

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **December 18, 2018**

Outlook Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37759
(Commission File Number)

38-3982704
(IRS Employer Identification No.)

7 Clarke Drive
Cranbury, New Jersey
(Address of principal executive offices)

08512
(Zip Code)

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

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 2.02 Results of Operations and Financial Condition

On December 18, 2018, the Company issued a press release announcing its financial results for its fiscal year ended September 30, 2018. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Item 2.02 and in the accompanying Exhibit 99.1 shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events

On December 17, 2018, the Company received formal notification from The Nasdaq Stock Market LLC (“Nasdaq”) that the Nasdaq Hearings Panel (the “Panel”) had determined to grant the Company’s request to extend through April 22, 2019 the period within which it needed to evidence compliance with all applicable requirements for continued listing on Nasdaq, including the applicable \$1.00 minimum bid price for a period of at least ten consecutive days.

Item 9.01. Financial Statements and Exhibits

The information contained in Exhibit 99.1 shall not be deemed filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated December 18, 2018.

SIGNATURE

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 hereunto duly authorized.

Outlook Therapeutics, Inc.

Date: December 18, 2018

By: /s/ Lawrence A. Kenyon

Lawrence A. Kenyon

Chief Executive Officer and Chief Financial Officer



Outlook Therapeutics Provides Business Update and Reports Financial Results for Fiscal Year 2018

CRANBURY, N.J., December 18, 2018 – Outlook Therapeutics, Inc. (NASDAQ:OTLK) (the “Company”) today reported financial results and business highlights for its fiscal year ended September 30, 2018.

Recent Highlights:

- Initiated ONS-5010 clinical study in wet AMD with first patient dosed; study now over 50% enrolled
- Changed name to “Outlook Therapeutics, Inc.”
- Strengthened management team with appointment of Jeff Evanson as Chief Commercial Officer and Terry Dagnon as Chief Operating Officer
- Received a commitment from BioLexis for a \$20.0 million private placement of common stock; received \$12.0 million to date, with an additional \$8.0 million to be funded in Q1 2019
- Restructured and extended maturity on \$13.5 million of outstanding senior secured notes

“In recent months, we have made tremendous progress implementing a complete shift in strategy for our development pipeline and we recapitalized the business. This new strategy, which includes significantly restructured operations and reduced costs, improves our ability to pursue a high value opportunity with ONS-5010 in the multi-billion dollar anti-VEGF ophthalmic market,” said Lawrence A. Kenyon, President, Chief Executive Officer and Chief Financial Officer. “The development of ONS-5010 is being overseen by a new executive team, with significant experience in the ophthalmic markets and the program is gaining momentum as we have now reached the mid-point for enrollment in our first clinical trial. With this exciting new program, experienced team and the financial commitment from our key investors, we expect to make great progress in 2019 towards providing more options to patients and creating value for our stockholders.”

Recent Operational Highlights

The Company’s wet AMD clinical program was reviewed at a successful end of Phase 2 meeting held with the U.S. Food and Drug Administration (FDA) conducted in 2018. The Company initiated its first clinical trial for ONS-5010, a proprietary ophthalmic bevacizumab product candidate, in patients with wet age related macular degeneration (wet AMD). The study is being conducted outside of the U.S. and is designed to serve as the first of two adequate and well controlled studies for wet AMD. The U.S. portion of the second study is expected to begin in early 2019 upon the submission of an investigational new drug (IND) application. If the clinical program is successful, it will support the Company’s plans to submit for regulatory approval in multiple markets in 2020.

The Company appointed two new executives to its leadership team, including Jeff Evanson as Chief Commercial Officer and Terry Dagnon as Chief Operating Officer. Mr. Evanson joins the Company with more than 25 years of commercial expertise, most notably with Novartis (Alcon) between 2010 and 2014 where he was most recently the Vice President and Global Commercial Head of the Pharmaceutical Franchise where he was responsible for all aspects of strategy, portfolio (both internal and external opportunities), global brands, launches and campaigns.

As the Company’s new Chief Operating Officer, Mr. Dagnon brings more than 20 years of regulatory experience with domestic and global investigational and marketing approvals in the pharmaceutical and medical device industries, including serving as the North America Head of Regulatory Affairs at Alcon, a Novartis company. He is also experienced in quality and compliance and working with R&D, marketing, sales, legal, and manufacturing, quality and supply chain organizations.

On December 3, 2018, the Company announced that it changed its name from Oncobiologics, Inc. to Outlook Therapeutics, Inc. The Company continues to be listed on the Nasdaq Capital Market and its common stock and Series A warrants began trading under the new ticker symbols “OTLK” and “OTLKW,” respectively, beginning on Tuesday, December 4, 2018.

Financial Highlights for the Fiscal Year Ended September 30, 2018

For the fiscal year ended September 30, 2018, the Company reported a net loss attributable to common stockholders of \$48.0 million, or \$1.22 per diluted share, compared to \$40.0 million, or \$1.80 per diluted share, for fiscal 2017.

For the fiscal year ended September 30, 2018, the Company reported an adjusted net loss attributable to common stockholders of \$29.9 million, or \$0.76 per diluted share, as compared to an adjusted net loss of \$26.7 million, or \$1.24 per diluted share, in fiscal 2017. Adjusted net loss attributable to common stockholders in fiscal 2018 includes \$2.0 million of non-cash stock-based compensation, \$3.1 million of depreciation and amortization, \$1.3 million of noncash interest expense, \$1.3 million of loss on extinguishment of debt, \$16.0 million for recognition of the beneficial conversion feature for convertible preferred stock, and a \$1.9 million stock dividend for the Company’s Series A and A-1 convertible preferred stock, which was partially offset by \$1.0 million of income from a decrease in the fair value of warrant liability, \$3.2 million of tax benefit recognized from the sale of state of New Jersey net operating losses and \$3.2 million of benefit from the settlement of a clinical development contract. For the fiscal year ended September 30, 2017, adjusted net loss attributable to common stockholders included \$8.6 million of non-cash stock-based compensation expense, \$2.7 million of depreciation and amortization, \$1.2 million for recognition of the beneficial conversion feature for convertible preferred stock, and \$4.0 million of noncash interest expense, which was partially offset by \$3.2 million of income from a decrease in the fair value of warrant liability.

At September 30, 2018, the Company had cash of \$1.7 million, compared to \$3.2 million at September 30, 2017.

On November 5, 2018, Outlook Therapeutics announced that it has received an equity financing commitment for \$20.0 million from BioLexis and restructured and extended the maturity of its senior secured notes that were previously scheduled to mature on December 22, 2018. To date, the Company has completed the sale of the first two tranches of common stock to BioLexis in this private placement for aggregate cash proceeds of \$12.0 million. The remaining \$8.0 will be funded in two equal tranches on each of January 3, 2019 and February 1, 2019, subject to meeting certain funding milestones as set forth in the purchase agreement. In combination with these improvements to its balance sheet, the Company has committed to reduce expenses, sell or license the rights to some or all of its clinical stage biosimilar assets and to explore strategic options for its manufacturing plant.

Nasdaq Listing Update

The Company received formal notice on December 17, 2018 that the Nasdaq Hearings Panel has granted the Company’s request for an extension through April 22, 2019 to evidence compliance with all applicable requirements for continued listing on Nasdaq, including the applicable \$1.0 minimum bid price requirement for at least ten consecutive trading days.

About ONS-5010

ONS-5010 is a proprietary ophthalmic formulation of bevacizumab to be administered as an intravitreal injection for the treatment of wet AMD and other retina diseases. Bevacizumab is a full length humanized anti-VEGF (Vascular Endothelial Growth Factor) antibody that inhibits VEGF and associated angiogenic activity. The Company's proprietary ophthalmic bevacizumab product candidate is an anti-VEGF recombinant humanized monoclonal antibody (or mAb) formulated as a single use vial for IVT injection. By inhibiting the VEGF receptor from binding, bevacizumab prevents the growth and maintenance of tumor blood vessels. Previously, this product candidate met the primary and secondary endpoints in a 3-arm single-dose pharmacokinetic (PK) Phase 1 clinical trial. All of the PK endpoints met the bioequivalency criteria of the geometric mean ratios within 90% confidence interval of 80-125% when compared to both U.S.- and EU-sourced Avastin® reference products.

About Outlook Therapeutics, Inc.

Outlook Therapeutics is a clinical-stage biopharmaceutical company focused on developing its lead clinical program, ONS-5010, a proprietary ophthalmic bevacizumab product candidate for the treatment of wet age related macular degeneration (wet AMD). ONS-5010 is currently in its first clinical trial, which is being conducted outside of the U.S. and is designed to serve as the first of two adequate and well controlled studies for wet AMD. For more information, please visit www.outlooktherapeutics.com.

Non-GAAP Financial Measure – Adjusted Net Loss Attributable to Common Stockholders

Outlook Therapeutics prepares its consolidated financial statements in conformity with accounting principles generally accepted in the United States of America (U.S. GAAP) and pursuant to accounting requirements of the Securities and Exchange Commission. In an effort to provide investors with additional information regarding the results and to provide a meaningful period-over-period comparison of Outlook Therapeutics financial performance, Outlook Therapeutics sometimes uses non-U.S. GAAP financial measures (NGFM) as defined by the Securities and Exchange Commission. In this press release, Outlook Therapeutics uses the NGFM, "adjusted net loss attributable to common stockholders." Management uses this NGFM because it adjusts for certain transactions management believes are not related to the Company's core business or events that may not recur, such as losses from extinguishment of debt, sales of state net operating losses, as well as the settlement of a clinical development contract in connection with the decision to postpone Phase 3 clinical trials of two biosimilar programs, as well as significant non-cash items that impact financial results but not cash flows, such as the recognition of the beneficial conversion feature due to the issuance of Series A Convertible Preferred Stock to BioLexis and related stock dividends, stock-based compensation expense, depreciation and amortization expense, interest expense, and fair value measurements for the Company's equity and debt securities. Management used this NGFM to evaluate Outlook Therapeutics financial performance against internal budgets and targets. Management believes that this NGFM is useful for evaluating Outlook Therapeutics core operating results and facilitating comparison across reporting periods. Outlook Therapeutics believes this NGFM should be considered in addition to, and not in lieu of, GAAP financial measures. Outlook Therapeutics NGFM may be different from the same NGFM used by other companies.

Forward-Looking Statements

This press release contains forward-looking statements. All statements other than statements of historical facts are “forward-looking statements,” including those relating to future events. In some cases, you can identify forward-looking statements by terminology such as “may,” “might,” “will,” “should,” “expect,” “plan,” “anticipate,” “project,” “believe,” “estimate,” “predict,” “potential,” “intend” or “continue,” the negative of terms like these or other comparable terminology, and other words or terms of similar meaning. These include statements about the Company’s planned clinical trials for ONS-5010, the outcome of such clinical trials and plans for seeking regulatory approval for ONS-5010, as well as the Company’s ability to provide more options to patients, create stockholder value, and complete its BioLexis private placement, and otherwise reduce expenses and monetize its assets. Although the Company believes that it has a reasonable basis for forward-looking statements contained herein, they are based on current expectations about future events affecting the Company and are subject to risks, uncertainties and factors relating to its operations and business environment, all of which are difficult to predict and many of which are beyond its control. These risk factors include those risks associated with developing pharmaceutical product candidates, risks of conducting clinical trials, and risks in obtaining necessary regulatory approvals, as well as those risks detailed in the Company’s filings with the Securities and Exchange Commission. These risks may cause actual results to differ materially from those expressed or implied by forward-looking statements in this press release. All forward-looking statements included in this press release are expressly qualified in their entirety by the foregoing cautionary statements. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company does not undertake any obligation to update, amend or clarify these forward-looking statements whether as a result of new information, future events or otherwise, except as may be required under applicable securities law.

For additional details on the Company’s financial performance during the quarter, please see the Company’s filings with the [Securities and Exchange Commission](#).

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Outlook Therapeutics, Inc.
Consolidated Statements of Operations
(Amounts in thousands, except per share data)

	Year Ended September 30,	
	2018	2017
Collaboration revenues	\$ 3,088	\$ 3,812
Operating expenses:		
Research and development	18,504	23,810
General and administrative	14,228	15,882
	<u>32,732</u>	<u>39,692</u>
Loss from operations	(29,644)	(35,880)
Interest expense, net	3,891	5,626
Loss on extinguishment of debt	1,253	-
Change in fair value of warrant liability	(1,048)	(3,158)
Loss before income taxes	(33,740)	(38,348)
Income tax (benefit) expense	(3,648)	501
Net loss	(30,092)	(38,849)
Recognition of beneficial conversion feature upon sale of Series A and A-1 convertible preferred stock	(16,023)	(1,177)
Series A and A-1 convertible preferred stock dividends and related settlement	(1,904)	-
Net loss attributable to common stockholders	<u>\$ (48,019)</u>	<u>\$ (40,026)</u>
Per share information:		
Net loss per share of common stock, basic	\$ (1.22)	\$ (1.67)
Net loss per share of common stock, diluted	\$ (1.22)	\$ (1.80)
Weighted average shares outstanding, basic	<u>39,458</u>	<u>24,022</u>
Weighted average shares outstanding, diluted	<u>39,458</u>	<u>24,042</u>

Consolidated Balance Sheet Data
(Amounts in thousands)

	September 30,	
	2018	2017
Cash	\$ 1,717	\$ 3,186
Total assets	\$ 22,283	\$ 20,734
Current liabilities	\$ 32,042	\$ 28,738
Series A and A-1 convertible preferred stock	\$ 4,734	\$ 2,924
Total stockholders' deficit	\$ (25,545)	\$ (33,651)

**Reconciliation Between Reported Net Loss (GAAP) and Adjusted Net Loss (Non-GAAP), in each case
Attributable to Common Stockholders**
(Amounts in thousands, except per share data)

	Year Ended September 30,	
	2018	2017
Net loss attributable to common stockholders, as reported (GAAP)	\$ (48,019)	\$ (40,026)
Adjustments for reconciled items:		
Stock-based compensation, non-cash	1,986	8,571
Depreciation and amortization	3,054	2,692
Non-cash interest expense	1,316	4,015
Loss on extinguishment of debt	1,253	-
Change in fair value of warrant liability	(1,048)	(3,158)
Income tax benefit from sale of New Jersey NOLs	(3,151)	-
Recognition of beneficial conversion feature upon issuance of Series A and A-1 convertible preferred stock	16,023	1,177
Series A and A-1 convertible preferred stock dividends and related settlement	1,904	-
Settlement of clinical development contract	(3,229)	-
Adjusted net loss attributable to common stockholders (non-GAAP)	<u>\$ (29,911)</u>	<u>\$ (26,729)</u>
Net loss attributable to common stockholders per share of common stock - diluted, as reported (GAAP)	\$ (1.22)	\$ (1.80)
Adjustments for reconciled items:		
Stock-based compensation, non-cash	0.05	0.36
Depreciation and amortization	0.08	0.11
Non-cash interest expense	0.03	0.17
Loss on extinguishment of debt	0.03	-
Change in fair value of warrant liability	(0.03)	(0.13)
Income tax benefit from sale of New Jersey NOLs	(0.08)	-
Recognition of beneficial conversion feature upon issuance of Series A and A-1 convertible preferred stock	0.41	0.05
Series A and A-1 convertible preferred stock dividends and related settlement	0.05	-
Settlement of clinical development contract	(0.08)	-
Adjusted net loss attributable to common stockholders per share of common stock - diluted (non-GAAP)	<u>\$ (0.76)</u>	<u>\$ (1.24)</u>