 to stop developing its biosimilar assets as described fully above.

As of September 30, 2019, 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, 2019 and 2018, the Company recognized deferred revenues of $1,664,085 and $261,072, respectively. As of September 30, 2018, deferred revenue included in the Company's consolidated balance sheets was $848,486.

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 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 had been deferred and were being recognized ratably on a straight-line basis through December 2021, the expected date in which the research and development would be completed prior to the Company's decision in the fourth quarter of the year ended September 30, 2019 to stop developing its biosimilar assets as described fully above.

As of September 30, 2019, the Company has received an aggregate of $3.0 million of upfront and milestone payments from Liomont. During the years ended September 30, 2019 and 2018, the Company recognized deferred revenue of $1,097,412 and $236,641, respectively. As of September 30, 2018, deferred revenue included in the Company's consolidated balance sheets was $769,083.

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's favor, subject to adjustment as provided in the agreement.

During the years ended September 30, 2019 and 2018, the Company recognized revenue of $556,042 and $1,874,999, respectively, under the BioLexis agreements. As of September 30, 2018, deferred revenue included in the Company's consolidated balance sheet was $526,042.

14. Related-Party Transactions

MTTR — Strategic Partnership Agreement (ONS-5010)

In November 2018, the board of directors of the Company appointed Mr. Terry Dagnon as Chief Operating Officer, and Mr. Jeff Evanson as Chief Commercial Officer. Both Mr. Dagnon and Mr. Evanson are providing services to the Company pursuant to the February 2018 strategic partnership agreement with MTTR, LLC ("MTTR"). Mr. Dagnon and Mr. Evanson are both principals in MTTR. The Company will not be paying Mr. Dagnon or Mr. Evanson any direct compensation as consultants or as employees. Both Mr. Dagnon and Mr. Evanson are compensated directly by MTTR for services provided to the Company as the Company's Chief Operating Officer and Chief Commercial Officer, respectively, pursuant to the ONS-5010 Agreement. Mr. Dagnon and Mr. Evanson have also agreed to provide consulting services to an affiliate of BioLexis pursuant to a separate arrangement.

In February 2018, the Company entered into a strategic partnership agreement with 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. MTTR earned an aggregate $1,744,933 and $602,629 during the years ended September 30, 2019 and 2018, respectively, which includes monthly consulting fees and expense reimbursement. As of September 30, 2019 and 2018, amounts due to MTTR were $365,301 and $116,552, respectively, which amounts are included in accrued expenses in the accompanying consolidated balance sheets.

Sonnet Biotherapeutics, Inc. – Contract Development and Manufacturing

In May 2018, the Company negotiated a contract with Sonnet Biotherapeutics, Inc. ("Sonnet") to provide contract development and manufacturing ("CDMO") services. 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 former Class III director. In July 2019, the Company and Sonnet mutually agreed to terminate the contract.

For other related party transactions during the years ended September 30, 2019 and 2018, refer to the Stockholder Notes (Note 7), Debt (Note 8) and the BioLexis Agreement (Note 13).

15. Income Taxes

Income tax benefit for the years ended September 30, 2019 and 2018 consists of the following:

	Year ended September 30,	
	2019	**2018**
State tax	$ (3,413,806)	$ (3,148,216)
Foreign tax provision	2,805	(500,000)
	$ (3,411,001)	$ (3,648,216)

During the years ended September 30, 2019 and 2018, the Company sold New Jersey State net operating losses in the amount of $31,168,800 and $38,470,278, and in the year ended September 30, 2019, unused R&D tax credits in the amount of $944,045, resulting in the recognition of income tax benefits of $3,415,806 and $3,150,716, respectively, recorded in the Company's statement of operations.

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,	
	2019	**2018**
U.S. federal statutory rate	(21.0)%	(24.3)%
State taxes, net of federal benefit	(6.6)	(6.9)
Sale of New Jersey net operating losses	(7.1)	(7.1)
Net operating loss	6.1	8.0
Change in tax rates	-	66.6
Foreign withholding tax	-	(1.5)
Permanent differences	(0.2)	(0.6)
Foreign tax credits	-	1.5
Research and development credit	0.8	(22.9)
Change in valuation allowance	18.6	(23.7)
Other	0.4	0.1
Effective income tax rate	(9.0)%	(10.8)%

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

	September 30,	
	2019	**2018**
Deferred tax assets		
Net operating loss carryforwards	$ 47,664,187	$ 39,532,689
Stock-based compensation	10,583,524	10,227,514
Deferred revenue	-	1,264,069
Research and development credit carryforward	8,180,511	8,491,452
Foreign tax credits	2,357,309	2,357,309
Accruals and others	410,390	605,173
Gross deferred tax assets	69,195,921	62,478,206
Less: valuation allowance	(68,967,686)	(61,893,959)
	228,235	584,247
Deferred tax liability:		
Fixed assets	(228,235)	(584,247)
Net deferred tax assets	$ -	$ -

As of September 30, 2019, the Company has approximately $202.7 million and $71.8 million of U.S. federal and New Jersey net operating losses that will begin to expire in 2030 and 2037, respectively. As of September 30, 2019, the Company has federal and state research and development tax credit carryforwards of $7.0 million and $1.2 million available, respectively, to reduce future tax liabilities which will begin to expire in 2032 and 2024, respectively. As of September 30, 2019, the Company has federal foreign tax credit (FTC) carryforwards of $2.4 million available to reduce future tax liabilities which will begin to expire starting in 2023, of which $1.9 million of the FTC carryforward is included in the balance of unrecognized tax benefits. Realization of the deferred tax asset is contingent on future taxable income and based upon the level of historical losses, management has concluded that the deferred tax asset does not meet the more-likely-than-not threshold for realizability. Accordingly, a full valuation allowance continues to be recorded against the Company's deferred tax assets as of September 30, 2019 and 2018. The valuation allowance increased $7.1 million during the year ended September 30, 2019 and decreased $8.0 million during the year ended September 30, 2018.

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.

In December 2017, the Tax Cuts and Jobs Act of 2017 (the "Act") was signed into law making significant changes to the Internal Revenue Code. The corporate tax rate decreased from 34% to 21% effective for tax years beginning after December 31, 2017; for the fiscal year ended September 30, 2018, the federal tax rate is 24.3%; and for the fiscal year ended September 30, 2019, the federal tax rate is 21.0%. The 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.

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

	Year ended September 30,	
	2019	**2018**
Balance at beginning of year	$ 1,856,129	$ 2,352,129
Changes based on tax positions related to the current year	3,305	(496,000)
Balance at end of year	$ 1,859,434	$ 1,856,129

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 2018 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 carry forward is subject to any Internal Revenue Code Section 382 limitation. To the extent there is a limitation, there would be a reduction in the deferred tax assets with an offsetting reduction in the valuation allowance.

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, 2019.

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, 2019.

As an emerging growth company, as defined under the Terms of the JOBS Act of 2012, our 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, 2019 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, 2019. There are no family relationships among any of our directors or executive officers.

Name	Age	Position(s)
Executive Officers		
Lawrence A. Kenyon	54	President, Chief Executive Officer, Chief Financial Officer, Treasurer, Corporate Secretary and Director
Terry Dagnon	58	Chief Operating Officer
Jeff Evanson	51	Chief Commercial Officer
Non-Employee Directors		
Ralph H. “Randy” Thurman	70	Executive Chairman
Yezan Haddadin	44	Director
Kurt J. Hilzinger	59	Director
Faisal G. Sukhtian	35	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**.** Our 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 of directors.

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. Mr. Dagnon has an ownership interest in our strategic alliance partner, MTTR.

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 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. Mr. Evanson has an ownership interest in our strategic alliance partner, MTTR.

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, as the Executive Chairman of the board of directors of Zest Dental, Inc., and as a member of the board of directors of TFF Pharmaceuticals, 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. Our 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 of directors.

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 holds a J.D. from Northwestern University Law School and a B.S. in Foreign Service from Georgetown University. Mr. Haddadin was initially appointed to fill a vacancy on our board and was designated for such vacancy by BioLexis Pte. Ltd., or BioLexis, pursuant to the Investor Rights Agreement by and between our company and BioLexis dated September 11, 2017, as amended from time to time, or the BioLexis IRA. Our board believes Mr. Haddadin's managerial and capital raising experience qualifies him to serve on our board of directors.

Kurt J. Hilzinger. Mr. Hilzinger has served as a member of our board of directors since December 2015. Since 2007, Mr. Hilzinger has served as a partner at Court Square Capital Partners L.P., an independent private equity firm, where he is responsible for investing in the healthcare sector. Since July 2003, Mr. Hilzinger also has served in various capacities as a member of the board of directors at Humana, Inc., a managed care company, including serving as Lead Director from August 2010 to January 2014, and as Chairman since January 2014. In addition, Mr. Hilzinger also has served 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. Our board believes Mr. Hilzinger's experience and financial expertise in the healthcare sector qualifies him to serve on our board of directors.

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 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. Mr. Sukhtian was initially appointed to fill a vacancy on our board and was designated for such vacancy by BioLexis pursuant to the BioLexis IRA,Our board believes Mr. Sukhtian'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 or executive officers.

Delinquent Section 16(a) Reports

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.

To our knowledge, based solely on a review of Form 3, Form 4 and Form 5 (including amendments) filed electronically with the SEC and written representations made to us that no other reports were required, during the fiscal year ended September 30, 2019, 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, Mr. Kenyon, our President, Chief Executive Officer and Chief Financial Officer, failed to timely file one Form 4 during our fiscal year ended September 30, 2019 to report the number of shares required to be sold to cover the tax withholding obligation in connection with the settlement of vested restricted stock units, or RSUs. This sale was mandated by an election under our equity incentive plans to require Mr. Kenyon to fund his tax withholding obligation by completing a "sell to cover" transaction with a brokerage firm designated by us and was reported on Form 4 filed on September 23, 2019.

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 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, http://ir.oncobiologics.com/phoenix.zhtml?c=254316&p=irol-govhighlights. 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 Yezan Haddadin. Our Nominating and Corporate Governance Committee reviews 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, 2019, our named executive officers are:

- Lawrence A. Kenyon, our President, Chief Executive Officer, Chief Financial Officer, Treasurer, Corporate Secretary and Director;
- Kenneth M. Bahrt, our former Chief Medical Officer;
- Stephen J. McAndrew, Ph.D., our former Senior Vice President, Business Strategy & Development
- Terry Dagnon, our Chief Operating Officer; and
- Jeff Evanson, our Chief Commercial Officer.

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)	Option Awards ($)(2)	All Other Compensation ($)(3)	Total ($)
Lawrence A. Kenyon [4]	2019	425,000	-	1,419,880	19,021	1,863,901
Director, Chief Executive Officer, President, Chief Financial Officer, Treasurer and Corporate Secretary	2018	371,635	-	326,192	18,305	716,132
Kenneth M. Bahrt, M.D. [5]	2019	240,000	-	911,427	473,823	1,625,250
Former Chief Medical Officer	2018	400,000	-	-	29,082	429,082
Terry Dagnon [6]	2019	-	-	-	-	-
Chief Operating Officer	2018	-	-	-	-	-
Jeff Evanson [6]	2019	-	-	-	-	-
Chief Commercial Officer	2018	-	-	-	-	-
Stephen J. McAndrew, Ph.D. [7]	2019	34,615	-	135,838	244,095	414,548
Former SVP, Business Strategy & Development	2018	300,000	-	14,060	12,011	326,071

(1) Discretionary bonus amounts for fiscal year ended September 30, 2019 have not yet been determined.

(2) 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 "Consolidated Financial Statements and Supplementary Data - Notes to the Consolidated Financial Statements - Note 12 - Stock-Based Compensation."

(3) Amounts in this column reflect the payment of term life and disability insurance premiums, along with 401(k) matching contributions. All of these benefits are provided to the named executive officers on the same terms as provided to all of our regular full-time employees. In addition, the amounts include severance payments under separation and release agreements with our separated named executive officers.

(4) 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.

(5) Dr. Bahrt was terminated as Chief Medical Officer in April 2019 when we eliminated his position. All other compensation for fiscal 2019 includes benefits to which Dr. Bahrt became entitled under his separation and release agreement effective April 23, 2019 which comprised of (i) $400,000 of his base salary and (ii) $26,885 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 May 1, 2019.

(6) Messrs. Dagnon and Evanson were appointed as executive officers in November 2018 but are compensated under our arrangement with MTTR. We do not pay any compensation directly to Messrs. Dagnon and Evanson. MTTR earned an aggregate $1,744,933 in the year ended September 30, 2019. Messrs. Dagnon and Evanson have ownership interests in MTTR. See Item 13 "Certain Relationships and Related Person Transactions, and Director Independence" for additional information regarding our arrangement with MTTR.

(7) Dr. McAndrew was terminated as Senior Vice President, Business Strategy & Development in November 2018 when we eliminated his position. All other compensation for fiscal 2019 includes benefits to which Dr. McAndrew became entitled under his separation and release agreement effective November 9, 2018, which includes $225,000 of his base salary and $19,095 of vacation pay, term life and disability insurance premiums.

Agreements with our Named Executive Officers

Below are written descriptions of our employment arrangements with our named executive officers. We do not have separate employment arrangements with Messrs. Dagnon and Evanson as they are providing services to our company under our agreement with MTTR. See Item 13 "Certain Relationships and Related Person Transactions, and Director Independence" for more information regarding our MTTR agreement.

Mr. Kenyon. In February 2016, we entered into a new employment agreement with Mr. Kenyon that took effect in connection with our initial public offering, or 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 was entitled to an initial annual base salary of $400,000 and 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. Bahrt was employed by and performing services for us on a full-time basis through April 2019, when we eliminated his position. His employment agreement did not have a specified term and his employment could have been terminated by us or by Dr. Bahrt at any time, with or without cause. Dr. Bahrt 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. Bahrt's position as Chief Medical Officer in April 2019, we entered into a separation and release agreement in April 2019. The terms of his separation and release agreement 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 (other than Messrs. Dagnon and Evanson), the named executive officer is generally entitled to receive amounts earned during his or her term of service, including salary and unused vacation pay. We do not provide for any additional severance or change of control benefits to Messrs. Dagnon and Evanson, who receive compensation directly from MTTR for the services provided to our company. The MTTR Agreement provides MTTR certain rights in the event of a Change of Control as defined in such agreement. See Item 1 "Business—Collaboration and Licensing Agreements—MTTR-Strategic Partnership Agreement (ONS-5010)")" for more information regarding such rights.

Mr. Kenyon. Pursuant to Mr. Kenyon's current executive employment agreement, as amended, 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. We eliminated Dr. Bahrt's position in April 2019 in connection with our change in focus to ophthalmic indications. In connection therewith, he entered into a separation and release agreement, effective on April 23, 2019, providing for, as severance, his current base salary for the equivalent of 12 months, or a total of $400,000. Dr. Bahrt will receive 12 months of COBRA reimbursement, and full vesting of 50% of his then unvested equity awards, and reimbursement of expenses owed to him through the date of his termination. He also agreed to non-solicit and non-compete covenants, as well as executed a general release of claims in connection therewith.

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, 2019.

		Option 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**
Lawrence A. Kenyon	8/1/2018	15,625	46,875(2)	-	6.88	8/1/2028
	2/19/2019	-	100,000(3)	-	10.56	2/19/2029
	9/12/2019	-	450,000(4)	-	1.75	9/12/2029

(1) The outstanding equity awards as of September 30, 2019 are 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 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.

(2) The shares underlying the option vests in four equal installments of which 25% vested on August 1, 2019. 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 shares underlying the option shall vest in four equal installments beginning on February 19, 2020 such that the option shall be vested in full on February 19, 2023, 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.

(4) The shares underlying the option shall vest in four equal installments beginning on September 12, 2020 such that the option shall be vested in full on September 12, 2023, 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.

Director Compensation

The following table sets forth information concerning the compensation earned for service on our board of directors during the year ended September 30, 2019. Mr. Kenyon's compensation as an executive officer is set forth under "Executive Compensation — Summary Compensation Table." Mr. Kenyon did not receive any additional compensation for service as a director. None of our directors earned any compensation other than cash fees or stock option awards under the 2015 Plan during the fiscal year ended September 30, 2019, 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 ($)	Total ($)
Randy Thurman [3]	-	348,000	-	348,000
Kurt Hilzinger	-	125,000	-	125,000
Yezan Haddadin [4]	-	-	-	-
Faisal G. Sukhtian [4]	-	-	-	-
Joe Thomas [4] [5]	-	-	-	-
Pankaj Mohan, Ph.D. [6]	-	70,000	-	70,000
Joerg Windisch, Ph.D. [7]	-	80,000	-	80,000

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

(2) See discussion of Option Awards in Lieu of Cash Fees below. 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 "Consolidated Financial Statements and Supplementary Data - Notes to the Consolidated Financial Statements - Note 12 - Stock-Based Compensation."

(3) Mr. Thurman was appointed Executive Chairman of our board of directors in June 2018.

(4) Messrs. Haddadin, Sukhtian and Thomas waived their right to cash and equity compensation for their services as directors of our company and did not receive any fees during the fiscal year ended September 30, 2019.

(5) Mr. Thomas joined our board of directors in September 2017 and resigned from our board of directors and the Audit Committee in December 2019.

(6) Dr. Mohan's term as a Class III director ended upon our 2019 annual meeting of stockholders.

(7) Dr. Windisch joined our board of directors and the Compensation Committee in March 2018 and resigned from our board of directors and the Compensation Committee in July 2019.

Option Awards in lieu of Cash Fees

In November 2018, to reduce cash expenses, the Compensation Committee of our board of directors suspended cash payments under our non-employee director compensation policy described below 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 equity grants listed below. Messrs. Haddadin, Sukhtian and Thomas had previously waived their right to cash and equity compensation for their services as directors of our company the fiscal year ended September 30, 2019 and thus did not receive a one-time equity grant.

	Option awards						
Name	**Grant date**	**Number of securities underlying unexercised options (#) exercisable**	**Grant date fair value ($) [1]**	**Number of securities underlying unexercised options (#) unexercisable**	**Equity incentive plan awards: Number of securities underlying unexercised unearned options (#)**	**Option exercise price ($)**	**Option expiration date**
Randy Thurman	11/09/2018	70,940	348,000	-	-	7.12	11/09/2028
Kurt Hilzinger	11/09/2018	25,481	125,000	-	-	7.12	11/09/2028
Joerg Windisch, Ph.D.[2]	11/09/2018	16,308	80,000	-	-	7.12	11/09/2028
Pankaj Mohan, Ph.D. [3]	11/09/2018	14,269	70,000	-	-	7.12	11/09/2028

(1) 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 "Consolidated Financial Statements and Supplementary Data - Notes to the Consolidated Financial Statements - Note 12- Stock-Based Compensation."

(2) Dr. Windisch resigned from our board of directors effective July 18, 2019.

(3) Dr. Mohan's term as a Class III director ended upon our 2019 annual meeting of stockholders.

Non-Employee Director Compensation Policy

We 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 and was in effect for the fiscal year ended September 30, 2019.

Equity Compensation

Initial Grant

Under the non-employee director compensation policy, which was in effect for the fiscal year ended September 30, 2019, each new non-employee director who joined our board of directors was granted a non-statutory stock option to purchase 3,125 shares of common stock under the 2015 Plan, which options vested annually over three years from the grant date, subject to continued service as a director through the applicable vesting date. Messrs. 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 12,500 shares of common stock under the 2015 Plan, which vests annually in three equal installments.

Annual Grant

Under the non-employee director compensation policy, which was in effect for the fiscal year ended September 30, 2019, on the date of each annual meeting of our stockholders, each current non-employee director was granted an annual non-statutory stock option to purchase 1,875 shares of common stock under the 2015 Plan, which options vested on the first anniversary of the grant date, subject to continued service as a director though the applicable vesting date. All non-employee directors waived the automatic grants that they would have received on the date of our 2019 annual meeting of stockholders.

Cash Compensation

Under the non-employee director compensation policy in effect for the fiscal year ended September 30, 2019, each non-employee director received an annual cash retainer of $35,000 for serving on our board of directors. The chairperson of our board of directors received 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 were generally entitled to the following annual cash retainers under our non-employee director compensation policy that was in effect for the fiscal year ended September 30, 2019:

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 were 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. As discussed above under "—Option Awards in lieu of Cash Fees," these cash fees were suspended and all non-employee directors who had not previously waived fees received a one-time equity grant in lieu of cash fees.

Amended and Restated Non-Employee Director Compensation Policy

In September 2019, our board of directors approved a new non-employee director compensation policy that took effect on October 1, 2019, the first day of our fiscal year. The terms of our new non-employee director compensation program are as follows:

Equity Compensation

Under the amended and restated non-employee director compensation policy, each new non-employee director who joins our board of directors will be 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, provided however, that all unvested shares subject to such stock options will accelerate and vest in full upon a change in control, subject to continued service as a director immediately prior to the change in control.

Under the amended and restated 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, provided however, that all unvested shares subject to such stock options will accelerate and vest in full upon a change in control, subject to continued service as a director immediately prior to the change in control.

Cash Compensation

Under the amended and restated non-employee director compensation policy, each non-employee director will be eligible to receive an annual cash retainer of $40,000 for serving on our board of directors. The chairperson of our board of directors is eligible to 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 eligible to receive 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 amended and restated 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
Executive Committee	-	30,000

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. Each non-employee director may elect to receive all annual cash compensation the form of stock options granted pursuant to the 2015 Plan. This election must be made prior to the beginning for the applicable fiscal year, and each non-employee director must submit a new election for each fiscal year. If a non-employee director elects to receive compensation in the form of stock options, such stock options will automatically be granted on the third business day in October of such fiscal year. Any award will vest as follow: (i) 25% will vest on the last day of the first fiscal quarter during such fiscal year, and (ii) 25% will vest on the last day of each subsequent fiscal quarter during such fiscal year, provided the non-employee director is in service as a director on the first day of the fiscal quarter of the applicable scheduled vesting date.

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

The following table sets forth certain information relating to the beneficial ownership of our common stock as of November 30, 2019, 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 29,401,936 shares of common stock and 66,451 shares of voting Series A-1 convertible preferred stock outstanding as of November 30, 2019. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown beneficially owned by them, subject to applicable community property laws. Shares of common stock issuable upon vesting, exercise or conversion of outstanding equity awards or preferred stock that are exercisable, subject to vesting or convertible within 60 days after November 30, 2019 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 Preferred		
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)]	23,589,499	60.6%	66,451	100.0%	49.9%
Named Executive Officers and Directors:					
Lawrence A. Kenyon, *Director, Chief Executive Officer, Chief Financial Officer, Treasurer and Corporate Secretary*	24,551	*	-	-	†
Ralph H. "Randy" Thurman, *Executive Chairman* [(2)]	131,656	*	-	-	†
Yezan Haddadin, *Director* [(3)]	20,044	*	-	-	-
Kurt J. Hilzinger, *Director* [(4)]	67,561	*	-	-	†
Faisal G. Sukhtian, *Director* [(5)]	21,693	*	-	-	-
Kenneth Bahrt, M.D. *former Chief Medical Officer* [(6)]	5,110	*	-	-	†
Stephen McAndrew, Ph.D. *former SVP Business Strategy & Development*	-	*	-	-	†
Jeff Evanson, *Chief Commercial Officer*	-	*	-	-	-
Terry Dagnon, *Chief Operating Officer*	-	*	-	-	-
All executive officers and directors as a group (7 persons)	265,505	*	-	-	†

*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) 1,255,789 shares of common stock issuable upon conversion of 66,451 shares of our voting Series A-1 convertible preferred stock. basis) and (b) warrants to acquire 8,294,216 shares of our common stock, all of which 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) Represents 1,875 shares and 129,781 vested options held by Mr. Thurman.
(3) Represents vested options held directly by Mr. Haddadin.
(4) Includes 23,107 shares and 44,454 vested options held directly by Mr. Hilzinger.
(5) Represents vested options held directly by Mr. Sukhtian.
(6) Includes warrants to acquire 125 shares held directly by Dr. Bahrt.

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, 2019.

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	15,691	$ 49.97(1)	-(2)
2015 Equity Incentive Plan	1,390,108	(3)	1,309,950(4)
2016 Employee Stock Purchase Plan	-	-	68,145(5)
Equity compensation plans not approved by security holders:			
None	-	-	-
Total	1,405,799		1,378,095

(1) Represents the base price per outstanding performance stock unit, or PSU, awards at September 30, 2019.
(2) Upon approval of the 2015 Equity Incentive Plan, no additional options or awards were granted under the 2011 Stock Incentive Plan; all outstanding stock awards 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, 2019 is comprised of 1,389,999 option awards with a weighted-average exercise price of $3.46, and 109 RSUs with a weighted-average grant date fair value of $96.00.
(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) 220,000 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

The following is a summary of transactions since October 1, 2016 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, 2018 or 2019, 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 Item 11 in the sections titled "Executive Compensation" and "Director Compensation." We also describe below certain other transactions with our directors, former directors, executive officers and stockholders.

Financings

Loans and Guarantees

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, or the Note 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 0.3 million shares of our common stock. The warrants initially had a five-year term and an exercise price of $24.00 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 240,062 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 47,437 shares of our common stock in January 2017. Under the Note Agreement, we agreed to customary negative covenants restricting our ability to repay indebtedness to officers, pay dividends to stockholders, repay or incur other indebtedness other than as permitted, grant or suffer to exist a security interest in any of our assets, other than as permitted, or enter into any transactions with affiliates. In addition to the negative covenants in the Note 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 Agreement, or the First Amendment, with the required holders of our outstanding senior secured promissory notes named therein. The primary purpose of the First 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 $24.00 per share) to acquire an aggregate 208,125 shares of its common stock in connection therewith. In connection with the First Amendment, we issued an additional $3.5 million in note principal and warrants to acquire an aggregate 145,625 shares of common stock. On May 31, 2017, we issued the remaining $1.5 million in note principal and warrants to acquire 62,437 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, we entered into a Second Note and Warrant Amendment and Waiver, or the Second Amendment, 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 $8.9539 per share (120% of the price per share paid by BioLexis in the private placement). Under this Second 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 made the 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 December 7, 2018; (ii) approximately $1.0 million of interest on December 22, 2018; and (iii) approximately $1.5 million of principal and interest on February 15, 2019. Additionally, although we raised $20.0 million of additional equity capital on or prior to June 30, 2019, in June 2019, following the redemption of approximately $1.8 million of outstanding aggregate principal amount of senior notes, we entered into a Third Note and Warrant Amendment and Waiver, with the secured noteholders of the remaining $6.7 million outstanding aggregate principal amount, pursuant to which we amended the maturity date of the senior secured notes to December 22, 2019, and the scheduled payments of principal and interest on or prior to each of June 30, 2019 ($3.0 million), July 31, 2019 ($1.0 million) and August 31, 2019 ($1.0 million) were removed. We also increased the interest rate payable to 12.0% per annum from 5.0% per annum.

In addition, in November 2018, we and the then holders of the senior notes mutually agreed to reduce the exercise price of the warrants held by them to acquire an aggregate of 474,062 shares of our common stock to $12.00 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 $12.00 and further extend the expiration date of our outstanding Series A warrants (Nasdaq: OTLKW) by three years. Such Series A warrants had an exercise price of $52.80 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 $58.00 per share and (b) February 18, 2019. In January 2019, we reduced the exercise price of these warrants from $52.80 to $12.00 and further extended the exercise period from February 18, 2019 to February 18, 2022.

Employment and Other Compensation Arrangements, Equity Plan Awards

We have entered into employment agreements with certain of our executive officers in connection with their employment. For more information regarding the executives' existing offer letters, see Item 11 in 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.

Mohan Consulting Agreement

Following Dr. Mohan's resignation as Chairman of our board of directors and as our Chief Executive Officer, on July 2, 2018, we entered into a consulting agreement with Dr. Mohan. Under the agreement, Dr. Mohan agreed to a six-month consulting arrangement, pursuant to which he was paid at 50% of his base salary prior to his resignation and focused on the ONS-5010 development program. Such consulting arrangement terminated in January 2019 in accordance with its terms.

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.

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 was estimated to be approximately $5.14 million, if all milestones were 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 company's development and manufacturing facilities. Such leases were personally guaranteed by Dr. Mohan, our former Chairman and Chief Executive Officer and Class III director. We subsequently terminated the CDMO contract in 2019 in connection with the shift in focus to our ONS-5010 product candidate.

Dr. Mohan, our founder and former Class III director, 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.

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 voting Series A Convertible Preferred Stock, or the Series A Convertible, for $25.0 million and warrants to acquire an aggregate 2,093,750 shares of our common stock. The Series A Convertible was initially convertible into 4,724,493 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.

BioLexis received the following quarterly in-kind dividends on the Series A Convertible: 4,678 shares (December 31, 2017), 6,367 shares (March 31, 2018), 6,526 shares (July 18, 2018).

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, 1,594,345 shares of common stock and warrants to acquire an aggregate 2,564,102 shares of our common stock for $15.0 million in two tranches. We completed the sale of the first tranche of 797,172 shares of common stock and warrants to acquire an aggregate 1,282,051 shares of our common stock for $7.5 million in May 2018. In June 2018, we consummated the sale of the remaining 797,172 shares of common stock and warrants to acquire an aggregate 1,282,051 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 Preferred Stock

In June 2018, BioLexis converted 208,836 shares of its Series A Convertible into 3,946,577 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 voting Series A-1 convertible preferred stock, or the Series A-1 Convertible.

In July 2018, our board of directors 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.

BioLexis has received the following quarterly in-kind dividends on the Series A-1 Convertible: 1,468 shares (September 30, 2018), 1,505 shares (December 31, 2018), 1,542 shares (March 31, 2019), 1,581 shares (June 30, 2019), 1,620 shares (September 30, 2019).

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 1,072,156 shares of common stock for $8.0 million in November 2018, and the second tranche of 536,078 shares of common stock for $4.0 million in December 2018. We agreed to close the remaining two tranches of $4.0 million (or 536,078 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.

April 2019 Public Offering

In April 2019, we completed an underwritten public offering of an aggregate of 10,340,000 shares of our common stock, 15-month warrants to purchase an aggregate of 10,340,000 shares of our common stock, and 5-year warrants to purchase an aggregate of 10,340,000 shares of our common stock at a combined public offering price of $2.75 per share and accompanying warrants. The 15-month and 5-year warrants have an exercise price of $2.90 per share. BioLexis was allocated, and acquired from the underwriters, 3,636,364 shares of our common stock, 15-month warrants to acquire 3,636,364 shares of our common stock and 5-year warrants to acquire 3,636,364 shares of our common stock, for approximately $10.0 million. In June 2019, we amended the terms of the 15-month warrants to remove the beneficial ownership limitations, and BioLexis cashless exercised such warrants pursuant to their terms, as amended, and received .60 of the underlying shares (or 2,181,818 shares of our common stock).

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 264,084 shares of our common stock. We closed the exchange on October 30, 2017. In June 2018, following the conversion of the Series A Convertible by BioLexis, the Series B Convertible was converted into an aggregate into 264,084 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. We amended the agreement in March 2018 and June 2019. Under the current terms of the agreement as amended, we agreed to pay MTTR a fee of $105,208 per month, which will increase to $170,833 per month after the launch of ONS-5010 in the United States (subject to reduction by 50% in the event net sales of ONS-5010 are below a certain threshold million per year). Beginning June 2019 through December 2019, we also agreed to pay MTTR an additional retainer of $115,516 per month, $50,000 of which is credited against the monthly fee. 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. We also agreed to pay a one-time fee of $268,553 to MTTR by September 2020 if certain regulatory milestones are achieved earlier than anticipated. Terry Dagnon and Jeff Evanson are two of our executive officers and provide services to us pursuant to our strategic partnership agreement with MTTR, are compensated by MTTR, and have ownership interests in MTTR, as does Mark Humayun, M.D., one of our outside advisors.

MTTR earned an aggregate $1,744,933 and $602,629 during the years ended September 30, 2019 and 2018, respectively, which includes monthly consulting fees and expense reimbursement.

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 four directors are independent directors within the meaning of the applicable Nasdaq listing standards: Messrs. Thurman, Haddadin, Hilzinger and Sukhtian. 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, 2019 and 2018 by KPMG LLP, our principal accountant.

	Fiscal year ended	
	2019	2018
Audit Fees	$ 300,000	$ 350,000
Audit-related Fees	130,000	32,500
Tax Fees	80,809	139,986
Total Fees	$ 510,809	$ 522,486

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 services rendered in connection with registration statements, including a comfort letter and consents.

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

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 13, 2019).
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#	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).
10.8†	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).
10.9†	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).
10.10†	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).
10.11	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).
10.12¥	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 (incorporated by reference to Exhibit 10.18 to the Registrant's annual report on Form 10-K filed with the SEC on December 18, 2018).
10.13¥	Amendment dated March 4, 2019 of Strategic Partnership Agreement between the Registrant and MTTR LLC effective as of February 15, 2018, as amended.
10.14¥	Amendment dated June 4, 2019 of Strategic Partnership Agreement between the Registrant and MTTR LLC effective as of February 15, 2018, as amended (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K, filed with the SEC on June 10, 2019).

10.15	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).
10.16	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).
10.17	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).
10.18	Amendment #3 to the Warrant Agreement dated May 18, 2016 by and between the Registrant and American Stock Transfer & Trust Company LLC, as Warrant Agent, dated January 22, 2019 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on January 22, 2019).
10.19	Form of Series A warrant certificate (included in Exhibit 10.15).
10.20	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).
10.21	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).
10.22	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).
10.23	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).
10.24	Form of Senior Secured Promissory Note (included as Exhibit A to the Note and Warrant Purchase Agreement filed as Exhibit 10.20).
10.25	Third Note Amendment between the Registrant and the holders of its senior secured notes dated June 28, 2019 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on July 1, 2019).
10.26	Form of Warrant (included as Exhibit B to the Note and Warrant Purchase Agreement filed as Exhibit 10.20).
10.27	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).
10.28	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).
10.29	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).
10.30	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).
10.31	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).
10.32	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).
10.33	Third Amendment to Investor Rights 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 10.2 to the Registrant's current report on Form 8-K filed with the SEC on November 9, 2018).
10.34	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).

10.35	Warrant Agreement, including form of 15-Month Warrant and form of Five-Year Warrant by and between the Registrant and American Stock Transfer & Trust Company, LLC, as Warrant Agent, dated April 12, 2019 (incorporated by reference to Exhibit 10.1 to the Registrant's quarterly report on Form 10-Q filed with the SEC on May 15, 2019).
10.36	Amendment #1 dated June 11, 2019 of Warrant Agreement by and between the Registrant and American Stock Transfer & Trust Company, LLC, as Warrant Agent, dated April 12, 2019 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on June 14, 2019).
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

† 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.

* Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

# Indicates management contract or compensatory plan.

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 19, 2019

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 19, 2019
/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 19, 2019
/s/ Yezan Haddadin Yezan Haddadin	Director	December 19, 2019
/s/ Kurt J. Hilzinger Kurt J. Hilzinger	Director	December 19, 2019
/s/ Faisal G. Sukhtian Faisal G. Sukhtian	Director	December 19, 2019

Exhibit 10.13

[***] = Certain confidential information contained in this document, marked by brackets, is omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

MTTR, LLC
[***]
Attn: [***]
Email: [***]

March 4, 2019

Outlook Therapeutics, Inc.
7 Clarke Drive
Cranbury, NJ 08512
Attn: Mr. Lawrence A. Kenyon
Email: [***]
Re: Strategic Partnership Agreement between MTTR, LLC and Outlook Therapeutics, Inc.

Dear Larry:

As we have discussed, this letter acknowledges that the Strategic Partnership Agreement entered into by MTTR, LLC ("**MTTR**") and Oncobiologics, Inc. ("**Oncobiologics**") dated February 15, 2018 and amended by the letter amendment dated March 2, 2018 (the "**Agreement**") shall continue in full force and effect as between MTTR and Outlook as a result of Oncobiologic's change in name to Outlook Therapeutics, Inc. ("**Outlook**") without any effect other than that the terms "Oncobiologics, Inc." and "Oncobiologics" in the Agreement shall instead refer to "Outlook Therapeutics, Inc." and "Outlook", respectively.

Additionally, this letter confirms Outlook's approval of the replacement of [***] under the Agreement with Mr. Jeff Evanson, as required under Section 2.2(d) of the Agreement. As a result of such replacement and pursuant to Section 2.2(e) of the Agreement, any and all references in the Agreement to [***] or [***] shall be deemed to refer to Mr. Jeff Evanson, an individual and citizen of the U.S. residing as of the date of this letter, in the state of Texas. If the foregoing is agreeable to you, please sign this letter and return the countersigned letter to us at your convenience.

Regards,
MTTR, LLC

By: /s/ [***]
[***]
Title: Founder

Acknowledged and Agreed:
OUTLOOK TERAPEUTICS, INC.

By: /s/ Mr. Lawrence A. Kenyo
Mr. Lawrence A. Kenyon
Title: President and Chief Executive Officer
Date: March 5, 2019

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, 333-223064, 333-229685 and 333-234024) on Form S-8, (Nos. 333-223063 and 333-231922) on Form S-3 and (Nos. 333-209011, 333-212351, 333-216610, 333-229761 and 333-230791) on Form S-1 of Outlook Therapeutics, Inc. of our report dated December 19, 2019, with respect to the consolidated balance sheets of Outlook Therapeutics, Inc. as of September 30, 2019 and 2018, 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, 2019 annual report on Form 10-K of Outlook Therapeutics, Inc.

Our report dated December 19, 2019 contains an explanatory paragraph that states that Outlook Therapeutics, Inc. has incurred recurring losses and negative cash flows from operations and has a stockholders' deficit of $16.1 million, $6.7 million of convertible senior secured notes that become due on December 22, 2019, $3.6 million of unsecured indebtedness due on demand and $1.0 million of unsecured indebtedness also due on demand, but subject to a forbearance agreement through March 2020, that raise 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 19, 2019

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 19, 2019

/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 TO18 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, 2019 (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 19, 2019

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.