UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended December 31, 2018
or

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

For the transition period from to

COMMISSION FILE NO. 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)

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 that 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 definitions 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 the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The number of shares of the registrant's common stock, $0.01 par value per share, outstanding as of February 12, 2019 was 93,673,654.

Outlook Therapeutics, Inc.
Table of Contents

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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this report, including statements regarding our future financial condition, business strategy and plans, and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "believe," "may," "could," "will," "estimate," "continue," "anticipate," "intend," "seek," "plan," "expect," "should," "would," "potentially" or the negative of these terms or similar expressions in this report.

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of known and unknown risks, uncertainties and assumptions, including risks described in the section titled "Risk Factors" contained in our annual report on Form 10-K for the year ended September 30, 2018 filed with the SEC on December 18, 2018, including, among other things, risks associated with:

- the timing and the success of the design of the clinical trials and planned clinical trials of our lead product candidate, ONS-5010;
- whether the results of our clinical trials will be sufficient to support domestic or global regulatory approvals;
- our ability to obtain and maintain regulatory approval for ONS-5010 in the United States and other markets if we successfully complete clinical trials;
- our expectations regarding the potential market size and the size of the patient populations for our product candidates, if approved, for commercial use;
- our ability to fund our working capital requirements;
- the rate and degree of market acceptance of our current and future product candidates;
- the implementation of our business model and strategic plans for our business and product candidates;
- developments or disputes concerning our intellectual property or other proprietary rights;
- our ability to maintain and establish collaborations or obtain additional funding;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to compete in the markets we serve; and
- the factors that may impact our financial results.

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

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Outlook Therapeutics, Inc.
Consolidated Balance Sheets
(unaudited)

	December 31, 2018	September 30, 2018
Assets		
Current assets:		
Cash	$ 227,716	$ 1,717,391
Prepaid and other current assets	2,077,791	1,585,089
Total current assets	2,305,507	3,302,480
Property and equipment, net	15,941,866	18,489,976
Other assets	462,326	491,039
Total assets	$ 18,709,699	$ 22,283,495
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Convertible senior secured notes	$ 9,058,120	$ 13,179,449
Current portion of long-term debt	56,541	66,480
Current portion of capital lease obligations	342,706	520,794
Stockholder notes	4,612,500	4,612,500
Accounts payable	4,696,258	3,609,607
Accrued expenses	4,520,883	6,458,471
Income taxes payable	1,856,129	1,856,129
Deferred revenue	2,392,684	1,738,603
Total current liabilities	27,535,821	32,042,033
Long-term debt	86,947	98,487
Capital lease obligations	3,400,123	3,453,256
Warrant liability	1,057,615	1,227,225
Deferred revenue	4,700,841	2,758,262
Other liabilities	3,397,692	3,514,738
Total liabilities	40,179,039	43,094,001
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, 61,708 shares issued and outstanding at December 31, 2018 and 60,203 shares issued and outstanding at September 30, 2018	4,884,924	4,734,416
Total convertible preferred stock	4,884,924	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	-	-
Common stock, par value $0.01 per share; 200,000,000 shares authorized; 85,091,786 shares issued and outstanding at December 31, 2018 and 72,220,351 shares issued and outstanding at September 30, 2018	850,918	722,204
Additional paid-in capital	202,493,283	190,040,237
Accumulated deficit	(229,698,465)	(216,307,363)
Total stockholders' equity (deficit)	(26,354,264)	(25,544,922)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 18,709,699	$ 22,283,495

The accompanying notes are an integral part of these unaudited interim consolidated financial statements.

Outlook Therapeutics, Inc.
Consolidated Statements of Operations
(unaudited)

	Three months ended December 31,	
	2018	**2017**
Collaboration revenues	$ 1,067,598	$ 771,890
Operating expenses:		
Research and development	8,420,925	402,402
General and administrative	2,903,988	3,549,252
	11,324,913	3,951,654
Loss from operations	(10,257,315)	(3,179,764)
Interest expense, net	1,120,849	717,883
Loss on extinguishment of debt	-	1,252,353
Change in fair value of warrant liability	(1,636,320)	(78,783)
Loss before income taxes	(9,741,844)	(5,071,217)
Income tax (benefit) expense	-	(3,150,716)
Net loss	(9,741,844)	(1,920,501)
Recognition of beneficial conversion feature upon issuance of Series A and A-1 convertible preferred stock	-	(15,355,019)
Series A and A-1 convertible preferred stock dividends and related settlement	(150,508)	(450,801)
Net loss attributable to common stockholders	$ (9,892,352)	$ (17,726,321)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.13)	$ (0.71)
Weighted average shares outstanding, basic and diluted	78,748,320	25,003,055

The accompanying notes are an integral part of these unaudited interim consolidated financial statements.

Outlook Therapeutics, Inc.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(unaudited)

	Convertible Preferred Stock Series A-1		Stockholders' Equity (Deficit)				
			Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance at October 1, 2018	60,203	$ 4,734,416	72,220,351	$ 722,204	$ 190,040,237	$ (216,307,363)	$ (25,544,922)
Cumulative effect of adoption of ASU 2014-09 (Topic 606)	-	-	-	-	-	(3,649,258)	(3,649,258)
Proceeds from exercise of common stock warrants	-	-	4,407	44	(44)	-	-
Private placement sale of common stock, net of costs	-	-	12,865,872	128,659	11,682,199	-	11,810,858
Issuance of vested restricted stock units	-	-	1,156	11	(11)	-	-
Series A-1 convertible preferred stock dividends and related settlement	1,505	150,508	-	-	(150,508)	-	(150,508)
Stock-based compensation expense	-	-	-	-	921,410	-	921,410
Net loss	-	-	-	-	-	(9,741,844)	(9,741,844)
Balance at December 31, 2018	61,708	$ 4,884,924	85,091,786	$ 850,918	$ 202,493,283	$ (229,698,465)	$ (26,354,264)

	Convertible Preferred Stock Series A		Stockholders' Equity (Deficit)						
			Series B Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance at October 1, 2017	32,628	$ 2,924,441	-	$ -	24,933,944	$ 249,339	$ 152,315,088	$ (186,215,402)	$ (33,650,975)
Issuance of vested restricted stock units	-	-	-	-	596,783	5,968	(5,968)	-	-
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	-	-	-	-	-	-	(450,801)	-	(450,801)
Conversion of senior secured notes into Series B convertible preferred stock	-	-	1,500,000	2,661,972	-	-	-	-	2,661,972
Stock-based compensation expense	-	-	-	-	-	-	1,889,820	-	1,889,820
Net loss	-	-	-	-	-	-	-	(1,920,501)	(1,920,501)
Balance at December 31, 2017	250,000	$ 17,190,302	1,500,000	$ 2,661,972	25,530,727	$ 255,307	$ 160,130,320	$ (188,135,903)	$ (25,088,304)

The accompanying notes are an integral part of these unaudited interim consolidated financial statements.

Outlook Therapeutics, Inc.
Consolidated Statements of Cash Flows
(unaudited)

	Three months ended December 31,	
	2018	**2017**
OPERATING ACTIVITIES		
Net loss	$ (9,741,844)	$ (1,920,501)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	823,077	676,624
Loss on extinguishment of debt	-	1,252,353
Non-cash interest expense	450,381	579,586
Stock-based compensation	872,289	1,889,820
Change in fair value of warrant liability	(1,636,320)	(78,783)
Loss on disposal of property and equipment	2,349,403	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(73,343)	(792,757)
Other assets	21,913	14,917
Accounts payable	(260,452)	(6,949,861)
Accrued expenses	(1,419,055)	(2,559,713)
Deferred revenue	(1,052,598)	(771,889)
Other liabilities	(137,137)	(10,873)
Net cash used in operating activities	(9,803,686)	(8,671,077)
INVESTING ACTIVITIES		
Purchase of property and equipment	(236,433)	(1,075,143)
Net cash used in investing activities	(236,433)	(1,075,143)
FINANCING ACTIVITIES		
Proceeds from the sale of common stock, net of offering costs	11,885,833	-
Proceeds from issuance of Series A convertible preferred stock	-	21,737,200
Payments of capital leases obligations	(231,221)	(219,106)
Repayment of debt	(3,126,479)	(30,456)
Payment of financing costs	-	(1,089,158)
Net cash provided by financing activities	8,528,133	20,398,480
Effect of foreign exchange rate on cash	22,311	-
Net (decrease) increase in cash	(1,489,675)	10,652,260
Cash at beginning of period	1,717,391	3,185,519
Cash at end of period	$ 227,716	$ 13,837,779
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 1,657,157	$ 25,505
Supplemental schedule of noncash investing activities:		
Purchases of property and equipment in accounts payable and accrued expenses	$ 625,830	$ 90,162
Supplemental schedule of noncash financing activities:		
Issuance of Series B convertible preferred stock upon conversion of senior secured notes, net of unamortized debt discount	$ -	$ 1,409,619
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 and related settlement	$ 150,508	$ 450,801
Deferred offering costs and common stock issuance costs in accounts payable and accrued expenses	$ 74,975	$ -
Accrued directors fees settled in fully vested stock options	$ 49,121	$ -

The accompanying notes are an integral part of these unaudited interim consolidated financial statements.

1. Organization and Description of 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, a complex monoclonal antibody ("mAb") therapeutic for various ophthalmic indications. The Company is based in Cranbury, New Jersey.

2. Liquidity

The Company has incurred substantial losses and negative cash flows from operations since its inception and has an accumulated deficit of $229.7 million as of December 31, 2018. As of December 31, 2018, the Company had substantial indebtedness that included $10.4 million of senior secured notes that may become due in fiscal 2019 and $4.6 million of unsecured notes, all of which was due on demand as of such date. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

On November 5, 2018, the Company entered into a purchase agreement with BioLexis Pte. Ltd. ("BioLexis"), formerly known as GMS Tenshi Holdings Pte. Limited, a Singapore private limited company, and the Company's controlling stockholder and strategic partner, providing for the private placement of $20.0 million of shares of its common stock at $0.9327 per share. During the three months ended December 31, 2018, the Company closed the sale of the first two tranches of this private placement for an aggregate of 12,865,872 shares of the Company's common stock for aggregate cash proceeds of $12.0 million. The remaining $8.0 million for the sale of an aggregate of 8,577,248 shares of common stock was received in January and February 2019. The Company intends to use the net proceeds from the private placement primarily for clinical trials for its lead product candidate, ONS-5010, and for working capital and general corporate purposes, including the agreed repayments on the senior secured notes.

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

Management believes that the Company's existing cash as of December 31, 2018, the $8.0 million funding from the November 2018 BioLexis private placement received in January and February 2019 and anticipated proceeds from the sale of New Jersey NOLs and R&D credits will be sufficient to fund its operations into June 2019, excluding any unscheduled repayment of debt. Substantial additional financing will be needed by the Company to fund its operations in the future and to commercially develop its product candidates. Management is currently evaluating different strategies to obtain the required funding for future operations. These strategies may include, but are not limited to: private placements of equity and/or debt, payments from potential strategic research and development partners, licensing and/or marketing arrangements with pharmaceutical companies, sale of its development stage product candidates to third parties and public or private offerings of equity and/or debt securities. There can be no assurance that these future funding efforts will be successful.

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

3. Basis of Presentation and Summary of Significant Accounting Policies

Basis of presentation

The accompanying unaudited interim consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. 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").

In the opinion of management, the accompanying unaudited interim consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company's financial position as of December 31, 2018 and its results of operations and cash flows for the three months ended December 31, 2018 and 2017. Operating results for the three months ended December 31, 2018 are not necessarily indicative of the results that may be expected for the full year ending September 30, 2019. The unaudited interim consolidated financial statements, presented herein, do not contain the required disclosures under GAAP for annual consolidated financial statements. The accompanying unaudited interim consolidated financial statements should be read in conjunction with the annual audited consolidated financial statements and related notes as of and for the year ended September 30, 2018 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on December 18, 2018.

Use of estimates

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

Net loss per share

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

For purposes of calculating diluted 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. The diluted loss per common share calculation is further affected by an add-back of change in fair value of warrant liability to the numerator under the assumption that the change in fair value of warrant liability would not have been incurred if the warrants had been converted into common stock.

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

	Three months ended December 31,	
	2018	2017
Net loss	$ (9,892,352)	$ (17,726,321)
Common stock outstanding (weighted average)	78,748,320	25,003,055
Basic and diluted net loss per share	$ (0.13)	$ (0.71)

The following potentially dilutive securities (in common stock equivalents) have been excluded from the computation of diluted weighted-average shares outstanding as of December 31, 2018 and 2017, as they would be antidilutive:

	As of December 31,	
	2018	2017
Series A convertible preferred stock	-	37,795,948
Series A-1 convertible preferred stock	9,329,248	-
Series B convertible preferred stock	-	2,112,676
Convertible senior secured notes	9,303,958	-
Performance-based stock units	129,095	163,934
Restricted stock units	59,663	309,532
Stock options	3,089,977	-
Common stock warrants	45,288,125	28,116,505

Recently issued and adopted accounting pronouncements

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 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. The Company 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 which the Company will recognize over the estimated performance period.

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. For the three months ended December 31, 2018, the Company would have recognized $0.8 million of collaboration revenues under revenue recognition guidance in effect during fiscal 2018 prior to the adoption of ASU 2014-09.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* ("ASC 842"). The FASB issued subsequent amendments to the initial guidance in July 2018 with ASU 2018-10 and in August 2018 with ASU 2018-11. ASC 842 supersedes the current accounting for leases. The new standard requires lessees to record a right of use asset and a related liability for the rights and obligations associated with a lease, regardless of lease classification, and eliminates the required use of bright-line tests in current U.S. GAAP for determining lease classification. This ASU is effective for annual periods beginning after December 15, 2018 (i.e., calendar periods beginning on January 1, 2019), and interim periods thereafter. Earlier application is permitted for all entities, however the Company does not plan to early adopt. The new standard must be adopted using either the modified retrospective approach, which requires application of the new guidance at the beginning of the earliest comparative period presented or the optional alternative approach, which requires application of the new guidance at the beginning of the standard's effective date. The Company has arrangements currently classified as operating leases which will be recorded as a right of use asset and corresponding liability on the balance sheet and is currently evaluating the impact these changes will have on the consolidated financial statements.

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

	December 31, 2018		
	(Level 1)	(Level 2)	(Level 3)
Liabilities			
Warrant liability	$ -	$ -	$ 1,057,615

	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 three months ended December 31, 2018:

Balance at October 1, 2018	$ 1,227,225
Senior note warrants modification	1,466,710(i)
Change in fair value	(1,636,320)
Balance at December 31, 2018	$ 1,057,615

(i) In connection with the November 2018 BioLexis private placement, the Company reduced the exercise price of the warrants issued in connection with the senior secured notes (the "Senior Note Warrants") from $3.00 to $1.50 and extended the expiration of the Senior Note Warrants by three years. Such Senior Note Warrants now expire eight years from their initial exercise date.

The Senior Note Warrants issued in connection with the senior secured notes (see Note 7) are classified as liabilities on the accompanying consolidated balance sheet as the Senior Note Warrants include cash settlement features at the option of the holders under certain circumstances. The warrant liability is revalued each reporting period with the change in fair value recorded in the accompanying consolidated statements of operations until the warrants are exercised or expire. The fair value of the warrant liability is estimated using the Black-Scholes option pricing model using the following assumptions:

	December 31, 2018	September 30, 2018
Risk-free interest rate	2.55%	2.90%
Remaining contractual life of warrant	5.98 years	3.39 years
Expected volatility	85%	82%
Annual dividend yield	0%	0%
Fair value of common stock	$ 0.50 per share	$ 0.98 per share

5. Property and Equipment, Net

Property and equipment, net, consists of:

	December 31, 2018	September 30, 2018
Laboratory equipment	$ 13,980,292	$ 14,333,624
Leasehold improvements	10,095,100	10,095,100
Computer software and hardware	497,799	483,807
Land and building	3,000,000	3,000,000
Construction in progress	852,791	2,276,737
	28,425,982	30,189,268
Less: accumulated depreciation and amortization	(12,484,116)	(11,699,292)
	$ 15,941,866	$ 18,489,976

Depreciation and amortization expense was $823,077 and $676,624 for the three months ended December 31, 2018 and 2017 respectively.

At December 31, 2018 and 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. The Company's corporate office lease matures in February 2028. The term of the equipment leases are between 12 and 36 months and qualify as capital leases. The equipment leases bear interest between 4.0% and 19.4% and the effective interest rate on the corporate office lease is 43.9%. At December 31, 2018 and September 30, 2018, $1,802,164 and $1,619,741, respectively, of accumulated amortization related to capital leases.

During the three months ended December 31, 2018, the Company wrote off certain construction in progress and laboratory equipment with a carrying amount of $2,349,403. The charge was recorded to research and development on the consolidated statements of operations. The Company determined that the carrying amount of these assets as of December 31, 2018 was not recoverable and was less than the fair value less the cost to sell due to the Company changing its operations to focus solely on developing and commercializing ONS-5010.

6. Accrued Expenses

Accrued expenses consists of:

	December 31, 2018	September 30, 2018
Compensation	$ 1,621,260	$ 2,231,122
Severance and related costs	623,995	396,138
Lease termination obligation	374,980	395,071
Research and development	625,362	1,065,169
Interest payable	935,137	1,991,044
Professional fees	336,274	313,585
Director fees	-	59,122
Other accrued expenses	3,875	7,220
	$ 4,520,883	$ 6,458,471

7. Senior Secured Notes

	December 31, 2018	September 30, 2018
Convertible senior secured notes	$ 10,395,000	$ 13,500,000
Unamortized debt discount	(1,336,880)	(320,551)
	$ 9,058,120	$ 13,179,449

In September 2017, the Company entered into a purchase and exchange agreement (the "Exchange Agreement") with two existing investors and holders of its senior secured notes (the "Exchanging Noteholders"), pursuant to which the Exchanging Noteholders exchanged $1.5 million aggregate principal amount of senior secured notes for 1,500,000 shares of Series B convertible preferred stock ("Series B Convertible") and $41,507 of accrued interest on such exchanged senior secured notes in October 2017. The Company recognized a loss on extinguishment of $1,252,353 in connection with the exchange and represents the excess fair value of the Series B Convertible issued over the net carrying amount of the debt and accrued interest.

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, up to 12 months, or until December 22, 2019, in exchange for making several payments of principal and interest through August 31, 2019, subject to meeting additional capital raising commitments. In addition, the Company agreed to make the senior secured notes convertible into common stock at a price of $1.11924 per share (120% of the price per share paid by BioLexis under the November 2018 purchase agreement) and reduced the exercise price of warrants to purchase 3,882,001 shares of common stock held by the senior secured noteholders from $3.00 per share to $1.50 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. The Company repaid $3.1 million of principal and $1.3 million of accrued interest of such notes during the three months ended December 31, 2018. As of December 31, 2018, the senior secured notes remain classified as a current liability because raising additional capital is outside the Company's control.

Interest expense on the senior secured notes for the three months ended December 31, 2018 and 2017 was $151,052 and $504,585, respectively.

8. Commitments

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. 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.

At December 31, 2018, the current portion of the lease termination obligation of $374,980 is included in accrued expenses and $3,328,730 is included in other liabilities on the consolidated balance sheets. A rollforward of the charges incurred to general and administrative expense for the three months ended December 31, 2018 is as follows:

	Balance October 1, 2018	Expensed / Accrued Expense	Cash Payments	Balance December 31, 2018
Lease termination payments	$ 3,850,081	$ 3,629	$ (150,000)	$ 3,703,710

9. Common Stock, Convertible Preferred Stock and Stockholders' Equity (Deficit)

Common stock

Pursuant to the November 5, 2018 BioLexis private placement, the Company closed the sale of the first two tranches of this private placement for an aggregate of 12,865,872 shares of the Company's common stock for gross cash proceeds of $12.0 million ($11.8 million net of issuance costs) during the three months ended December 31, 2018.

During the three months ended December 31, 2018 and 2017, the Company issued 1,156 and 596,783 respectively, shares of common stock upon the vesting of RSUs.

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 16,750,000 shares of common stock. In September 2017, the Company completed the initial sale of 32,628 shares of Series A Convertible to BioLexis for $3,262,800 in cash. In October 2017, the Company completed the sale of the remaining 217,372 shares of Series A Convertible and the BioLexis Warrants to BioLexis in the Initial Private Placement, for $21,737,200 in cash.

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

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

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

Series A-1 Convertible Preferred Stock

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

The Series A-1 accrue dividends at a rate of 10% per annum, compounded quarterly, payable quarterly at the Company's option in cash or in kind in additional shares of Series A-1. The Series A-1 is also entitled to dividends on an as-if-converted basis in the same form as any dividends actually paid on shares of Common Stock or other securities. The initial conversion rate is subject to appropriate adjustment in the event of a stock split, stock dividend, combination, reclassification or other recapitalization affecting the Common Stock. The holders of the Series A-1 have the right to vote on matters submitted to a vote of the Company's stockholders on an as-converted basis, voting with the Company's other stockholders as a single class. In addition, without the prior written consent of a majority of the outstanding shares of Series A-1, the Company may not take certain actions, including amending its certificate of incorporation or bylaws, or issuing securities ranking pari passu or senior to the Series A-1.

During the three months ended December 31, 2018, the Company issued 1,505 shares of Series A-1 Convertible to settle the related dividends that are due on a quarterly basis.

The terms of the Series A-1 distinguish between certain liquidation events (such as a voluntary or involuntary liquidation, dissolution or winding up of the Company) and "deemed" liquidation events (such as a sale of all or substantially all of the Company's assets, various merger and reorganization transactions, being delisted from Nasdaq, and the occurrence of an event of default under the terms of the senior secured notes), in each case as defined in the Certificate of Designation. In the event of a liquidation (as defined in the Certificate of Designation), the liquidation preference payable equals the sum of (A) 550% of the Series A-1 stated value per share plus (B) an amount equal to (x) 550% of any accrued, but unpaid, preferred dividends (as defined in the Certificate of Designation) plus (y) any unpaid participating dividends (as defined in the Certificate of Designation). In the case of a deemed liquidation event (as defined in the Certificate of Designation), the multiplier is increased to 600%.

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

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

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

Series B Convertible Preferred Stock

Concurrent with completing the sale of Series A Convertible in October 2017, the Noteholders exchanged $1,500,000 in aggregate principal borrowings and $41,507 in accrued interest for 1,500,000 shares of Series B Convertible. The Series B Convertible were convertible into 2,112,675 shares of common stock. The exchange was accounted for as an extinguishment of debt, See Note 7. During May and June 2018, the Noteholders converted all 1,500,000 shares of Series B Convertible into 2,112,675 shares of common stock. Accordingly, there are no longer any shares of Series B Convertible issued and outstanding.

Common stock warrants

As of December 31, 2018, the Company had the following warrants outstanding to acquire shares of its common stock:

Outstanding	Exercise Price Per Share	Expiration Date	
3,333,333	$ 1.50	February 18, 2022	(i)
809,971	$ 0.01	November 11, 2019	
3,882,001	$ 1.50	December 22, 2024	(ii)
16,750,000	$ 0.90	October 31, 2025	
10,256,410	$ 0.975	May 10, 2026	
10,256,410	$ 0.975	June 8, 2026	
45,288,125			

(i) In January 2019, the Company reduced the exercise price of these warrants from $6.60 to $1.50 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 $3.00 to $1.50 and extended the expiration of the Senior Note Warrants by three years to December 22, 2024.

During the three months ended December 31, 2018, warrants to purchase 4,407 shares with an exercise price of $0.01 were exercised.

10. 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 851,926. As of December 31, 2018, PSUs representing 129,095 shares of the Company's common stock were outstanding under the 2011 Plan. In light of the December 2015 adoption of the 2015 Equity Incentive Plan, (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 8,404,023. As of December 31, 2018, 3,926,136 shares remained available for grant under the 2015 Plan.

Stock options and RSUs are granted under the Company's 2015 Plan and 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.

The Company recorded stock-based compensation expense in the following expense categories of its statements of operations for the three months ended December 31, 2018 and 2017:

	Three months ended December 31,	
	2018	2017
Research and development	$ 91,209	$ 318,241
General and administrative	781,080	1,571,579
	$ 872,289	$ 1,889,820

During the three months ended December 31, 2018, the Company awarded stock options with a fair value of $49,121 as settlement for directors fees accrued as of September 30, 2018.

Stock options

As of December 31, 2018, options to purchase common stock of the Company outstanding under the 2015 Plan were as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Balance at October 1, 2018	1,457,145	$ 0.90	
Granted	1,995,995	0.89	
Expired	(15,000)	1.32	
Forfeited	(348,163)	0.91	
Balance at December 31, 2018	3,089,977	0.90	9.3
Vested and exercisable	1,160,995	0.90	8.8
Vested and expected to vest at December 31, 2018	3,089,977	$ 0.90	9.3

The weighted average grant date fair value of the options awarded to employees for the three months ended December 31, 2018 was $0.64 per share. 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. As of December 31, 2018, the aggregate intrinsic value of options was $0.

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:

	Three months ended December 31, 2018
Risk-free interest rate	3.02%
Expected life	5.6 years
Expected volatility	87.2%
Expected dividend yield	-

As of December 31, 2018, there was $1,059,498 of unrecognized compensation expense that is expected to be recognized over a weighted-average period of 3.3 years.

Performance-based stock units

The Company has issued performance-based stock units, 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 three months ended December 31, 2018:

	Number of PSUs	Base Price Per PSU	Weighted Average Remaining Contractual Term (Years)
Balance at October 1, 2018	129,095	$ 6.25	
Forfeitures	-	-	
Balance at December 31, 2018	129,095	6.25	5.5
Vested and exercisable at December 31, 2018	128,950	6.23	5.5
Vested and expected to vest at December 31, 2018	129,095	$ 6.25	5.5

As of December 31, 2018, there was $532 of unamortized expense that will be recognized over a weighted-average period of 0.3 years.

Restricted stock units

The following table summarizes the activity related to RSUs during the three months ended December 31, 2018:

	Number of RSUs	Weighted Average Grant Date Fair Value
Balance at October 1, 2018	61,109	$ 19.23
Vested and settled	(1,156)	12.00
Forfeitures	(290)	12.00
Balance at December 31, 2018	59,663	$ 19.41

As of December 31, 2018, there was $378,925 of unamortized expense that will be recognized over a weighted-average period of 0.75 years.

11. 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 has a 16.66% ownership interest 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. During the three months ended December 31, 2018, MTTR earned an aggregate of $290,480, which includes monthly consulting fees and expense reimbursement.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read this section in conjunction with our unaudited interim consolidated financial statements and related notes included in Part I. Item 1 of this report and our audited consolidated financial statements and related notes thereto and management's discussion and analysis of financial condition and results of operations for the years ended September 30, 2018 and 2017 included in our Annual Report on Form 10-K for the year ended September 30, 2018, filed with the Securities and Exchange Commission, or SEC, on December 18, 2018.

Forward-Looking Statements

This discussion 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, or the Exchange Act. Forward-looking statements are identified by words such as "believe," "may," "could," "will," "estimate," "continue," "anticipate," "intend," "seek," "plan," "expect," "should," "would," "potentially" or the negative of these terms or similar expressions in this report. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to certain risks and uncertainties that could cause a difference include, but are not limited to, those discussed under the caption "Risk Factors" in our Annual Report on Form 10-K for the year ended September 30, 2018, filed with the SEC on December 18, 2018, and elsewhere in this report. See "Special Note Regarding Forward-Looking Statements." Forward-looking statements are based on our management's current beliefs and assumptions and based on information currently available to our management. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments.

Overview

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

ONS-5010 is an innovative mAb therapeutic product candidate currently enrolling patients in a Phase 3 clinical trial (ONS-5010-001) in Australia designed to serve as the first of two adequate and well controlled studies evaluating ONS-5010 against ranibizumab (Lucentis) for wet AMD. Enrollment in ONS-5010-001 is approximately 75% complete. The second of the two Phase 3 studies (ONS-5010-002) has been initiated in Australia and is expected to begin enrolling patients in March 2019. We plan to submit an investigational new drug, or IND, application with the U.S. Food and Drug Administration, or FDA, in the first quarter of calendar 2019 to allow us to begin enrolling patients in the U.S. portion of ONS-5010-002 shortly thereafter. The ONS-5010-002 study is expected to enroll a total of at least 180 patients. Our ONS-5010 clinical program was reviewed at a successful end of Phase 2 meeting with the FDA conducted in 2018. If the program is successful, it will support our plans to submit for regulatory approval in multiple markets in 2020 including the United States, Europe and Japan. Because there are no approved bevacizumab products for the treatment of retinal diseases in such major markets, we are developing ONS-5010 as an innovative therapy and not using the biosimilar drug development pathway. If approved, we believe ONS-5010 has potential to mitigate risks associated with off-label use of Avastin or other drugs. Off label use of Avastin is currently estimated to account for approximately 50% of all wet AMD prescriptions in the United States.

Separately, we have licensed the emerging markets rights to third parties for development in those markets for two biosimilar product candidates: ONS-3010, a biosimilar to adalimumab (Humira), and ONS-1045, a biosimilar to bevacizumab (Avastin). We do not plan to further advance ONS-3010 and ONS-1045 in major markets, including the United States. At this time, ONS-5010 is our only product candidate in active development.

Through December 31, 2018, we have funded substantially all of our operations with $207.3 million in proceeds from the sale and issuance of our equity and debt securities. We have also received $29.0 million pursuant to our collaboration and licensing agreements. On November 5, 2018, we entered into a purchase agreement with BioLexis providing for the private placement of $20.0 million of shares of our common stock at $0.9327 per share. In November and December 31, 2018, we closed the sale of the first two tranches of this private placement for an aggregate of 12,865,872 shares of our common stock for aggregate cash proceeds of $12.0 million. The remaining $8.0 million for the sale of 8,577,248 shares of common stock was received in January and February 2019. We intend to use the net proceeds from the private placement primarily for clinical trials for our lead product candidate, ONS-5010, and for working capital and general corporate purposes, including the agreed repayments on the senior secured notes discussed below.

Also on November 5, 2018, we reached an agreement with the holders of our $13.5 million senior secured notes to extend the maturity of the senior secured notes up to 12 months, or until December 22, 2019, among other items, in exchange for making several payments of principal and interest through August 31, 2019, subject to meeting additional capital raising commitments. In November and December 2018, we paid $4.4 million of principal and interest. In addition, we agreed to make the senior secured notes convertible into common stock at a price of $1.11924 per share (120% of the price per share paid by BioLexis under the November 2018 purchase agreement) and reduced the exercise price of the warrants held by such holders to $1.50 and extended the expiration of these warrants by three years. In January 2019, we reduced the exercise price of our outstanding Series A warrants (originally issued in connection with our initial public offering, or IPO) from $6.60 to $1.50 and further extended the expiration date of these warrants from February 18, 2019 to February 18, 2022.

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

We have incurred recurring losses and negative cash flows from operations since inception and had an accumulated deficit at December 31, 2018 of $229.7 million. As of December 31, 2018, we had substantial indebtedness that included $10.4 million of senior secured notes that may become due in fiscal 2019 and $4.6 million of unsecured notes, all of which was due on demand as of such date. 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 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 $0.2 million as of December 31, 2018, the remaining $8.0 million funding from the November 2018 BioLexis private placement received in January and February 2019 and the anticipated proceeds from the sale of New Jersey NOLs and R&D credits, are expected to fund our operations into June 2019, excluding any unscheduled repayment of debt. To provide additional working capital, we continue to engage in active discussions with global and regional pharmaceutical companies for licensing and/or co-development rights to our late- and early-stage pipeline product candidates. If we are not successful in raising additional capital or entering into one or more licensing and/or co-development rights agreements, we may be required to, among other things, make reductions in our workforce, discontinue our development programs, liquidate all or a portion of our assets, and/or seek protection under the provisions of the U.S. Bankruptcy Code.

We do not have any products approved for sale and we have only generated revenue from our collaboration agreements. We have incurred operating losses and negative operating cash flows since inception and there is no assurance that we will ever achieve profitable operations, and if achieved, that profitable operations will be sustained. Our net loss for the three months ended December 31, 2018 was $9.7 million. 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. During the three months ended December 31, 2018, MTTR earned an aggregate of $290,480, which includes monthly consulting fees and expense reimbursement.

Selexis SA

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

Selexis also granted us a non-transferrable option to obtain a perpetual, non-exclusive, worldwide commercial license under the Selexis Technology to manufacture, or have manufactured, a recombinant protein produced by a cell line developed using the Selexis Technology for clinical testing and commercial sale. We exercised this option in April 2013 and entered into three commercial license agreements with Selexis for our ONS-3010, ONS-1045 (which covers ONS-5010) and ONS-1050 product candidates. We paid an upfront licensing fee to Selexis for each commercial license and also agreed to pay a fixed milestone payment for each licensed product. In addition, we are required to pay a single-digit royalty on a final product-by-final product and country-by-country basis, based on worldwide net sales of such final products by us or any of our affiliates or sub-licensees during the royalty term. At any time during the term, we have the right to terminate our royalty payment obligation by providing written notice to Selexis and paying Selexis a royalty termination fee.

As of December 31, 2018, we have paid Selexis an aggregate of approximately $0.4 million under the commercial license agreements.

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

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

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

As of December 31, 2018, we have received an aggregate of $5.0 million of payments from IPCA under our various agreements.

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

In June 2014, we entered into a strategic license agreement with Laboratories Liomont, S.A. de C.V., or Liomont, under which we granted Liomont and its affiliates an exclusive, sublicenseable license in Mexico for the research, development, manufacture, use or sale of the ONS-3010 and ONS-1045 biosimilar product candidates in Mexico. Under the terms of the agreement, we received an upfront payment from Liomont, and we are eligible to earn milestone payments for each of ONS-3010 and ONS-1045. In addition, we are eligible to receive tiered royalties at upper single-digit to low teens percentage rates of annual net sales of products by Liomont and its affiliates in Mexico. As of December 31, 2018, we have received an aggregate of $3.0 million of upfront and milestone payments from Liomont.

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

In May 2013, we entered into a series of agreements with Zhejiang Huahai Pharmaceutical Co., Ltd., or Huahai, to form an alliance for the purpose of developing and obtaining regulatory approval for, and commercial launch and marketing of licensed products in an agreed territory, as described below. The agreements include a strategic alliance agreement, which sets out the governance framework for the relationship, along with a joint participation agreement regarding joint development and commercialization of ONS-3010, and a co-development and license agreement for each of ONS-3010 and ONS-1045. As of September 30, 2018, we have received an aggregate of $16.0 million of upfront and milestone payments from Huahai.

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

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

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

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

On September 7, 2017, in connection with the entry into the BioLexis purchase agreement for the Series A Convertible and warrants, we also entered into a joint development and license agreement providing for the license of rights to ONS-3010 and ONS-1045 in emerging markets, excluding China, India and Mexico, which superseded and replaced a previous strategic licensing agreement dated July 25, 2017. As of December 31, 2018, we have received an aggregate of $5.0 million of payments from BioLexis under our joint development and license agreement.

Components of our Results of Operations

Collaboration Revenue

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

On October 1, 2018, we adopted Accounting Standards Update, or ASU, No. 2014-09, *Revenue from Contracts with Customers*, or ASU 2014-09, 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. Our arrangements fall under Accounting Standards Codification, or ASC, 808, *Collaborations*, or 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 and should be recognized when the performance obligation is satisfied, which results in such amounts being recognized over the estimated performance period. We adopted the new accounting standard utilizing the modified retrospective method, and recorded the cumulative effect of adopting the standard as an adjustment to increase accumulated deficit by $3.6 million.

Research and Development Expenses

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

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

The successful development of ONS-5010 and any of our other 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 ONS-5010 or 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 ONS-5010 or our other 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 FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Product commercialization will take several years and millions of dollars in development costs.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size, complexity and duration of later-stage clinical trials.

General and Administrative Expenses

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

We anticipate that our general and administrative expenses will increase if and when we believe a regulatory approval of a product candidate appears likely, and we anticipate an increase in payroll and expense as a result of our preparation for commercial operations, particularly as it relates to the sales and marketing of our product.

Interest Expense

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

Loss on Extinguishment of Debt

We recorded a loss on the extinguishment of debt of $1.3 million during the three months ended December 31, 2017 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.

Income Taxes

On November 30, 2018, we received approval from the New Jersey Economic Development Authority's Technology Business Tax Certificate Transfer Program to sell approximately $3.7 million of our unused New Jersey NOLs and R&D credits. We expect to receive approximately $3.4 million of proceeds from the sale of the New Jersey NOLs and R&D credits. Since inception, we have not recorded any U.S. federal or state income tax benefits (excluding the sale of New Jersey NOLs and R&D credits) for the net losses we have incurred in each year or on our earned R&D credits, due to our uncertainty of realizing a benefit from those items. As of September 30, 2018, we had federal and state NOL carryforwards of $164.2 million and $67.6 million, respectively that will begin to expire in 2030 and 2036, respectively. As of September 30, 2018, we had federal foreign tax credit carryforwards of $2.4 million available to reduce future tax liabilities, which begin to expire starting in 2023. As of September 30, 2018, we also had federal R&D tax credit carryforwards of $8.5 million that begin to expire in 2032.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its NOLs to offset future taxable income. We have not completed a study to assess whether an ownership change has occurred in the past. Our existing NOLs may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change, 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, if any, may be subject to limitations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

Results of Operations

Comparison of Three Months Ended December 31, 2018 and 2017

	Three months ended December 31,	
	2018	**2017**
Collaboration revenues	$ 1,067,598	$ 771,890
Operating expenses:		
Research and development	8,420,925	402,402
General and administrative	2,903,988	3,549,252
	11,324,913	3,951,654
Loss from operations	(10,257,315)	(3,179,764)
Interest expense, net	1,120,849	717,883
Loss on extinguishment of debt	-	1,252,353
Change in fair value of warrant liability	(1,636,320)	(78,783)
Loss before income taxes	(9,741,844)	(5,071,217)
Income tax (benefit) expense	-	(3,150,716)
Net loss	$ (9,741,844)	$ (1,920,501)

Collaboration Revenues

The following table sets forth a summary of revenue recognized from our collaboration and licensing agreements for the three months ended December 31, 2018 and 2017, all of which was from the recognition of deferred revenues under such agreements:

	Three months ended December 31,	
	2018	**2017**
IPCA Collaboration	$ 128,007	$ 65,268
Liomont Collaboration	99,414	59,160
Huahai Collaboration	371,427	178,712
BioLexis Collaboration	468,750	468,750
	$ 1,067,598	$ 771,890

Collaboration revenues increased by $0.3 million to $1.1 million for the three months ended December 31, 2018, as compared to $0.8 million for the three months ended December 31, 2017. The increase is primarily due to the adoption of ASU No. 2014-09, effective October 1, 2018 which changed our revenue recognition policies for milestone payments. 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 and should be recognized when the performance obligation is satisfied, which results in such amounts being recognized over the estimated performance period.

Research and Development Expenses

The following table summarizes our research and development expenses by functional area for the three months ended December 31, 2018 and 2017:

	Three months ended December 31,	
	2018	2017
Preclinical and clinical development	$ 3,233,553	$ 927,071
Settlement of clinical development contract	-	(3,228,613)
Compensation and related benefits	1,884,649	1,426,402
Stock-based compensation	91,209	318,241
Loss on disposal of property and equipment	2,349,403	-
Other research and development	862,111	959,301
Total research and development expenses	$ 8,420,925	$ 402,402

The following table summarizes our research and development expenses by compound for the three months ended December 31, 2018 and 2017:

	Three months ended December 31,	
	2018	2017
ONS-3010	$ -	$ 497,837
ONS-1045	-	280,903
ONS-5010	3,233,553	-
Early-stage compounds	-	148,331
Settlement of clinical development contract	-	(3,228,613)
Personnel related and stock-based compensation	1,975,858	1,744,643
Loss on disposal of property and equipment	2,349,403	-
Other research and development	862,111	959,301
Total research and development expenses	$ 8,420,925	$ 402,402

Research and development expenses for the three months ended December 31, 2018 increased by $8.0 million compared to the three months ended December 31, 2017. The increase was primarily due to a write off of certain construction in progress assets and laboratory equipment resulting from our decision to focus on ONS-5010 and to outsource the commercial manufacturing for the program, and an increase in development costs related to the commencement of the ONS-5010 clinical program combined with a favorable settlement of a contract related to our inactive biosimilar product candidates for the three months ended December 31, 2017.

General and Administrative Expenses

The following table summarizes our general and administrative expenses by type for the three months ended December 31, 2018 and 2017:

	Three months ended December 31,	
	2018	2017
Professional fees	$ 1,480,974	$ 728,021
Compensation and related benefits	161,181	596,246
Stock-based compensation	781,080	1,571,579
Facilities, fees and other related costs	480,753	653,406
Total general and administrative expenses	$ 2,903,988	$ 3,549,252

General and administrative expenses for the three months ended December 31, 2018 decreased by $0.6 million compared to the three months ended December 31, 2017. The decrease was due to a reduction in stock-based compensation expense, which decreased because the first quarter of fiscal 2018 reflected the completion of the vesting period for many of our pre-IPO equity grants, and a decrease in compensation due to the reversal of previously accrued compensation costs. These decreases were offset by an increase in professional fees due to advisory services related to the restructuring of our senior secured notes.

Interest Expense

Interest expense increased by $0.4 million to $1.1 million for the three months ended December 31, 2018 as compared to $0.7 million for the three months ended December 31, 2017. The increase was primarily due to a $0.3 million net increase in interest expense from equipment loans, and capital lease obligations and $0.1 million increase in amortization of debt discount and interest expense on the senior secured notes issued due to the modification made to the notes during the quarter.

Change in Fair Value of Warrant Liability

During the three months ended December 31, 2018, we recorded income of $1.6 million related to the decrease in the fair value of our common stock warrant liability associated with the warrants issued in connection with our senior secured notes, which resulted from a decrease in the price of our common stock.

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 December 31, 2018, we have funded substantially all of our operations through the receipt of $207.3 million net proceeds from the issuance of our equity securities, debt securities and borrowings under debt facilities. We have also received an aggregate of $29.0 million pursuant to our collaboration and licensing agreements.

In November and December 2018, we issued 12,865,872 shares of the common stock to BioLexis for aggregate cash proceeds of $12.0 million pursuant our November 2018 purchase agreement. In January and February 2019, we issued 8,577,248 shares of common stock for the remaining $8.0 million aggregate cash proceeds thereunder. In November 2018, we also reached an agreement with the holders of our $13.5 million senior secured notes to extend the maturity of the senior secured notes, up to 12 months, or until December 22, 2019, among other items, in exchange for making several payments of principal and interest through August 31, 2019, subject to meeting additional capital raising commitments. In addition, we agreed to make the senior secured notes convertible into common stock at a price of $1.11924 per share (120% of the price per share paid by BioLexis under the purchase agreement) and reduced the exercise price of the warrants held by such holders to $1.50 and extended the expiration of these warrants by three years. In November and December 2018, we paid a total of $4.4 million of principal and interest on the senior secured notes.

In November 2018, we received approval from the New Jersey Economic Development Authority's Technology Business Tax Certificate Transfer Program to sell approximately $3.7 million of our unused New Jersey NOLs and R&D credits. We expect to receive approximately $3.4 million of proceeds from the sale of the New Jersey NOLs and R&D credits in the second quarter of fiscal 2019.

As of December 31, 2018, we had an accumulated deficit of $229.7 million and a cash balance of $0.2 million. In addition, we have $10.4 million of senior secured notes whose maturity was extended on November 5, 2018 up to 12 months, or until December 22, 2019, in exchange for making several payments of principal and interest through August 31, 2019, subject to customary conditions and achieving certain funding milestones. We also have $4.6 million of unsecured notes, all of which was due on demand as of such date. These matters raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. We anticipate incurring additional losses until such time, if ever, that we can generate significant sales of our product candidates currently in development. We will need substantial additional financing to fund our operations and to commercially develop our product candidates. Management is currently evaluating various strategic opportunities to obtain the required funding for future operations. These strategies may include, but are not limited to private placements of equity and/or debt, payments from potential strategic research and development, licensing and/or marketing arrangements with pharmaceutical companies, and public offerings of equity and/or debt securities. 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.

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 December 31, 2018, together with the $8.0 million proceeds from the sale and issuance of our common stock to BioLexis in January and February 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 June 2019, excluding any unscheduled repayment of debt. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We will need to raise substantial additional capital in order to complete our planned ONS-5010 development program. We plan to finance our future operations with a combination of proceeds from the issuance of equity securities, the issuance of additional debt, potential strategic collaborations, sale of the development and commercial rights to our drug product candidates and revenues from potential future product sales, if any. If we raise additional capital through the sale of equity or convertible debt securities, your ownership will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. There are no assurances that we will be successful in obtaining an adequate level of financing for the development and commercialization of ONS-5010 or any other current or future product candidates. Alternatively, we will be required to, among other things, make reductions in our workforce, scale back our plans and place certain activities on hold, discontinue our development programs, liquidate all or a portion of our assets, and/or seek protection under the provisions of the U.S. Bankruptcy Code.

Cash Flows

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

	Three months ended December 31,	
	2018	**2017**
Net cash used in operating activities	$ (9,803,686)	$ (8,671,077)
Net cash used in investing activities	(236,433)	(1,075,143)
Net cash provided by financing activities	8,528,133	20,398,480

Operating Activities.

During the three months ended December 31, 2018, we used $9.8 million of cash in operating activities resulting primarily from our net loss of $9.7 million, as well as an increase in cash outflows from working capital changes primarily due to payments of our outstanding accounts payable and accrued expenses from September 30, 2018. Our cash flows are impacted by our underlying results from operations and related timing of cash receipts and cash disbursements. During the three months ended December 31, 2017, we used $8.7 million of cash in operating activities, primarily resulting from our net loss of $1.9 million and the change in our operating assets and liabilities of $11.0 million. 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 three months ended December 31, 2018 and 2017, we used cash of $0.2 million and $1.1 million, respectively, in investing activities for the purchase of property and equipment.

Financing Activities.

During the three months ended December 31, 2018, net cash provided by financing activities was $8.5 million, primarily attributable to $11.8 million in net proceeds from the November 2018 BioLexis private placement. In November and December 31, 2018, we closed the sale of the first two tranches of this private placement for an aggregate of 12,865,872 shares of our common stock for gross cash proceeds of $12.0 million. We also made $3.3 million in debt and capital lease obligations payments.

During the three months ended December 31, 2017, net cash provided by financing activities was $20.4 million, primarily attributable to $20.6 million in net proceeds from our second closing of our Series A Convertible to BioLexis in October 2017. We also made $0.2 million in debt payments.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of December 31, 2018.

Contractual Obligations and Commitments

Not applicable.

Critical Accounting Policies and Significant Judgments and Estimates

The Critical Accounting Policies and Significant Judgments and Estimates included in our Form 10-K for the fiscal year ended September 30, 2018, filed with the SEC on December 18, 2018, have not materially changed with the exception of our revenue recognition policies.

On October 1, 2018, we adopted ASU No. 2014-09 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 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 which results in such amounts being recognized over the estimated performance period. For the three months ended December 31, 2018, we would have recognized $0.8 million of collaboration revenues under revenue recognition guidance in effect during fiscal 2018 prior to the adoption of ASU 2014-09.

JOBS Act Accounting Election

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Because there are inherent limitations in all control systems, a control system, no matter how well conceived and operated, can provide only reasonable, as opposed to absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective, at the reasonable assurance level, as of the end of the period covered by this report.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(d) and 15d-15(f) under the Exchange Act) that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting during our first fiscal quarter ended December 31, 2018.

Part II. Other Information

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

Not applicable.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Not applicable.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

EXHIBIT INDEX

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	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).
10.2	Separation Agreement and Release by and between the Registrant and Stephen J. McAndrew, Ph.D., effective as of November 26, 2018 (incorporated by reference to Exhibit 10.12 to the Registrant's annual report on Form 10-K filed with the SEC on December 18, 2018).
10.3+	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).
10.4	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).
10.5	Purchase Agreement by and between the Registrant and BioLexis Pte. Ltd., dated November 5, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on November 9, 2018).
10.6	Third Amendment to Investor Rights Agreement by and between the Registrant and BioLexis Pte. Ltd., dated November 5, 2018 (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K filed with the SEC on November 9, 2018).
31.1	Certification of Principal Executive and Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive and Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

+ Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been filed separately with the SEC.

* This certification is being furnished solely to accompany this Quarterly Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

SIGNATURES

Pursuant to the requirements of 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.

OUTLOOK THERAPEUTICS, INC.

Date: February 14, 2019

By: /s/ Lawrence A. Kenyon
Lawrence A. Kenyon
Chief Executive Officer and Chief Financial Officer
(Principal Executive, Accounting, and Financial Officer)

Exhibit 31.1

CERTIFICATIONS

I, Lawrence A. Kenyon, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Outlook Therapeutics, Inc.;

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 us 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; and

(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: February 14, 2019

By: /s/ Lawrence A. Kenyon
Lawrence A. Kenyon
Chief Executive Officer and Chief Financial Officer
(Principal Executive, Financial, and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Outlook Therapeutics, Inc. (the "Company") for the period ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 14, 2019

By /s/ Lawrence A. Kenyon
Lawrence A. Kenyon
Chief Executive Officer and Chief Financial Officer

"This certification accompanies the Form 10-Q 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 Outlook Therapeutics, Inc. 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 Form 10-Q), irrespective of any general incorporation language contained in such filing."