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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 March 31, 2026
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 May 12, 2026 was 120,863,252.

Outlook Therapeutics, Inc.
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In this report, unless otherwise stated or as the context otherwise requires, references to "Outlook Therapeutics," "Outlook," "the Company," "we," "us," "our" and similar references refer to Outlook Therapeutics, Inc. 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.

References to ONS-5010 and/or LYTENAVA refer to an ophthalmic formulation of bevacizumab for use in retinal indications which, as the context requires: (i) is currently commercially available in Germany and in the United Kingdom as LYTENAVA™ (bevacizumab gamma) for the treatment of wet age-related macular degeneration (wet AMD) and (ii) is currently the subject of a Biologics License Application under review by the U.S. Food and Drug Administration.

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, 2025, filed with the Securities and Exchange Commission ("SEC") on December 19, 2025, and in Part II, Item 1A. "Risk Factors" of this Quarterly Report, including, among other things, risks associated with:

- our ability to obtain and maintain regulatory approval for ONS-5010/LYTENAVA in the United States and other markets;
- our ability to successfully commercialize and generate revenues from the sale of LYTENAVA™ (bevacizumab gamma) in the United Kingdom and European Union;
- 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;
- our ability to fund our working capital requirements, the sufficiency of our current cash resources and our need for additional funding;
- our expectations regarding the potential market size and the size of the patient populations for our product candidates, if approved, for commercial use;
- whether the results of our clinical trials will be sufficient to support domestic or global regulatory approvals;
- 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;
- the implementation of our business model and strategic plans for our business and product candidates;
- developments or disputes concerning our intellectual property or other proprietary rights;
- our ability to maintain and establish collaborations or obtain additional funding;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to compete in the markets we serve; and
- the factors that may impact our financial results.

These risks are not exhaustive. Additional factors could harm our business and financial performance, such as risks associated with the current macroeconomic environment, including as a result of the impacts of fluctuations in inflation, and interest rates, tariffs and trade tensions, current or potential future bank failures or geopolitical instability and uncertainty. 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.

1 PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Outlook Therapeutics, Inc.
Consolidated Balance Sheets
(unaudited)

	March 31, 2026	September 30, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 7,748,226	$ 8,083,085
Accounts receivable	2,719,828	1,490,931
Inventory	3,344,242	3,338,404
Prepaid expenses and other current assets	7,092,415	4,476,549
Total current assets	20,904,711	17,388,969
Operating lease right-of-use assets, net	198,975	225,508
Equity method investment	468,430	552,183
Other assets	320,290	417,523
Total assets	$ 21,892,406	$ 18,584,183
Liabilities and stockholders' deficit		
Current liabilities:		
Current portion of unsecured convertible promissory note	$ 9,845,000	$ 29,947,000
Current portion of unsecured promissory note	6,000,000	—
Current portion of operating lease liabilities	62,003	58,897
Accounts payable	13,635,834	10,192,388
Accrued expenses	9,039,153	5,314,320
Income taxes payable	302,000	302,000
Total current liabilities	38,883,990	45,814,605
Unsecured promissory note	11,124,000	—
Operating lease liabilities	156,958	188,801
Warrant liability	722,229	4,768,438
Total liabilities	50,887,177	50,771,844
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; 260,000,000 shares authorized; 104,614,219 and 53,887,233 shares issued and outstanding at March 31, 2026 and September 30, 2025, respectively	1,046,143	538,873
Additional paid-in capital	603,180,065	572,983,229
Accumulated deficit	(633,220,979)	(605,709,763)
Total stockholders' deficit	(28,994,771)	(32,187,661)
Total liabilities and stockholders' deficit	$ 21,892,406	$ 18,584,183

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 March 31,		Six months ended March 31,	
	2026	**2025**	**2026**	**2025**
Revenues, net	$ 127,439	$ —	$ (1,080,394)	$ —
Cost of revenues	149,327	—	178,953	—
Gross profit	(21,888)	—	(1,259,347)	—
Operating expenses:				
Research and development	4,500,520	4,407,019	8,134,872	14,067,169
Selling, general and administrative	9,504,579	7,984,509	18,116,720	19,931,211
Loss from operations	(14,026,987)	(12,391,528)	(27,510,939)	(33,998,380)
Loss on equity method investment	45,119	36,409	83,753	69,704
Interest (income) expense , net	(3)	18,502	(3)	(30,379)
(Gain) loss from change in fair value of promissory notes	(2,495,400)	2,111,028	4,248,336	3,415,028
Warrant inducement expenses (Note 10)	—	33,856,814	—	33,856,814
Gain from change in fair value of warrant liability	(6,838,022)	(2,059,875)	(4,046,209)	(42,332,755)
Gain on extinguishment of debt	(285,600)	—	(285,600)	—
Net loss before income taxes	(4,453,081)	(46,354,406)	(27,511,216)	(28,976,792)
Income tax expense	—	2,800	—	2,800
Net loss	$ (4,453,081)	$ (46,357,206)	$ (27,511,216)	$ (28,979,592)
Per share information:				
Loss income per share of common stock, basic and diluted	$ (0.05)	$ (1.50)	$ (0.39)	$ (1.05)
Weighted average shares outstanding, basic and diluted	81,835,900	30,874,396	70,901,617	27,517,692

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	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Deficit
Balance at September 30, 2025	53,887,233	$ 538,873	$ 572,983,229	$ (605,709,763)	$ (32,187,661)
Issuance of common stock in connection with exercise of warrants	428,571	4,286	903,055	—	907,341
Sale of common stock, net of issuance costs	10,227,166	102,271	14,774,833	—	14,877,104
Issuance of common stock in connection with conversion of convertible promissory note	13,600	136	30,600	—	30,736
Stock-based compensation expense	—	—	881,150	—	881,150
Net loss	—	—	—	(23,058,135)	(23,058,135)
Balance at December 31, 2025	64,556,570	645,566	589,572,867	(628,767,898)	(38,549,465)
Sale of common stock and warrants , net of issuance costs	25,000,000	250,000	6,090,292		6,340,292
Issuance of common stock in connection with conversion of convertible promissory note	15,057,649	150,577	6,759,423	—	6,910,000
Stock-based compensation expense	—	—	757,483	—	757,483
Net loss	—	—	—	(4,453,081)	(4,453,081)
Balance at March 31, 2026	104,614,219	$ 1,046,143	$ 603,180,065	$ (633,220,979)	$ (28,994,771)

	Stockholders' Deficit				
	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Deficit
Balance at September 30, 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)
Issuance of common stock and common stock warrants in connection with exercise of common stock warrants	7,074,637	70,746	60,980,296	—	61,051,042
Sale of common stock, net of issuance costs	926,742	9,268	1,401,947	—	1,411,215
Stock-based compensation expense	—	—	1,722,778	—	1,722,778
Net loss	—	—	—	(46,357,206)	(46,357,206)
Balance at March 31, 2025	32,907,014	$ 329,071	$ 539,472,816	$(572,264,492)	$ (32,462,605)

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

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

	Six months ended March 31,	
	2026	**2025**
OPERATING ACTIVITIES		
Net Loss	$ (27,511,216)	$ (28,979,592)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization	60,491	57,903
Stock-based compensation	1,638,634	5,395,198
Loss from change in fair value of promissory notes	4,248,336	3,415,028
Gain on extinguishment of debt	(285,600)	—
Warrant inducement expenses (Note 10)	—	33,856,814
Gain from change in fair value of warrant liability	(4,046,209)	(42,332,755)
Loss on equity method investment	83,753	69,704
Changes in operating assets and liabilities:		
Accounts receivable	(1,228,897)	—
Inventory	(5,838)	(3,604,531)
Prepaid expenses and other current assets	(2,615,866)	5,842,233
Operating lease liabilities	(28,737)	(24,443)
Accounts payable	2,832,493	(405,697)
Accrued expenses	4,091,490	(840,943)
Net cash used in operating activities	(22,767,166)	(27,551,081)
FINANCING ACTIVITIES		
Proceeds from the sale of common stock and warrants to purchase common stock	21,830,393	3,158,752
Proceeds from exercise of common stock warrants	601,914	16,831,132
Proceeds from debt	17,000,000	33,100,000
Repayment of debt	(17,000,000)	(32,910,028)
Net cash provided by financing activities	22,432,307	20,179,856
Net decrease in cash and cash equivalents	(334,859)	(7,371,225)
Cash and cash equivalents at beginning of period	8,083,085	14,927,538
Cash and cash equivalents at end of period	$ 7,748,226	$ 7,556,313
Supplemental schedule of non-cash financing activities:		
Convertible promissory note converted into common stock	$ 6,940,736	$ —
Fair value of common stock warrants exercised reclassified from warrant liability to equity	$ —	$ 13,262,801
Common stock issuance costs in accounts payable and accrued expenses	$ 610,953	$ —
Common stock and warrant issuance costs in accounts payable and accrued expenses	$ —	$ 951,648
Reclassification of deferred offering costs against ATM proceeds	$ 63,275	$ 11,495

The accompanying notes are an integral part of these 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 June 2025, the Company launched LYTENAVA commercially in both Germany and the UK, and commenced commercial sales in those countries.

In the fourth quarter of calendar 2023, the Company agreed to conduct an additional adequate and well-controlled clinical trial to support its Biologics License Application ("BLA") for ONS-5010/LYTENAVA. The Company submitted a Special Protocol Assessment ("SPA") for the NORSE EIGHT study in December 2023, and in January 2024 the FDA agreed that the protocol, if successful, would satisfy the requirement for a second adequate and well-controlled trial. The Company also identified approaches to address the Chemistry, Manufacturing, and Controls ("CMC") comments in the Complete Response Letter ("CRL"). In November 2024, the Company announced that NORSE EIGHT did not meet the pre-specified non-inferiority endpoint; however, results demonstrated improvements in vision, evidence of biologic activity, and a favorable safety profile, which were further supported by the full week 12 data set. The Company resubmitted the BLA in February 2025. On August 27, 2025, the FDA issued a second CRL citing a single deficiency related to substantial evidence of effectiveness and recommended submission of confirmatory efficacy data, while reaffirming that the NORSE TWO trial met its primary endpoint. Following a Type A meeting in September 2025, the Company resubmitted the BLA on November 3, 2025, and received a third CRL on December 31, 2025.

Following receipt of the CRL in December 2025, the company engaged with the FDA on multiple occasions, including a formal Type A meeting held on March 2, 2026, which led to the submission of the FDRR and the associated meeting request. In April 2026, the meeting with the deciding official was conducted as part of the Company's ongoing efforts to align with the FDA regarding the regulatory pathway for ONS-5010/LYTENAVA™ (bevacizumab-vikg). The meeting also served as a follow-up to the Company's March 2026 Type A meeting with the Division of Ophthalmology and the Office of Specialty Medicine regarding the December 30, 2025 CRL for the Biologics License Application ("BLA") for ONS-5010/LYTENAVA™ for the treatment of neovascular age-related macular degeneration.

2. Liquidity

The Company has incurred recurring losses and negative cash flows from operations since its inception and has an accumulated deficit of $633,220,979 as of March 31, 2026. As of March 31, 2026, the Company had a working capital deficit. Additionally, the Company has $10,407,965 of principal, accrued interest and exit fees due under an unsecured convertible promissory note issued to Avondale Capital, LLC ("Avondale") in March 2025 (the "March 2025 Note"), maturing on December 31, 2026, as amended. The Company also had $19,817,334 of principal, accrued interest, and exit fees outstanding under an unsecured promissory note issued to Atlas Sciences LLC ("Atlas") in March 2026 (the "March 2026 Note"), which matures on June 16, 2027. See Note 7 for additional information regarding the March 2025 Note and the March 2026 Note.

On December 31, 2025, the Company did not satisfy the required $3,000,000 Quarterly Debt Reduction Obligation (as defined below in Note 7) under the March 2025 Note. The failure to make this required payment constituted a Major Trigger Event (as defined below in Note 7). During the three months ended March 31, 2026, Avondale converted $6,910,000 of principal and accrued interest on the March 2025 Note into 15,057,649 shares of the Company's common stock. As a result of this conversion, the Quarterly Debt Reduction Obligation was satisfied for the quarters ended December 31, 2025 and March 31, 2026. This Major Trigger Event has not resulted in an Event of Default (as defined below in Note 7).

Pursuant to the terms of the March 2025 Note, the occurrence of a Major Trigger Event resulted in (i) an automatic 10% increase to the outstanding balance, effective January 1, 2026, and (ii) an adjustment to the Conversion Price (as defined below). Following the adjustment, the Conversion Price is equal to the lesser of the fixed conversion price of $2.26 or 90% of the lowest closing bid price during the three trading days immediately preceding the delivery of a conversion notice, provided that the Conversion Price may not be reduced below the contractual floor price of $0.404. See Note 7 – Debt, for more information related to the March 2025 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.

Management does not believe that the existing cash and cash equivalents as of March 31, 2026 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, fully commercialize 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 offerings (refer to Note 9 for further details), and revenues from product sales. There can be no assurance that any of 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 commercialize ONS-5010/LYTENAVA, including executing marketing arrangements or completing revenue-generating partnerships with other companies; (iii) the success of its research and development; (iv) the development of competitive therapies by other biotechnology and pharmaceutical companies; and, ultimately, (v) regulatory approval and market acceptance of the Company's proposed future products.

3. Basis of Presentation and Summary of Significant Accounting Policies

Basis of presentation

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

In the opinion of management, the accompanying unaudited interim consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company's financial position as of March 31, 2026 and its results of operations for the three and six months ended March 31, 2026 and 2025, cash flows for the six months ended March 31, 2026 and 2025, and stockholders' deficit for the three and six months ended March 31, 2026 and 2025. Operating results for the six months ended March 31, 2026 are not necessarily indicative of the results that may be expected for the full year ending September 30, 2026. 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, 2025 included in the Company's Annual Report on Form 10-K filed with the SEC on December 19, 2025.

Accounts Receivable

As of March 31, 2026, the Company had no allowance for credit losses. An allowance for credit losses is determined based

on the Company's assessment of the creditworthiness and financial condition of its customers, aging of receivables, as well as the general economic environment. Any allowance would reduce the net receivables to the amount that is expected to be collected.

Inventory

The Company values inventory at the lower of cost or net realizable value, computed on a weighted average basis. 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 March 31, 2026.

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. The Company expenses prelaunch inventory as research and development expense in the period incurred unless objective and persuasive evidence exists that regulatory approval and subsequent commercialization of a product candidate is probable and where the Company also expects the future economic benefit from the sales of the product candidate to be realized. There were no costs related to prelaunch inventory included in inventory as of March 31, 2026, and September 30, 2025. As of March 31, 2026 and September 30, 2025, inventory consisted of the following:

	March 31, 2026	September 30, 2025
Raw materials	$ 2,344,459	$ 2,350,239
Work-in-process	797,880	958,539
Finished goods	201,903	29,626
Total	$ 3,344,242	$ 3,338,404

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, tariffs and trade tensions, and geopolitical instability and uncertainty, 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.

Revenue recognition

The Company recognizes revenue from sales of a single product, LYTENAVA (bevacizumab gamma) (the "Product") in accordance with ASC Topic 606 – *Revenue from Contracts with Customers*. LYTENAVA (bevacizumab gamma) became available for commercial sale and shipment to patients in Europe in fiscal year 2025. The Company sells the Product to several customers who are pharmaceutical wholesalers/distributors (the "Customers") who in turn sell the Product directly to clinics, hospitals, and pharmacies. Revenue is recognized as the Product is physically delivered to the customers.

Gross product sales are reduced by corresponding Gross-to-Net ("GTN") estimates using the expected value method, resulting in the Company's reported "Revenues, net" in the accompanying consolidated statements of operations. Revenues, net reflects the amount the Company ultimately expects to realize in net cash proceeds, taking into account the current period gross sales and related cash receipts and the subsequent cash disbursements on these sales that the Company estimates for the various GTN categories discussed below. The GTN estimates are based upon information received from external sources, such as written or oral information obtained from customers with respect to their period-end inventory levels and sales to end-users during the period, in combination with management's informed judgments. Due to the inherent uncertainty of these estimates, the actual amount of product returns, rebates and administrative fees may be

materially above or below the amount estimated. The variance between actual amounts and estimated amounts may result in prospective adjustments to the reported net product revenue.

Each of the GTN estimate categories are discussed below:

- Sales returns are estimated by the Company based on the relative risk of return based on expiration date, and other qualitative factors that can impact the volume of future returns, including competitive developments, product discontinuation, or new product introductions. The Company will consider the level of inventory in the distribution channel by monitoring inventories held at the distributor and wholesalers to assess whether historical rates of returns continue to be appropriate.
- Administrative fees are contractually charged by the wholesalers and are typically credited directly against amounts due to the Company.
- Rebates are contractually charged to the Company by customers, including a Voluntary Scheme for Branded Medicines Pricing, Access and Growth rebate with the National Health System in the UK.

During the six months ended March 31, 2026, the Company decreased its returns reserve by $1.2 million. This net decrease consisted of a $1.2 million increase in return reserves related to sales in the UK and Germany, offset by a $2.4 million reversal of reserves associated with product that became unsellable due to minimum shelf-life constraints, resulting in a corresponding write-off of accounts receivable. Returns reserves are reviewed on a quarterly basis and may be adjusted based on ongoing assessments of business conditions and distributor-level sales forecasts. Additionally, during the six months ended March 31, 2026, the Company recognized administrative fees under contractual arrangements with its wholesalers.

Cost of revenues

Cost of revenues consists primarily of the cost of inventory sold, which includes direct manufacturing, production and packaging materials for LYTENAVA (bevacizumab gamma) sales. Prior to receiving authorization to sell LYTENAVA (bevacizumab gamma) in Europe, the Company expensed costs associated with manufacturing of LYTENAVA (bevacizumab gamma) as a component of research and development expense. The cost of previously expensed inventory that would have been recognized in cost of revenue for the three and six months ended March 31, 2026 were immaterial.

Net (loss) income per share

Basic net (loss) income per share of common stock is computed by dividing net (loss) income attributable to common stockholders by the weighted-average number of shares of common stock outstanding during each period. Diluted net (loss) income 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.

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

	Three months ended March 31,		Six months ended March 31,	
	2026	2025	2026	2025
Numerator:				
Net loss attributable to common stockholders	$ (4,453,081)	$ (46,357,206)	$ (27,511,216)	$ (28,979,592)
Denominator:				
Weighted average shares outstanding, basic	81,835,900	30,874,396	70,901,617	27,517,692
Basic net loss per share	$ (0.05)	$ (1.50)	$ (0.39)	$ (1.05)

The following potentially dilutive securities (in common stock equivalents) have been excluded from the computation of diluted weighted-average shares outstanding for the three and six months ended March 31, 2026 and 2025, as they would be antidilutive:

	Three months ended March 31,		Six months ended March 31,	
	2026	2025	2026	2025
Performance-based stock options	30,000	190,000	30,000	190,000
Stock options	6,355,161	2,812,893	6,355,161	2,812,893
Common stock warrants	56,828,913	21,259,767	56,828,913	21,259,767
Convertible debt	(i) 23,964,921	(ii) 14,718,808	(i) 23,964,921	(ii) 14,718,807

(i) The potentially dilutive securities related to the March 2025 Note were calculated based on a fixed conversion price of $0.404, which is subject to change as described in Note 7.

(ii) The potentially dilutive securities related to the March 2025 Note were calculated based on a fixed conversion price of $2.26, which is subject to change as described in Note 7.

Recently issued accounting pronouncements

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. The ASU requires greater disaggregation of income tax disclosures primarily on the income tax rate reconciliation and income taxes paid. This authoritative guidance will be effective for fiscal years beginning after December 15, 2024, and for interim periods within fiscal years beginning after December 15, 2025, with early adoption permitted. The Company is currently evaluating the effect of this new standard on the Company's 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.

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

	March 31, 2026		
	(Level 1)	(Level 2)	(Level 3)
Liabilities			
Unsecured convertible promissory note (measured at fair value)	$ —	$ —	$ 9,845,000
Unsecured promissory note (measured at fair value)	$ —	$ —	$ 17,124,000
Warrant liability	—	—	722,229
Total	$ —	$ —	$ 27,691,229

	September 30, 2025		
	(Level 1)	(Level 2)	(Level 3)
Liabilities			
Unsecured convertible promissory note (measured at fair value)	$ —	$ —	$ 29,947,000
Warrant liability	—	—	4,768,438
Total	$ —	$ —	$ 34,715,438

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 and non-convertible promissory notes for the six months ended March 31, 2026:

	Unsecured Promissory Note	Unsecured Convertible Promissory Note	Warrants
Balance at September 30, 2025	$ —	$ 29,947,000	$ 4,768,438
Issuance of promissory notes	17,000,000	—	—
Principal and accrued interest converted to common stock	—	(6,940,736)	—
Loss (gain) from change in fair value	124,000	4,124,336	(4,046,209)
Repayment	—	(17,000,000)	—
Gain on extinguishment of debt	—	(285,600)	—
Balance at March 31, 2026	$ 17,124,000	$ 9,845,000	$ 722,229

The $4.1 million loss (gain) from the change in fair value shown in the table above includes a note increase of $3.0 million as a result of the Major Trigger Event (see Note 7 for more details) during the 6 months ended March 31, 2026.

Unsecured convertible promissory note

As further described in Note 7, the Company elected the fair value option to account for the unsecured convertible promissory notes. The fair value 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 values of the unsecured convertible promissory notes were estimated using a binomial lattice model with the following assumptions:

	March 31, 2026	September 30, 2025
Term (years)	0.8	0.8
Volatility	173.0 %	118.0 %
Risk-free rate	3.7 %	3.8 %
Dividend yield	— %	— %
Credit-adjusted discount rate	24.8 %	18.8 %
Stock price	0.21	$ 1.06

March 2026 Note

As further described in Note 7, the Company elected the fair value option to account for the March 2026 Note. The fair value is estimated using a discounted cash flow model which estimates the fair value of the instrument based on the present value of expected future cash flows, using assumptions that reflect the instrument's terms and risk characteristics.

Significant estimates in the discounted cash flow model include the term, final redemption value and discount rate.

	March 31, 2026
Term (years)	1.2
Credit spread	24.6 %
Final redemption value	$ 121.8

Common stock warrants

The warrants issued in connection with private placements that closed on March 18, 2024 and April 15, 2024 (the "Private Placement Warrants") were classified as liabilities on the accompanying unaudited interim consolidated balance sheets as the Company assessed that they are not indexed to the Company's own stock.

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

	March 31, 2026	September 30, 2025
Risk-free interest rate	3.81 %	3.64 %
Remaining contractual term of warrants (years)	3.0	3.5
Expected volatility	169.8 %	148.6 %
Annual dividend yield	— %	— %
Stock price	$ 0.21	$ 1.06

5. Equity Method Investment

In connection with the execution of a stock purchase agreement with Syntone Ventures, LLC ("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 $3,000,000.

6. Accrued Expenses

Accrued expenses consist of:

	March 31, 2026	September 30, 2025
Compensation	$ 718,606	$ 1,437,049
Severance and related costs	525,531 (i)	1,590,835
Professional fees	308,644	195,623
Research and development	4,444,281	1,188,212
Accrued rebates	2,850,549	317,754
Other accrued expenses	191,542	584,847
	$ 9,039,153	$ 5,314,320

(i) In September 2025, the Company implemented workforce reductions to conserve capital. Both the Company's Chief Executive Officer and Chief Commercial Officer departed from the Company during the fiscal year ended September 30, 2025, and their departures each constituted terminations without cause. Accordingly, each was entitled to 12 months of base salary, a lump sum of 100% of their target bonus for the year, employee benefits for up to 12 months, full vesting of 50% of their unvested equity awards, and reimbursement of expenses owed up to their termination dates. At a minimum, all employees affected by the workforce reduction were 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.

7. Debt

Debt consists of:

	March 31, 2026	September 30, 2025
Unsecured convertible promissory note (measured at fair value)	$ 9,845,000	$ 29,947,000
Less: current portion	(9,845,000)	(29,947,000)
Unsecured promissory note (measured at fair value)	17,124,000	—
Less: current portion	(6,000,000)	—
Long-term debt	$ 11,124,000	$ —

March 2025 Note

On March 13, 2025, the Company issued the March 2025 Note for $33,100,000 to Avondale pursuant to a Securities Purchase Agreement ("Purchase Agreement") dated January 31, 2025. Certain terms of the March 2025 Note were approved at the Company's annual meeting of stockholders on March 11, 2025.The net proceeds from the March 2025 Note were used to repay the Company's unsecured convertible promissory note issued on December 22, 2022 (the "December 2022 Note").

The March 2025 Note bears interest at the prime rate plus 3% (subject to a floor of 9.5%), originally matured on July 1, 2026, but was amended on March 16, 2026 to mature on December 31,2026, and is 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 March 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. During the six months ended March 31, 2026, Avondale converted $6,940,736 of outstanding principal and accrued interest on the March 2025 Note into 15,071,249 shares of the Company's common stock. As a result of this conversion, the Quarterly Debt Reduction Obligation was satisfied for the quarters ended December 31, 2025 and March 31, 2026.

On March 16, 2026, the Company made a cash repayment of $17,000,000 of outstanding principal and accrued interest under the March 2025 Note using proceeds from the issuance of the March 2026 Note, as defined below. The Company accounted for this pay down as a partial extinguishment under ASC 470. As a result, the Company recognized a $285k gain on partial extinguishment in the unaudited condensed consolidated statement of operations during the three and six months ended March 31, 2026 In connection with the issuance of the March 2026 Note, the Company amended the March 2025 Note to extend its maturity date to December 31, 2026. For additional information regarding the March 2026 Note, see the discussion below.

Avondale has the right to convert all or any portion of the outstanding balance under the March 2025 Note into shares of common stock, calculated by dividing the amount of the March 2025 Note being converted by the Conversion Price. Furthermore, the Company retains the right to convert any portion of the outstanding balance under the March 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 March 2025 Note stipulates that the Company shall not permit any conversion of the March 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 March 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 Purchase Agreement and the March 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 March 2025 Note by 10% in the case of a Major Trigger Event (as defined in the March 2025 Note) and by 5% for a Minor Trigger Event (as defined in the March 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 March 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 March 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.

On December 31, 2025, the Company did not meet the required $3,000,000 Quarterly Debt Reduction Obligation. The failure to make this required payment constituted a Major Trigger Event under the March 2025 Note. This Major Trigger Event has not resulted in an Event of Default. During the first three months ended March 31, 2026, the Company completed multiple conversions of outstanding principal and accrued interest under the March 2025 Note into shares of the Company's common stock, as discussed above.

Pursuant to the terms of the March 2025 Note, the occurrence of a Major Trigger Event resulted in (i) an automatic 10% increase to the outstanding balance, effective January 1, 2026, and (ii) an adjustment to the Conversion Price. Following the adjustment, the Conversion Price is equal to the lesser of the fixed conversion price of $2.26 or 90% of the lowest closing bid price during the three trading days immediately preceding the delivery of a conversion notice, provided that the Conversion Price may not be reduced below the contractual floor price of $0.404.

The Company elected to account for the March 2025 Note at fair value (Note 4) and was not required to bifurcate the conversion option as a derivative and as a result the debt issuance costs of were written off upon election to fair value and accounted for as interest.

March 2026 Note

On March 16, 2026, the Company entered into a note purchase agreement with Atlas Sciences, LLC ("Atlas"), pursuant to which the Company issued an unsecured promissory note (the "March 2026 Note") with an original principal balance of $18,360,000 at an original issue discount of $1,360,000, resulting in gross proceeds of $17,000,000. The proceeds were used solely to partially repay $17,000,000 of outstanding principal and accrued interest under the Company's March 2025 Note.

The promissory note bears interest at the prime rate, as published in The Wall Street Journal, plus 3%, subject to a minimum rate of 9.5%, and matures 15 months from issuance. Interest is calculated on the basis of a 360-day year and is compounded daily. Beginning on the six-month anniversary of issuance, Atlas has the right to redeem up to $3,000,000 of the outstanding balance per calendar quarter. All cash payments made by the Company under the note, including prepayments, redemptions, or repayment at maturity, are subject to a 7.5% exit fee.

The note is unsecured and contains customary representations and warranties, affirmative and negative covenants, and provisions governing Trigger Events, events of default, and remedies. Trigger Events include, among other things, failure to make payments when due, insolvency or bankruptcy-related events, the occurrence of certain fundamental transactions without Atlas' consent, covenant breaches, and material misrepresentations. Upon the occurrence of certain Trigger Events, Atlas has the right to increase the outstanding balance of the note, subject to contractual limitations, and if a Trigger Event is not cured within specified time periods, it may result in an event of default. Upon an event of default, Atlas has the right to accelerate the outstanding balance, apply default interest of up to 22% per annum, and pursue available remedies.

The Company elected to account for the March 2026 Note at fair value (Note 4). As the March 2026 Note contains embedded features that require bifurcation, the Company has elected to account for this note with the fair value option. Debt issuance costs were written off upon election of the fair value option and recognized as interest expense.

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 seek damages and interest, and an award of reasonable costs, including attorneys' fees. On December 23, 2025, the court dismissed the plaintiffs' second amended complaint in part with prejudice and in part with leave to amend. The plaintiffs filed a third amended complaint in February 2026.

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 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.

Purchase Commitments

As of March 31, 2026, the Company had outstanding contractual commitments of approximately $955,050, primarily related to fill-finish manufacturing services for ONS-5010/LYTENAVA to be performed by its contract manufacturers.

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 and six months ended March 31, 2026 and 2025 are as follows:

	Three months ended March 31, 2026	2025	Six months ended March 31, 2026	2025
Lease cost:				
Operating lease cost	19,080	19,080	38,160	38,160
Total lease cost	$ 19,080	$ 19,080	$ 38,160	$ 38,160

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

	March 31, 2026	September 30, 2025
Operating leases:		
Right-of-use asset	$ 198,975	$ 225,508
Operating lease liabilities	218,961	247,698
Weighted-average remaining lease term (years):		
Operating leases	3.1	3.6
Weighted-average discount rate:		
Operating leases	9.9%	9.9%

Other information related to leases for the six months ended March 31, 2026 and 2025 are as follows:

	Six months ended March 31, 2026	2025
Cash paid for amounts included in the measurement of lease obligations:		
Operating cash flows from operating leases	$ 39,278	$ 38,657

Future minimum lease payments under non-cancelable leases at March 31, 2026 are as follows for the years ending September 30:

	Operating leases
2026 (remaining six months)	$ 40,365
2027	81,817
2028	83,680
2029	49,447
Total undiscounted lease payments	255,309
Less: Imputed interest	36,348
Total lease obligations	$ 218,961

9. Common Stock and Stockholders' Equity

Preferred Stock

The number of authorized shares of preferred stock under the Company's Certificate of Incorporation is 10,000,000 shares.

Common stock

On March 11, 2025, following receipt of stockholder approval at the Company's 2025 annual meeting of stockholders, the number of authorized shares of common stock under the Company's Certificate of Incorporation increased from 60,000,000 shares to 260,000,000 shares.

BTIG, LLC At-the-Market Offering Agreement

On May 16, 2023, the Company entered into an At-the-Market Sales Agreement with BTIG as sales agent (as amended, the "ATM Agreement" or the "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 in connection with the execution of the ATM Agreement, 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 ATM Offering. As of March 31, 2026, the remaining balance under the ATM Agreement was $61,960,654 and $219,145 of unamortized deferred costs are included in other assets on the unaudited interim consolidated balance sheets.

Under the 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 ATM Agreement. The offering of common stock pursuant to the ATM Agreement will terminate upon the earlier of (i) the sale of all common stock subject to the ATM Agreement or (ii) termination of the ATM Agreement in accordance with its terms.

During the three months ended March 31, 2026, the Company sold 5,000,000 shares of common stock under the ATM Offering and generated $2,425,000 in net proceeds after payment of fees to BTIG of $75,000. During the six months ended March 31, 2026, the Company sold 15,227,166 shares of common stock under the ATM Offering and generated $17,356,537 in net proceeds after payment of fees to BTIG of $536,800.

Public Offering

On March 23, 2026, the Company entered into a securities purchase agreement with certain investors in connection with a best-efforts public offering, for which H.C. Wainwright & Co., LLC acted as the exclusive placement agent. The offering closed on March 25, 2026, and the Company issued an aggregate of 20,000,000 shares of common stock together with accompanying warrants to purchase up to 20,000,000 shares of common stock, with each share issued together with a warrant to purchase one share, at a combined public offering price of $0.25 per share and accompanying warrant. Gross proceeds to the Company were $5,000,000 before deducting placement agent fees and other offering expenses, and approximately $3,863,097 after such deductions.

Each warrant has an exercise price of $0.25 per share, is exercisable immediately upon issuance, and expires five years from the date of issuance, subject to customary ownership limitations and antidilution adjustments. In connection with the offering, the Company also issued to the placement agent warrants to purchase up to 1,400,000 shares of common stock at an exercise price of $0.3125 per share, which are exercisable immediately and expire five years from the commencement of sales in the offering, and paid the placement agent customary fees and reimbursed certain expenses.

Common stock warrants

As of March 31, 2026, 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
November 23, 2026		104,999	$ 31.25
March 18, 2029	(i)	5,782,496	$ 7.70
April 15, 2029	(i)	1,071,429	$ 7.70
January 17, 2030		13,198,561	$ 2.26
May 27, 2030		15,271,428	$ 1.40
March 25, 2031		20,000,000	$ 0.25
March 25, 2031		1,400,000	$ 0.3125
		56,828,913	

(i) The Private Placement 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.

During the six months ended March 31, 2026, warrants to purchase an aggregate of 131,601 shares of common stock with a weighted average exercise price of $24.22 expired. In addition, warrants to purchase an aggregate of 428,571 shares of common stock with an exercise price of $2.26 were exercised generating net proceeds of $907,341 after deducting expenses associated with such exercises.

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, at which time, 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 7,293,901. As of March 31, 2026, there were 1,858,785 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.

The Company recorded stock-based compensation expense in the following expense categories of its unaudited interim consolidated statements of operations for the three and six months ended March 31, 2026 and 2025:

	Three months ended March 31,		Six months ended March 31,	
	2026	2025	2026	2025
Research and development	$ 93,119	$ 88,224	$ 190,937	$ 198,253
General and administrative	664,364	1,615,441	1,447,697	5,177,832
Total	$ 757,483	$ 1,703,665	$ 1,638,634	$ 5,376,085

Stock options

As of March 31, 2026, 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 September 30, 2025	3,611,362	$ 11.36	7.6	$ —
Granted	3,298,887	1.18		
Forfeited	(480,720)	1.34		
Expired	(74,368)	22.70		
Balance at March 31, 2026	6,355,161	$ 6.70	8.3	$ —
Vested and exercisable at March 31, 2026	2,837,958	$ 13.22	6.8	$ —

The aggregate intrinsic value represents the total amount by which the fair value of the common stock subject to options exceeds the exercise price of the related options. As of March 31 the intrinsic value was $0.

The weighted average grant date fair value of the options awarded to employees for the six months ended March 31, 2026 and 2025 was $1.05 and $4.63 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:

	Six months ended March 31,	
	2026	2025
Risk-free interest rate	3.8 %	3.5 %
Expected term (years)	5.6	5.5
Expected volatility	132.1 %	134.0 %
Expected dividend yield	—	—

As of March 31, 2026, there was $3,265,512 of unrecognized compensation expense that is expected to be recognized over a weighted-average period of 0.8 year.

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.

A summary of the activity under the performance share option plan as of March 31, 2026 and changes during the six months then ended are presented below.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at September 30, 2025	125,500	$ 12.92	7.6	$ —
Forfeited	(90,500)	6.78		
Expired	(5,000)	28.80		
Balance at March 31, 2026	30,000	$ 28.80	5.7	$ —
Vested and exercisable at March 31, 2026	30,000	$ 28.80	5.7	$ —

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 and six months ended March 31, 2026 as the performance conditions were not deemed probable of being met. The Company did not record any expense related to the performance-based stock options during the three and six months ended March 31, 2025. As of March 31, 2026, 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. Segment Information

Operating segments are components of an enterprise for which discrete financial information is available and reviewed by the chief operating decision maker (“CODM”) to allocate resources and assess performance. The Company has one reportable segment, which consists of the development and commercialization of ONS-5010/LYTENAVA™, an ophthalmic formulation of bevacizumab for the treatment of wet AMD. The Company’s CODM is its Chief Executive Officer, who evaluates and manages the business on a consolidated basis for purposes of resource allocation and performance assessment.

The accounting policies of the Company’s single segment are the same as those described in the summary of significant accounting policies. To date, the Company has generated insignificant product revenue. The Company expects to continue to incur significant expenses and operating losses for the foreseeable future as it advances product candidates through all stages of development and clinical trials and, ultimately, seek regulatory approval. The CODM assesses performance for its segment based on net loss, which is reported on the consolidated statements of operations. The CODM uses budget versus forecasted expense and cash forecast models in making decisions. Such models are reviewed to assess the entity-wide operating results and performance, including how long cash is expected to be sufficient. The measure of segment assets is reported on the consolidated balance sheet as total assets.

The table below summarizes the significant expense categories regularly reviewed by the CODM for the three and six months ended March 31, 2026 and 2025:

	Three months ended March 31,	
	2026	2025
Revenues, net	$ 127,439	$ —
Cost of revenues	149,327	—
Gross profit	(21,888)	—
Operating expenses:		
Research and development expenses		
ONS-5010/LYTENAVA development	3,749,743	3,709,799
Compensation and related benefits	543,483	356,538
Stock-based compensation	93,118	88,224
Other research and development	114,176	252,458
	4,500,520	4,407,019
Selling, general and administrative expenses		
Professional fees	2,014,358	1,720,110
Compensation and related benefits	1,666,751	1,082,722
Stock-based compensation	664,365	1,615,441
Europe commercial expenses	4,076,040	2,607,861
Facilities, fees and other related costs	1,083,065	958,375
	9,504,579	7,984,509
Segment loss from operations	(14,026,987)	(12,391,528)
Other segment items [(i)]	9,573,906	(33,965,678)
Segment loss before income taxes	$ (4,453,081)	$ (46,357,206)

	Six months ended March 31,	
	2026	2025
Revenues, net	$ (1,080,394)	$ —
Cost of revenues	178,953	—
Gross profit	(1,259,347)	—
Operating expenses:		
Research and development expenses		
ONS-5010/LYTENAVA development	6,344,656	12,435,648
Compensation and related benefits	1,158,018	925,665
Stock-based compensation	190,937	198,253
Other research and development	441,261	507,603
	8,134,872	14,067,169
Selling, general and administrative expenses		
Professional fees	3,177,177	4,440,832
Compensation and related benefits	2,581,216	3,862,911
Stock-based compensation	1,447,697	5,177,832
Europe commercial expenses	8,876,774	4,674,937
Facilities, fees and other related costs	2,033,856	1,774,699
	18,116,720	19,931,211
Segment loss from operations	(27,510,939)	(33,998,380)
Other segment items [(i)]	(277)	5,021,588
Segment loss before income taxes	$ (27,511,216)	$ (28,976,792)

Other segment items included in segment loss include loss on equity method investment, interest income, interest expense, loss from change in fair value of promissory notes, warrant related expenses, warrant inducement expenses, and gain from change in fair value of warrant liability.

12. Subsequent Events

On April 23, 2026, the Company announced the closing of a registered direct offering priced at-the-market under Nasdaq rules for the purchase and sale of an aggregate of 16,129,033 shares of its common stock at an offering price of $0.31 per share of common stock. Additionally, in a concurrent private placement, the Company issued unregistered warrants to purchase up to an aggregate of 16,129,033 shares of common stock at an exercise price of $0.31 per share. The unregistered warrants will become exercisable on the later of (i) the date of stockholder approval of the issuance of the shares underlying the warrants and (ii) the effective date of an amendment to the Company's certificate of incorporation to increase the authorized shares of the Company and will expire five years following the later of (x) the date the unregistered warrants are first exercisable and (y) the effective date of the registration statement registering the resale of the shares of common stock issuable upon exercise of the unregistered warrants.

The aggregate gross proceeds to the Company from the offering were approximately $5.0 million, before deducting the placement agent's fees and other offering expenses payable by the Company. The potential additional gross proceeds to the Company from the unregistered warrants, if fully exercised on a cash basis, will be approximately $5.0 million. No assurance can be given that any of the unregistered warrants will be exercised for cash. The Company intends to use the net proceeds from this offering primarily for working capital and general corporate purposes.

On May 13, 2026, the Company entered into an At The Market Offering Agreement (the "Sales Agreement") with H.C. Wainwright & Co., LLC ("H.C. Wainwright"), pursuant to which the Company may issue and sell shares of its common stock, $0.01 par value per share ("Common Stock"), from time to time through H.C. Wainwright as sales agent and/or principal having an aggregate offering price of up to $100,000,000. The offering has been registered under the Securities Act of 1933, as amended (the "Securities Act"), pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-278340), which was declared effective by the Securities and Exchange Commission (the "Commission") on April 5, 2024. The Company filed a prospectus supplement, dated May 13, 2026, with the Commission relating to the Shares. The Sales Agreement may be terminated by the Company at any time upon five business days' prior written notice to H.C. Wainwright, or by H.C. Wainwright at any time.

In connection with entering into the Sales Agreement, the Company terminated, effective May 12, 2026, its at-the-market sales agreement, dated as of May 16, 2023 (as amended, the "Prior Sales Agreement") with BTIG, LLC with respect to an at-the-market offering program under which the Company could offer and sell, from time to time at its sole discretion, shares of its Common Stock having an aggregate offering price of up to $100,000,000 (the "Prior ATM Program"). As a result of the termination of the Prior Sales Agreement, the Company will not offer or sell any additional shares of Common Stock under the Prior ATM Program.

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, 2025 and 2024 included in our Annual Report on Form 10-K for the year ended September 30, 2025, filed with the Securities and Exchange Commission, or SEC, on December 19, 2025.

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, 2025, filed with the SEC on December 19, 2025, 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 that has developed LYTENAVA™ (bevacizumab gamma) as the first and only ophthalmic formulation of bevacizumab approved by the European Commission in the European Union, or EU, and the Medicines and Healthcare products Regulatory Agency, or MHRA, in the United Kingdom, or UK, for use in adults for the treatment of wet age-related macular degeneration, or wet AMD. Starting in June 2025, we launched directly into the initial markets of Germany and the UK. In 2026, we expanded into Austria and are planning for launches in other EU countries either directly or with a licensing partner. Additionally, we are attempting to receive approval for ONS-5010/LYTENAVA by the U.S. Food and Drug Administration, or FDA, for the use of ONS-5010/LYTENAVA as a treatment for wet AMD in the United States. If approved in the U.S., our goal is to also launch directly in the United States as the first and only approved ophthalmic bevacizumab for the treatment of wet AMD. In addition to Europe and the United States, we may seek approval to launch the product in other markets outside of Europe and the U.S. either directly or with licensing partners.

Bevacizumab is a full-length, humanized anti-VEGF (Vascular Endothelial Growth Factor) recombinant monoclonal antibody, or mAb, that inhibits VEGF and associated angiogenic activity. Prior to the approval of ONS-5010/LYTENAVA in the EU and UK, bevacizumab had only been approved for use in the treatment of various forms of cancer and had not been optimized for use in the treatment of retina diseases. Because there previously were no approved bevacizumab products for the treatment of retinal diseases in the United States and other major markets, we submitted standard biologic therapeutic applications and are not using the biosimilar drug regulatory pathway that would be required if bevacizumab were an approved drug for the targeted disease. Off-label repackaged bevacizumab is a frequently used first-line anti-VEGF treatment in Europe (approximately 2.8 million injections annually) and the United States (approximately 2.7 million injections annually) based on data compiled from various sources (Citeline (2023), Global Data (2023) and Market Scope (2022); ASRS 2024 Membership Survey; Market Scope 2024 US Retina Quarterly Updates; GlobalData: Age-Related Macular Degeneration: Global Drug Forecast and Market Analysis to 2028 (April 2020)). We believe ONS-

5010/LYTENAVA has potential to mitigate risks associated with off-label use of unapproved bevacizumab. We believe there is significant opportunity in Europe with a total anti-VEGF retina market estimated to be approximately $3.6 billion, including approximately 1.52 million treated patients and approximately 8.3 million total anti-VEGF units (Global Data (2023); Market Scope (2022); IQVIA MIDAS data Q3 2023; Graefe's Archive for Clinical and Experimental Ophthalmology (2020) 258:503–511). We similarly see significant opportunity in the United States, with an estimated $8.5 billion total anti-VEGF retina market, where 55% of physician state off-label repackaged bevacizumab is the preferred first-line product. It is estimated that 34% of the total anti-VEGF market is off-label bevacizumab (new and maintenance therapy) (Citeline (2023); Global Data (2023); Market Scope (2022); ASRS 2024 Membership Survey; Market Scope 2024 US Retina Quarterly Updates; GlobalData: Age-Related Macular Degeneration: Global Drug Forecast and Market Analysis to 2028 (April 2020)). We estimate the global market for anti-VEGF retina to be approximately $16 billion (Citeline (2023), Global Data (2023) and Market Scope (2022)).

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. In July 2024, the MHRA granted marketing authorization for ONS-5010/LYTENAVA for the treatment of wet AMD in the UK 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. 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 to the FDA for ONS-5010/LYTENAVA for the treatment of wet AMD. 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 in August 2022, and in October 2022, we received confirmation from the FDA that our BLA had been accepted for filing. In August 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 required 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 would 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. 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. Analysis of the complete week 12 data set for NORSE EIGHT provided additional evidence of improvement in vision and biological activity. We resubmitted the BLA for ONS-5010/LYTENAVA in February 2025. On August 27, 2025, we received a second CRL from the FDA. This CRL included only one deficiency, for a lack of substantial evidence of effectiveness. In the CRL, the FDA advised that, because ONS-5010 did not meet the primary efficacy endpoint in NORSE EIGHT, it was recommended that confirmatory evidence of efficacy be submitted to support the application for ONS-5010. Additionally, the FDA reiterated that NORSE TWO met its primary endpoint for effectiveness. Following a September 2025 Type A meeting with the FDA, we resubmitted the BLA in October 2025. On December 31, 2025, we reported that we had received a third CRL in which the FDA noted that the additional mechanistic and natural history data information provided in the BLA resubmission does not alter the previous review conclusion that while the one adequate and well-controlled study demonstrated efficacy, and the FDA has again recommended that confirmatory evidence of efficacy be submitted to support the application. However, the FDA did not indicate in the CRL what type of confirmatory evidence would be acceptable. In March 2026, the Company conducted a Type A meeting with the FDA to discuss the CRL and potential regulatory pathways for ONS-5010. In April 2026, the Company reported that we had submitted a formal dispute resolution request (FDRR) to the FDA as a follow-up to the March 2026 Type A meeting and that the FDA accepted the FDRR and granted a meeting with the deciding official that was conducted in April 2026. We are currently awaiting the formal decision by the deciding official, which is expected in May 2026. If approved, we expect to receive 12 years of regulatory exclusivity in the United States.

Macroeconomic and Geopolitical Factors

Global uncertainty due to tariffs and global macroeconomic conditions may have a material adverse effect on our commercialization efforts. The global financial markets recently have experienced significant disruptions due to various macroeconomic factors, including, among other things, the impacts of fluctuations in inflation and interest rates, tariffs and trade tensions, and geopolitical instability and uncertainty. If these 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. There is inherent risk, based on the complex relationships among the U.S. and the countries in which we conduct our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty. The United States may continue to announce tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, including with respect to the pharmaceutical industry. In response, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. These developments have created a dynamic and unpredictable trade landscape, which may adversely impact our business, results of operations, financial condition and prospects. Current or future tariffs will result in increased research and development expenses, including with respect to increased costs associated with raw materials, laboratory equipment and research materials and components. In addition, such tariffs will increase our supply chain complexity and could also potentially disrupt our existing supply chain. Trade restrictions and tariffs affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence, negatively impacting our ability to secure additional financing on favorable terms or at all. In addition, as we continue to expand our commercialization efforts, tariffs and trade restrictions could hinder our ability to establish cost-effective production capabilities, negatively impacting our growth prospects. We currently manufacture ONS-5010/LYTENAVA in the United States, which helps mitigate exposure to global tariff volatility. However, this concentration of manufacturing may adversely affect our pricing and competitiveness in the United Kingdom and European Union.

Going Concern

Through March 31, 2026, we have funded substantially all of our operations with $650.3 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 loss for the six months ended March 31, 2026 was $27.5 million. We also had a net loss of $29.0 million for the six months ended March 31, 2025. We have not generated any significant 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 March 31, 2026 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. Our unaudited interim consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

Components of our Results of Operations

Revenues, net

We recognize revenue from sales of a single product, LYTENAVA (bevacizumab gamma), which became available for commercial sale and shipment to patients in the UK and Germany in June 2025.

Cost of revenues

Cost of revenues consists primarily of the cost of inventory sold, which includes direct manufacturing, production and packaging materials for LYTENAVA sales. Prior to receiving authorization to sell LYTENAVA in Europe, we expensed

costs associated with manufacturing of LYTENAVA as a component of research and development expense that would have been included in cost of revenues.

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.

Selling, general and administrative expenses

Selling, general and administrative expenses consist principally of distribution expenses, 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, professional fees for business development, legal, auditing and tax services, and insurance costs.

Following the launch of our product in Germany and the UK, we have incurred additional expenses related to commercial operations, including sales and marketing activities in these regions. We anticipate that our general and administrative expenses will continue to increase as we expand our commercial presence, support ongoing operations in these markets, and as the Company prepares for potential launches in additional territories.

Loss on equity method investment

Loss on equity method investment represents our proportionate share for the period of the net loss 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.

(Gain) loss from 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.

Gain on extinguishment of debt

In March 2026 we recognized a gain on a $17,000,000 partial repayment of the Avondale convertible promissory note, based on the fair value of the note at March 16, 2025. The gain represents the difference between the fair value and the cash paid.

Gain from 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 credits) for the net losses we have incurred in each year or on our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. As of September 30, 2025, we had federal and state NOL carryforwards of $441.0 million and $243.6 million, respectively, that will begin to expire in 2030 and 2039, respectively. As of September 30, 2025, we had federal foreign tax credit carryforwards of $0.1 million available to reduce future tax liabilities, which begin to expire starting in 2024. As of September 30, 2025, we also had federal and state research and development tax credit carryforwards of $11.6 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, 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.

On July 4, 2025, the One Big Beautiful Bill Act, or the OBBBA, was enacted in the United States. The legislation includes significant corporate tax reforms, including the permanent reinstatement of the ability to deduct domestic research and development expenditures as incurred beginning in fiscal 2026, replacing the previous requirement to capitalize and amortize such expenditures over five years. The OBBBA also introduces modifications to the international tax framework, including changes to the foreign-derived intangible income, or FDII, regime. Under the legislation, FDII is renamed foreign-derived deduction-eligible income, or FDDEI, with the current FDDEI effective tax rate of 13% maintained through fiscal 2026, followed by a permanent adjustment to a 14% rate beginning in fiscal 2027 (compared to 16% under prior law). The legislation contains multiple effective dates, with certain provisions effective in 2025 and others becoming effective in subsequent years. The effects of OBBBA are not expected to have a material impact on our financial statements.

Segment reporting

We operate in a single reportable segment focused on the development and commercialization of ONS-5010/LYTENAVA™, an ophthalmic formulation of bevacizumab for treating wet AMD. Our Chief Executive Officer serves as the chief operating decision maker, or CODM, and manages our operations on a consolidated basis.

Our segment's accounting policies align with those outlined in the summary of significant accounting policies. To date, we have generated minimal product revenue and expect to continue incurring significant expenses and operating losses as we advance product candidates through development, clinical trials, and regulatory review.

The CODM evaluates segment performance based on net loss, as reported in our consolidated statements of operations, and uses budget-to-forecast comparisons and cash flow models to guide decision-making. Segment assets are reported as total assets on our consolidated balance sheet.

Results of Operations

Comparison of Three Months Ended March 31, 2026 and 2025

	Three months ended March 31,		
	2026	2025	Change
Revenues, net	$ 127,439	$ —	$ 127,439
Cost of revenues	149,327	—	149,327
Gross profit	(21,888)	—	(21,888)
Operating expenses:			
Research and development	$ 4,500,520	$ 4,407,019	$ 93,501
Selling, general and administrative	9,504,579	7,984,509	1,520,070
Loss from operations	(14,026,987)	(12,391,528)	(1,635,459)
Loss on equity method investment	45,119	36,409	8,710
Interest income (expense)	(3)	18,502	(18,505)
(Loss) gain from change in fair value of promissory notes	(2,495,400)	2,111,028	(4,606,428)
Gain from change in fair value of warrant liability	(6,838,022)	(2,059,875)	(4,778,147)
Gain on extinguishment of debt	(285,600)	—	(285,600)
Loss before income taxes	(4,453,081)	(46,354,406)	41,901,325
Income tax expense	—	2,800	(2,800)
Net loss	$ (4,453,081)	$ (46,357,206)	$ 41,904,125

Revenues, net

During the three months ended March 31, 2026, net revenue was $0.1 million, compared to zero for the same period in the prior year. Returns reserves are reviewed quarterly and may be adjusted based on our ongoing assessment of business conditions and distributor-level sales forecasts. In addition, we recognized administrative fees assessed under contractual arrangements with our wholesalers during the three months ended March 31, 2026.

Cost of revenues

Cost of revenues for the three months ended March 31, 2026 was $0.1 million. Prior to receiving regulatory approval for LYTENAVA for the treatment of wet AMD by the European Commission in the EU and the MHRA in the UK, inventory and related manufacturing costs were recognized as research and development expenses. Accordingly, the research and development expenses that would have been classified as cost of revenues for the current period were also immaterial.

Research and development expenses

The following table summarizes our research and development expenses by functional area for the three months ended March 31, 2026 and 2025:

	Three months ended March 31,	
	2026	2025
ONS-5010/LYTENAVA development	$ 3,749,743	$ 3,709,799
Compensation and related benefits	543,483	356,538
Stock-based compensation	93,118	88,224
Other research and development	114,176	252,458
Total research and development expenses	$ 4,500,520	$ 4,407,019

Research and development expenses for the three months ended March 31, 2026 increased by $0.1 million compared to the three months ended March 31, 2025.

Selling, general and administrative expenses

The following table summarizes our selling, general and administrative expenses by type for the three months ended March 31, 2026 and 2025:

	Three months ended March 31,	
	2026	2025
Professional fees	$ 1,155,070	$ 1,720,110
Compensation and related benefits	1,666,751	1,082,722
Stock-based compensation	664,365	1,615,441
Europe commercial expenses	4,800,734	2,607,861
Facilities, fees and other related costs	1,217,659	958,375
Total selling, general and administrative expenses	$ 9,504,579	$ 7,984,509

Selling, general and administrative expenses for the three months ended March 31, 2026 increased by $1.5 million when compared to the three months ended March 31, 2025. The increase was primarily due to increased Europe commercial expenses of $2.2 million offset by a decrease in stock-based compensation of $0.9 million,

Interest income

During the three months ended March 31, 2026 and 2025 interest income was immaterial.

Loss (gain) from 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. The gain recognized during the three months ended March 31, 2026, was primarily driven by the conversion of debt into equity. The loss recognized in the comparative period was primarily due to a reduction in the remaining term of the instrument and increased volatility.

Gain from change in fair value of warrant liability

The gain recognized during the three months ended March 31, 2026, resulted from a decrease in the price per share of common stock from December 31, 2025 to March 31, 2026. The gain recorded during the three months ended March 31, 2025, was primarily due to the reduction in the price per share of common stock from December 31,2024 to March 31, 2025.

Gain on extinguishment of debt

The gain recognized during the three months ended March 31, 2026 resulted from the partial repayment of the March 2025 Avondale unsecured convertible promissory note.

Comparison of Six Months Ended March 31, 2026 and 2025

	Six months ended March 31,		
	2026	2025	Change
Revenues, net	$ (1,080,394)	$ —	$ (1,080,394)
Cost of revenues	178,953	—	178,953
Gross profit	(1,259,347)	—	(1,259,347)
Operating expenses:			
Research and development	8,134,872	14,067,169	(5,932,297)
Selling, general and administrative	18,116,720	19,931,211	(1,814,491)
Loss from operations	(27,510,939)	(33,998,380)	6,487,441
Loss on equity method investment	83,753	69,704	14,049
Interest income	(3)	(30,379)	30,376
Loss from change in fair value of promissory notes	4,248,336	3,415,028	833,308
Gain from change in fair value of warrant liability	(4,046,209)	(42,332,755)	38,286,546
Gain on extinguishment of debt	(285,600)	—	(285,600)
Loss before income taxes	(27,511,216)	(28,976,792)	1,465,576
Income tax expense	—	2,800	(2,800)
Net loss	$ (27,511,216)	$ (28,979,592)	$ 1,468,376

Revenues, net

During the six months ended March 31, 2026, net revenue was negative $1.1 million, compared to zero for the same period in the prior year. The negative revenue for the six months ended March 31, 2026 was primarily due to a $1.1 million increase in the returns reserve related to estimated product returns from our UK distributor due to lower-than-forecasted sell-through during the three months ended December 31, 2025. There were no adjustments for these batches in the three months ended March 31, 2026, and we do not anticipate further adjustments for these batches in fiscal 2026. Returns reserves are reviewed quarterly and may be adjusted based on our ongoing assessment of business conditions and distributor-level sales forecasts. In addition, we recognized administrative fees assessed under contractual arrangements with our wholesalers during the six months ended March 31, 2026. When combined with the increase in the returns reserve, these fees contributed to the negative net revenue for the period.

Cost of revenues

Cost of revenues for the six months ended March 31, 2026 exceeded net revenues for the same period. Prior to receiving regulatory approval for LYTENAVA for the treatment of wet AMD by the European Commission in the EU and the MHRA in the UK, inventory and related manufacturing costs were recognized as research and development expenses. Accordingly, the research and development expenses that would have been classified as cost of revenues for the current period were also immaterial.

Research and development expenses

The following table summarizes our research and development expenses by functional area for the six months ended March 31, 2026 and 2025:

	Six months ended March 31,	
	2026	2025
ONS-5010/LYTENAVA development	$ 6,344,656	$ 12,435,648
Compensation and related benefits	1,158,018	925,665
Stock-based compensation	190,937	198,253
Other research and development	441,261	507,603
Total research and development expenses	$ 8,134,872	$ 14,067,169

Research and development expenses for the six months ended March 31, 2026 decreased by $6.0 million compared to the

six months ended March 31, 2025. The decrease was primarily due to a decrease of $6.1 million in ONS-5010/LYTENAVA development expenses related to conducting the NORSE EIGHT clinical trial, which was initiated and began enrolling patients in January 2024 and completed enrollment in September 2024.

Selling, general and administrative expenses

The following table summarizes our selling, general and administrative expenses by type for the six months ended March 31, 2026 and 2025:

	Six months ended March 31,	
	2026	2025
Professional fees	$ 3,177,177	$ 4,440,832
Compensation and related benefits	2,581,216	3,862,911
Stock-based compensation	1,447,697	5,177,832
Europe commercial expenses	8,876,774	4,674,937
Facilities, fees and other related costs	2,033,856	1,774,699
Total selling, general and administrative expenses	$ 18,116,720	$ 19,931,211

Selling, general and administrative expenses for the six months ended March 31, 2026 decreased by $1.8 million when compared to the six months ended March 31, 2025. The decrease was primarily due to a $5.0 million combined decrease in cash and stock-based compensation, which was primarily related to severance costs from the departure of our former Chief Executive Officer and reductions in headcount in December 2024. In addition, professional fees declined by $1.2 million due to ongoing efforts to reduce expenditures unrelated to launch activities. These decreases were partially offset by a $4.2 million increase in commercial expenses associated with LYTENAVA in Europe.

Interest income

During the six months ended March 31, 2026 and 2025 interest income was immaterial.

Loss from 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. The loss recognized during the six months ended March 31, 2026, was primarily driven by favorable conversion feature triggered by the Major Trigger Event, and increased stock price volatility. The loss recognized in the comparative period was primarily due to a reduction in the remaining term of the instrument and increased volatility.

Gain from change in fair value of warrant liability

The gain recognized during the six months ended March 31, 2026, resulted from an decrease in the price per share of common stock from September 30, 2025 to March 31, 2026. The gain recorded during the six months ended March 31, 2025, was primarily due to the reduction in the price per share of common stock from September 30, 2024 to March 31, 2025.

Gain on extinguishment of debt

The gain recognized during the six months ended March 31, 2026 resulted from the partial repayment of the March 2025 Avondale unsecured convertible promissory note in March 2026.

Liquidity and Capital Resources

We have not generated any significant revenue from product sales. Since inception, we have incurred net losses and negative cash flows from our operations. Through March 31, 2026, we have funded substantially all of our operations with $650.3 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 in the future, fully commercialize ONS-5010/LYTENAVA, to develop any other product candidates 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, we entered into an At-the-Market Sales Agreement with BTIG, LLC, or BTIG, as sales agent, as amended, the ATM Agreement or the ATM Offering, under which we may issue and sell shares of our common stock having an aggregate offering price of up to $100.0 million from time to time through BTIG. Under the ATM Agreement, we pay BTIG a commission equal to 3.0% of the aggregate gross proceeds of any sales of common stock under the ATM Agreement. The offering of common stock pursuant to the ATM Agreement will terminate upon the earlier of (i) the sale of all common stock subject to the ATM Agreement or (ii) termination of the ATM Agreement in accordance with its terms.

During the six months ended March 31, 2026, we sold 15,227,166 shares of common stock under the ATM Offering and generated approximately $17.4 million in net proceeds after paying fees to BTIG and other issuance costs of $0.5 million.

On December 22, 2022, we entered into a Securities Purchase Agreement and issued an unsecured convertible promissory note with a face amount of $31.8 million, or the December 2022 Note, to Streeterville Capital, LLC. On March 13, 2025, we used the proceeds from the March 2025 Note (as defined below) to pay off the December 2022 Note.

On March 13, 2025, we issued an unsecured convertible promissory note for $33.1 million, or the March 2025 Note, to Avondale Capital, LLC, or Avondale, pursuant to a Securities Purchase Agreement, or the Purchase Agreement, dated January 31, 2025. For a description of the Purchase Agreement and the March 2025 Note, see “Description of Indebtedness” below for additional detail.

On December 31, 2025, we did not meet the required $3.0 million Quarterly Debt Reduction Obligation, as defined below. The failure to make this required payment constituted a Major Trigger Event, as defined below, under the March 2025 Note. Pursuant to the terms of the March 2025 Note, the occurrence of a Major Trigger Event resulted in (i) an automatic 10% increase to the outstanding balance, effective January 1, 2026, and (ii) an adjustment to the Conversion Price. Following the adjustment, the Conversion Price is equal to the lesser of the fixed conversion price of $2.26 or 90% of the lowest closing bid price during the three trading days immediately preceding the delivery of a conversion notice, provided that the Conversion Price may not be reduced below the contractual floor price of $0.404. During the six months ended March 31, 2026, Avondale converted 6.9 million of principal and accrued interest on the March 2025 Note into 15,057,649 shares of our common stock. As a result of this conversion, the Quarterly Debt Reduction Obligation was satisfied for the quarters ended December 31, 2025 and March 31, 2026. For additional information regarding the March 2025 Note, refer to Note 7 to the unaudited interim consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

On March 16, 2026, we made a cash repayment of $17,000,000 of outstanding principal and accrued interest under the March 2025 Note using proceeds from the issuance of the March 2026 Note, see below. In connection with the issuance of the March 2026 Note, we amended the March 2025 Note to extend its maturity date to December 31, 2026.

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 March 31, 2026 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. Our unaudited interim 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 commercialize ONS-5010/LYTENAVA, including executing marketing arrangements, 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. See "Overview —Macroeconomic and Geopolitical Factors" for additional information regarding the macroeconomic and geopolitical factors that could have a material adverse effect on our business and results of operations.

Funding Requirements

We plan to focus in the near term on working with the FDA to discern a potential regulatory pathway for ONS-5010 and to prepare for the potential launch of ONS-5010/LYTENAVA, if approved, to support the generation of commercial revenues, in the U.S. 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 March 31, 2026, together with $5.0 million in gross proceeds from the Registered Direct Stock Offering completed in April 2026, are sufficient to fund our operations through one year from the date of this Quarterly Report on Form 10-Q. Our unaudited interim 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:

	Six months ended March 31,	
	2026	2025
Net cash used in operating activities	$ (22,767,166)	$ (27,551,081)
Net cash provided by financing activities	22,432,307	20,179,856
Net decrease in cash and cash equivalents	$ (334,859)	$ (7,371,225)

Operating Activities

During the six months ended March 31, 2026, we used $22.7 million of cash in operating activities resulting primarily from our net loss of $27.5 million. This use of cash was partially offset by $1.6 million of non-cash items such as stock-based compensation, loss from change in fair value of promissory notes, gain from change in fair value of warrant liability, loss on equity method investment and amortization expense. The net cash inflow of $3.0 million from changes in operating assets and liabilities was driven primarily by a $6.9 million increase in accounts payable and accrued expenses due to payment timing, partially offset by a $2.6 million increase in prepaid expenses, a $1.2 million increase in accounts receivable, and minor changes in inventory and lease liabilities.

During the six months ended March 31, 2025, we used $27.6 million of cash in operating activities resulting primarily from our net income of $29.0 million. This use of cash was partially offset by $0.5 million of non-cash items such as stock-based compensation, loss from change in fair value of promissory notes, warrant inducement expenses, gain from change in fair value of warrant liability, loss on equity method investment and depreciation and amortization expense. The net cash inflow of $1.0 million from changes in our operating assets and liabilities was primarily due to a decrease in prepaid expenses of $5.8 million associated with ONS-5010/LYTENAVA development costs relating to clinical trial and drug development costs, partially offset by an increase in inventory of $3.6 million relating to commercial inventory manufactured during the period and a decrease in accounts payable and accrued expenses of $1.2 million, primarily due to timing of payments.

Financing Activities

During the six months ended March 31, 2026, net cash provided by financing activities was $22.4 million, driven primarily by $21.8 million in net proceeds from the sale of common stock and $0.6 million from the exercise of common stock warrants.

During the six months ended March 31, 2025, net cash provided by financing activities was $20.2 million, primarily attributable to net proceeds of $19.9 million from the issuance of common stock and $33 million from the issuance of debt, offset by $32.9 million of debt repayment.

Description of Indebtedness

As of March 31, 2026, the Company's outstanding indebtedness primarily consisted of an unsecured promissory note issued in March 2026, the March 2026 Note, and a remaining balance under a convertible promissory note issued in March 2025, the March 2025 Note.

March 2025 Note

On March 13, 2025, we issued the March 2025 Note for $33,100,000 to Avondale pursuant to the Purchase Agreement. Certain terms of the March 2025 Note were approved at our annual meeting of stockholders on March 11, 2025, and we used the proceeds from the March 2025 Note to pay off the December 2022 Note. On March 28, 2025, we filed a registration statement registering the resale of common stock issuable upon conversion of the March 2025 Note.

The March 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 March 2025 Note is scheduled to mature on July 1, 2026, and will be convertible into common stock. We are obligated to repay a minimum of $3,000,000 of the outstanding balance of the March 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.

Effective March 28, 2025, or the Conversion Commencement Date, Avondale has the right to convert all or any portion of the outstanding balance under the March 2025 Note into shares of common stock, calculated by dividing the amount of the March 2025 Note being converted by the Conversion Price (as defined below). Furthermore, we retain the right to convert any portion of the outstanding balance under the March 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 March 2025 Note stipulates that we shall not permit any conversion of the March 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 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 March 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 Purchase Agreement and the March 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 March 2025 Note by 10% in the case of a Major Trigger Event (as defined in the March 2025 Note) and by 5% for a Minor Trigger Event (as defined in the March 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 March 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 March 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.

On December 31, 2025, we did not meet the required $3.0 million Quarterly Debt Reduction Obligation. The failure to make this required payment constituted a Major Trigger Event under the terms of the March 2025 Note. Subsequent to December 31, 2025, Avondale converted $6.9 million of principal and accrued interest on the March 2025 Note into 15,057,649 shares of our common stock. This Major Trigger Event has not resulted in an Event of Default. As a result of this conversion, the Quarterly Debt Reduction Obligation was satisfied for the quarters ended December 31, 2025 and March 31, 2026.

On March 16, 2026, we made a cash repayment of $17,000,000 of outstanding principal and accrued interest under the March 2025 Note using proceeds from the issuance of the March 2026 Note, see below. In connection with the issuance of the March 2026 Note, we amended the March 2025 Note to extend its maturity date to December 31, 2026.

Pursuant to the terms of the March 2025 Note, the occurrence of a Major Trigger Event resulted in (i) an automatic 10% increase to the outstanding balance, effective January 1, 2026, and (ii) an adjustment to the Conversion Price. Following the adjustment, the Conversion Price is equal to the lesser of the fixed conversion price of $2.26 or 90% of the lowest closing bid price during the three trading days immediately preceding the delivery of a conversion notice, provided that the Conversion Price may not be reduced below the contractual floor price of $0.404.

March 2026 Note

On March 16, 2026, the Company issued the March 2026 Note with an original principal balance of $18,360,000, which was issued at an original issue discount of $1,360,000, resulting in net proceeds of $17,000,000. The March 2026 Note bears interest at the prime rate, as published in The Wall Street Journal, plus 3%, subject to a minimum interest rate of 9.5%, and matures 15 months from issuance. Interest is calculated on the basis of a 360-day year and compounds daily. Beginning on the six-month anniversary of issuance, the holder has the right to redeem up to $3,000,000 of the outstanding balance per calendar quarter. All cash payments under the March 2026 Note, including prepayments, redemptions, or repayment at maturity, are subject to a 7.5% exit fee. The March 2026 Note is unsecured and contains customary representations and warranties, affirmative and negative covenants, and provisions governing Trigger Events, events of default, and remedies, subject to customary cure periods. Upon the occurrence of certain Trigger Events or an event of default, the holder may exercise customary remedies, including acceleration of amounts due, application of default interest, and enforcement of its rights under the note and applicable law.

The Company used the proceeds from the March 2026 Note to partially repay its convertible promissory note issued in March 2025. On March 16, 2026, the Company repaid $17,000,000 of outstanding principal and accrued interest under the March 2025 Note, after which $10,806,991 remained outstanding. In connection with the issuance of the March 2026 Note, the Company amended the March 2025 Note to extend its maturity date to December 31, 2026.

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, 2025, filed with the SEC on December 19, 2025, 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 chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective, at the reasonable assurance level, as of the end of the period covered by this report.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(d) and 15d-15(d) 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 March 31, 2026.

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 seek damages and interest, and an award of reasonable costs, including attorneys' fees. On December 23, 2025, the court dismissed the plaintiffs' second amended complaint in part with prejudice and in part with leave to amend. The plaintiffs filed a third amended complaint in February 2026.

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 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

The following risk factors supplement and, to the extent inconsistent therewith, supersede the risk factors previously disclosed in Item 1A of the Company's Annual Report on Form 10-K for the year ended September 30, 2025, filed with the SEC on December 19, 2025 (the "Annual Report"). You should carefully consider these risk factors together with all other information contained in this Quarterly Report on Form 10-Q and in our Annual Report before making any investment decision. If any of these risks occurs, our business, financial condition, results of operations and prospects could be materially adversely affected.

There is substantial doubt about our ability to continue as a going concern. We will continue to need to raise substantial additional funding to complete the development of ONS-5010/LYTENAVA outside the EU and UK and support our operations until we are able to generate sufficient revenue from the sales of ONS-5010/LYTENAVA in the EU and UK. This additional funding may not be available on acceptable terms or at all. Failure to obtain this

necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

Developing product candidates is an expensive, risky and lengthy process. We have received a marketing authorization from the European Commission and the MHRA for ONS-5010/LYTENAVA for the treatment of wet AMD in the EU and UK, respectively. We are currently advancing ONS-5010/LYTENAVA through the regulatory approval process in the United States, which may ultimately require additional clinical and/or non-clinical studies. Our expenses may increase in connection with our ongoing activities, particularly as we continue the research and development of, continue and initiate clinical trials of, and seek marketing approval for, ONS-5010/LYTENAVA outside the EU and UK.

As of March 31, 2026, our cash and cash equivalents balance was $7.7 million. We do not believe that our cash and cash equivalents as of March 31, 2026, together with the $4.5 million of net proceeds of the Registered Direct Offering and concurrent private placement in April 2026 are sufficient to fund our operations through one year from the date of this Quarterly Report on Form 10-Q. On March 13, 2025, we issued a $33.1 million promissory note, or the March 2025 Note, to Avondale Capital, LLC, or Avondale. The March 2025 Note bears interest at the prime rate plus 3%, with a minimum rate of 9.5%, and is convertible into common stock. We must repay at least $3.0 million (by cash or conversions into common stock) of the outstanding balance on the March 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), 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. The failure to make this required payment constituted a Major Trigger Event under the March 2025 Note. This Major Trigger Event has not resulted in an Event of Default. During the three months ended March 31, 2026, we completed multiple conversions of outstanding principal and accrued interest under the March 2025 Note into shares of our common stock and accordingly the Quarterly Debt Reduction Obligation was satisfied as of March 31, 2026. On March 16, 2026, we entered into a Note Purchase Agreement with Atlas, pursuant to which we agreed to issue to Atlas the March 2026 Note, which we agreed to use for the partial repayment of $17 million of the March 2025 Note. As of March 31, 2026, there were approximately $9.7 million in remaining obligations under the March 2025 Note. In connection with entry into the Note Purchase Agreement with Atlas, we and Avondale entered into an amendment to the March 2025 Note to extend the maturity thereof to December 31, 2026.

We do not believe our cash and cash equivalents, together with net proceeds of $[__] million from the April 2026 Offering, will be adequate to fund our currently planned operations through at least the next 12 months from the date of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2026. As a result, there is substantial doubt about our ability to continue as a going concern. We will require substantial additional capital to continue to operate as a going concern. Although we continue to pursue discussions with additional potential strategic partners for ONS-5010/LYTENAVA outside of the United States, there is no guarantee that we will be successful in reaching any such agreement, nor that such agreement, if successful, will cover the anticipated commercialization costs for ONS-5010/LYTENAVA. Moreover, on December 31, 2025, we reported that we had received a third CRL with respect to our BLA for ONS-5010, and the FDA has again recommended that confirmatory evidence of efficacy be submitted to support the application. However, the FDA did not indicate in the CRL what type of confirmatory evidence would be acceptable, and it is possible that we may need to conduct additional clinical and/or non-clinical studies of ONS-5010 in order to satisfy the FDA's requirements, which would require substantial resources, which may be difficult to obtain or which may be unavailable to us on acceptable terms or at all. Our operating plan may also change as a result of many factors currently unknown to us, and, we will continue to actively seek substantial additional capital through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as through other collaborations, strategic alliances and licensing arrangements, or a combination of these approaches. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Additionally, we may not achieve the expected benefits of these cost reduction measures and other cost reduction plans on the anticipated timeline, or at all, which could otherwise accelerate our liquidity needs and could force us to further curtail or suspend our operations. If we are unable to obtain the substantial additional funding needed to operate our business, our business and prospects would be materially and adversely affected, and we may be required to cease operations entirely, liquidate all or a portion of our assets, and/or seek protection under the U.S. Bankruptcy Code, and you may lose all or part of your investment.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. We may experience difficulties in accessing the capital markets due to external factors beyond our control, such as volatility in the equity markets for emerging biotechnology companies and general economic and market conditions both in the United States and abroad. For example, our ability to raise additional capital may be adversely impacted by global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide, such as has been experienced recently due in part to, among other things, the impacts of inflation, geopolitical instability and uncertainty, and disruptions in access to bank deposits and lending commitments due to bank failure. In addition, our financial position may make it more difficult for us to secure additional funding. We cannot be certain that we will be able to obtain financing on terms acceptable to us, or at all. Our failure to obtain adequate and timely funding will adversely affect our business and our ability to develop our technology and products candidates. Moreover, the terms of any financing may negatively impact the holdings or the rights of our stockholders, and the issuance of additional securities, whether equity or debt, by us or the possibility of such issuance may cause the market price of our securities to decline. The incurrence of indebtedness could result in increased fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, in order to obtain necessary funding, any of which may harm our business, operating results and prospects. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or for specific strategic considerations. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our development programs or the commercialization of ONS-5010/LYTENAVA or any product candidates, if approved. We may also be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could harm our business, financial condition and results of operations.

Raising additional capital, modifications to our existing convertible securities, may cause dilution to our securityholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate sufficient product revenues, we expect to finance our cash needs through a combination of equity and debt financings, as well as selectively continuing to enter into collaborations, strategic alliances and licensing arrangements. We do not currently have any committed external source of funding. To the extent that we raise additional capital through the sale of equity, including via the HCW ATM Agreement, or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a securityholder.

We are obligated to repay a minimum of $3.0 million of the outstanding balance of the March 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%. 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.

Avondale may convert any portion of the March 2025 Note into common stock at a conversion price of $2.26, as further described in the March 2025 Note. In addition, we may convert the March 2025 Note if our stock trades at or above $3.00 per share for 30 consecutive days with an average daily trading volume of at least $1.0 million. Trigger Events (e.g., payment default, covenant breaches) may increase the March 2025 Note balance by 5-10%. Unresolved issues after 10 trading days trigger default, accelerating the March 2025 Note with 22% interest. If the Conversion Price drops below $0.404, conversions must be paid in cash. Conversions of amounts outstanding under the March 2025 Note may result in the issuance of a substantial number of shares of common stock. On December 31, 2025, we did not satisfy the required $3.0 million Quarterly Debt Reduction Obligation, which constituted a Major Trigger Event under the March 2025 Note. As of March 31, 2026, Avondale had converted $6.9 million of principal and accrued interest on the March 2025 Note into shares of common stock at a weighted average conversion price of $0.46. If we are unable to satisfy future repayment obligations under the March 2025 Note, Avondale may continue to effectuate conversions at prices

significantly below the initial $2.26 conversion price, with such conversion price to be determined in accordance with the terms set out in the March 2025 Note. Such conversion could result in significant dilution.

Additional debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and may be secured by all or a portion of our assets. If we secure development funds for ONS-5010/LYTENAVA or any future product candidate through entering into collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish additional valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts, including for ONS-5010/LYTENAVA, or grant rights to develop and market ONS-5010/LYTENAVA or other product candidates that we would otherwise prefer to develop and market ourselves, terminate product development or future commercialization efforts, including for ONS-5010/LYTENAVA, or to cease operations altogether.

Our common stock may be delisted from The Nasdaq Capital Market and begin trading in the over-the-counter markets if we are not successful in regaining compliance with Nasdaq's continued listing standards, which may negatively impact the price of our common stock and our ability to access the capital markets.

On February 18, 2026, we received a letter from the Listing Qualifications Staff, or the Nasdaq Staff, of The Nasdaq Stock Market LLC, or Nasdaq, notifying us that for the last 30 consecutive business days, the bid price of our common stock had closed below $1.00 per share, the minimum closing bid price required by the continued listing requirements of Nasdaq Listing Rule 5550(a)(2).

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have a period of 180 calendar days, or until August 17, 2026, or the Compliance Date, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of our common stock must be at least $1.00 per share for a minimum of ten consecutive business days before the Compliance Date. If we do not achieve compliance by the Compliance Date, we may be eligible for an additional 180-day period to regain compliance if we meet the continued listing requirement for market value of publicly held shares and all other initial listing standards, with the exception of the bid price requirement, and provide written notice to Nasdaq of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. However, if it appears to the Nasdaq Staff that we will not be able to cure the deficiency, or if we are otherwise not eligible for the additional compliance period, and we do not regain compliance by the Compliance Date, The Nasdaq Capital Market will provide written notification to us that our common stock is subject to delisting. At that time, we may appeal the delisting determination to a hearings panel pursuant to the procedures set forth in the applicable Nasdaq listing rules. However, there can be no assurance that, if we do appeal the delisting determination by Nasdaq to the panel, such appeal would be successful.

We intend to actively monitor the closing bid price of our common stock between now and the Compliance Date and will evaluate available options to resolve the deficiency and regain compliance with the minimum bid price rule.

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

None.

Item 3. Defaults Upon Senior Securities

None. However, as described in Note 7 to the unaudited interim consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, on December 31, 2025, the Company did not satisfy the required $3,000,000 Quarterly Debt Reduction Obligation under the March 2025 Note, which constituted a "Major Trigger Event" (as defined in the March 2025 Note) and resulted in (i) an automatic 10% increase to the outstanding balance and (ii) an adjustment to the Conversion Price. Subsequent to December 31, 2025, Avondale converted $6,910,000 of principal and accrued interest into 15,057,649 shares of common stock, satisfying the Quarterly Debt Reduction Obligation for both the quarters

ended December 31, 2025 and March 31, 2026. Avondale has confirmed that this Major Trigger Event has not resulted in an Event of Default (as defined in the March 2025 Note).

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

During the three months ended March 31, 2026, 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	Certificate of Amendment of the Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's current report on Form 8-K filed with the SEC on March 14, 2025)
3.3	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).
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of 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 pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of 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.

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: May 15, 2026

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

Exhibit 31.1

CERTIFICATIONS

I, Robert C. Jahr, 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: May 15, 2026

By: /s/ Robert C. Jahr
Robert C. Jahr
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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: May 15, 2026

By: /s/ Lawrence A. Kenyon
Lawrence A. Kenyon
Chief Financial Officer
(Principal 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 March 31, 2026, 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: May 15, 2026

By: /s/Robert C. Jahr
Robert C. Jahr
Chief Executive Officer
(Principal Executive 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."

Exhibit 32.2

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 March 31, 2026, 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: May 15, 2026

By: /s/ Lawrence A. Kenyon
Lawrence A. Kenyon
Chief Financial Officer
(Principal 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."