**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, 2019**
**or**

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

**For the transition period from to**

**Commission File 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)**

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

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

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 7, 2020 was 43,088,776.

**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, 2019 filed with the SEC on December 19, 2019, 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, 2019 | September 30, 2019 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash | $ 1,333,559 | $ 8,015,528 |
| Prepaid expenses and other current assets | 4,707,497 | 4,986,033 |
| Assets held for sale | 500,000 | 500,000 |
| Total current assets | 6,541,056 | 13,501,561 |
| | | |
| Property and equipment, net | 587,184 | 3,175,960 |
| Operating lease right-of-use assets, net | 282,107 | — |
| Finance lease right-of-use assets, net | 2,450,000 | — |
| Other assets | 562,748 | 457,476 |
| Total assets | $ 10,423,095 | $ 17,134,997 |
| | | |
| **Liabilities, convertible preferred stock and stockholders' equity (deficit)** | | |
| | | |
| Current liabilities: | | |
| Convertible senior secured notes | $ 7,065,928 | $ 6,699,000 |
| Current portion of long-term debt | 48,936 | 1,026,168 |
| Current portion of finance lease liabilities | 172,609 | 192,290 |
| Current portion of operating lease liabilities | 170,228 | — |
| Stockholder notes | 3,612,500 | 3,612,500 |
| Accounts payable | 2,567,995 | 2,277,817 |
| Accrued expenses | 4,602,769 | 4,622,988 |
| Income taxes payable | 1,859,434 | 1,859,434 |
| Total current liabilities | 20,100,399 | 20,290,197 |
| | | |
| Long-term debt | 38,011 | 50,285 |
| Redemption feature | 8,226,506 | — |
| Finance lease liabilities | 3,344,505 | 3,365,790 |
| Operating lease liabilities | 142,129 | — |
| Warrant liability | 54,356 | 255,734 |
| Other liabilities | 3,923,913 | 3,942,948 |
| Total liabilities | 35,829,819 | 27,904,954 |
| | | |
| 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, 68,112 shares issued and outstanding at December 31, 2019 and 66,451 shares issued and outstanding at September 30, 2019 | 5,525,537 | 5,359,404 |
| Total convertible preferred stock | 5,525,537 | 5,359,404 |
| | | |
| 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; 38,430,924 shares issued and outstanding at December 31, 2019 and 28,609,995 shares issued and outstanding at September 30, 2019 | 384,309 | 286,100 |
| Additional paid-in capital | 239,766,786 | 238,064,947 |
| Accumulated deficit | (271,083,356) | (254,480,408) |
| Total stockholders' equity (deficit) | (30,932,261) | (16,129,361) |
| Total liabilities, convertible preferred stock and stockholders' equity (deficit) | $ 10,423,095 | $ 17,134,997 |

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, | |
|---|---|---|
| | 2019 | 2018 |
| Collaboration revenues | $ — | $ 1,067,598 |
| Operating expenses: | | |
| Research and development | 5,847,302 | 6,071,522 |
| General and administrative | 2,336,724 | 2,903,988 |
| Impairment of property and equipment | — | 2,349,403 |
| | 8,184,026 | 11,324,913 |
| Loss from operations | (8,184,026) | (10,257,315) |
| Interest expense, net | 597,665 | 1,120,849 |
| Loss on extinguishment of debt | 8,060,580 | — |
| Change in fair value of redemption feature | (37,945) | — |
| Change in fair value of warrant liability | (201,378) | (1,636,320) |
| Net loss | (16,602,948) | (9,741,844) |
| Series A-1 convertible preferred stock dividends and related settlement | (166,133) | (150,508) |
| Deemed dividend upon modification of warrants | (1,708,603) | — |
| Net loss attributable to common stockholders | $ (18,477,684) | $ (9,892,352) |
| | | |
| Per share information: | | |
| Net loss per share of common stock, basic and diluted | $ (0.62) | $ (1.00) |
| Weighted average shares outstanding, basic and diluted | 29,901,285 | 9,843,540 |

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 | | Stockholders' Equity (Deficit) | | | | |
|---|---|---|---|---|---|---|---|
| | Series A-1 | | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Total Stockholders' Equity (Deficit) |
| | Shares | Amount | Shares | Amount | | | |
| Balance at October 1, 2019 | 66,451 | $5,359,404 | 28,609,995 | $ 286,100 | $ 238,064,947 | $(254,480,408) | $(16,129,361) |
| Issuance of common stock in connection with exercise of warrants | — | — | 8,345,562 | 83,455 | (25,177) | — | 58,278 |
| Issuance of common stock in connection with conversion of stockholder notes | — | — | 1,475,258 | 14,753 | 1,533,673 | — | 1,548,426 |
| Issuance of vested restricted stock units | — | — | 109 | 1 | (1) | — | — |
| Series A-1 convertible preferred stock dividends and related settlement | 1,661 | 166,133 | — | — | (166,133) | — | (166,133) |
| Stock-based compensation expense | — | — | — | — | 359,477 | — | 359,477 |
| Net loss | — | — | — | — | — | (16,602,948) | (16,602,948) |
| Balance at December 31, 2019 | 68,112 | $5,525,537 | 38,430,924 | $ 384,309 | $ 239,766,786 | $(271,083,356) | $(30,932,261) |

| | Convertible Preferred Stock | | Stockholders' Equity (Deficit) | | | | |
|---|---|---|---|---|---|---|---|
| | Series A-1 | | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Total Stockholders' Equity (Deficit) |
| | Shares | Amount | Shares | Amount | | | |
| Balance at October 1, 2018 | 60,203 | $4,734,416 | 9,027,491 | $ 90,275 | $ 190,672,166 | $(216,307,363) | $(25,544,922) |
| Cumulative effect of adoption of ASU 2014-09 (Topic 606) | — | — | — | — | — | (3,649,258) | (3,649,258) |
| Proceeds from exercise of common stock warrants | — | — | 554 | 6 | (6) | — | — |
| Private placement sale of common stock, net of costs | — | — | 1,608,234 | 16,082 | 11,794,776 | — | 11,810,858 |
| Issuance of vested restricted stock units | — | — | 144 | 1 | (1) | — | — |
| Series A-1 convertible preferred stock dividends and related settlement | 1,505 | 150,508 | — | — | (150,508) | — | (150,508) |
| Stock-based compensation expense | — | — | — | — | 872,289 | — | 872,289 |
| Accrued directors fees settled in fully vested stock options | — | — | — | — | 49,121 | — | 49,121 |
| Net loss | — | — | — | — | — | (9,741,844) | (9,741,844) |
| Balance at December 31, 2018 | 61,708 | $4,884,924 | 10,636,423 | $ 106,364 | $ 203,237,837 | $(229,698,465) | $(26,354,264) |

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, | |
|---|---|---|
| | 2019 | 2018 |
| **OPERATING ACTIVITIES** | | |
| Net loss | $ (16,602,948) | $ (9,741,844) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 175,341 | 823,077 |
| Loss on extinguishment of debt | 8,060,580 | — |
| Non-cash interest expense | 15,722 | 450,381 |
| Stock-based compensation | 359,477 | 872,289 |
| Change in fair value of redemption feature | (37,945) | — |
| Change in fair value of warrant liability | (201,378) | (1,636,320) |
| Impairment of property and equipment | — | 2,349,403 |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | 288,930 | (50,486) |
| Other assets | (115,666) | 21,913 |
| Operating lease liability | (39,815) | — |
| Accounts payable | 290,178 | (260,943) |
| Accrued expenses | 1,105,318 | (1,419,110) |
| Deferred revenue | — | (1,052,598) |
| Other liabilities | 28,530 | (137,137) |
| Net cash used in operating activities | (6,673,676) | (9,781,375) |
| **INVESTING ACTIVITIES** | | |
| Purchase of property and equipment | — | (236,433) |
| Net cash used in investing activities | — | (236,433) |
| **FINANCING ACTIVITIES** | | |
| Proceeds from the sale of common stock, net of offering costs | — | 11,885,833 |
| Proceeds from exercise of common stock warrants | 58,278 | — |
| Payments of finance lease obligations | (55,031) | (231,221) |
| Repayment of debt | (11,540) | (3,126,479) |
| Net cash (used in) provided by financing activities | (8,293) | 8,528,133 |
| Net decrease in cash | (6,681,969) | (1,489,675) |
| Cash at beginning of period | 8,015,528 | 1,717,391 |
| Cash at end of period | $ 1,333,559 | $ 227,716 |
| Supplemental disclosure of cash flow information | | |
| Cash paid for interest | $ 360,904 | $ 1,657,157 |
| Supplemental schedule of noncash investing activities: | | |
| Purchases of property and equipment in accounts payable and accrued expenses | $ — | $ 625,830 |
| Supplemental schedule of noncash financing activities: | | |
| Unsecured notes and accrued interest converted into common stock | $ 1,548,426 | $ — |
| Issuance of exchange notes at estimated fair value | $ 7,050,206 | $ — |
| Issuance of redemption feature at estimated fair value | $ 8,264,451 | $ — |
| Change in fair value of convertible senior secured notes warrants capitalized as deferred financing costs | $ — | $ 1,466,710 |
| Series A-1 convertible preferred stock dividends and related settlement | $ 166,133 | $ 150,508 |
| 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.

**Outlook Therapeutics, Inc.**
**Notes to Unaudited Interim Consolidated Financial Statements**

## 1. Organization and Description of Business

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

## 2. Liquidity

The Company has incurred substantial losses and negative cash flows from operations since its inception and has a stockholders' deficit of $30.9 million as of December 31, 2019. As of December 31, 2019, the Company had substantial indebtedness that included $7.6 million outstanding aggregate principal amount and accrued interest of senior secured notes that mature on December 31, 2020 and $3.6 million unsecured notes that were 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 unaudited interim 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 unaudited interim consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

On December 11, 2019, the Company received approval from the New Jersey Economic Development Authority's Technology Business Tax Certificate Transfer Program to sell approximately $3.6 million of its unused New Jersey net operating losses ("NOLs") and research and development tax credits ("R&D credits"). The Company expects to receive approximately $3.3 million of proceeds from the sale of the New Jersey NOLs and R&D credits in March 2020.

Management believes that the Company's existing cash as of December 31, 2019, the $1.1 million of cash proceeds from the exercise of warrants in January 2020, and the $3.3 million of proceeds from the sale of New Jersey NOLs and R&D credits expected to be received in March 2020, will be sufficient to fund its operations through March 2020, excluding any repayment of debt. Substantial additional financing will be needed by the Company to fund its operations in the future and to commercially develop its product candidates. Management is currently evaluating different strategies to obtain the required funding for future operations. These strategies may include but are not limited to: payments from potential strategic research and development partners, licensing and/or marketing arrangements with pharmaceutical companies, private placements of equity and/or debt securities, sale of its development stage product candidates to third parties and public offerings of equity and/or debt securities. There can be no assurance that these future funding efforts will be successful.

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

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

### Basis of presentation

The accompanying 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").

**Outlook Therapeutics, Inc.**
**Notes to Unaudited Interim Consolidated Financial Statements**

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, 2019 and its results of operations for the three months ended December 31, 2019 and 2018, cash flows for the three months ended December 31, 2019 and 2018, and convertible preferred stock and stockholders' equity for the three months ended December 31, 2019 and 2018. Operating results for the three months ended December 31, 2019 are not necessarily indicative of the results that may be expected for the full year ending September 30, 2020. 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, 2019 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on December 19, 2019.

**Reverse stock-split**

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

**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 attributable to common stockholders by the weighted-average number of shares of common stock 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. For all periods presented, there is no difference in the number of shares used to compute basic and diluted shares due to the Company's loss.

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

| | Three months ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Net loss attributable to common stockholders | $ (18,477,684) | $ (9,892,352) |
| Common stock outstanding (weighted average) | 29,901,285 | 9,843,540 |
| Basic and diluted net loss per share | $ (0.62) | $ (1.00) |

**Outlook Therapeutics, Inc.**
**Notes to Unaudited Interim Consolidated Financial Statements**

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, 2019 and 2018, as they would be antidilutive:

| | As of December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Series A-1 convertible preferred stock | 1,287,178 | 1,166,156 |
| Convertible senior secured notes | — | 1,162,994 |
| Performance-based stock units | 2,470 | 16,136 |
| Restricted stock units | — | 7,457 |
| Stock options | 1,791,500 | 386,247 |
| Common stock warrants | 5,559,763 | 5,661,015 |

**Recently issued and adopted accounting pronouncements**

On October 1, 2019, the Company adopted ASU No. 2016-02, *Leases* ("ASC 842" or "ASU 2016-02") issued by the FASB in February 2016 which was subsequently supplemented by clarifying guidance to improve financial reporting of leasing transactions. The new lease accounting guidance requires lessees to recognize lease liabilities and right-of-use assets on the balance sheet for all leases with initial terms longer than 12 months and provides enhanced disclosures on key information of leasing arrangements. The guidance allowed companies to apply the requirements retrospectively, either to all prior periods presented or through a cumulative adjustment in the year of adoption.

The Company adopted the new standards effective October 1, 2019 using the modified retrospective transition method using the package of practical expedients and a discount rate of 9% and elected to not apply the standard in the comparative periods presented in the year of adoption. The Company has implemented the internal controls to monitor and record historical and future lease arrangements and required disclosures. For all existing operating leases as of September 30, 2019, the Company recorded right of use assets of $352,172 and corresponding lease liabilities of $318,672 with an offset to other liabilities of $33,500 to eliminate deferred rent on the consolidated balance sheets. The Company recorded right of use assets of $2,525,000 and corresponding finance lease liabilities of $3,558,080 for leases previously classified as capital leases. This did not include an existing lease termination obligation of approximately $3,909,448 pertaining to a lease for the Company's planned office and laboratory expansion space in Cranbury, New Jersey that remained unchanged as a result of the transition. Refer to Note 9 for the Company's lease disclosures.

At lease commencement, the Company records a lease liability based on the present value of lease payments over the expected lease term including any options to extend the lease that the Company is reasonably certain to exercise. The Company calculates the present value of lease payments using an incremental borrowing rate as the Company's leases do not provide an implicit interest rate. The Company's incremental borrowing rate for a lease is the rate of interest it would have to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms. At the lease commencement date, the Company records a corresponding right-of-use lease asset based on the lease liability, adjusted for any lease incentives received and any initial direct costs paid to the lessor prior to the lease commencement date. The Company may enter into leases with an initial term of 12 months or less ("Short-Term Leases"). For Short-Term Leases, the Company records the rent expense on a straight-line basis and does not record the leases on the consolidated balance sheet. The Company had no Short-Term Leases as of December 31, 2019.

After lease commencement, the Company measures its leases as follows: (i) the lease liability based on the present value of the remaining lease payments using the discount rate determined at lease commencement and (ii) the right-of-use lease asset based on the re-measured lease liability, adjusted for any unamortized lease incentives received, any unamortized initial direct costs and the cumulative difference between rent expense and amounts paid under the lease agreement. Any lease incentives received, and any initial direct costs are amortized on a straight-line basis over the expected lease term. Rent expense is recorded on a straight-line basis over the expected lease term.

The adoption of the new lease accounting standard did not have a material impact on the Company's results of operations or cash flows.

**Outlook Therapeutics, Inc.**
**Notes to Unaudited Interim 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* ("ASU 2018-13"), which removes and modifies some existing disclosure requirements and adds others. ASU 2018-13 modifies the disclosure requirements for fair value measurements and removes the requirement to disclose (1) the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, (2) the policy for timing of transfers between levels, and (3) the valuation processes for Level 3 fair value measurements. ASU 2018-13 requires disclosure of changes in unrealized gains and losses for the period included in other comprehensive income (loss) for recurring Level 3 fair value measurements held at the end of the reporting period and the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. The ASU is effective for all entities for fiscal years beginning after December 15, 2019, including interim periods therein. Early adoption is permitted for any eliminated or modified disclosures upon issuance of this ASU. The Company is currently evaluating the impact of the adoption of this standard.

**Reclassifications**

Certain reclassifications have been made to the prior year financial statements to conform to the current year presentation.

**4. Fair Value Measurements**

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

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

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

**Outlook Therapeutics, Inc.**
**Notes to Unaudited Interim Consolidated Financial Statements**

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

| | December 31, 2019 | | |
|---|---|---|---|
| | (Level 1) | (Level 2) | (Level 3) |
| **Liabilities** | | | |
| Redemption feature | $ — | $ — | $ 8,226,506 |
| Warrant liability | — | — | 54,356 |
| | $ — | $ — | $ 8,280,862 |

| | September 30, 2019 | | |
|---|---|---|---|
| | (Level 1) | (Level 2) | (Level 3) |
| **Liabilities** | | | |
| Redemption feature | $ — | $ — | $ — |
| Warrant liability | — | — | 255,734 |
| | $ — | $ — | $ 255,734 |

The Company evaluated a redemption feature within the senior secured notes issued in December 2019 and determined bifurcation of the redemption feature was required. The redemption feature is accounted for as a derivative instrument and re-measured at each reporting period until the redemption feature is exercised, expires, or otherwise settled.

The table presented below is a summary of changes in the fair value of the Company's Level 3 valuation for the warrant liability and redemption feature for the three months ended December 31, 2019:

| | Warrants | Redemption Feature |
|---|---|---|
| Balance at October 1, 2019 | $ 255,734 | $ — |
| Addition of feature on December 20, 2019 | — | 8,264,451 |
| Change in fair value | (201,378) | (37,945) |
| Balance at December 31, 2019 | $ 54,356 | $ 8,226,506 |

The warrants issued in connection with the senior secured notes (see Note 7) are classified as liabilities on the accompanying consolidated balance sheet as the 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, 2019 | September 30, 2019 |
|---|---|---|
| Risk-free interest rate | 1.70 % | 1.56 % |
| Remaining contractual life of warrant | 5.13 years | 5.38 years |
| Expected volatility | 88 % | 89 % |
| Annual dividend yield | 0 % | 0 % |
| Fair value of common stock | $ 0.59 per share | $ 1.49 per share |

The fair value of the redemption feature is estimated by using a Monte Carlo simulation model and a with-and-without perspective, where the fair value of debt instrument is measured with the derivative and without the derivative and the difference is the implied fair value of the redemption feature. The value of the debt instrument with the redemption feature depends on the daily stock price path followed by the Company's common stock price. This model simulates daily common stock prices from the issuance date thru the maturity date for the debt instrument. At issuance, the Company utilized a volatility estimate of 130% based upon the observed historical volatility of both the Company and peer group for 1-year and 2-year periods. Risk-free interest rate was based upon US treasury yields.

**Outlook Therapeutics, Inc.**
**Notes to Unaudited Interim Consolidated Financial Statements**

## 5. Property and Equipment, Net

Property and equipment, net, consists of:

| | December 31, 2019 | September 30, 2019 |
|---|---|---|
| Laboratory equipment | $ 1,067,351 | $ 1,067,351 |
| Leasehold improvements | 160,086 | 160,086 |
| Land and building | — | 3,000,000 |
| | 1,227,437 | 4,227,437 |
| Less: accumulated depreciation and amortization | (640,253) | (1,051,477) |
| | $ 587,184 | $ 3,175,960 |

Depreciation and amortization expense was $63,776 and $823,077 for the three months ended December 31, 2019 and 2018, respectively.

On October 1, 2019, the Company adopted ASC 842, which resulted in the reclassification of property and equipment under capital leases to finance lease right-of-use assets separately disclosed on the consolidated balance sheets. Refer to Note 9 for the Company's lease disclosures.

At September 30, 2019, $3,000,000 represented the Company's corporate office lease that was classified as a capital lease. The Company's corporate office lease matures in February 2028 and the effective interest rate on the corporate office lease is 43.9%. At September 30, 2019, $475,000 of accumulated amortization related to capital leases.

**Impairment Charge**

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 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 outsource the manufacturing of ONS-5010.

## 6. Accrued Expenses

Accrued expenses consists of:

| | December 31, 2019 | September 30, 2019 |
|---|---|---|
| Compensation | $ 969,399 | $ 919,394 |
| Severance and related costs | 389,558 | 505,570 |
| Research and development | 2,765,669 | 1,692,040 |
| Interest payable | 23,125 | 934,145 |
| Professional fees | 285,747 | 419,216 |
| Other accrued expenses | 169,271 | 152,623 |
| | $ 4,602,769 | $ 4,622,988 |

**Outlook Therapeutics, Inc.**
**Notes to Unaudited Interim Consolidated Financial Statements**

## 7. Debt

### Senior secured notes

| | December 31, 2019 | September 30, 2019 |
|---|---|---|
| Convertible senior secured notes | $ 7,589,027 | $ 6,699,000 |
| Unamortized debt discount | (523,099) | — |
| | $ 7,065,928 | $ 6,699,000 |

In December 2019, the Company entered into an exchange agreement with the holders of its approximately $7.3 million outstanding aggregate principal amount and accrued interest of senior secured notes (the "Old Senior Notes") originally issued pursuant to the certain Note and Warrant Purchase Agreement dated December 22, 2017, as amended on April 13, 2017, November 5, 2018, and June 28, 2019 (the "Exchange Agreement"). Pursuant to the Exchange Agreement, the holders of the Old Senior Notes exchanged the entire outstanding principal and accrued interest for new senior secured notes having an aggregate outstanding original principal amount of $7.6 million, which includes an aggregate exchange fee of approximately $0.3 million.

The new senior secured notes are substantially similar to the Old Senior Notes, as amended through the date of the Exchange Agreement, bear interest at a rate of 12.0% per annum and will mature December 31, 2020 (subject to extension to June 30, 2021 at the Company's option upon payment of an extension fee equal to 3% of the outstanding balance and being in compliance with applicable Nasdaq listing requirements). The new senior secured notes are convertible, at the option of the holder, beginning April 1, 2020, into shares of the Company's common stock at a conversion price equal to 90% of the two lowest closing bid prices in the 20 trading days immediately preceding such conversion, subject to a floor price of $0.232 per share. In the event the conversion price is lower than the floor price for 20 consecutive trading days, the Company is required to make a cash redemption equal to $350,000 (provided that it shall not be required to make more than one redemption in any calendar month, nor shall a trading day where the conversion price is lower than the floor price be included in more than one 20-trading day period). The conversion feature was determined to be a redemption feature and was bifurcated from the debt instrument. The estimated fair value of the redemption feature was $8.3 million at issuance (see Note 4).

The Exchange Agreement was accounted for as an extinguishment of debt. Loss on extinguishment of convertible senior secured notes recognized during the three months ended December 31, 2019 was $8.0 million and equal to the excess fair value of the notes and bifurcated redemption feature over the notes' net carrying value.

Aggregate interest expense on the Old Senior Notes and the new senior secured notes for the three months ended December 31, 2019 and 2018 was $201,521 and $151,052, respectively.

### Stockholder Notes

The Company previously repurchased shares of its restricted stock in exchange for notes in the amount of $800,000 that do not bear interest and are due on demand.

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

**Outlook Therapeutics, Inc.**
**Notes to Unaudited Interim Consolidated Financial Statements**

## 8. Other Indebtedness

The Company has other outstanding debt consisting of equipment loans and unsecured notes.

| | December 31, 2019 | September 30, 2019 |
|---|---|---|
| Unsecured notes | $ — | $ 977,966 |
| Equipment loans | 86,947 | 98,487 |
| | 86,947 | 1,076,453 |
| Less: current portion | (48,936) | (1,026,168) |
| Long-term debt | $ 38,011 | $ 50,285 |

On March 7, 2019, the Company entered into a Forbearance and Exchange Agreement (the "Agreement") with Iliad Research and Trading, L.P., a Utah limited partnership (the "Lender"). Concurrently with the execution of this Agreement, the Lender purchased two stockholder notes issued by the Company previously in the original principal amount of $1,000,000 with an aggregate outstanding balance as of March 7, 2019 of $1,947,133 including accrued interest. The stockholder notes were accruing interest at the rate of 2.5% per month. The Lender agreed to refrain and forbear from bringing any action to collect under the stockholder notes until March 7, 2020 and to reduce the interest rates currently in effect to 12.0% per annum simple interest during such forbearance period. The Company also agreed to, at Lender's election, repay or exchange the stockholder notes (or portions thereof) for shares of the Company's common stock at an exchange rate of $13.44 per share or, beginning September 2019, at 95% of the average of the two lowest closing bid prices in the prior twenty trading days, as applicable.

In September 2019, the Lender began exchanging the outstanding principal and accrued interest from those notes for the Company’s common stock per the terms of a forbearance agreement dated March 7, 2019. During the three months ended December 31, 2019, the remaining unsecured notes with a carrying amount of $977,966 and accrued interest of $570,460 were exchanged for 1,475,258 shares of the Company’s common stock at a weighted average exchange price of $1.10. As of December 31, 2019, these unsecured notes were no longer outstanding.

During the three months ended December 31, 2019 and 2018, the Company recognized interest expense related to the unsecured notes of $12,997 and $75,000, respectively.

## 9. Leases

The Company has finance leases for its corporate office and a commitment under an operating lease for warehouse space in the State of New Jersey. The Company’s leases for the corporate office and warehouse mature in February 2028 with two five-year renewal options and in September 2021, respectively. The terms of the equipment leases are between 12 and 36 months and are recorded as finance 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%. Certain lease agreements contain provisions for future rent increases. Payments due under the lease contracts include minimum payments that the Company is obligated to make under the non-cancelable initial terms of the leases as the renewal terms are at the Company’s option. Lease expense is included in research and development or general and administrative based on the use of the lease asset.

**Outlook Therapeutics, Inc.**
**Notes to Unaudited Interim Consolidated Financial Statements**

The components of lease cost for the three-month period ended December 31, 2019 are as follows:

| | Three months ended December 31, 2019 |
|---|---|
| **Finance lease cost:** | |
| Amortization of right-of-use assets | $ 75,000 |
| Interest on lease liabilities | 372,223 |
| Total finance lease cost | 447,223 |
| Operating lease cost | 43,625 |
| Total lease cost | $ 490,848 |

Amounts reported in the consolidated balance sheets for leases where the Company is the lessee as of December 31, 2019 were as follows:

| | December 31, 2019 |
|---|---|
| **Operating leases:** | |
| Right-of-use asset | $ 282,107 |
| Operating lease liabilities | 312,357 |
| **Finance leases:** | |
| Right-of-use asset | $ 2,450,000 |
| Financing lease liabilities | 3,517,114 |
| **Weighted-average remaining lease term (years):** | |
| Operating leases | 1.8 |
| Finance leases | 7.7 |
| **Weighted-average discount rate:** | |
| Operating leases | 9.0% |
| Finance leases | 41.8% |

Other information related to leases for the three-month period ended December 31, 2019 are as follows:

| | Three months ended December 31, 2019 |
|---|---|
| **Cash paid for amounts included in the measurement of lease obligations:** | |
| Operating cash flows from finance leases | $ 358,159 |
| Operating cash flows from operating leases | 46,875 |
| Financing cash flows from finance leases | 55,031 |
| **Right-of-use assets obtained in exchange for lease obligations:** | |
| Operating leases | $ — |
| Finance leases | — |

**Outlook Therapeutics, Inc.**
**Notes to Unaudited Interim Consolidated Financial Statements**

Future minimum lease payments under non-cancelable leases as of December 31, 2019 are as follows for the years ending September 30:

| | Operating leases | Finance leases |
|---|---|---|
| 2020 (remaining nine months) | $ 140,625 | $ 1,208,977 |
| 2021 | 195,000 | 1,518,146 |
| 2022 | — | 1,535,809 |
| 2023 | — | 1,564,028 |
| 2024 | — | 1,597,371 |
| Thereafter | — | 5,753,515 |
| Total undiscounted lease payments | $ 335,625 | $ 13,177,846 |
| Less: Imputed interest | 23,268 | 9,660,732 |
| Total lease obligations | $ 312,357 | $ 3,517,114 |

Future minimum rental payments under non-cancelable leases prior to adoption of ASC 842, Leases, as of September 30, 2019 were as follows:

| | Operating leases | Finance leases |
|---|---|---|
| 2020 | $ 187,500 | $ 1,608,067 |
| 2021 | 195,000 | 1,506,592 |
| 2022 | — | 1,535,809 |
| 2023 | — | 1,564,027 |
| 2024 | — | 1,593,291 |
| Thereafter | — | 5,691,492 |
| Total undiscounted lease payments | $ 382,500 | $ 13,499,278 |
| Less: Imputed interest | — | 9,941,198 |
| Total lease obligations | $ 382,500 | $ 3,558,080 |

**Lease termination obligation**

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, 2019, the lease termination obligation of $3,923,913 is included in other liabilities on the consolidated balance sheets. A roll forward of the charges incurred to general and administrative expense for the three months ended December 31, 2019 is as follows:

| | Balance October 1, 2019 | Expensed / Accrued Expense | Cash Payments | Balance December 31, 2019 |
|---|---|---|---|---|
| Lease termination payments | $ 3,909,448 | $ 164,465 | $ (150,000) | $ 3,923,913 |

**Outlook Therapeutics, Inc.**
**Notes to Unaudited Interim Consolidated Financial Statements**

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

### Common stock

During the three months ended December 31, 2018, the Company issued an aggregate of 1,608,234 shares of the Company's common stock for gross cash proceeds of $12.0 million ($11.8 million net of issuance costs) pursuant to the November 5, 2018 private placement agreement with BioLexis Pte. Ltd. ("BioLexis").

During the three months ended December 31, 2019 and 2018, the Company issued 109 and 144 shares of common stock, respectively, upon the vesting of RSUs.

### 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 "Certificate of Designation"). The shares of Series A-1 have a stated value of $100.00 per share, and rank senior to all junior securities (as defined in the Certificate of Designation).

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

At December 31, 2019, 68,112 shares of Series A-1 would be convertible into 1,287,178 shares of common stock. During the three months ended December 31, 2019, the Company issued 1,661 shares of Series A-1 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.

**Outlook Therapeutics, Inc.**
**Notes to Unaudited Interim Consolidated Financial Statements**

Refer to Note 13 for detailed discussion of proposed changes to the Series A-1 to be effected after December 31, 2019.

**Common stock warrants**

As of December 31, 2019, shares of common stock issuable upon the exercise of outstanding warrants were as follows:

| Expiration Date | Shares of common stock issuable upon exercise of warrants | Exercise Price Per Share | |
|---|---|---|---|
| February 18, 2022 | 416,666 | $ 12.00 | |
| December 22, 2024 | 277,122 | $ 12.00 | |
| April 13, 2025 | 145,686 | $ 12.00 | |
| May 31, 2025 | 62,437 | $ 12.00 | |
| October 31, 2025 | 2,093,750 | $ 7.20 | (i) |
| May 10, 2026 | 1,282,051 | $ 7.80 | (i) |
| June 8, 2026 | 1,282,051 | $ 7.80 | (i) |
| | 5,559,763 | | |

(i) On January 27, 2020, the Company amended the exercise price of its outstanding warrants to purchase an aggregate 4,657,852 shares of its common, all of which were held by BioLexis, the Company's controlling stockholder, to $0.232 per share. BioLexis exercised all such warrants for cash payment of approximately $1.1 million on January 29, 2020.

On December 23, 2019, the Company amended the terms of its outstanding 15-month warrants and five-year warrants issued April 12, 2019 (the "April 2019 Warrants"), which originally had an exercise price of $2.90 per share of the Company's common stock. The exercise price of all outstanding April 2019 Warrants was reduced to $0.2320 per share and the exercise period was amended such that all April 2019 Warrants expire on December 24, 2019. Immediately prior to expiration, all then unexercised April 2019 Warrants were automatically net exercised pursuant to the amended provisions.

During the three months ended December 31, 2019, warrants topurchase an aggregate of 10,427,388 shares of common stock with a weighted averaged exercise price of $0.232 were exercised for an aggregate 8,345,562 shares of the Company's common stock; and warrants to purchase an aggregate of 80,797 shares of common stock with a weighted averaged exercise price of $0.08 expired. Of these exercised warrants, 10,157,050 of them were April 2019 Warrants, described above, exercised pursuant to the net exercise provisions therein, as amended.

**11. Stock-Based Compensation**

**2011 Equity Incentive Plan**

The Company's 2011 Equity Compensation Plan (the "2011 Plan") provided for the Company to sell or issue restricted common stock, RSUs, performance-based awards ("PSUs"), cash-based awards or to grant stock options for the purchase of common stock to officers, employees, consultants and directors of the Company. The 2011 Plan was administered by the board of directors or, at the discretion of the board of directors, by a committee of the board. The number of shares of common stock reserved for issuance under the 2011 Plan is 106,490. As of December 31, 2019, PSUs representing 2,470 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.

**Outlook Therapeutics, Inc.**
**Notes to Unaudited Interim Consolidated Financial Statements**

**2015 Equity Incentive Plan**

In December 2015, the Company adopted the 2015 Plan. The 2015 Plan provides for the grant of stock options, stock appreciation rights, restricted stock awards, RSU awards, performance stock awards and other forms of equity compensation to Company employees, directors and consultants. The aggregate number of shares of common stock authorized for issuance pursuant to the Company's 2015 Plan is 2,869,598. As of December 31, 2019, 908,449 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 one 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, 2019 and 2018:

| | Three months ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Research and development | $ 107,790 | $ 91,209 |
| General and administrative | 251,687 | 781,080 |
| | $ 359,477 | $ 872,289 |

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, 2019, 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, 2019 | 1,389,999 | $ 3.46 | |
| Granted | 558,084 | 1.40 | |
| Forfeited | (156,583) | 3.02 | |
| Balance at December 31, 2019 | 1,791,500 | 2.85 | 9.7 |
| Vested and exercisable | 245,111 | 4.63 | 8.6 |
| Vested and expected to vest at December 31, 2019 | 1,791,500 | $ 2.85 | 9.7 |

As of December 31, 2019, the aggregate intrinsic value of options outstanding was zero. The aggregate intrinsic value represents the total amount by which the fair value of the common stock subject to options exceeds the exercise price of the related options.

**Outlook Therapeutics, Inc.**
**Notes to Unaudited Interim Consolidated Financial Statements**

The weighted average grant date fair value of the options awarded to employees for the three months ended December 31, 2019 and 2018 was $0.99 and $5.16 per option, respectively. The fair value of the options was estimated on the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions:

| | December 31, 2019 | September 30, 2019 |
|---|---|---|
| Risk-free interest rate | 1.36 % | 2.02 % |
| Expected life (years) | 5.34 | 6.14 |
| Expected volatility | 88.6 % | 92.7 % |
| Expected dividend yield | — | — |

As of December 31, 2019, there was $3,306,331 of unrecognized compensation expense that is expected to be recognized over a weighted-average period of 2.96 years.

**Performance-based stock units**

The Company has issued PSUs, which generally have a ten-year life from the date of grant. Upon exercise, the PSU holder receives common stock or cash at the Company's discretion.

The following table summarizes the activity related to PSUs during the three months ended December 31, 2019:

| | Number of PSUs | Base Price Per PSU | Weighted Average Remaining Contractual Term (Years) |
|---|---|---|---|
| Balance at October 1, 2019 | 15,691 | $ 49.97 | |
| Forfeitures | (13,221) | 50.60 | |
| Balance at December 31, 2019 | 2,470 | 49.97 | 4.7 |
| Vested and exercisable at December 31, 2019 | 2,470 | 49.97 | 4.7 |
| Vested and expected to vest at December 31, 2019 | 2,470 | $ 49.97 | 4.7 |

**Restricted stock units**

The following table summarizes the activity related to RSUs during the three months ended December 31, 2019:

| | Number of RSUs | Weighted Average Grant Date Fair Value |
|---|---|---|
| Balance at October 1, 2019 | 109 | $ 150.24 |
| Vested and settled | (109) | 150.24 |
| Balance at December 31, 2019 | — | $ — |

**Outlook Therapeutics, Inc.**
**Notes to Unaudited Interim Consolidated Financial Statements**

## 12. Related-Party Transactions

### MTTR - Strategic Partnership Agreement (ONS-5010)

In February 2018, the Company entered into a strategic partnership agreement with MTTR, LLC ("MTTR") to advise on regulatory, clinical and commercial strategy and assist in obtaining approval of ONS-5010, the Company's bevacizumab therapeutic product candidate for ophthalmic indications. MTTR earned an aggregate $611,424 and $290,480 during the three months ended December 31, 2019 and 2018, respectively, which includes monthly consulting fees and expense reimbursement. As of December 31, 2019, and September 30, 2019, amounts due to MTTR were $421,354 and $365,301, respectively, which amounts are included in accrued expenses in the accompanying consolidated balance sheets.

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. Mr. Dagnon and Mr. Evanson are both principals in MTTR. The Company did not pay Mr. Dagnon or Mr. Evanson any direct compensation as consultants or as employees during the three months ended December 31, 2019 or 2018. Both Mr. Dagnon and Mr. Evanson were 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 strategic partnership agreement. Mr. Dagnon and Mr. Evanson have also agreed to provide consulting services to an affiliate of BioLexis pursuant to a separate arrangement.

Refer to Note 13 for a detailed discussion of changes to the MTTR strategic partnership agreement effected after December 31, 2019.

## 13. Subsequent Events

### Series A-1 Convertible Preferred Stock

On January 27, 2020, the Company entered into an agreement with BioLexis, whereby the Company agreed to seek stockholder approval to amend the terms of the Series A-1, and the issuance of its common stock pursuant to such amended terms, and BioLexis agreed to promptly convert its shares of Series A-1 pursuant to such amended terms, and in any event, within five business days of stockholder approval thereof. As proposed to be amended, the effective conversion rate will be increased from the current $18.89797 per share to $431.03447263 per share, which, if approved, would result in 29,358,621 shares issuable upon conversion of the 68,112 shares of Series A-1 outstanding (or an effective conversion rate of $0.232 per share). The Series A-1 rank senior to the common equity and have protective provisions, as well as a current redemption premium of $37.5 million and a liquidation preference of $40.9 million, all of which will be eliminated if converted to common stock.

### MTTR - Strategic Partnership Agreement (ONS-5010)

On January 27, 2020, the Company entered into a termination agreement and mutual release with MTTR to terminate the strategic partnership agreement. Pursuant to the agreement, the Company agreed (x) to issue to the four principals of MTTR (who include two of its named executive officers, Messrs. Dagnon and Evanson), an aggregate of 7,244,739 shares of its common stock, subject to stockholder approval, (y) to enter into consulting agreements with each of the four principals setting forth the terms of his respective compensation arrangement, and (z) to pay MTTR a one-time settlement fee of $110,000, upon effectiveness of the agreement. The termination agreement is effective upon stockholder approval of the share issuance.

Concurrently, the Company also entered into consulting agreements directly with each of the four principals of MTTR setting forth the terms of his respective compensation arrangement, as well as providing for certain transfer restrictions and repurchase rights applicable to the shares of common stock to be issued pursuant thereto. The consulting agreements are effective upon stockholder approval of the share issuances contemplated thereby.

**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, 2019 and 2018 included in our Annual Report on Form 10-K for the year ended September 30, 2019, filed with the Securities and Exchange Commission, or SEC, on December 19, 2019.*

***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, 2019, filed with the SEC on December 19, 2019, 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 working to develop the first ophthalmic formulation of bevacizumab approved by the U.S. Food and Drug Administration, or FDA, for use in retinal indications. Our goal is to launch ONS-5010 as the first and only approved bevacizumab in the United States, Europe, Japan and other markets for the treatment of wet age-related macular degeneration, or wet AMD, diabetic macular edema, or DME, and branch retinal vein occlusion, or BRVO.

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

Our Phase 3 program for ONS-5010 in wet AMD involves two clinical trials, which we refer to as NORSE 1 and NORSE 2, evaluating ONS-5010 against ranibizumab (LUCENTIS). Enrollment in the NORSE 1 study is complete with 61 patients enrolled, all in Australia. The endpoint for NORSE 1 is the difference in mean change from baseline in visual acuity at 11 months for ONS-5010 dosed on a monthly basis compared to LUCENTIS dosed using the alternative PIER clinical trial dosing regimen of three monthly doses followed by quarterly dosing. While not designed as a pivotal study, NORSE 1 is one of two studies agreed upon with the FDA in April 2018 and will provide initial safety and efficacy data relating to ONS-5010 in wet AMD patients. We expect to report top line data from NORSE 1 in August 2020.

The NORSE 2 study began enrolling wet AMD patients in July 2019. NORSE 2 is expected to enroll a total of at least 220 patients and is being conducted in the United States. With agreement from the FDA, we have made a change to the endpoint for NORSE 2 by changing the primary endpoint to the difference in proportion of participants who gain at least 15 letters in the best corrected visual acuity, or BCVA, at 11 months for ONS-5010 dosed on a monthly basis compared to LUCENTIS dosed using the alternative PIER clinical trial dosing regimen. Previously, this had been the key secondary endpoint for NORSE 2. The previous primary endpoint, mean change from baseline in visual acuity, will still be measured as a key secondary endpoint. This revised endpoint is a standard measure of success for the treatment of wet AMD and is

expected to further enhance the probability for a positive outcome from the pivotal NORSE 2 clinical trial. Enrollment in NORSE 2 is expected to be completed no later than the end of May 2020.

In addition, we received agreements from the FDA on three Special Protocol Assessments (SPAs) for three additional registration clinical trials for our ongoing Phase 3 program for ONS-5010. These SPAs cover the protocols for NORSE 4, a registration clinical trial to treat branch retinal vein occlusion (BRVO), and NORSE 5 and NORSE 6, two registration clinical trials to treat diabetic macular edema (DME).

Currently, the cancer drug Avastin (bevacizumab) is used off-label for the treatment of wet AMD and other retinal diseases such as DME and BRVO even though Avastin has not been approved by regulatory authorities for use in these diseases. If the ONS-5010 clinical program is successful, it will support our plans to submit for regulatory approval in multiple markets in 2021 including the United States, Europe and Japan, as well as other markets. Because there are no approved bevacizumab products for the treatment of retinal diseases in such major markets, we are developing ONS-5010 as a standard Biologics License Application, or BLA and not using the biosimilar drug development pathway that would be required if Avastin were an approved drug for the targeted diseases. If approved, we believe ONS-5010 has potential to mitigate risks associated with off-label use of bevacizumab. Off-label use of bevacizumab is currently estimated to account for at least 50% of all wet AMD prescriptions in the United States.

**Going Concern**

Through December 31, 2019, we have funded substantially all of our operations with $241.4 million in proceeds from the sale and issuance of our equity and debt securities. We have also received $29.0 million pursuant to our collaboration and licensing agreements.

Our current cash resources of $1.3 million as of December 31, 2019, the $1.1 million of cash proceeds received in January 2020 from the exercise of warrants, and the anticipated $3.3 million of proceeds from the sale of our New Jersey net operating losses, or NOLs, and research and development, or R&D, credits expected to be received in March 2020 are expected to fund our operations through March 2020 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 ONS-5010. If we are not successful in raising additional capital or entering into one or more licensing and/or co-development rights agreements, we may be required to, among other things, modify our clinical trial plans for ONS-5010 in additional indications, make reductions in our workforce, discontinue our development programs, liquidate all or a portion of our assets, and/or seek protection under the provisions of the U.S. Bankruptcy Code.

We do not have any products approved for sale and we have only generated revenue from our collaboration agreements. We have incurred operating losses and negative operating cash flows since inception and there is no assurance that we will ever achieve profitable operations, and if achieved, that profitable operations will be sustained. Our net loss for the three months ended December 31, 2019 was $16.6 million. In addition, development activities, clinical and preclinical testing and commercialization of our product candidates will require significant additional financing.

In December 2019, we received approval from the New Jersey Economic Development Authority's Technology Business Tax Certificate Transfer Program to sell approximately $3.6 million of our unused New Jersey NOLs and R&D credits. We expect to receive approximately $3.3 million of proceeds from the sale of the New Jersey NOLs and R&D credits during March 2020.

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

In December 2019, we entered into an exchange agreement with the holders of our approximately $7.3 million outstanding aggregate principal amount and accrued interest of senior secured notes originally issued pursuant to the certain Note and Warrant Purchase Agreement dated December 22, 2017, as amended on April 13, 2017, November 5, 2018, and June 28,

2019. Pursuant to the exchange agreement, the holders of the senior secured notes exchanged the entire outstanding principal and accrued interest for new senior secured notes having an aggregate outstanding original principal amount of $7.6 million, which includes an aggregate exchange fee of approximately $0.3 million. The new senior secured notes are substantially similar to the old senior secured notes, as amended through the date of the exchange, bear interest at a rate of 12.0% per annum and will mature December 31, 2020 (subject to extension to June 30, 2021 at our option upon payment of an extension fee equal to 3% of the outstanding balance), and are secured by all of our assets pursuant to the same security agreements applicable to the old notes. The new senior secured notes are convertible, at the option of the holder, from time to time beginning April 1, 2020, into shares of our common stock at a conversion price equal to 90% of the two lowest closing bid prices in the 20 trading days immediately preceding such conversion, subject to a floor price of $0.232 per share (added by amendment in January 2020). Under the January amendment, we also agreed to redeem $350,000 of the new senior secured notes for cash in the event that the conversion price does not exceed the floor price for 20 consecutive trading days (although we will not be required to make more than one redemption in any calendar month, and no trading day will be included in more than one 20-day period for purposes of determining if a redemption is payable).

We have incurred recurring losses and negative cash flows from operations since inception and had a stockholders' deficit at December 31, 2019 of $30.9 million. As of December 31, 2019, we had substantial indebtedness that included $7.6 million outstanding aggregate principal amount and accrued interest of senior secured notes that mature on December 31, 2020 and $3.6 million of unsecured notes that are due on demand. We will need to raise substantial additional capital to fund our planned future operations, commence clinical trials, receive approval for and commercialize ONS-5010, or to develop other product candidates. We plan to finance our future operations with a combination of proceeds from potential licensing and/or marketing arrangements with pharmaceutical companies, the issuance of equity securities, 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.

**Capital Structure Changes**

In December 2019, we also began implementing additional steps to improve our balance sheet and simplify our capitalization structure, which carried into the second fiscal quarter of 2020.

On December 23, 2019, we amended the terms of our outstanding 15-month warrants and five-year warrants issued April 12, 2019, which originally had an exercise price of $2.90 per share and had anti-dilution price protection features. As amended, the exercise price of all outstanding warrants was reduced to $0.2320 per share and the exercise period was amended such that all of the warrants issued April 2019 expired at 5:00 P.M., Eastern time on December 24, 2019. As a result of this amendment, such warrants to purchase an aggregate of 10,408,250 shares of common stock issued April 2019 were exercised in full for an aggregate 8,327,642 shares pursuant to the amended terms and are no longer outstanding. Of these exercised warrants, 10,157,050 were exercised pursuant to the net exercise provisions therein, as amended.

On January 27, 2020, we also amended the exercise price of our outstanding warrants to purchase an aggregate 4,657,852 shares of our common stock (originally issued in October 2017, May 2018 and June 2018), all of which were held by BioLexis Pte. Ltd., or BioLexis, our controlling stockholder, to $0.232 per share (from $7.20 to $7.80 per share). BioLexis exercised all such warrants for a cash payment of approximately $1.1 million on January 29, 2020.

As a result of the foregoing, as of the date of this quarterly report on Form 10-Q, we have outstanding warrants to acquire an aggregate 901,911 shares of our common stock, with an exercise price of $12.00 per share.

In addition, on January 27, 2020, we also entered into an agreement with BioLexis, whereby we agreed to seek stockholder approval to amend the terms of our Series A-1 Preferred Convertible Preferred Stock, par value $0.01 per share, or the Series A-1 Preferred, and the issuance of our common stock pursuant to such amended terms, and BioLexis agreed to promptly convert its shares of Series A-1 Preferred pursuant to such amended terms, and in any event, within five business days of stockholder approval thereof. As proposed to be amended, the effective conversion rate will be increased from the current $18.89797 per share to $431.03447263 per share, which, if approved, would result in 29,358,621 shares

issuable upon conversion of the 68,112 shares of Series A-1 Preferred outstanding (rather than 1,287,178) (or an effective conversion rate of $0.232 per share). The Series A-1 Preferred rank senior to our common equity and have protective provisions, as well as a current redemption premium of $37.5 million and a liquidation preference of $40.9 million, all of which will be eliminated if converted to common stock.

***Collaboration, License and Strategic Partnership Agreements***

From time to time, we enter into collaboration and license agreements for the research and development, manufacture and/or commercialization of our products and/or product candidates. These agreements generally provide for non-refundable upfront license fees, development and commercial performance milestone payments, cost sharing, royalty payments and/or profit sharing.

***MTTR, LLC - ONS 5010***

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

In June 2019, we entered into a further amendment of our strategic partnership agreement with MTTR pursuant to which we increased the aggregate monthly payments to MTTR under the existing agreement from $105,208 to $170,724 through December 2019 by adding an additional monthly retainer of $115,916, and an offset of $50,000 to the existing monthly retainer while the additional monthly retainer is in effect. MTTR earned an aggregate $611,424 and $290,480 during the three months ended December 31, 2019 and 2018, respectively, which includes monthly consulting fees and expense reimbursement.

On January 27, 2020, we entered into a termination agreement and mutual release with MTTR to terminate the strategic partnership agreement. Pursuant to the agreement, we agreed (x) to issue to the four principals of MTTR (who include two of our named executive officers, Messrs. Dagnon and Evanson), an aggregate of 7,244,739 shares of our common stock, subject to stockholder approval, (y) to enter into consulting agreements with each of the four principals setting forth the terms of his respective compensation arrangement, and (z) to pay MTTR a one-time settlement fee of $110,000, upon effectiveness of the agreement. The termination agreement is effective upon stockholder approval of the share issuance.

As contemplated by the termination agreement, on January 27, 2020, we also entered into consulting agreements directly with each of the four principals of MTTR setting forth the terms of each respective compensation arrangement, as well as providing for certain transfer restrictions and repurchase rights applicable to the shares of our common stock to be issued pursuant thereto. The consulting agreements are effective upon stockholder approval of the share issuances contemplated thereby. The consulting agreements contemplate the payment of monthly fees for services based on an agreed number of hours, and provide that the shares proposed to be issued may generally not be sold until the earlier of (i) six months following FDA approval of ONS-5010, (ii) the date we publicly announce not to pursue development of ONS-5010, (iii) a “Change of Control” as defined therein or (iv) January 2025, subject to limited exceptions, including a pro rata exception if BioLexis disposes of any of its shares to an unaffiliated third party for consideration. We also have the right to repurchase such shares for $0.01 per share if the consultant terminates his agreement other than for good reason (as defined therein), or we terminate the agreement for cause (as defined therein). The repurchase right also lapses in tiered percentages (15%-40%) tied to completion of enrollment of our NORSE 2 clinical trial of ONS-5010 by certain dates. It also lapses as to 50% or 100% of the shares if we enter into agreements pertaining to ONS-5010 that meet certain value thresholds, or our share price meets certain predefined targets. The repurchase right also lapses as to 100% of the shares upon the earliest to occur of (i) filing of the biologics license application for ONS-5010, (ii) termination of the agreement by the consultant for good reason (as defined therein) or by us other than for cause (as defined therein), (iii) in the event of disability (as defined therein), or (iv) upon a “Change of Control” as defined therein.

***Selexis SA***

In October 2011, we entered into a research license agreement with Selexis whereby we acquired a non-exclusive license to conduct research internally or in collaboration with third parties to develop recombinant proteins from cell lines created in mammalian cells using the Selexis expression technology, or the Selexis Technology. The research license expired on October 9, 2018 and accordingly, we are no longer using the Selexis Technology in our research.

Selexis also granted us a non-transferrable option to obtain a perpetual, non-exclusive, worldwide commercial license under the Selexis Technology to manufacture, or have manufactured, a recombinant protein produced by a cell line developed using the Selexis Technology for clinical testing and commercial sale. We exercised this option in April 2013 and entered into three commercial license agreements with Selexis for our ONS-3010, ONS-1045 (which covers ONS-5010) and ONS-1050 product candidates. We paid an upfront licensing fee to Selexis for each commercial license and also agreed to pay a fixed milestone payment for each licensed product. In addition, we are required to pay a single-digit royalty on a final product-by-final product and country-by-country basis, based on worldwide net sales of such final products by us or any of our affiliates or sub-licensees during the royalty term. At any time during the term, we have the right to terminate our royalty payment obligation by providing written notice to Selexis and paying Selexis a royalty termination fee. The initiation of our Phase 3 clinical program for ONS-5010 triggered a CHF 65,000 (approximately $0.1 million) a milestone payment under the commercial license agreement, which we paid in November 2019.

As of December 31, 2019, we have paid Selexis an aggregate of approximately $0.5 million under the commercial license agreements.

**Components of our Results of Operations**

***Collaboration Revenue***

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

We consider milestones payments from our collaboration agreements as a form of variable consideration that results in such amounts being recognized over the estimated performance period. All remaining deferred revenue under our collaboration agreements was fully recognized in fiscal 2019 as all future development would be completed by our partners without any further assistance by us.

***Research and Development Expenses***

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

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

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

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

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

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

***General and Administrative Expenses***

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

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

***Interest Expense***

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

***Loss on Extinguishment of Debt***

Loss on extinguishment of debt consists of modifications to senior secured notes that are deemed to be substantially different from the existing notes.

***Change in fair value of redemption feature***

Change in fair value of the redemption feature reflects the change in the fair value of the embedded derivative contained in the new senior secured notes issued in December 2019, as a result of the fact that such notes were convertible into a variable number of shares of our common stock and at a discount that is deemed to be substantial. This embedded

derivative was recorded at fair value and is subject to re-measurement at each balance sheet date until our obligations under the new senior secured notes are satisfied.

***Change in Fair Value of Warrant Liability***

Warrants to purchase our common stock that were issued in conjunction with the senior secured notes originally issued December 2017 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. We recorded income of $0.2 million and $1.6 million, respectively, related to the decrease in the fair value of our common stock warrant liability associated with the warrants issued in connection with the senior secured notes originally issued December 2017 during the three months ended December 31, 2019 and 2018, respectively, which resulted from a decrease in the price of our common stock.

***Income Taxes***

On December 11, 2019, we received approval from the New Jersey Economic Development Authority's Technology Business Tax Certificate Transfer Program to sell approximately $3.6 million of our unused New Jersey NOLs and R&D credits. We anticipate that we will receive approximately $3.3 million of proceeds from the sale of the New Jersey NOLs and R&D credits in March 2020.

Since inception, we have not recorded any U.S. federal or state income tax benefits (excluding the sale of New Jersey state NOLs and research credits) for the net losses we have incurred in each year or on our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. As of September 30, 2019, we had federal and state NOL carryforwards of $202.7 million and $71.8 million, respectively that will begin to expire in 2030 and 2037, respectively. As of September 30, 2019, we had federal foreign tax credit carryforwards of $2.4 million available to reduce future tax liabilities, which begin to expire starting in 2023. As of September 30, 2019, we also had federal research and development tax credit carryforwards of $7.0 million, which begin to expire in 2032.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its NOLs to offset future taxable income. We have not completed a study to assess whether an ownership change has occurred in the past. Our existing NOLs may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change, 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, 2019 and 2018***

| | Three months ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | Change |
| Collaboration revenues | $ — | $ 1,067,598 | $(1,067,598) |
| Operating expenses: | | | |
| Research and development | 5,847,302 | 6,071,522 | (224,220) |
| General and administrative | 2,336,724 | 2,903,988 | (567,264) |
| Impairment of property and equipment | — | 2,349,403 | (2,349,403) |
| | 8,184,026 | 11,324,913 | (3,140,887) |
| Loss from operations | (8,184,026) | (10,257,315) | 2,073,289 |
| Interest expense, net | 597,665 | 1,120,849 | (523,184) |
| Loss on extinguishment of debt | 8,060,580 | — | 8,060,580 |
| Change in fair value of redemption feature | (37,945) | — | (37,945) |
| Change in fair value of warrant liability | (201,378) | (1,636,320) | 1,434,942 |
| Net loss | $(16,602,948) | $ (9,741,844) | $(6,861,104) |

*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, 2019 and 2018, all of which was from the recognition of deferred revenues under such agreements:

| | Three months ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| IPCA Collaboration | $ — | $ 128,007 |
| Liomont Collaboration | — | 99,414 |
| Huahai Collaboration | — | 371,427 |
| BioLexis Collaboration | — | 468,750 |
| | $ — | $ 1,067,598 |

There were no collaboration revenues for the three months ended December 31, 2019 as compared to $1.1 million for the three months ended December 31, 2018. The decrease is due to the full recognition of IPCA Laboratories Limited, or IPCA, Liomont, S.A. de C.V., or Liomont, and Zhejiang Huahai Pharmaceutical Co., Ltd., or Huahai, deferred revenue during the fourth quarter of fiscal 2019, after we had assessed that we did not have any further performance obligations on these collaboration arrangements.

*Research and Development Expenses*

The following table summarizes our research and development expenses by functional area for the three months ended December 31, 2019 and 2018:

| | Three months ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| ONS-5010 development | $4,762,215 | $ 3,233,553 |
| Compensation and related benefits | 407,302 | 1,884,649 |
| Stock-based compensation | 107,790 | 91,209 |
| Other research and development | 569,995 | 862,111 |
| Total research and development expenses | $5,847,302 | $ 6,071,522 |

Research and development expenses for the three months ended December 31, 2019 decreased by $0.2 million compared to the three months ended December 31, 2018. The decrease is primarily due to lower compensation and related benefits, of an aggregate of $1.5 million and other research and development expenses of $0.3 million due to reduction in headcount and closure of our manufacturing and laboratory facilities in 2019 resulting from our decision to outsource the commercial manufacturing and remaining development for the ONS-5010 program. This reduction in expenses was partially offset by an increase in ONS-5010 development costs of $1.5 million as the ONS-5010 program advanced further into Phase 3 clinical trials in the fourth quarter of fiscal 2019.

*General and Administrative Expenses*

The following table summarizes our general and administrative expenses by type for the three months ended December 31, 2019 and 2018:

| | Three months ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Professional fees | $ 951,448 | $1,480,974 |
| Compensation and related benefits | 428,324 | 161,181 |
| Stock-based compensation | 251,687 | 781,080 |
| Facilities, fees and other related costs | 705,265 | 480,753 |
| Total general and administrative expenses | $2,336,724 | $2,903,988 |

General and administrative expenses for the three months ended December 31, 2019 decreased by $0.6 million compared to the three months ended December 31, 2018. The decrease was primarily due to reduced professional fees of $0.5 million related to advisory fees paid in fiscal 2018 for the restructuring of senior secured notes in December of 2018.

*Impairment of property and equipment*

During the three months ended December 31, 2018, we wrote off certain construction in progress and laboratory equipment with a carrying amount of $2,349,403. We 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 change in our operations to focus solely on developing and commercializing ONS-5010.

*Interest Expense*

Interest expense decreased by $0.5 million to $0.6 million for the three months ended December 31, 2019 as compared to $1.1 million for the three months ended December 31, 2018. The decrease was primarily due to repayment of notes in fiscal 2019.

*Debt Extinguishment*

In December, we exchanged old senior secured notes for new senior secured notes. The new senior secured notes were considered substantially different from the old notes, as such they qualified for extinguishment. The loss on extinguishment was $8.1 million.

**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, 2019, we have funded substantially all of our operations through the receipt of $241.4 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 emerging markets collaboration and licensing agreements for our inactive biosimilar development programs.

In September 2019, the holder of $1.0 million outstanding principal and interest of our unsecured notes began exchanging the outstanding principal and interest from those notes for our common stock per the terms of a forbearance and exchange agreement dated March 7, 2019. During September 2019, a total of $0.5 million of principal and accrued interest on these notes was exchanged for an aggregate 372,888 shares of our common stock. Subsequently, the holder exchanged the

remaining approximately $1.5 million of accrued interest and principal for an aggregate 1,475,258 shares of our common stock between October 1, 2019 and December 5, 2019 and such notes are no longer outstanding.

In December 2019, we received approval from the New Jersey Economic Development Authority's Technology Business Tax Certificate Transfer Program to sell approximately $3.6 million of our unused New Jersey NOLs and R&D credits. We expect to receive approximately $3.3 million of proceeds from the sale of the New Jersey NOLs and R&D credits in March 2020.

In December 2019, we entered into an exchange agreement with the holders of our approximately $7.0 million outstanding aggregate principal amount and accrued interest of senior secured notes (originally issued pursuant to the certain Note and Warrant Purchase Agreement dated December 22, 2017, as amended on April 13, 2017, November 5, 2018, and June 28, 2019 (. Pursuant to the exchange agreement, the holders of the old senior secured notes exchanged the entire outstanding principal and accrued interest for new senior secured notes having an aggregate outstanding original principal amount of $7.6 million, which includes an aggregate exchange fee of approximately $0.3 million. The new senior secured notes are substantially similar to the old senior secured notes, as amended through the date of the exchange, bear interest at a rate of 12.0% per annum and will mature December 31, 2020 (subject to extension to June 30, 2021 at our option upon payment of an extension fee equal to 3% of the outstanding balance), and are secured by all of our assets pursuant to the same security agreements applicable to the old notes. The new senior secured notes are convertible, at the option of the holder, from time to time beginning April 1, 2020, into shares of our common stock, par value $0.01 per share, at a conversion price equal to 90% of the two lowest closing bid prices in the 20 trading days immediately preceding such conversion, subject to a floor price of $0.232 per share (added by amendment in January 2020). Under the January amendment, we also agreed to redeem $350,000 of the new senior secured notes for cash in the event that the conversion price does not exceed the floor price for 20 consecutive trading days (although we will not be required to make more than one redemption in any calendar month, and no trading day will be included in more than one 20-day period for purposes of determining if a redemption is payable).

As of December 31, 2019, we had a stockholders' deficit of $30.9 million and a cash balance of $1.3 million. In addition, we have $7.6 million outstanding aggregate principal amount and accrued interest of senior secured notes that become due in December 2020, $3.6 million unsecured notes, which are 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 payments from potential strategic research and development, licensing and/or marketing arrangements with pharmaceutical companies and private placements and/or public offerings of equity and/or debt securities. There can be no assurance that these future funding efforts will be successful.

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

*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, 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, 2019, the $1.1 million of cash proceeds from BioLexis' warrant exercise in January 2020, and the anticipated proceeds from the sale of our New Jersey NOLs and R&D credits to be received in March 2020 of approximately $3.3 million, will fund our operations through March 2020 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 potential strategic collaborations, sale of the development and commercial rights to our drug product candidates, the issuance of equity securities, the issuance of additional debt, and revenues from potential future product sales, if any. If we raise additional capital through the sale of equity or convertible debt securities, your ownership will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. There are no assurances that we will be successful in obtaining an adequate level of financing for the development and commercialization of ONS-5010 or any other current or future product candidates. Alternatively, we will be required to, among other things, modify our clinical trial plans for ONS-5010 in additional indications, make reductions in our workforce, scale back our plans and place certain activities on hold, discontinue our development programs, liquidate all or a portion of our assets, and/or seek protection under the provisions of the U.S. Bankruptcy Code.

***Cash Flows***

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

| | Three months ended December 31, | |
|---|---|---|
| | **2019** | **2018** |
| Net cash used in operating activities | $(6,673,676) | $(9,781,375) |
| Net cash used in investing activities | — | (236,433) |
| Net cash (used in) provided by financing activities | (8,293) | 8,528,133 |

*Operating Activities.*

During the three months ended December 31, 2019, we used $6.7 million of cash in operating activities resulting primarily from our net loss of $16.6 million, This use of cash was partially offset by $8.4 million of noncash items such as non-cash interest expense, stock-based compensation, change in fair value of warrant liability, loss on disposal of property and equipment, loss on extinguishment of debt and depreciation and amortization expense. The change in our operating assets and liabilities of $1.6 million was primarily to a decrease in prepayments associated with our clinical trials and ONS 5010 development costs and increase in our accrued expenses from September 30, 2019.

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.

*Investing Activities.*

During the three months ended December 31, 2018, we used cash of $0.2 million in investing activities for the purchase of property and equipment.

*Financing Activities.*

During the three months ended December 31, 2019, net cash (used in) provided by financing activities was less than $0.1 million. We made $0.1 million in debt and finance lease obligations payments which was partially offset by net proceeds from exercise of common stock warrants of $0.1 million.

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 1,608,234 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.

**Off-Balance Sheet Arrangements**

We did not have any off-balance sheet arrangements as of December 31, 2019.

**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, 2019, filed with the SEC on December 19, 2019, have not materially changed.

**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, 2019.

## 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 | 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 March 18, 2019). |
| 3.5 | 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). |
| 3.6 | 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 | Exchange Agreement, dated December 20, 2019 (incorporated by reference to Exhibit 10.1 to the Registrant's quarterly report on Form 10-Q filed with the SEC on December 23, 2019). |
| 10.2 | Form of Senior Secured Note (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K filed with the SEC on December 23, 2019). |
| 10.3 | Amendment #2 dated December 23, 2019 of Warrant Agreement between the Company and American Stock Transfer & Trust Company LLC, as warrant agent, dated as of April 12, 2019, as amended. (incorporated by reference to Exhibit 10.5 to the Registrant's current report on Form 8-K filed with the SEC on December 23, 2019). |
| 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 |

* 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, 2020

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, 2020

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, 2019, 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, 2020

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."*