Table of Contents

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, 2024
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.)**
111 S. Wood Avenue, Unit #100 Iselin, New Jersey	**08830**
(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

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

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

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

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

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

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

The number of shares of the registrant's common stock, $0.01 par value per share, outstanding as of February 12, 2025 was 32,017,179.

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. and its consolidated subsidiaries. The Outlook logo, LYTENAVA 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. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

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 "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potentially," "seek," "should," "will," "would," 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, 2024, filed with the Securities and Exchange Commission ("SEC") on December 27, 2024, including, among other things, risks associated with:

- the initiation, timing, progress and results of our clinical trials of our lead product candidate, ONS-5010/LYTENAVA™;
- our reliance on our contract manufacturing organizations and other vendors;
- 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/LYTENAVA in the United States and other markets;
- 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, and our expectations regarding our current cash resources , including with respect to the closing of the refinancing of our outstanding convertible note;
- the rate and degree of market acceptance of our current and future product candidates, including our commercialization strategy and manufacturing capabilities for ONS-5010/LYTENAVA;
- 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;
- the factors that may impact our financial results; and
- our estimates regarding the sufficiency of our cash resources and our need for additional funding

These risks are not exhaustive. Additional factors could harm our business and financial performance, such as risks associated with the current macroeconomic environment, including as a result of the impacts of fluctuations in inflation, and interest rates, current or potential future bank failures or ongoing overseas conflict. 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. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Unless required by law, we undertake no obligation to update or revise any forward-looking statements to reflect new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. We qualify all of the forward-looking statements in this report by these cautionary statements.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Outlook Therapeutics, Inc.
Consolidated Balance Sheets
(unaudited)

	December 31, 2024	September 30, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 5,702,576	$ 14,927,538
Inventory	3,109,397	—
Prepaid expenses and other current assets	6,855,401	12,488,498
Total current assets	15,667,374	27,416,036
Operating lease right-of-use assets, net	262,822	274,645
Equity method investment	659,895	693,190
Other assets	415,974	439,283
Total assets	$ 17,006,065	$ 28,823,154
Liabilities and stockholders' deficit		
Current liabilities:		
Unsecured convertible promissory note	$ 30,744,000	$ 29,440,000
Current portion of operating lease liabilities	52,645	50,907
Accounts payable	12,192,747	7,968,725
Accrued expenses	3,391,232	3,237,468
Income taxes payable	1,856,629	1,856,629
Total current liabilities	48,237,253	42,553,729
Operating lease liabilities	233,113	246,922
Warrant liability	18,826,133	59,099,013
Total liabilities	67,296,499	101,899,664
Commitments and contingencies (Note 8)		
Stockholders' deficit:		
Preferred stock, par value $0.01 per share: 10,000,000 shares authorized, no shares issued and outstanding	—	—
Common stock, par value $0.01 per share; 60,000,000 shares authorized; 24,905,635 and 23,905,635 shares issued and outstanding at December 31, 2024 and September 30, 2024, respectively	249,057	239,057
Additional paid-in capital	475,367,795	469,969,333
Accumulated deficit	(525,907,286)	(543,284,900)
Total stockholders' deficit	(50,290,434)	(73,076,510)
Total liabilities and stockholders' deficit	$ 17,006,065	$ 28,823,154

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,	
	2024	**2023**
Operating expenses:		
Research and development	$ 9,660,150	$ 4,529,358
General and administrative	11,946,702	5,793,764
Loss from operations	(21,606,852)	(10,323,122)
Loss (income) on equity method investment	33,295	(2,548)
Interest income, net	(48,881)	(188,677)
Loss from change in fair value of promissory notes	1,304,000	993,000
(Gain) loss from change in fair value of warrant liability	(40,272,880)	53,342
Net income (loss)	$ 17,377,614	$ (11,178,239)
Per share information:		
Net income (loss) per share of common stock, basic	$ 0.72	$ (0.86)
Net income (loss) per share of common stock, diluted	$ 0.72	$ (0.86)
Weighted average shares outstanding, basic	24,233,957	13,012,833
Weighted average shares outstanding, diluted	24,233,957	13,012,833

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

Outlook Therapeutics, Inc.
Consolidated Statements of Stockholders' Deficit
(unaudited)

	Stockholders' Deficit				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Balance at October 1, 2024	23,905,635	$ 239,057	$ 469,969,333	$(543,284,900)	$ (73,076,510)
Sale of common stock, net of issuance costs	1,000,000	10,000	1,726,042	—	1,736,042
Stock-based compensation expense	—	—	3,672,420	—	3,672,420
Net income	—	—	—	17,377,614	17,377,614
Balance at December 31, 2024	24,905,635	$ 249,057	$ 475,367,795	$(525,907,286)	$ (50,290,434)

	Stockholders' Equity Deficit				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Balance at October 1, 2023	13,012,833	$ 130,128	$ 453,350,281	$(467,918,186)	$ (14,437,777)
Stock-based compensation expense	—	—	1,272,611	—	1,272,611
Net loss	—	—	—	(11,178,239)	(11,178,239)
Balance at December 31, 2023	13,012,833	130,128	454,622,892	(479,096,425)	(24,343,405)

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,	
	2024	**2023**
OPERATING ACTIVITIES		
Net income (loss)	$ 17,377,614	$ (11,178,239)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	28,801	28,195
Stock-based compensation	3,672,420	1,272,611
Loss from change in fair value of promissory notes	1,304,000	993,000
(Gain) loss from change in fair value of warrant liability	(40,272,880)	53,342
Loss (income) on equity method investment	33,295	(2,548)
Changes in operating assets and liabilities:		
Inventory	(3,109,397)	—
Prepaid expenses and other current assets	5,633,097	(2,445,363)
Operating lease liabilities	(12,071)	—
Accounts payable	4,224,022	(3,094,197)
Accrued expenses	153,764	1,341,030
Net cash used in operating activities	(10,967,335)	(13,032,169)
FINANCING ACTIVITIES		
Proceeds from the sale of common stock, net of issuance costs	1,742,373	—
Payments of finance lease obligations	—	(3,183)
Net cash provided by (used in) financing activities	1,742,373	(3,183)
Net decrease in cash and cash equivalents	(9,224,962)	(13,035,352)
Cash and cash equivalents at beginning of period	14,927,538	23,391,982
Cash and cash equivalents at end of period	$ 5,702,576	$ 10,356,630
Supplemental schedule of non-cash financing activities:		
Reclassification of deferred offering costs against ATM proceeds	$ 6,331	$ —

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, 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 biopharmaceutical company focused on developing and commercializing ONS-5010/LYTENAVA™, an ophthalmic formulation of bevacizumab for use in retinal indications. The Company is based in Iselin, New Jersey.

In May 2024 the Company received Marketing Authorization from the European Commission for LYTENAVA™ (bevacizumab gamma), an ophthalmic formulation of bevacizumab for the treatment of wet age-related macular degeneration ("AMD") in the European Union ("EU"). Additionally, in July 2024 the Company also received marketing authorization for LYTENAVA™ (bevacizumab gamma) in the United Kingdom ("UK") from the UK Medicines and Healthcare products Regulatory Agency ("MHRA"). LYTENAVA™ (bevacizumab gamma) is the first and only authorized ophthalmic formulation of bevacizumab for use in treating wet AMD in the EU and UK.

In the fourth quarter of calendar 2023, the Company agreed to conduct an additional adequate and well-controlled clinical trial following discussions with the U.S. Food and Drug Administration ("FDA") in support of the Company's Biologics License Application ("BLA") for ONS-5010/LYTENAVA. In December 2023, the Company submitted a Special Protocol Assessment ("SPA") to the FDA for this study (NORSE EIGHT) seeking confirmation that, if successful, it will address the FDA's requirement for a second adequate and well-controlled clinical trial to support its planned resubmission of the ONS-5010/LYTENAVA BLA. In January 2024, the Company received confirmation that the FDA had reviewed and agreed upon the NORSE EIGHT trial protocol pursuant to the SPA and that, if the NORSE EIGHT trial is successful, it would satisfy the FDA's requirement for a second adequate and well-controlled clinical trial to address fully the clinical deficiency identified in the Complete Response Letter ("CRL"). In addition, through a Type A meeting and additional interactions, the Company has identified the approaches needed to resolve the chemistry, manufacturing and controls ("CMC") comments in the CRL. In November 2024, the Company reported that ONS-5010/LYTENAVA did not meet the pre-specified non-inferiority endpoint at week 8 set forth in the SPA. In January 2025, the Company reported the complete data and safety results from NORSE EIGHT which demonstrated an improvement in vision and the presence of biologic activity, as well as a continued favorable safety profile for ONS-5010/LYTENAVA.

2. Liquidity

The Company has incurred recurring losses and negative cash flows from operations since its inception and has an accumulated deficit of $525,907,286 as of December 31, 2024. As of December 31, 2024, the Company had a working capital deficit including $32,229,130 of principal, accrued interest and exit fees due under an unsecured convertible promissory note issued in December 2022 (as amended, the "December 2022 Note"), maturing on July 1, 2025. Refer to Note 7 for further details on the December 2022 Note. As a result, there is 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 January 16, 2025, the Company entered into warrant exercise inducement offer letter agreements with GMS Ventures and Investments ("GMS"), the Company's largest stockholder, and certain other holders of existing warrants to purchase the Company's common stock, pursuant to which the holders agreed to exercise their existing warrants ("Existing Warrants") for an aggregate of 7,074,637 shares of common stock at a reduced exercise price of $2.51 per share. In exchange, the Company issued two new inducement warrants for each Existing Warrant exercised ("Inducement Warrants"), which are exercisable for an aggregate of up to 14,149,274 additional shares of common stock (the "Inducement Warrant Shares") at an exercise price of $2.26 per share (collectively, the "Warrant Inducement

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

Transaction"). The Company received net proceeds of $15,746,960 after capital markets advisory fees and estimated offering costs, from the Warrant Inducement Transaction.

Concurrently with the Warrant Inducement Transaction, the Company entered into a warrant exercise inducement offer letter agreement with Syntone Ventures, LLC ("Syntone"), pursuant to which Syntone agreed to exercise existing warrants ("Existing Syntone Warrants") for an aggregate of 1,071,429 shares of common stock at a reduced exercise price of $2.51 per share. In exchange, the Company agreed to issue two new inducement warrants for each Existing Syntone Warrant exercised (the "Syntone Inducement Warrants"), which will be exercisable for up to 2,142,858 shares of common stock (the "Syntone Inducement Warrant Shares") at an exercise price of $2.26 per share (the "Syntone Warrant Inducement Transaction"). The closing of the Syntone Warrant Inducement Transaction is subject to receipt of certain regulatory approvals. The Company expects to generate net proceeds of approximately $2,400,000 after capital markets advisory fees and estimated offering costs. Refer to Note 11 for further details on the Warrant Inducement Transaction and the Syntone Warrant Inducement Transaction.

On January 31, 2025, the Company entered into a Securities Purchase Agreement ("SPA") with Avondale Capital, LLC ("Avondale"), pursuant to which the Company agreed to issue to Avondale an unsecured convertible promissory note for $33,100,000 (the "January 2025 Note"). The Company expects to use the proceeds from the January 2025 Note to repay in full the remaining obligations, including accrued and unpaid interest and the applicable exit fee owed under the December 2022 Note. The December 2022 Note will be cancelled in connection with the issuance of the January 2025 Note. The closing of the transaction (the "Note Closing") is expected to occur shortly after the Company's 2025 annual meeting of stockholders, subject to certain closing conditions, including stockholder approval of the issuance of shares of the Company's common stock in excess of 19.99% of the outstanding common stock upon conversion of the January 2025 Note. Prior to the Note Closing, the Company has agreed not to sell common stock, other than issuances pursuant to the Company's at-the-market offering, below a per share price of $2.26 and must maintain its Nasdaq listing. The Company has agreed to file a registration statement registering the resale of common stock issuable upon conversion of the January 2025 Note within seven days of the Note Closing. The Company must use commercially reasonable efforts to have the registration statement declared effective within 45 days; otherwise, the outstanding balance on the January 2025 Note will automatically increase by 0.5% monthly until the registration statement is declared effective.

The January 2025 Note will bear interest at the prime rate plus 3% (subject to a floor of 9.5%), will be scheduled to mature on July 1, 2026, and will be convertible into common stock. The Company must repay at least $3,000,000 (by cash or conversions into common stock) of the outstanding balance on the January 2025 Note each quarter starting in the second calendar quarter of 2025 (subject to adjustments for conversions and to payment of a 7.5% exit fee) (the "Quarterly Debt Reduction Obligations"). Any amount converted by Avondale during a given calendar quarter in excess of the Quarterly Debt Reduction Obligations will be credited toward meeting the Quarterly Debt Reduction Obligations for the next quarter or quarters. Refer to Note 11 for further details on the January 2025 Note.

Management does not believe that the existing cash and cash equivalents as of December 31, 2024, together with net proceeds from the sale of shares of common stock in the Warrant Inducement Transaction, are sufficient to fund the Company's operations through one year from the date of this Quarterly Report on Form 10-Q. As a result, additional financing will be needed by the Company to fund its operations in the future and to commercially develop ONS-5010/LYTENAVA and to develop any other product candidates. Management is currently evaluating different strategies to obtain the required funding for future operations, including but not limited to, proceeds from potential licensing and/or marketing arrangements or collaborations with pharmaceutical or other companies, sale of the development and commercial rights to the Company's drug product candidates in regions outside of the U.S., the issuance of additional debt, the issuance of equity securities, including accessing capital through at-the-market offering agreements (refer to Note 9 for further details), and revenues from potential future product sales, if any. 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 successfully begin marketing of its product candidates or complete revenue-generating partnerships with other companies; (iii) the success of its research and

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

development; (iv) the development of competitive therapies by other biotechnology and pharmaceutical companies; and, ultimately, (v) regulatory approval and market acceptance of the Company's proposed future products.

3. Basis of Presentation and Summary of Significant Accounting Policies

Basis of presentation

The accompanying unaudited interim consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

In the opinion of management, the accompanying unaudited interim consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company's financial position as of December 31, 2024 and its results of operations for the three months ended December 31, 2024 and 2023, cash flows for the three months ended December 31, 2024 and 2023, and stockholders' deficit for the three months ended December 31, 2024 and 2023. Operating results for the three months ended December 31, 2024 are not necessarily indicative of the results that may be expected for the full year ending September 30, 2025. The unaudited interim consolidated financial statements presented herein do not contain all of 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, 2024 included in the Company's Annual Report on Form 10-K filed with the SEC on December 27, 2024.

Reverse stock split

Effective on March 14, 2024, the Company amended its amended and restated certificate of incorporation to implement a one-for-twenty reverse stock split of its common stock. As a result of the reverse stock split, the Company made corresponding adjustments to the share amounts under its employee incentive plans, outstanding options, and common stock warrant agreements with third parties. The disclosure of common shares and per common share data in the accompanying consolidated financial statements and related notes reflect the reverse stock split for all periods presented.

Inventory

The Company values inventory at the lower of cost or net realizable value. The Company regularly reviews its inventory quantities and, when appropriate, records a provision for obsolete and excess inventory to derive the new cost basis, which takes into account the Company's sales forecast and corresponding expiry dates. The Company has not recognized a provision for obsolete and excess inventory as of December 31, 2024.

Upon the initiation of production for the first commercial batches of drug product in October 2024, the Company began capitalizing the purchases of saleable inventory of the product from suppliers. As of December 31, 2024, all inventory is classified as work-in-process.

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, such as the current macroeconomic environment, including as a result of fluctuations in inflation, and interest rates or ongoing

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

overseas conflict, 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 income (loss) per share

Basic net income (loss) per share of common stock is computed by dividing net income (loss) attributable to common stockholders by the weighted-average number of shares of common stock outstanding during each period. Diluted net income (loss) per share of common stock includes the effect, if any, from the potential exercise or conversion of securities, such as convertible debt, warrants, performance-based stock options and units, and stock options using the treasury stock method, which would result in the issuance of incremental shares of common stock. 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. All common stock equivalents were considered anti-dilutive for the three months ended December 31, 2024 as they are all out of the money.

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

	Three months ended December 31,	
	2024	2023
Numerator:		
Net income (loss) attributable to common stockholders	$ 17,377,614	$ (11,178,239)
Effect of dilutive securities:		
(Gain) loss from change in fair value of warrant liability	—	—
Loss from change in fair value of promissory notes	—	—
Adjusted net income (loss) attributable to common stockholders	$ 17,377,614	$ (11,178,239)
Denominator:		
Weighted average shares outstanding, basic	24,233,957	13,012,833
Effect of dilutive securities:		
Common stock warrants	—	—
Convertible promissory notes	—	—
Dilutive effect of stock options	—	—
Weighted average shares outstanding, diluted	24,233,957	13,012,833
Basic net income (loss) per share	$ 0.72	$ (0.86)
Diluted net income (loss) per share	$ 0.72	$ (0.86)

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, 2024 and 2023, as they would be antidilutive:

	As of December 31,	
	2024	2023
Performance-based stock units	—	123
Performance-based stock options	190,000	35,000
Stock options	2,816,851	1,299,105
Common stock warrants	14,193,772 (i)	366,427
Convertible debt	1,191,479 (ii)	875,970

(i) Refer to Note 11 for disclosures on the warrant inducement transactions entered into in January 2025.

(ii) The calculation for potentially dilutive securities pertaining to convertible debt is as follows: $3,750,000 of outstanding principal and accrued interest as of December 31, 2024, is converted at a rate of $7.00, and the remaining amount is converted based on a fixed conversion price of $40.00 per share, which is subject to change as described in Note 7.

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

Recently issued accounting pronouncements

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. ASU 2023-07, which is applicable to entities with a single reportable segment and will primarily require enhanced disclosures about significant segment expenses and enhanced disclosures in interim periods. The guidance in ASU 2023-07 will be applied retrospectively and is effective for annual reporting periods in fiscal years beginning after December 15, 2023 and interim reporting periods in fiscal years beginning after December 31, 2024, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2023-07 will have on its consolidated financial statements and disclosures.

In November 2024, the FASB issued ASU 2024-03, *Disaggregation of Income Statement Expenses*. ASU 2024-03 requires additional disclosure of specific types of expenses included in the expense captions presented on the face of the income statement as well as disclosures about selling expenses. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and interim periods beginning after December 15, 2027, with early adoption permitted. The requirements will be applied prospectively with the option for retrospective application. The Company is currently evaluating the impact that the adoption of ASU 2024-03 will have on its consolidated financial statements and disclosures.

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 liabilities that are measured at fair value on a recurring basis:

	December 31, 2024		
	(Level 1)	(Level 2)	(Level 3)
Liabilities			
Unsecured convertible promissory note	$ —	$ —	$ 30,744,000
Warrant liability	—	—	18,826,133
Total	$ —	$ —	$ 49,570,133

	September 30, 2024		
	(Level 1)	(Level 2)	(Level 3)
Liabilities			
Unsecured convertible promissory note	$ —	$ —	$ 29,440,000
Warrant liability	—	—	59,099,013
Total	$ —	$ —	$ 88,539,013

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 unsecured convertible promissory note for the three months ended December 31, 2024:

	Unsecured Convertible Promissory Note	Warrants
Balance at October 1, 2024	$ 29,440,000	$ 59,099,013
Change in fair value	1,304,000	(40,272,880)
Balance at December 31, 2024	$ 30,744,000	$ 18,826,133

As further described in Note 7, the Company elected the fair value option to account for the December 2022 Note. The fair value of the December 2022 Note is estimated using a binomial lattice model, which evaluates the payouts under hold, convert or call decisions. Significant estimates in the binomial lattice model include the Company's stock price, volatility, risk-free rate of return, and credit-adjusted discount rate.

The fair value of the December 2022 Note was estimated using a binomial lattice model with the following assumptions:

	December 31, 2024	September 30, 2024
Term (years)	0.5	0.8
Volatility	134.0 %	91.0 %
Risk-free rate	4.2 %	4.2 %
Dividend yield	— %	— %
Credit-adjusted discount rate	20.5 %	20.4 %
Stock price	$ 1.89	$ 5.34

The warrants issued in connection with the convertible senior secured notes originally issued pursuant to that certain Note and Warrant Purchase Agreement dated December 22, 2017 and warrants issued in connection with private placements that closed on March 18, 2024 and April 15, 2024, are classified as liabilities on the accompanying unaudited interim consolidated balance sheets. The warrants related to the Note and Warrant Purchase Agreement dated December 22, 2017 are classified as liabilities as the warrants include cash settlement features at the option of the holders under certain circumstances. The warrants issued in connection with private placements that closed on March 18, 2024 and April 15, 2024 are classified as liabilities as the Company assessed that they are not indexed to the Company's own stock and must be classified as liabilities.

The above warrant liabilities are revalued each reporting period with the change in fair values recorded in the accompanying consolidated statements of operations until the warrants are exercised or expire. The fair values of the

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

warrant liabilities are estimated using the Black-Scholes option pricing model using the following weighted average assumptions:

	December 31, 2024	September 30, 2024
Risk-free interest rate	4.34 %	3.58 %
Remaining contractual term of warrants (years)	4.2	4.5
Expected volatility	135.5 %	125.0 %
Annual dividend yield	— %	— %
Stock price	$ 1.89	$ 5.34

5. Equity Method Investment

In connection with the execution of a stock purchase agreement with Syntone, the United States-based affiliate of Syntone Technologies Group Co. Ltd. ("Syntone PRC") on May 22, 2020, the Company and Syntone PRC entered into a joint venture agreement pursuant to which they agreed to form a People's Republic of China ("PRC") joint venture, Beijing Syntone Biopharma Ltd ("Syntone JV"), that is 80% owned by Syntone PRC and 20% owned by the Company. As the Company can exert significant influence over, but does not control, Syntone JV's operations through voting rights or representation on Syntone JV's board of directors, the Company accounts for this investment using the equity method of accounting. Upon formation of Syntone JV in April 2021, the Company entered into a royalty-free license with Syntone JV for the development, commercialization and manufacture of ONS-5010/LYTENAVA in the greater China market, which includes Hong Kong, Taiwan and Macau.

The Company made the initial investment of $900,000 in June 2020 and is committed to making capital contributions to Syntone JV of approximately $2,100,000, based upon the development plan contemplated in the license agreement. The maximum exposure to a loss as a result of the Company's involvement in Syntone JV is limited to the initial investment and the future capital contributions totaling approximately $2,100,000.

6. Accrued Expenses

Accrued expenses consist of:

	December 31, 2024	September 30, 2024
Compensation	$ 683,479	$ 1,012,962
Severance and related costs	1,388,397 (i)	—
Professional fees	979,178	1,798,767
Research and development	63,220	41,373
Other accrued expenses	276,958	384,366
	$ 3,391,232	$ 3,237,468

(i) In December 2024, the Chief Executive Officer of the Company resigned, and the Company implemented a workforce reduction to conserve capital. The Chief Executive Officer's departure constituted a termination and was entitled to 12 months of base salary, a lump sum of 100% of his target bonus for the year, employee benefits for up to 12 months, full vesting of 50% of his unvested equity awards, and reimbursement of expenses owed up to his termination date. At a minimum, all employees affected by the workforce reduction are eligible to receive severance payments and paid COBRA premiums for a specified time period post-termination, subject to execution of a general release of claims against the Company.

In connection with the departure of the Chief Executive Officer and the reduction in the workforce, during the three months ended December 31, 2024, the Company recognized $1,428,455 in severance related charges in connection with the workforce reduction, consisting of cash-based expenses related to employee

severance and notice period payments, benefits and related costs. In addition, during the three months ended December 31, 2024, the Company recorded a non-cash expense totaling $2,079,083 related to stock-based compensation for accelerated equity awards for the former Chief Executive Officer. During the three months ended December 31, 2024, the Company made cash payments totaling $40,058.

7. Debt

Debt consists of:

	December 31, 2024	September 30, 2024
Unsecured convertible promissory note (measured at fair value)	$ 30,744,000	$ 29,440,000
Less: current portion	(30,744,000)	(29,440,000)
Long-term debt	$ —	$ —

December 2022 Note

On December 22, 2022, the Company entered into a Securities Purchase Agreement and issued the December 2022 Note with a face amount of $31,820,000 to Streeterville Capital, LLC (the "Lender"), the holder of the Company's unsecured promissory note issued in November 2021 (the "November 2021 Note"). The December 2022 Note has an original issue discount of $1,820,000. The Company received net proceeds of $18,052,461 upon the closing on December 28, 2022 after deducting the Lender's transaction costs in connection with the issuance and a full payment of the remaining outstanding principal and accrued interest on the November 2021 Note.

In December 2023, the Company extended the maturity of the December 2022 Note from January 1, 2024 to April 1, 2024. The Company incurred a $475,000 extension fee, which was expensed and included in interest expense in the unaudited interim consolidated statement of operations.

The December 2022 Note bore interest at 9.5% per annum through April 1, 2024. The December 2022 Note contains customary covenants, including a restriction on the Company's ability to pledge certain of the Company's assets, subject to certain exceptions, without the Lender's consent. Beginning on April 1, 2023, the Lender had the right to convert the December 2022 Note at the Conversion Price (as defined below). The principal amount and conversion price of the December 2022 Note are subject to adjustment upon certain triggering events. In addition, the Company has the right to convert all or any portion of the outstanding balance under the December 2022 Note into shares of common stock at the Conversion Price if certain conditions have been met at the time of conversion, including if at any time after the six-month anniversary of the closing date, the daily volume-weighted average price of the common stock on Nasdaq equals or exceeds $50.00 per share (subject to adjustments for stock splits and stock combinations) for a period of 30 consecutive trading days. Payments may be made by the Company (i) in cash, (ii) in shares of common stock, with the number of shares being equal to the portion of the applicable payment amount divided by the Conversion Price (as defined below), or (iii) a combination of cash and shares of common stock. Any payments made by the Company in cash, including prepayments or repayment at maturity, will be subject to an additional fee of 7.5%. Upon the occurrence of certain events described in the December 2022 Note, including, among others, the Company's failure to pay amounts due and payable under the December 2022 Note, events of insolvency or bankruptcy, failure to observe covenants contained in the Securities Purchase Agreement and the December 2022 Note, breaches of representations and warranties in the Securities Purchase Agreement, and the occurrence of certain transactions without the Lender's consent (each such event, a "Trigger Event"), the Lender shall have the right, subject to certain exceptions, to increase the balance of the December 2022 Note by 10% for a Major Trigger Event (as defined in the December 2022 Note) and 5% for a Minor Trigger Event (as defined in the December 2022 Note). If a Trigger Event is not cured within ten (10) trading days of written notice thereof from the Lender, it will result in an event of default (such event, an "Event of Default"). Following an Event of Default, the Lender may accelerate the December 2022 Note such that all amounts thereunder become immediately due and payable, and interest shall accrue at a rate of 22% annually until paid. Prior to April 1, 2024, under the December 2022 Note,

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

"Conversion Price" meant, prior to a Major Trigger Event, $40.00 per share (subject to adjustment for stock splits and stock combinations), and following a Major Trigger Event, the lesser of (i) $40.00 per share (subject to adjustment for stock splits and stock combinations), and (ii) 90% multiplied by the lowest closing bid price of the Company's common stock in the three trading days prior to the date on which the conversion notice is delivered. If the Conversion Price is below $3.51 per share, the Company will be required to satisfy a conversion notice from the Lender in cash. Subject to certain exceptions, while the December 2022 Note is outstanding, the Lender will have a consent right on any future variable rate transactions or any debt and a 10% participation right in any future debt or equity financings.

On January 22, 2024, the Company entered into an amendment to the December 2022 Note (the "Note Amendment") with the Lender, which became effective on April 1, 2024 after satisfaction of certain conditions, including various required stockholder approvals and the closing of the private placement on March 18, 2024. The maturity of the December 2022 Note was extended to July 1, 2025. An extension fee of $2,681,847 (calculated as 7.5% of the outstanding balance of the December 2022 Note) was added to the outstanding balance on March 18, 2024. The extension fee was expensed in the quarter ended March 31, 2024 and included in interest expense in the unaudited interim consolidated statement of operations.

Under the Note Amendment, the initial conversion price with respect to $15,000,000 in aggregate principal amount of the December 2022 Note was changed to $7.00, the price per share in the private placement that closed on March 18, 2024. Effective April 1, 2024, the December 2022 Note bears interest at the prime rate (as published in the Wall Street Journal) plus 3% (subject to a floor of 9.5%) and the Company has an obligation to repay at least $3,000,000 (by either cash or conversion into common stock) of the outstanding balance of the December 2022 Note for each calendar quarter beginning with the second calendar quarter of 2024 (subject to adjustment for conversions by the Lender and to payment of an exit fee as set forth in the Note Amendment) and continuing until the December 2022 Note is repaid in full. Any amount converted by the Lender during a given calendar quarter in excess of $3,000,000 will be credited toward meeting the quarterly requirement for the next quarter or quarters. Refer to Note 11 for further details on the December 2022 Note.

The Company elected to account for the December 2022 Note at fair value (Note 4) and was not required to bifurcate the conversion option as a derivative and as a result the original issue discount of $1,820,000 and debt issuance costs were written off upon election to fair value and accounted for as interest. During the three months ended December 31, 2024 and 2023, no interest expense was recognized.

8. Commitments and Contingencies

Litigation

On November 3, 2023, a securities class action lawsuit was filed against the Company and certain of its officers in the United States District Court for the District of New Jersey. The class action complaint alleges violations of the Securities Exchange Act of 1934, as amended, or the Exchange Act, in connection with allegedly false and misleading statements made by the Company related to the Company's BLA during the period from August 3, 2021 through August 29, 2023. The complaint alleges, among other things, that the Company violated Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 by failing to disclose that there was an alleged lack of evidence supporting ONS-5010/LYTENAVA as a treatment for wet AMD and that the Company and/or their manufacturing partner had deficient CMC controls for ONS-5010/LYTENAVA, which remained unresolved at the time the Company's BLA was re-submitted to the FDA and, as a result, the FDA was unlikely to approve the Company's BLA, and that the Company's stock price dropped when such information was disclosed. The plaintiffs in the class action complaint seek damages and interest, and an award of reasonable costs, including attorneys' fees. On June 25, 2024, the defendants filed a motion to dismiss the amended class action complaint in its entirety. On February 6, 2025, the court entered an order granting the motion to dismiss and dismissing the complaint without prejudice and with leave to amend, and providing for the filing of a further amended complaint and briefing on the defendants' anticipated motion to dismiss such further amended complaint in the spring of 2025.

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

On October 10, 2024, certain of the company's officers and directors were named as defendants in a shareholder derivative action filed in the District Court of the District of Delaware. The derivative complaint alleges that defendants breached their fiduciary duties by causing and/or allowing the Company to violate federal securities laws based on the same alleged misstatements as the securities class action. The derivative complaint also alleges defendants violated Section 14(a) of the Exchange Act, as well as claims for contribution, unjust enrichment, and waste of corporate assets. The derivative complaint seeks unspecified damages, corporate governance reforms, restitution, contribution, attorneys' fees, and other costs. The derivative action is currently stayed, pending the final resolution of the November 3, 2023, securities class action pending in the United States District Court for the District of New Jersey.

The pending lawsuits and any other related lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. The outcome of the pending lawsuits and any other related lawsuits is necessarily uncertain. The Company could be forced to expend significant resources in the defense of the pending lawsuits and any additional lawsuits, and the Company may not prevail. In addition, the Company may incur substantial legal fees and costs in connection with such lawsuits. The Company currently is not able to estimate the possible cost to it from these matters, as the pending lawsuits are currently at an early stage, and the Company cannot be certain how long it may take to resolve the pending lawsuits or the possible amount of any damages that the Company may be required to pay. Such amounts could be material to the Company's financial statements if it does not prevail in the defense of the pending lawsuits and any other related lawsuits, or even if it does prevail. The Company has not established any reserve for any potential liability relating to the pending lawsuits and any other related lawsuits. It is possible that the Company could, in the future, incur judgments or enter into settlements of claims for monetary damages.

Leases

Corporate office

In March 2021, the Company entered into a three-year term corporate office lease for its former corporate headquarters in Iselin, New Jersey that ended on April 30, 2024.

In March 2024, the Company entered into a five-year term corporate office lease for its new corporate headquarters in Iselin, New Jersey that commenced on May 1, 2024.

The components of lease cost for the three months ended December 31, 2024 and 2023 are as follows:

	Three months ended December 31,	
	2024	2023
Lease cost:		
Interest on lease liabilities	$ —	$ 104
Total finance lease cost	—	104
Operating lease cost	19,080	11,217
Total lease cost	$ 19,080	$ 11,321

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

Amounts reported in the unaudited interim consolidated balance sheets for leases where the Company is the lessee are as follows:

	December 31, 2024	September 30, 2024
Operating leases:		
Right-of-use asset	$ 262,822	$ 274,645
Operating lease liabilities	285,758	297,829
Weighted-average remaining lease term (years):		
Operating leases	4.3	4.6
Weighted-average discount rate:		
Operating leases	9.9%	9.9%

Other information related to leases for the three months ended December 31, 2024 and 2023 are as follows:

	Three months ended December 31, 2024	2023
Cash paid for amounts included in the measurement of lease obligations:		
Operating cash flows from finance leases	$ —	$ 104
Operating cash flows from operating leases	19,329	—
Financing cash flows from finance leases	—	3,183

Future minimum lease payments under non-cancelable leases at December 31, 2024 are as follows for the years ending September 30:

	Operating leases
2025 (remaining nine months)	$ 58,762
2026	79,954
2027	81,817
2028	83,680
2029	49,447
Total undiscounted lease payments	353,660
Less: Imputed interest	67,902
Total lease obligations	$ 285,758

9. Common Stock and Stockholders' Equity

Preferred Stock

On May 13, 2024, the Company filed a Certificate of Elimination to its Certificate of Incorporation, as then amended, with the Secretary of State of the State of Delaware to eliminate from the Certificate of Incorporation all matters set forth in the Certificates of Designation filed with the Secretary of State of the State of Delaware on September 8, 2017 (with respect to its Series A Convertible Preferred Stock and the Series B Convertible Preferred Stock) and July 18, 2018, as amended on March 19, 2020 (with respect to its Series A-1 Convertible Preferred Stock) and returning each of the Series A Convertible Preferred Stock, Series B Convertible Preferred Stock and Series A-1 Convertible Preferred Stock to the status of authorized but unissued shares of preferred stock of the Company, without designation as to series. There were no outstanding shares of Series A Convertible Preferred Stock, Series B Convertible Preferred Stock or Series A-1 Convertible Preferred Stock as of May 13, 2024. Immediately following the filing of the Certificate of Elimination, the Company filed a Restated Certificate of Incorporation of the Company with the Secretary of State of the State of Delaware, which restates and integrates but does not further amend the Company's Certificate of Incorporation, as then amended. The number of authorized shares of preferred stock under the Company's Certificate of Incorporation is 10,000,000 shares.

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

Common stock

On March 7, 2024, following receipt of stockholder approval at the Company's 2024 annual meeting of stockholders, the number of authorized shares of common stock under the Company's Certificate of Incorporation was increased from 21,250,000 shares to 60,000,000 shares.

BTIG, LLC At-the-Market Offering Agreement

On May 16, 2023, the Company entered into an At-the-Market Sales Agreement with BTIG, LLC ("BTIG") as sales agent (as amended, the "BTIG ATM Agreement" or the "BTIG ATM Offering"), under which the Company may issue and sell shares of its common stock having an aggregate offering price of up to $100,000,000 from time to time through BTIG. The Company incurred financing costs of $353,688, which were capitalized and are being reclassified to additional paid in capital on a pro rata basis when the Company sells common stock under the BTIG ATM Offering. As of December 31, 2024, $325,181 of such deferred costs are included in other assets on the unaudited interim consolidated balance sheets.

Under the BTIG ATM Agreement, the Company pays BTIG a commission equal to 3.0% of the aggregate gross proceeds of any sales of common stock under the BTIG ATM Agreement. The offering of common stock pursuant to the BTIG ATM Agreement will terminate upon the earlier of (i) the sale of all common stock subject to the BTIG ATM Agreement or (ii) termination of the BTIG ATM Agreement in accordance with its terms.

During the three months ended December 31, 2024, the Company sold 1,000,000 shares of common stock under the BTIG ATM Offering and generated $1,742,373 in net proceeds. During the three months ended December 31, 2024, the Company paid fees to BTIG and other issuance costs of $53,888. No shares of common stock were sold under the BTIG ATM Offering during the three months ended December 31, 2023.

Common stock warrants

As of December 31, 2024, 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 24, 2025		8,642	$ 25.40
April 13, 2025	(i)	7,284	$ 240.00
May 31, 2025	(i)	3,121	$ 240.00
June 22, 2025		9,563	$ 30.38
December 28, 2025		25,787	$ 21.00
January 28, 2026		12,576	$ 25.00
February 2, 2026		93,238	$ 25.00
November 23, 2026		104,999	$ 31.25
March 18, 2029	(ii)	12,857,133	$ 7.70
April 15, 2029	(ii)	1,071,429	$ 7.70
		14,193,772	

(i) The warrants were issued in connection with the convertible senior secured notes originally issued pursuant to the certain Note and Warrant Purchase Agreement dated December 22, 2017 and are classified as liabilities on the accompanying unaudited interim consolidated balance sheets, as the warrants include cash settlement features at the option of the holders under certain circumstances. Refer to Note 4 for fair value measurements disclosures.

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

(ii) The warrants were issued in connection with private placements that closed on March 18, 2024 and April 15, 2024 are exercisable only for cash, except in limited circumstances, at any time after the date of issuance. The Company evaluated the warrants under ASC 815, *Derivatives and Hedging*, guidance and determined that the warrants did not meet Step 2 of the indexation, as a result they are not indexed to the Company's own stock and must be classified as liabilities. Refer to the disclosure in Note 4 for further details on classification and fair value measurements.

A holder of warrants may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than a specified percentage of the outstanding common stock (4.99%, 9.99% or 19.99%, as applicable), immediately after giving effect to such exercise, which may be increased or decreased at the holders' option (not to exceed 19.99%), effective 61 days after written notice to the Company. In addition, the Company may require the holders to cash exercise the warrants under certain circumstances as follows: (i) if the VWAP of the common stock equals or exceeds $20.00 per share (subject to adjustment in the event of stock splits, combinations or similar events, such as the reverse stock split implemented prior to Closing as discussed below) for 30 consecutive days (the "Stock Price Condition") at any time after the Company publicly announces topline data from its NORSE EIGHT clinical trial evidencing satisfaction of the trial's primary endpoints (the "NORSE EIGHT Announcement"), upon the consent of a majority of the members of the Company's board of directors, the Company may require the holders to exercise up to 20% of the aggregate number of warrants issued to such holder on the issue date; and (ii) the Company may require up to the remainder of the warrants be exercised (A) if the Stock Price Condition is satisfied at any time after the Company publicly announces approval from the FDA of its BLA for ONS-5010/LYTENAVA, upon the consent of a majority of the members of the board of directors or (B) if the Stock Price Condition is satisfied at any time after the NORSE EIGHT Announcement, upon the unanimous consent of the members of the Company's Board of Directors present at duly called meeting. Refer to Note 11 for disclosures on the warrant inducement transactions entered into in January 2025.

10. Stock-Based Compensation

2024 Equity Incentive Plan

In December 2015, the Company adopted the 2015 Equity Incentive Plan (the "2015 Plan"). The 2015 Plan provided for the grant of stock options, stock appreciation rights, restricted stock awards, restricted stock units ("RSUs") awards, performance stock awards and other forms of equity compensation to Company employees, directors and consultants. In August 2024, the Company's stockholders approved the amendment and restatement of the 2015 Plan and, in connection with amending and restating the 2015 Plan, the name of the 2015 Plan was updated to the Outlook Therapeutics, Inc. 2024 Equity Incentive Plan (the "2024 Plan"). The 2024 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 2024 Plan is 7,303,677. As of December 31, 2024, there were 4,287,050 shares available for grant under the 2024 Plan.

Stock options and RSUs are granted under the Company's 2024 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 RSU over its vesting period.

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

The Company recorded stock-based compensation expense in the following expense categories of its unaudited interim consolidated statements of operations for the three December 31, 2024 and 2023:

	Three months ended December 31,	
	2024	2023
Research and development	$ 110,029	$ 231,416
General and administrative	3,562,391	1,041,195
	$ 3,672,420	$ 1,272,611

Stock options

As of December 31, 2024, options to purchase common stock of the Company outstanding under the 2024 Plan were as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at October 1, 2024	1,946,646	$ 19.51		
Granted	1,179,276	5.22		
Forfeited	(304,636)	10.25		
Expired	(4,435)	46.78		
Balance at December 31, 2024	2,816,851	$ 14.49	8.2	$ —
Vested and exercisable at December 31, 2024	1,375,258	$ 22.83	6.7	$ —

The aggregate intrinsic value represents the total amount by which the fair value of the common stock subject to options exceeds the exercise price of the related options.

The weighted average grant date fair value of the options awarded to employees for the three months ended December 31, 2024 and 2023 was $4.67 and $5.20 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:

	Three months ended December 31,	
	2024	2023
Risk-free interest rate	3.5 %	4.6 %
Expected term (years)	5.5	5.5
Expected volatility	134.0 %	130.6 %
Expected dividend yield	—	—

As of December 31, 2024, there was $6,496,794 of unrecognized compensation expense that is expected to be recognized over a weighted-average period of 0.8 years.

Performance-based stock options

The Company granted certain officers of the Company option awards whose vesting is contingent upon meeting company-wide performance goals. The performance stock options were granted “at-the-money” and have a term of 10 years.

The fair value of each option grant under the performance share option plan was estimated on the date of grant using the same option valuation model used for non-statutory options above. Compensation expense for performance-based stock options is only recognized when management determines it is probable that the awards will vest.

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

A summary of the activity under the performance share option plan as of December 31, 2024 and changes during the three months then ended are presented below.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at October 1, 2024	666,500	$ 7.94		
Granted	—	—		
Forfeited	(476,500)	6.78		
Balance at December 31, 2024	190,000	$ 10.85	8.6	$ —
Vested and exercisable at December 31, 2024	35,000	$ 28.80	6.1	$ —

The vesting of the performance-based stock options is conditional upon FDA approval of ONS-5010/LYTENAVA. The expense for the performance-based stock options is not recognized until the performance conditions are deemed probable of achievement. The Company did not record any expense related to the performance-based stock options during the three months ended December 31, 2024 as the performance conditions were not deemed probable of being met. As of December 31, 2024, the Company assessed that the performance conditions related to the performance options granted were not probable of achievement. The assessment was based on the relevant facts and circumstances and therefore no compensation costs were recognized.

11. Subsequent Events

Warrant Inducement Transaction

In connection with the Warrant Inducement Transaction (see Note 2), half of the Inducement Warrants (the "Tranche A Inducement Warrants"), representing warrants to purchase up to 7,074,637 shares of common stock are exercisable immediately and expire on January 17, 2030. The remaining Inducement Warrants (the "Tranche B Inducement Warrants") will be exercisable upon the effective date of an amendment to the Company's Certificate of Incorporation to increase the number of authorized shares of common stock. The Company plans to present a proposal at its 2025 annual meeting of stockholders to authorize a sufficient increase in the number of authorized shares. The Tranche A Inducement Warrants, Tranche B Inducement Warrants and the underlying Inducement Warrant Shares were offered in a private placement and are exempt from Securities Act registration. The Company has committed to filing resale registration statements with the SEC to register the resale of the Inducement Warrant Shares underlying the Tranche A Inducement Warrants and Tranche B Inducement Warrants within specified time frames. GMS, the Company's largest stockholder affiliated with Yezan Haddadin and Faisal G. Sukhtian, directors of the Company participated in the Warrant Inducement Transaction. In this transaction, GMS exercised Existing Warrants for an aggregate of 3,458,571 shares of common stock at a reduced exercise price of $2.51 per share, generating gross proceeds of $8,681,013 to the Company, in exchange for Inducement Warrants to purchase 6,917,142 shares of common stock.

Syntone Warrant Inducement Transaction

In connection with the Syntone Warrant Inducement Transaction (see Note 2), half of the Syntone Inducement Warrants (the "Syntone Tranche A Inducement Warrants") will be immediately exercisable upon receipt of certain regulatory approvals and will expire on the five-year anniversary of the date of issuance. The remaining Syntone Inducement Warrants (the "Syntone Tranche B Inducement Warrants") will be exercisable upon receipt of certain regulatory approvals and the effective date of an amendment to the Company's Certificate of Incorporation to increase the number of authorized shares of common stock. The Company plans to present a proposal at its 2025 annual meeting of stockholders to authorize a sufficient increase in the number of authorized shares.

The Syntone Tranche A Inducement Warrants, Syntone Tranche B Inducement Warrants and the underlying Syntone

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

Inducement Warrant Shares were offered in a private placement exempt from Securities Act registration. The Company has committed to filing resale registration statements with the SEC to register the resale of the Syntone Inducement Warrant Shares underlying the Syntone Tranche A Inducement Warrants and Syntone Tranche B Inducement Warrants within specified time frames.

Unsecured Convertible Promissory Note Securities Purchase Agreement

Commencing on the earlier of (i) six months following the issuance of the January 2025 Note (see Note 2) or (ii) the date on which the registration statement is declared effective (the "Conversion Commencement Date"), Avondale shall have the right to convert all or any portion of the outstanding balance under the January 2025 Note into shares of common stock, calculated by dividing the amount of the January 2025 Note being converted by the Conversion Price (as defined below). Furthermore, the Company retains the right to convert any portion of the outstanding balance under the January 2025 Note into shares of common stock at the Conversion Price, provided certain conditions are met at the time of conversion, including, but not limited to, the condition that the daily volume-weighted average price of the Company's common stock on Nasdaq equals or exceeds $3.00 per share (subject to adjustments for stock splits and combinations) for a continuous period of 30 trading days, and that the median daily dollar trading volume during the preceding 30 consecutive trading day period meets or exceeds $1,000,000. The Company reserves the right to make payments (i) in cash, (ii) in shares of common stock, calculated as the applicable payment amount divided by the Conversion Price, or (iii) a combination of both cash and shares of common stock. Any cash payments made by the Company, including prepayments or payments made at maturity, will incur an additional fee of 7.5%.

The January 2025 Note stipulates that the Company shall not permit any conversion of the January 2025 Note if, following such conversion, Avondale and its affiliates would beneficially own shares of common stock exceeding 4.99% of the total number of outstanding shares as of that date (the "Beneficial Ownership Limitation"). However, this limitation shall increase to 9.99% when the Company's market capitalization falls below $25,000,000. Avondale may, by written notice to the Company, adjust the Beneficial Ownership Limitation for itself, though any such adjustment will not take effect until the 61st day after such notice is received.

In the event that specific occurrences outlined in the January 2025 Note transpire—such as the Company's failure to fulfill payment obligations, non-compliance with the Quarterly Debt Reduction Obligations, insolvency or bankruptcy events, breaches of covenants in the SPA and the January 2025 Note, and unauthorized transactions without Avondale's consent (collectively referred to as "Trigger Events")—Avondale reserves the right to increase the balance of the January 2025 Note by 10% in the case of a Major Trigger Event (as defined in the January 2025 Note) and by 5% for a Minor Trigger Event (as defined in the January 2025 Note). Should any Trigger Event persist without resolution for ten trading days following written notification from Avondale, this will constitute an event of default (such event, an "Event of Default"). Upon an event of default, Avondale may accelerate the January 2025 Note, resulting in all amounts becoming immediately due and payable, with interest accruing at a rate of 22% per annum until full payment is made.

Under the terms of the January 2025 Note, the "Conversion Price" is defined as $2.26 per share prior to a Major Trigger Event (subject to adjustments for stock splits and combinations). Following a Major Trigger Event, the Conversion Price will be the lesser of (i) $2.26 per share (subject to adjustments) or (ii) 90% of the lowest closing bid price over the three trading days preceding the conversion notice. Furthermore, if the Conversion Price falls below $0.404 per share (subject to adjustments), the Company will be required to fulfill a conversion notice from Avondale in cash.

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, 2024 and 2023 included in our Annual Report on Form 10-K for the year ended September 30, 2024, filed with the Securities and Exchange Commission, or SEC, on December 27, 2024.

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 "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potentially," "seek," "should," "will," "would," 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 material difference including, but not limited to, those discussed under the caption "Risk Factors" in our Annual Report on Form 10-K for the year ended September 30, 2024, filed with the SEC on December 27, 2024, 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 biopharmaceutical company working to launch the first ophthalmic formulation of bevacizumab approved by the European Commission in the European Union, or EU, the Medicines and Healthcare products Regulatory Agency, or MHRA, in the United Kingdom, or UK, and the U.S. Food and Drug Administration, or FDA, for use in retinal indications. Our initial goal is to launch directly in the EU and UK, and, if approved, to launch directly in the United States as the first and only approved ophthalmic bevacizumab for the treatment of retina conditions, including wet age-related macular degeneration, or wet AMD. Our plans also include seeking approval and launching the product in Japan and other markets. On May 27, 2024, we received a marketing authorization from the European Commission for ONS-5010/LYTENAVA for the treatment of wet AMD. The authorization is valid throughout the European Economic Area, or the EEA, and provides eight years of data exclusivity and 10 years of market exclusivity. On July 8, 2024, we also received marketing authorization for ONS-5010/LYTENAVA for the treatment of wet AMD in the UK, followed by a recommendation by the UK National Institute for Health and Care Excellence, or NICE, for LYTENAVA™ (bevacizumab gamma), as an option for the treatment of wet AMD on December 4, 2024. Outside of the United States, we are currently moving ahead with our plans to launch directly in the initial markets of Germany and the UK in the second quarter of calendar 2025.

Bevacizumab is a full-length, humanized anti-VEGF (Vascular Endothelial Growth Factor) recombinant monoclonal antibody, or mAb, that inhibits VEGF and associated angiogenic activity. In October 2022 we submitted a Marketing Authorization Application, or MAA, for ONS-5010/LYTENAVA with the European Medicines Agency, or EMA. The MAA was submitted as a 'full-mixed marketing authorization application' based on Article 8.3 of Directive 2001/83/EC. On March 22, 2024, the EMA's Committee for Medicinal Products for Human Use, or CHMP issued a positive opinion concerning the authorization of ONS-5010/LYTENAVA (bevacizumab gamma), an investigational ophthalmic formulation of bevacizumab for the treatment of wet age-related macular degeneration, or wet AMD, in the EU. In May 2024, the European Commission granted the Marketing Authorization for ONS-5010/LYTENAVA for the treatment of wet AMD in the EU. The decision applied automatically in all 27 EU Member States, and, within 30 days, also to Iceland, Norway and Liechtenstein. Additionally, in April 2024, we submitted a MAA to the MHRA in the UK seeking approval of ONS-5010/LYTENAVA (bevacizumab gamma) for the treatment of wet AMD. The submission was completed under the new International Recognition Procedure, or IRP, which allows the MHRA to rely on an authorization received for the same product from one of MHRA's specified Reference Regulators, or RRs, when considering an application for marketing authorization in the UK. These RRs include a positive opinion by the EMA's CHMP concerning an application

for grant of marketing authorization for the same product in the EU. In July 2024, the MHRA granted marketing authorization for ONS-5010/LYTENAVA for the treatment of wet AMD in the UK. ONS-5010/LYTENAVA is the first and only authorized ophthalmic formulation of bevacizumab for use in treating wet AMD in the EU and UK.

Separately, in March 2022, we submitted a BLA with the FDA for ONS-5010/LYTENAVA, an investigational ophthalmic formulation of bevacizumab, which we have developed to be administered as an intravitreal injection for the treatment of wet AMD and other retinal diseases. In May 2022, we voluntarily withdrew our BLA to provide additional information requested by the FDA. We re-submitted the BLA to the FDA for ONS-5010/LYTENAVA on August 30, 2022, and in October 2022, we received confirmation from the FDA that our BLA had been accepted for filing with a goal date of August 29, 2023 for a review decision by the FDA. On August 29, 2023, we received a Complete Response Letter, or CRL, in which the FDA concluded it could not approve the BLA during this review cycle due to several chemical, manufacturing and control, or CMC, issues, open observations from pre-approval manufacturing inspections, and a lack of substantial evidence. At subsequent Type A meetings with the FDA, we learned that the FDA requires the completion of an additional adequate and well-controlled clinical trial evaluating ONS-5010/LYTENAVA, as well as additional requested CMC data indicated in the CRL to approve ONS-5010/LYTENAVA for use in wet AMD.

We agreed to conduct an additional adequate and well-controlled clinical trial following discussions with the FDA in support of our BLA for ONS-5010/LYTENAVA. In December 2023, we submitted a Special Protocol Assessment, or SPA, to the FDA for this study (NORSE EIGHT) seeking confirmation that, if successful, it will address the FDA's requirement for a second adequate and well-controlled clinical trial to support our planned resubmission of the ONS-5010/LYTENAVA BLA. In January 2024, we received confirmation that the FDA had reviewed and agreed upon the NORSE EIGHT trial protocol pursuant to the SPA. If the NORSE EIGHT trial is successful, it would satisfy the FDA's requirement for a second adequate and well-controlled clinical trial to address fully the clinical deficiency identified in the CRL. In addition, through a Type A meeting and additional interactions with the FDA, we identified the approaches needed to resolve the CMC comments in the CRL. We believe that we have addressed the open CMC items and have concluded a series of Type C and Type D meetings with the FDA to help resolve these comments. In November 2024, we reported that ONS-5010/LYTENAVA did not meet the pre-specified non-inferiority endpoint at week 8 set forth in the SPA. However, the preliminary data from the trial demonstrated an improvement in vision and the presence of biologic activity, as well as a continued favorable safety profile for ONS-5010/LYTENAVA. Analysis of the complete week 12 data set for NORSE EIGHT has now been completed and provided additional evidence of improvement in vision and biological activity. We plan to resubmit the BLA for ONS-5010/LYTENAVA in the first quarter of calendar 2025.

Our BLA and MAA submissions for ONS-5010/LYTENAVA in wet AMD involved three clinical trials, which we refer to as NORSE ONE, NORSE TWO and NORSE THREE. The study design for our clinical program to evaluate ONS-5010/LYTENAVA 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. In August 2020, we reported achieving the anticipated safety and efficacy proof-of-concept results from NORSE ONE, a clinical experience study. NORSE TWO was our pivotal Phase 3 clinical trial comparing ONS-5010/LYTENAVA to ranibizumab (LUCENTIS). The topline results reported from NORSE TWO in August 2021 showed that ONS-5010/LYTENAVA met the primary and key secondary endpoints for efficacy with clinically impactful change observed for treated patients. In March 2021, we reported that the results from NORSE THREE showed a positive safety profile for ONS-5010/LYTENAVA.

As agreed to with the FDA in the SPA, NORSE EIGHT is a randomized, controlled, parallel-group, masked, non-inferiority study of approximately 400 newly diagnosed, wet AMD subjects randomized in a 1:1 ratio to receive 1.25 mg ONS-5010/LYTENAVA or 0.5 mg ranibizumab intravitreal injections. Subjects received injections at Day 0 (randomization), Week 4, and Week 8 visits. The primary endpoint is the mean change in best corrected visual acuity (BCVA) from baseline to week 8. In November 2024, we reported that ONS-5010/LYTENAVA did not meet the pre-specified non-inferiority endpoint at week 8 set forth in the SPA. The difference in the means between the ONS-5010/LYTENAVA and ranibizumab arms in the NORSE EIGHT trial was -2.257 BCVA letters with a 95% confidence interval of (-4.044, -0.470) while the lower bound of the pre-specified non-inferiority margin in the SPA was -3.5 at a 95% confidence interval; the hypothesis of noninferiority was not met ($p>0.025$). In the intent-to-treat, or ITT, primary dataset, NORSE EIGHT demonstrated a mean +4.2 letter improvement in BCVA in the ONS-5010/LYTENAVA arm and +6.3 letter improvement in BCVA in the ranibizumab arm. However, the preliminary data from the trial demonstrated an improvement in vision and the presence of biologic activity, as well as a continued favorable safety profile for ONS-

5010/LYTENAVA. In January 2025, we reported the complete week 12 data and safety results from NORSE EIGHT, which continued to demonstrate an improvement in vision and the presence of biologic activity, as well as a continued favorable safety profile. At week 12, the difference in the mean between ONS-5010/LYTENAVA and ranibizumab was -1.009 BCVA letters with a 95% confidence interval of (-2.865, 0.848) in the NORSE EIGHT trial. Applying the statistical parameters from the week 8 primary endpoint with the lower bound of the non-inferiority margin at -3.5 with a 95% confidence interval, the noninferiority margin was met at week 12, indicating that the two study arms are not different at this timepoint. In the ITT population, NORSE EIGHT demonstrated a mean 5.5 letter improvement in BCVA in the ONS-5010/LYTENAVA arm and 6.5 letter improvement in BCVA in the ranibizumab arm. Additionally, the change in central retinal thickness, a measure of anatomical response, was similar in both study arms at all three study timepoints. The safety results demonstrated across the full duration of NORSE EIGHT are consistent with previously reported safety results from the NORSE ONE, NORSE TWO, and NORSE THREE clinical trials, with no cases of retinal vasculitis reported in either study arm. We plan to resubmit the BLA application for ONS-5010/LYTENAVA in the first quarter of calendar 2025. If approved, we expect to receive 12 years of regulatory exclusivity in the United States.

Previously, in November 2021, we began enrolling patients in our NORSE SEVEN clinical trial. The study compares the safety of ophthalmic bevacizumab in vials versus pre-filled syringes in subjects diagnosed with a retinal condition that would benefit from treatment with intravitreal injection of bevacizumab, including exudative age-related macular degeneration, DME, or BRVO. Subjects will be treated for three months, and the enrollment of subjects in the arm of the study receiving ONS-5010/LYTENAVA in vials has been completed.

We have also received agreement from the FDA on three Special Protocol Assessments, or SPAs, for three additional registration clinical trials for our ongoing Phase 3 program for ONS-5010/LYTENAVA. The agreements reached with the FDA on these SPAs cover the protocols for NORSE FOUR, a registration clinical trial evaluating ONS-5010/LYTENAVA to treat BRVO, and NORSE FIVE and NORSE SIX, two registration clinical trials evaluating ONS-5010/LYTENAVA to treat DME. The timing for initiating these studies has not been determined pending initial FDA approval for wet AMD.

Because there are no approved bevacizumab products for the treatment of retinal diseases in the United States and other major markets, we submitted a standard BLA and are not using the biosimilar drug regulatory pathway that would be required if Avastin were an approved drug for the targeted diseases. If approved in the United States, we believe ONS-5010/LYTENAVA has potential to mitigate risks associated with off-label use of unapproved bevacizumab. In the United States, 66.3% of retina physicians state off-label repackaged bevacizumab is their most commonly used first-line anti-VEGF (ASRS 2022 Membership Survey Presented at ASRS NY 2022).

Going Concern

On January 16, 2025, we entered into warrant exercise inducement offer letter agreements, or the Warrant Inducement Transaction, with GMS Ventures and Investments, or GMS, and certain other holders of existing warrants to purchase the Company's common stock, pursuant to which the holders agreed to exercise their existing warrants, or Existing Warrants, for an aggregate of 7,074,637 shares of common stock at a reduced exercise price of $2.51 per share. In exchange, we issued two new inducement warrants for each Existing Warrant exercised, or the Inducement Warrants, which are exercisable for an aggregate of up to 14,149,274 shares of common stock, or the Inducement Warrant Shares, at an exercise price of $2.26 per share. We received net proceeds of $15.7 million, after capital markets advisory fees and estimated offering costs, from the Warrant Inducement Transaction.

Concurrently with the Warrant Inducement Transaction, we entered into a warrant exercise inducement offer letter agreement, or the Syntone Warrant Inducement Transaction, with Syntone Ventures, LLC, or Syntone, pursuant to which Syntone agreed to exercise existing warrants, or the Existing Syntone Warrants, for an aggregate of 1,071,429 shares of common stock at a reduced exercise price of $2.51 per share. In exchange, we agreed to issue two new inducement warrants for each Existing Syntone Warrant exercised, or the Syntone Inducement Warrants, which will be exercisable for up to 2,142,858 shares of common stock, or the Syntone Inducement Warrant Shares, at an exercise price of $2.26 per share. The closing of the Syntone Warrant Inducement Transaction is subject to receipt of certain regulatory approvals. We expect to generate net proceeds of approximately $2.4 million after capital markets advisory fees and estimated offering costs. For further details on the Warrant Inducement Transaction and the Syntone Warrant Inducement Transaction, refer to Note 11 to the unaudited consolidated interim financial statements included elsewhere in this Quarterly Report on Form 10-Q.

On January 31, 2025, we entered into a Securities Purchase Agreement, or SPA, with Avondale Capital, LLC, or Avondale, pursuant to which we agreed to issue to Avondale an unsecured convertible promissory note for $33,100,000, or the January 2025 Note. We expect to use the proceeds from the January 2025 Note to repay in full the remaining obligations, including accrued and unpaid interest and the applicable exit fee, owed under the December 2022 Note with Streeterville Capital, or, as amended, the December 2022 Note. The December 2022 Note will be cancelled in connection with the issuance of the January 2025 Note. The closing of the transaction, or Note Closing, is expected to occur shortly after our 2025 annual meeting of stockholders, subject to certain closing conditions, including stockholder approval of the issuances of shares of our common stock in excess of 19.99% of the outstanding common stock upon conversion of the January 2025 Note. For a description of the SPA and the January 2025 Note, see "Description of Indebtedness" below for additional detail.

Through December 31, 2024, we have funded substantially all of our operations with $532.6 million in net 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 through such date. Our net income for the three months ended December 31, 2024 was $17.4 million. We also had a net loss of $11.2 million for the three months ended December 31, 2023. We have not generated any revenue from product sales. We anticipate incurring additional losses until such time, if ever, that we can generate significant sales of ONS-5010/LYTENAVA or any other product candidate we may develop.

We evaluated whether there are conditions or events considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern. We do not believe that the existing cash and cash equivalents as of December 31, 2024, together with net proceeds from the sale of shares of common stock in the Warrant Inducement Transaction, are sufficient to fund our operations through one year from the date of this Quarterly Report on Form 10-Q. As a result, there is substantial doubt about our ability to continue as a going concern. For further details on the warrants to purchase shares of common stock, refer to Note 9 of the unaudited consolidated interim financial statements included elsewhere in this Quarterly Report on Form 10-Q. The Company's consolidated financial statements do not include any adjustments that might be necessary if it is unable to continue as a going concern.

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. We have also licensed rights to our inactive biosimilar program product candidates (ONS-3010, ONS-1045 and ONS-5010/LYTENAVA) in other markets.

Syntone – PRC Joint Venture

In May 2020, we entered into a stock purchase agreement with Syntone, the United States-based affiliate of Syntone Technologies Group Co. Ltd., or Syntone PRC, pursuant to which we sold and issued in June 2020, in a private placement, 800,000 shares of our common stock at a purchase price of $20.00 per share, for aggregate gross proceeds of $16.0 million. In connection with the entry into the stock purchase agreement, we entered into a joint venture agreement with Syntone PRC pursuant to which we agreed to form a People's Republic of China, or PRC joint venture, Beijing Syntone Biopharma Ltd, or Syntone JV, that is 80% owned by Syntone PRC and 20% owned by us. Upon formation of Syntone JV in April 2021, we entered into a royalty-free license with Syntone JV for the development, commercialization and manufacture of ONS-5010/LYTENAVA in the greater China market, which includes Hong Kong, Taiwan and Macau.

We used approximately $0.9 million of the proceeds from the May 2020 private placement to Syntone to fund our initial capital contribution to Syntone JV and are committed to making capital contributions to Syntone JV of approximately $2.1 million, based upon the development plan contemplated in the license agreement. The maximum exposure to a loss as a result of our involvement in Syntone JV is limited to the initial investment and the future capital contributions totaling approximately $2.1 million.

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/LYTENAVA triggered a CHF 65,000 (approximately $0.1 million) milestone payment under the commercial license agreement, which we paid in November 2019.

Components of our Results of Operations

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. Full product commercialization will take several years and millions of dollars in additional 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.

Loss (income) on Equity Method Investment

Loss (income) on equity method investment represents our proportionate share for the period of the net loss (income) of our investee to which the equity method of accounting is applied. We account for equity investments where we own a non-controlling interest, but have the ability to exercise significant influence, under the equity method of accounting.

Interest income

Interest income is earned from short term investments primarily money market investments.

Interest Expense

Interest expense consists of cash paid and non-cash interest expense related to our senior secured notes, equipment loans, lease liabilities and other finance obligations.

Change in Fair Value of Promissory Notes

The change in fair value relates to convertible promissory notes that we elected to account for at fair value. As permitted under ASC 825, we elected the fair value option to account for our convertible promissory notes. We recorded the convertible promissory note at fair value with changes in fair value recorded in the consolidated statements of operations.

Change in Fair Value of Warrant Liability

We issued warrants to purchase our common stock in conjunction with convertible senior secured notes issued pursuant to a certain Note and Warrant Purchase Agreement dated December 22, 2017. Additionally, we issued warrants in connection with private placements that closed on March 18, 2024 and April 15, 2024. These warrants are categorized as liabilities and recorded at fair value. The warrants are subject to re-measurement at each balance sheet date, and we recognize any change in fair value in our statements of operations.

Income Taxes

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 and development, or R&D, tax credits) for the net losses we have incurred in each year or on our earned R&D tax credits, due to our uncertainty of realizing a benefit from those items. As of September 30, 2024, we had federal and state NOL carryforwards of $406.7 million and $242.5 million, respectively, that will begin to expire in 2030 and 2039, respectively. As of September 30, 2024, we had federal foreign tax credit carryforwards of $0.3 million available to reduce future tax liabilities, which begin to expire starting in 2023. As of September 30, 2024, we also had federal and state R&D tax credit carryforwards of $13.0 million and $0.8 million, respectively, that will begin to expire in 2032 and 2033, respectively.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its NOLs to offset future taxable income. We have not completed a study to assess whether an ownership change has occurred in the past. Our existing NOLs may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change in connection with or after our Initial Public Offering, or IPO, our ability to utilize NOLs could be further limited by Section 382 of the Code. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Code. Our NOLs are also subject to international regulations, which could restrict our ability to utilize our NOLs. Furthermore, our ability to utilize NOLs of companies that we may acquire in the future may be subject to limitations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

Furthermore, our ability to utilize NOLs of companies that we may acquire in the future may be subject to limitations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

Results of Operations

Comparison of Three Months Ended December 31, 2024 and 2023

	Three months ended December 31,		
	2024	2023	Change
Operating expenses:			
Research and development	$ 9,660,150	$ 4,529,358	$ 5,130,792
General and administrative	11,946,702	5,793,764	6,152,938
Loss from operations	(21,606,852)	(10,323,122)	(11,283,730)
Loss (income) on equity method investment	33,295	(2,548)	35,843
Interest income	(48,881)	(188,677)	139,796
Loss from change in fair value of promissory notes	1,304,000	993,000	311,000
(Gain) loss from change in fair value of warrant liability	(40,272,880)	53,342	(40,326,222)
Net income (loss)	$ 17,377,614	$ (11,178,239)	$ 28,555,853

Research and development expenses

The following table summarizes our research and development expenses by functional area for the three months ended December 31, 2024 and 2023:

	Three months ended December 31,	
	2024	2023
ONS-5010/LYTENAVA development	$ 8,725,849	$ 3,326,461
Compensation and related benefits	569,127	750,224
Stock-based compensation	110,029	231,416
Other research and development	255,145	221,257
Total research and development expenses	$ 9,660,150	$ 4,529,358

Research and development expenses for the three months ended December 31, 2024 increased by $5.1 million compared to the three months ended December 31, 2023. The increase was due to an increase in ONS-5010/LYTENAVA development expenses related to conducting the NORSE EIGHT clinical trial, which was initiated and began enrolling patients in January 2024.

General and administrative expenses

The following table summarizes our general and administrative expenses by type for the three months ended December 31, 2024 and 2023:

	Three months ended December 31,	
	2024	2023
Professional fees	$ 2,321,458	$ 2,142,669
Compensation and related benefits	2,780,189	1,977,487
Stock-based compensation	3,562,391	1,041,195
Europe prelaunch expenses	2,466,342	—
Facilities, fees and other related costs	816,322	632,413
Total general and administrative expenses	$ 11,946,702	$ 5,793,764

General and administrative expenses for the three months ended December 31, 2024 increased by $6.2 million when compared to the three months ended December 31, 2023. This increase was due to $2.5 million in prelaunch expenses for Europe and an increase of $3.3 million in combined cash and stock-based compensation, which was primarily related to severance costs from the resignation of our former Chief Executive Officer and our December 2024 reduction in headcount.

Interest income

Interest income for the three months ended December 31, 2024 and 2023 was earned from short term investments primarily money market investments.

Change in fair value of promissory notes

The change in fair value relates to the promissory notes that we elected to account for at fair value. As permitted under ASC 825, we elected the fair value option to account for our promissory note. We record the promissory note at fair value with changes in fair value recorded in the unaudited interim consolidated statements of operations.

Change in fair value of warrant liability

We issued warrants to purchase our common stock in conjunction with convertible senior secured notes issued pursuant to a certain Note and Warrant Purchase Agreement dated December 22, 2017. Additionally, we issued warrants in connection with private placements that closed on March 18, 2024 and April 15, 2024. These warrants are categorized 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. The gain recorded during the quarter ended December 31, 2024 was primarily due to the reduction in the price per share of common stock from September 30, 2024 to December 31, 2024.

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, 2024, we have funded substantially all of our operations with $532.6 million in net proceeds from the sale and 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.

We anticipate incurring additional losses until such time, if ever, that we can generate significant sales of ONS-5010/LYTENAVA or any other product candidate we may develop. We will need additional financing to fund our operations and to commercially develop ONS-5010/LYTENAVA or any other product candidate we may develop and to continue as a going concern. Management is currently evaluating various strategic opportunities to obtain the required funding for future operations. These strategies may include but are not limited to potential licensing and/or marketing arrangements or collaborations with pharmaceutical or other companies, the issuance of equity securities, including through an at-the-market offering program, the issuance of additional debt, and revenues from potential future product sales, if any. Alternatively, we may be required to, among other things, modify our clinical trial plans for ONS-5010/LYTENAVA 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.

On May 16, 2023, the Company entered into an At-the-Market Sales Agreement with BTIG, LLC, or BTIG, as sales agent, as amended, the BTIG ATM Agreement or the BTIG ATM Offering, under which the Company may issue and sell shares of its common stock having an aggregate offering price of up to $100.0 million from time to time through BTIG. Under the BTIG ATM Agreement, the Company pays BTIG a commission equal to 3.0% of the aggregate gross proceeds of any sales of common stock under the BTIG ATM Agreement. The offering of common stock pursuant to the BTIG ATM Agreement will terminate upon the earlier of (i) the sale of all common stock subject to the BTIG ATM Agreement or (ii) termination of the BTIG ATM Agreement in accordance with its terms.

During the three months ended December 31, 2024, we sold 1,000,000 shares of common stock under the BTIG ATM Offering and generated approximately $1.7 million in net proceeds.

In January 2025, we sold 36,907 shares of common stock under the BTIG ATM Agreement and generated $0.1 million in net proceeds after paying fees to BTIG and other issuance costs assessed as immaterial.

On December 22, 2022, we entered into a Securities Purchase Agreement and issued the December 2022 Note with a face amount of $31.8 million to Streeterville Capital, LLC, or the Lender, the holder of our November 2021 Note. The December 2022 Note has an original issue discount of $1.8 million. A portion of the proceeds from the December 2022 Note were used to repay in full the remaining outstanding principal and accrued interest on the November 2021 Note, which was cancelled upon repayment. We received net proceeds of $18.1 million upon the closing on December 28, 2022, after deducting the Lender's transaction costs in connection with the issuance and November 2021 Note repayment. In December 2023, the Company extended the maturity of the December 2022 Note from January 1, 2024 to April 1, 2024. The Company incurred a $475 thousand extension fee. The December 2022 Note bore interest at 9.5% per annum through April 1, 2024. On January 22, 2024, the Company entered into an amendment to the December 2022 Note, or the Note Amendment, with the Lender, which became effective on April 1, 2024 after satisfaction of certain closing conditions, including various required stockholder approvals and the closing of the private placement that closed on March 18, 2024. The maturity of the December 2022 Note was extended to July 1, 2025. An extension fee of $2.7 million (calculated as 7.5% of the outstanding balance of the December 2022 Note) was added to the outstanding balance on March 18, 2024. Under the Note Amendment, the initial conversion price with respect to $15.0 million in aggregate principal amount of the December 2022 Note was changed to $7.00, the price per share in the private placement that closed on March 18, 2024 and the remaining aggregate principal amount is converted at a price of $40.00 per share. Effective April 1 2024, the December 2022 Note bears interest at the prime rate (as published in the Wall Street Journal) plus 3% (subject to a floor of 9.5%) and the Company has an obligation to repay at least $3.0 million (by either cash or conversion into common stock) of the outstanding balance of the December 2022 Note for each calendar quarter beginning with the second calendar quarter of 2024 (subject to adjustment for conversions by the Lender and to payment of an exit fee as set forth in the December 2022 Note) and continuing until the December 2022 Note is repaid in full. The December 2022 Note contains customary covenants, including a restriction on the Company's ability to pledge certain of the Company's assets, subject to certain exceptions, without the Lender's consent. See "Description of Indebtedness" below for additional detail.

On January 16, 2025, we entered into a Warrant Inducement Transaction with GMS and certain other holders of Existing Warrants, pursuant to which the holders agreed to exercise their Existing Warrants for an aggregate of 7,074,637 shares of common stock at a reduced exercise price of $2.51 per share. In exchange, we issued two new Inducement Warrants for each Existing Warrant exercised, which are exercisable for an aggregate of up to 14,149,274 Inducement Warrant Shares at an exercise price of $2.26 per share. We received net proceeds of $15.7 million, after capital markets advisory fees and estimated offering costs, from the Warrant Inducement Transaction.

Concurrently with the Warrant Inducement Transaction, the Company entered into the Syntone Warrant Inducement Transaction, pursuant to which Syntone agreed to exercise the Existing Syntone Warrants for an aggregate of 1,071,429 shares of common stock at a reduced exercise price of $2.51 per share. In exchange, the Company agreed to issue two new Syntone Inducement Warrants for each existing warrant exercised, which will be exercisable for up to 2,142,858 Syntone Inducement Warrant Shares at an exercise price of $2.26 per share. The closing of the Syntone Warrant Inducement Transaction is subject to receipt of certain regulatory approvals. The Company expects to generate net proceeds of approximately $2.4 million after capital markets advisory fees and estimated offering costs. For further details on the Warrant Inducement Transaction and Syntone Warrant Inducement Transaction, refer to Note 11 to the unaudited consolidated interim financial statements included elsewhere in this Quarterly Report on Form 10-Q.

On January 31, 2025, we entered into a SPA with Avondale, pursuant to which we agreed to issue to Avondale the January 2025 Note. We expect to use the proceeds from the January 2025 Note to repay in full the remaining obligations, including accrued and unpaid interest and the applicable exit fee, owed under the December 2022 Note. The December 2022 Note will be cancelled in connection with the issuance of the January 2025 Note. The Note Closing is expected to occur shortly after our 2025 annual meeting of stockholders, subject to certain closing conditions, including stockholder approval of the issuances of shares of our common stock in excess of 19.99% of the outstanding common stock upon conversion of the January 2025 Note. For a description of the SPA and the January 2025 Note, see "Description of Indebtedness" below for additional detail.

We evaluated whether there are conditions or events considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern. We do not believe that the existing cash and cash equivalents as of December 31, 2024, together with the net proceeds from the sale of shares of common stock in the Warrant Inducement Transaction, are sufficient to fund the Company's operations through one year from the date of this Quarterly Report on Form 10-Q. As a result, there is substantial doubt about the Company's ability to continue as a going concern. For further details on the

warrants to purchase shares of common stock, refer to Note 10 of the unaudited consolidated interim financial statements included elsewhere in this Quarterly Report on Form 10-Q. Our consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

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 successfully begin marketing of our product candidates or complete revenue-generating partnerships with other 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. Additionally, the global financial markets have experienced significant disruptions due to various macroeconomic factors, including, among other things, the impacts of ongoing overseas conflict, resulting in a general global economic slowdown. Furthermore, inflation rates, particularly in the United States and the United Kingdom, have increased recently to levels not seen in decades. In addition, the U.S. Federal Reserve has raised interest rates in response to concerns about inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may further increase economic uncertainty and heighten these risks. Moreover, the recent closures of Silicon Valley Bank, Signature Bank and First Republic Bank have resulted in broader financial institution liquidity risk and concerns. If other banks and financial institutions fail or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our cash, cash equivalents and investments may be threatened and our ability to raise additional capital could be substantially impaired. If the disruptions and slowdown deepen or persist, we may not be able to access additional capital on favorable terms, or at all, which could in the future negatively affect our ability to pursue our business strategy.

Funding Requirements

We plan to focus in the near term on supporting the review of our BLA submission for ONS-5010/LYTENAVA with the FDA and to prepare for the potential launch of LYTENAVA™, if approved, 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 successfully commercialize ONS-5010/LYTENAVA if, among other things, the FDA does not approve our BLA when we expect, or at all, or if we are not able to secure sufficient funding of our expected post-launch commercial costs.

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 the development of our lead product candidate and any other product candidates we may choose to pursue.

We do not believe that the existing cash and cash equivalents as of December 31, 2024, together with the net proceeds from the sale of shares of common stock in the Warrant Inducement Transaction, are sufficient to fund our operations through one year from the date of this Quarterly Report on Form 10-Q. For further details on the warrants to purchase shares of common stock, refer to Note 10 of the unaudited consolidated interim financial statements included herein. Our consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

We plan to finance our future operations with a combination of proceeds from potential licensing and/or marketing arrangements or collaborations with pharmaceutical or other companies, sale of the development and commercial rights to our drug product candidates in regions outside of the U.S., the issuance of additional debt, the issuance of equity securities, including accessing capital through at-the-market offering agreements, 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. Further, due to current market volatility, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. There are no assurances that we will be successful in obtaining an adequate level of financing for the commercialization of ONS-5010/LYTENAVA or the development of any other current or future product candidates. Alternatively, we will be required to, among other things, modify our clinical trial plans for ONS-5010/LYTENAVA 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,	
	2024	2023
Net cash used in operating activities	$ (10,967,335)	$ (13,032,169)
Net cash provided by financing activities	1,742,373	(3,183)
Net decrease in cash and cash equivalents	$ (9,224,962)	$ (13,035,352)

Operating Activities

During the three months ended December 31, 2024, we used $11.0 million of cash in operating activities resulting primarily from our net income of $17.4 million. This use of cash was partially offset by $35.2 million of non-cash items such as stock-based compensation, change in fair value of promissory notes, change in fair value of warrant liability, loss on equity method investment and depreciation and amortization expense. The net cash inflow of $6.9 million from changes in our operating assets and liabilities was primarily due to an increase in accounts payable and accrued expenses of $4.4 million primarily due to timing of payments and a decrease in prepaid expenses of $5.6 million associated with ONS-5010/LYTENAVA development costs relating to clinical trial and drug development costs partially offset by an increase in inventory of $3.1 million relating to commercial inventory manufactured during the period.

During the three months ended December 31, 2023, we used $13.0 million of cash in operating activities resulting primarily from our net loss of $11.2 million. This use of cash was partially offset by $2.3 million of non-cash items such as stock-based compensation, change in fair value of promissory notes, change in fair value of warrant liability, income on equity method investment and depreciation and amortization expense. The net cash outflow of $4.2 million from changes in our operating assets and liabilities was primarily due to a net decrease in accounts payable and accrued expenses of $1.8 million and a decrease in prepaid expenses of $2.4 million for timing of payments associated with ONS-5010/LYTENAVA development costs.

Financing Activities

During the three months ended December 31, 2024, net cash provided by financing activities was $1.7 million, primarily attributable to net proceeds from the sale of common stock under our BTIG ATM Offering.

During the three months ended December 31, 2023, net cash used in financing activities was immaterial.

Description of Indebtedness

On December 22, 2022, we entered into the Securities Purchase Agreement and issued the December 2022 Note to the Lender. The December 2022 Note, which was amended in December 2023, has a face value of $31.8 million and an original issue discount of $1.8 million. In December 2023, the Company extended the maturity of the December 2022 Note from January 1, 2024 to April 1, 2024. On January 22, 2024, the Company entered into an amendment to the December 2022 Note with the Lender, which became effective on April 1, 2024 after satisfaction of certain closing conditions, including various required stockholder approvals and the closing of the private placement that closed on March 18, 2024. Effective April 1, 2024, the initial conversion price with respect to $15.0 million in aggregate principal amount of the December 2022 Note was changed to $7.00, the price per share in the private placement that closed on March 18, 2024 and bears interest at the prime rate (as published in the Wall Street Journal) plus 3% (subject to a floor of 9.5%) and the Company has an obligation to repay at least $3.0 million (by either cash or conversion into common stock) of the outstanding balance of the December 2022 Note for each calendar quarter beginning with the second calendar quarter of 2024 (subject to adjustment for conversions by the Lender and to payment of an exit fee as set forth in the December 2022 Note) and continuing until the December 2022 Note is repaid in full. Any amount converted by the Lender during a given calendar quarter in excess of $3.0 million will be credited toward meeting the quarterly requirement for the next quarter or quarters.

The December 2022 Note contains customary covenants, including a restriction on the Company's ability to pledge certain of the Company's assets, subject to certain exceptions, without the Lender's consent. Beginning on April 1, 2023, the

Lender had the right to convert the December 2022 Note at the Conversion Price (as defined below). The principal amount and conversion price of the December 2022 Note were subject to adjustment upon certain triggering events. In addition, the Company had the right to convert all or any portion of the outstanding balance under the December 2022 Note into shares of common stock at the Conversion Price if certain conditions have been met at the time of conversion, including if at any time after the six-month anniversary of the closing date, the daily volume-weighted average price of the common stock on Nasdaq equals or exceeds $50.00 per share (subject to adjustments for stock splits and stock combinations) for a period of 30 consecutive trading days. Payments may be made by the Company (i) in cash, (ii) in shares of common stock, with the number of shares being equal to the portion of the applicable payment amount divided by the Conversion Price (as defined below), or (iii) a combination of cash and shares of common stock. Any payments made by the Company in cash, including prepayments or repayment at maturity, will be subject to an additional fee of 7.5%. Upon the occurrence of certain events described in the December 2022 Note, including, among others, the Company's failure to pay amounts due and payable under the December 2022 Note, events of insolvency or bankruptcy, failure to observe covenants contained in the Securities Purchase Agreement and the December 2022 Note, breaches of representations and warranties in the Securities Purchase Agreement, and the occurrence of certain transactions without the Lender's consent (each such event, a "Trigger Event"), the Lender shall have the right, subject to certain exceptions, to increase the balance of the December 2022 Note by 10% for a Major Trigger Event (as defined in the December 2022 Note) and 5% for a Minor Trigger Event (as defined in the December 2022 Note). If a Trigger Event is not cured within ten (10) trading days of written notice thereof from the Lender, it will result in an event of default (such event, an "Event of Default"). Following an Event of Default, the Lender may accelerate the December 2022 Note such that all amounts thereunder become immediately due and payable, and interest shall accrue at a rate of 22% annually until paid. Prior to April 1, 2024, under the December 2022 Note, "Conversion Price" meant, prior to a Major Trigger Event, $40.00 per share (subject to adjustment for stock splits and stock combinations), and following a Major Trigger Event, the lesser of (i) $40.00 per share (subject to adjustment for stock splits and stock combinations), and (ii) 90% multiplied by the lowest closing bid price of the Company's common stock in the three trading days prior to the date on which the conversion notice is delivered. If the Conversion Price is below $3.51 per share, the Company will be required to satisfy a conversion notice from the Lender in cash. Subject to certain exceptions, while the December 2022 Note is outstanding, the Lender will have a consent right on any future variable rate transactions or any debt and a 10% participation right in any future debt or equity financings.

On January 31, 2025, we executed a SPA with Avondale, pursuant to which we agreed to issue to Avondale an unsecured convertible promissory note in the amount of $33,100,000. The funds generated from the January 2025 Note will be utilized to completely settle the December 2022 Note, which will be fully extinguished. The Note Closing outlined in the SPA and the January 2025 Note is anticipated to occur shortly after our 2025 annual meeting of stockholders, contingent upon the fulfillment of customary closing conditions, as well as obtaining stockholder approval for the issuance of shares exceeding 19.99% of the outstanding common stock upon conversion of the January 2025 Note. Until the Note Closing, we have agreed not to sell common stock, other than issuances pursuant to our at-the-market offering, below a per share price of $2.26 and must maintain its Nasdaq listing. We have agreed to file a registration statement registering the resale of common stock issuable upon conversion of the January 2025 Note within seven days of the Note Closing, with an objective for effectiveness within 45 days; failure to achieve this will result in an increase of the January 2025 Note balance by 0.5% on a monthly basis until effectiveness is attained.

The January 2025 Note will initially bear interest at the prime rate as published in the Wall Street Journal, plus an additional 3%, subject to a floor of 9.5%. The January 2025 Note is scheduled to mature on July 1, 2026, and will be convertible into common stock. The Company is obligated to repay a minimum of $3,000,000 of the outstanding balance of the January 2025 Note each calendar quarter starting with the second calendar quarter of 2025, subject to adjustments for conversions by Avondale and the payment of an exit fee of 7.5%, or the Quarterly Debt Reduction Obligations. Any amount converted by Avondale during a given calendar quarter in excess of the Quarterly Debt Reduction Obligations will be credited toward meeting the Quarterly Debt Reduction Obligations for the next quarter or quarters.

Commencing on the earlier of (i) six months following the issuance of the January 2025 Note or (ii) the date on which the Registration Statement is declared effective, or the Conversion Commencement Date, Avondale shall have the right to convert all or any portion of the outstanding balance under the January 2025 Note into shares of common stock, calculated by dividing the amount of the January 2025 Note being converted by the Conversion Price (as defined below). Furthermore, the Company retains the right to convert any portion of the outstanding balance under the January 2025 Note into shares of common stock at the Conversion Price, provided certain conditions are met at the time of conversion, including, but not limited to, the condition that the daily volume-weighted average price of our common stock on Nasdaq equals or exceeds

$3.00 per share (subject to adjustments for stock splits and combinations) for a period of 30 consecutive trading days, and that the median daily dollar trading volume during the preceding 30 trading day period meets or exceeds $1,000,000. We reserve the right to make payments (i) in cash, (ii) in shares of common stock, calculated as the applicable payment amount divided by the Conversion Price, or (iii) a combination of both cash and shares of common stock. Any cash payments made by us, including prepayments or payments made at maturity, will incur an additional fee of 7.5%.

The January 2025 Note stipulates that we shall not permit any conversion of the January 2025 Note if, following such conversion, Avondale and its affiliates would beneficially own shares of common stock exceeding 4.99% of the total number of outstanding shares as of that date, or the Beneficial Ownership Limitation. However, this limitation shall increase to 9.99% when the our market capitalization falls below $25,000,000. Avondale may, by written notice to us, adjust the Beneficial Ownership Limitation for itself, though any such adjustment will not take effect until the 61st day after such notice is received.

In the event of specific occurrences outlined in the January 2025 Note—such as our failure to fulfill payment obligations, non-compliance with the Quarterly Debt Reduction Obligations, insolvency or bankruptcy events, breaches of covenants in the SPA and the January 2025 Note, and unauthorized transactions without Avondale's consent, collectively referred to as Trigger Events—Avondale reserves the right to increase the balance of the January 2025 Note by 10% in the case of a Major Trigger Event (as defined in the January 2025 Note) and by 5% for a Minor Trigger Event (as defined in the January 2025 Note). Should any Trigger Event persist without resolution for ten trading days following written notification from Avondale, this will constitute an event of default, such event, an Event of Default. Upon an Event of Default, Avondale may accelerate the January 2025 Note, resulting in all amounts becoming immediately due and payable, with interest accruing at a rate of 22% per annum until full payment is made.

Under the terms of the January 2025 Note, the "Conversion Price" is defined as $2.26 per share prior to a Major Trigger Event (subject to adjustments for stock splits and combinations). Following a Major Trigger Event, the Conversion Price will be the lesser of (i) $2.26 per share (subject to adjustments) or (ii) 90% of the lowest closing bid price over the three trading days preceding the conversion notice. Furthermore, if the Conversion Price falls below $0.404 per share (subject to adjustments), we will be required to fulfill a conversion notice from Avondale in cash.

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, 2024, filed with the SEC on December 27, 2024, have not materially changed.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

As a "Smaller Reporting Company," this Item and the related disclosure are not required.

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 interim 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 interim 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, 2024.

Part II. Other Information

Item 1. Legal Proceedings

On November 3, 2023, a securities class action lawsuit was filed against us and certain of our officers in the United States District Court for the District of New Jersey. The class action complaint alleges violations of the Exchange Act in connection with allegedly false and misleading statements made by us related to our BLA during the period from August 3, 2021 through August 29, 2023. The complaint alleges, among other things, that we violated Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 by failing to disclose that there was an alleged lack of evidence supporting ONS-5010/LYTENAVA as a treatment for wet AMD and that we and/or our manufacturing partner had deficient CMC controls for ONS-5010/LYTENAVA, which remained unresolved at the time our BLA was re-submitted to the FDA and, as a result, the FDA was unlikely to approve our BLA, and that our stock price dropped when such information was disclosed. The plaintiffs in the class action complaint seek damages and interest, and an award of reasonable costs, including attorneys' fees. On June 25, 2024, the defendants filed a motion to dismiss the amended class action complaint in its entirety. On February 6, 2025, the court entered an order granting the motion to dismiss and dismissing the complaint without prejudice and with leave to amend, and providing for the filing of a further amended complaint and briefing on the defendants' anticipated motion to dismiss such further amended complaint in the spring of 2025.

On October 10, 2024, certain of the company's officers and directors were named as defendants in a shareholder derivative action filed in the District Court of the District of Delaware. The derivative complaint alleges that defendants breached their fiduciary duties by causing and/or allowing the company to violate federal securities laws based on the same alleged misstatements as the securities class action. The derivative complaint also alleges defendants violated Section 14(a) of the Exchange Act, as well as claims for contribution, unjust enrichment, and waste of corporate assets. The derivative complaint seeks unspecified damages, corporate governance reforms, restitution, contribution, attorneys' fees, and other costs. The derivative action is currently stayed, pending the final resolution of the November 3, 2023, securities class action pending in the United States District Court for the District of New Jersey.

The pending lawsuits and any other related lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. The outcome of the pending lawsuits and any other related lawsuits is necessarily uncertain. We could be forced to expend significant resources in the defense of the pending lawsuits and any additional lawsuits, and we may not prevail. In addition, we may incur substantial legal fees and costs in connection with such lawsuits. We currently are not able to estimate the possible cost to us from these matters, as the pending lawsuits are currently at an early stage, and we cannot be certain how long it may take to resolve the pending lawsuits or the possible amount of any damages that we may be required to pay. Such amounts could be material to our financial statements if we do not prevail in the defense of the pending lawsuits and any other related lawsuits, or even if we do prevail. We have not established any reserve for any potential liability relating to the pending lawsuits and any other related lawsuits. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages.

From time to time, we may also become involved in litigation relating to claims arising from the ordinary course of business. Our management believes that there are currently no additional 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

As of December 31, 2024, there have been no material changes to the risk factors that were previously disclosed in Item 1A in the Company's Form 10-K for the year ended September 30, 2024 filed with the SEC on December 27, 2024.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

During the three months ended December 31, 2024, none of the Company's directors or Section 16 officers adopted or terminated any contract, instruction or written plan for the purchase or sale of Company securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act or any "non-Rule 10b5-1 trading arrangement" as such term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits

Exhibit Number	Description
3.1	Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2024).
3.2	Second Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Company's current report on Form 8-K filed with the SEC on March 26, 2021).
10.1	Form of Tranche A Inducement Warrant (incorporated by reference to Exhibit 4.1 to the Company's current report on Form 8-K filed with the SEC on January 16, 2024).
10.2	Form of Tranche B Inducement Warrant (incorporated by reference to Exhibit 4.2 to the Company's current report on Form 8-K filed with the SEC on January 16, 2024).
10.3	Form of Syntone Tranche A Inducement Warrant (incorporated by reference to Exhibit 4.3 to the Company's current report on Form 8-K filed with the SEC on January 16, 2024).
10.4	Form of Syntone Tranche B Inducement Warrant (incorporated by reference to Exhibit 4.4 to the Company's current report on Form 8-K filed with the SEC on January 16, 2024).
10.5	Form of Inducement Letter (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K filed with the SEC on January 16, 2024).
10.6	Form of Syntone Inducement Letter (incorporated by reference to Exhibit 10.2 to the Company's current report on Form 8-K filed with the SEC on January 16, 2024).
10.7****	Securities Purchase Agreement, dated as of January 31, 2025 by and between the Company and Avondale Capital, LLC (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K filed with the SEC on January 31, 2025).
10.8	Form of Note (incorporated by reference to Exhibit 10.2 to the Company's current report on Form 8-K filed with the SEC on January 31, 2025).
31.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS**	Inline XBRL Instance Document.

101.SCH***	Inline XBRL Taxonomy Extension Schema Document.
101.CAL***	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF***	Inline XBRL Definition Linkbase Document.
101.LAB***	Inline XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE***	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104**	Cover Page Interactive Data File.

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

** The XBRL Instance Document and Cover Page Interactive Data File do not appear in the Interactive Data File because their XBRL tags are embedded within the Inline XBRL document.

*** Submitted electronically with the report.

****Certain of the exhibits and schedules to this exhibit have been omitted in accordance with Regulation S-K Item 601(a)(5). The Registrant agrees to furnish a copy of all omitted exhibits and schedules to the Securities and Exchange Commission upon its request.

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, 2025

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

(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, 2025

By: /s/ Lawrence A. Kenyon
Lawrence A. Kenyon
Chief Financial Officer and Interim Chief Executive 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, 2024, 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, 2025

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