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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, 2024
or

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

For the transition period from to

Commission File No. 001-37759

OUTLOOK THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**38-3982704**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
111 S. Wood Avenue, Unit #100 Iselin, New Jersey	**08830**
(Address of principal executive offices)	**(Zip Code)**

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	OTLK	Nasdaq Stock Market LLC

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

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

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

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

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

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

The number of shares of the registrant's common stock, $0.01 par value per share, outstanding as of May 13, 2024 was 23,405,637.

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.

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, 2023, filed with the Securities and Exchange Commission ("SEC") on December 22, 2023, including, among other things, risks associated with:

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

These risks are not exhaustive. Additional factors could harm our business and financial performance, such as risks associated with the current macroeconomic environment, including as a result of the impacts of inflation, high interest rates, current or potential future bank failures or ongoing overseas conflict. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Unless required by law, we undertake no obligation to update or revise any forward-looking statements to reflect new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. We qualify all of the forward-looking statements in this report by these cautionary statements.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Outlook Therapeutics, Inc.
Consolidated Balance Sheets
(unaudited)

	March 31, 2024	September 30, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 47,229,109	$ 23,391,982
Prepaid expenses and other current assets	10,556,696	7,587,216
Total current assets	57,785,805	30,979,198
Operating lease right-of-use assets, net	3,739	26,172
Equity method investment	765,885	793,932
Other assets	473,241	501,299
Total assets	$ 59,028,670	$ 32,300,601
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Unsecured convertible promissory note	$ 44,745,000	$ 35,551,000
Finance lease liabilities	—	4,267
Accounts payable	4,363,235	6,574,523
Accrued expenses	3,115,390	2,745,740
Income taxes payable	1,856,629	1,856,629
Total current liabilities	54,080,254	46,732,159
Warrant liability	139,184,543	6,219
Total liabilities	193,264,797	46,738,378
Commitments and contingencies (Note 8)		
Convertible preferred stock:		
Series A convertible preferred stock, par value $0.01 per share: 1,000,000 shares authorized, no shares issued and outstanding	—	—
Series A-1 convertible preferred stock, par value $0.01 per share: 200,000 shares authorized, no shares issued and outstanding	—	—
Total convertible preferred stock	—	—
Stockholders' deficit:		
Preferred stock, par value $0.01 per share: 7,300,000 shares authorized, no shares issued and outstanding	—	—
Series B convertible preferred stock, par value $0.01 per share: 1,500,000 shares authorized, no shares issued and outstanding	—	—
Common stock, par value $0.01 per share; 60,000,000 shares authorized; 22,012,827 and 13,012,833 shares issued and outstanding at March 31, 2024 and September 30, 2023, respectively	220,128	130,128
Additional paid-in capital	458,929,113	453,350,281
Accumulated deficit	(593,385,368)	(467,918,186)
Total stockholders' deficit	(134,236,127)	(14,437,777)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 59,028,670	$ 32,300,601

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,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 13,508,934	$ 544,948	$ 18,038,292	$ 10,407,372
General and administrative	5,431,041	6,292,982	11,224,805	12,118,586
	18,939,975	6,837,930	29,263,097	22,525,958
Loss from operations	(18,939,975)	(6,837,930)	(29,263,097)	(22,525,958)
Loss (income) on equity method investment	30,595	16,965	28,047	(4,540)
Interest expense (income), net	3,084,035	(187,794)	2,895,358	2,260,797
Loss on extinguishment of debt	—	—	—	577,659
Change in fair value of promissory notes	8,519,153	3,000	9,512,153	3,000
Warrant related expenses (Note 9)	34,097,568	—	34,097,568	—
Change in fair value of warrant liability	49,614,817	(18,615)	49,668,159	(48,875)
Loss before income taxes	(114,286,143)	(6,651,486)	(125,464,382)	(25,313,999)
Income tax expense	2,800	2,800	2,800	2,800
Net loss	$ (114,288,943)	$ (6,654,286)	$ (125,467,182)	$ (25,316,799)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (8.01)	$ (0.52)	$ (9.20)	$ (2.09)
Weighted average shares outstanding, basic and diluted	14,270,289	12,833,330	13,638,126	12,093,889

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

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

	Stockholders' Deficit				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders Deficit
	Shares	Amount			
Balance at October 1, 2023	13,012,833	$130,128	$ 453,350,281	$(467,918,186)	$ (14,437,777)
Stock-based compensation expense	—	—	1,272,611	—	1,272,611
Net loss	—	—	—	(11,178,239)	(11,178,239)
Balance at December 31, 2023	13,012,833	130,128	454,622,892	(479,096,425)	(24,343,405)
Sale of common stock, net of issuance costs	8,571,423	85,714	—	—	85,714
Issuance of common stock in connection with conversion of convertible promissory note	428,571	4,286	2,995,714	—	3,000,000
Stock-based compensation expense	—	—	1,310,507	—	1,310,507
Net loss	—	—	—	(114,288,943)	(114,288,943)
Balance at March 31, 2024	22,012,827	$220,128	$ 458,929,113	$(593,385,368)	$ (134,236,127)

	Stockholders' Equity				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at October 1, 2022	11,365,528	$ 113,655	$ 417,558,434	$(408,935,518)	$ 8,736,571
Sale of common stock, net of issuance costs	1,467,802	14,678	24,277,482	—	24,292,160
Stock-based compensation expense	—	—	1,392,393	—	1,392,393
Net loss	—	—	—	(18,662,513)	(18,662,513)
Balance at December 31, 2022	12,833,330	128,333	443,228,309	(427,598,031)	15,758,611
Stock-based compensation expense	—	—	1,383,405	—	1,383,405
Net loss	—	—	—	(6,654,286)	(6,654,286)
Balance at March 31, 2023	12,833,330	$ 128,333	$ 444,611,714	$(434,252,317)	$ 10,487,730

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,	
	2024	**2023**
OPERATING ACTIVITIES		
Net loss	$ (125,467,182)	$ (25,316,799)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	56,390	21,779
Loss on extinguishment of debt	—	577,659
Non-cash interest expense	2,681,847	2,529,830
Stock-based compensation	2,583,118	2,775,798
Change in fair value of promissory notes	9,512,153	3,000
Warrant related expenses (Note 9)	34,097,568	—
Change in fair value of warrant liability	49,668,159	(48,875)
Loss (income) on equity method investment	28,047	(4,540)
Interest paid on debt	—	(1,158,609)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(2,969,480)	713,199
Other assets	(5,899)	—
Operating lease liabilities	—	(23,066)
Accounts payable	(2,827,195)	128,263
Accrued expenses	342,868	2,786,497
Net cash used in operating activities	(32,299,606)	(17,015,864)
FINANCING ACTIVITIES		
Proceeds from the sale of common stock and warrants to purchase common stock, net of issuance costs	56,141,000	24,297,734
Proceeds from debt	—	30,000,000
Payments of finance lease obligations	(4,267)	(5,686)
Repayment of debt	—	(10,220,000)
Payment of financing costs	—	(823,894)
Net cash provided by financing activities	56,136,733	43,248,154
Net increase in cash and cash equivalents	23,837,127	26,232,290
Cash and cash equivalents at beginning of period	23,391,982	17,396,812
Cash and cash equivalents at end of period	$ 47,229,109	$ 43,629,102
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 475,000	$ 1,159,008
Supplemental schedule of non-cash financing activities:		
Convertible promissory note converted into common stock	$ 3,000,000	$ —
Recognition of warrant liability	$ 89,510,165	$ —
Common stock issuance costs in accounts payable and accrued expenses	$ 642,689	$ —
Deferred offering costs amortization	$ —	$ 5,573

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

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

1. Organization and Description of Business

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

In the fourth quarter of calendar 2023, the Company agreed to conduct an additional adequate and well-controlled clinical trial following discussions with the U.S. Food and Drug Administration ("FDA") in support of the Company's Biologics License Application ("BLA") for ONS-5010. In December 2023, the Company submitted a Special Protocol Assessment ("SPA") to the FDA for this study (NORSE EIGHT) seeking confirmation that, if successful, it will address the FDA's requirement for a second adequate and well-controlled clinical trial to support its planned resubmission of the ONS-5010 BLA. In January 2024, the Company received confirmation that the FDA has reviewed and agreed upon the NORSE EIGHT trial protocol pursuant to the SPA and that, if the NORSE EIGHT trial is successful, it would satisfy the FDA's requirement for a second adequate and well-controlled clinical trial to address fully the clinical deficiency identified in the Complete Response Letter ("CRL"). The first subject was enrolled in NORSE EIGHT in January 2024. In addition, through a Type A meeting and additional interactions, the Company has identified the approaches needed to resolve the chemistry, manufacturing and controls ("CMC") comments in the CRL.

Separately, in October 2022 the Company submitted a Marketing Authorization Application ("MAA"), for ONS-5010 with the European Medicines Agency ("EMA"). On December 22, 2022, the Company's MAA was validated for review by the EMA. In March 2024, the EMA's Committee for Medicinal Products for Human Use ("CHMP") was completed with a positive opinion issued on March 22, 2024. A related positive decision by the European Commission is estimated to be received in the second quarter of calendar 2024. ONS-5010 is the Company's sole product candidate in active development.

2. Liquidity

The Company has incurred recurring losses and negative cash flows from operations since its inception and has an accumulated deficit of $593,385,368 as of March 31, 2024, which raises substantial doubt about the Company's ability to continue as a going concern. The accompanying unaudited interim consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The unaudited interim consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

On April 15, 2024, in a private placement with Syntone Ventures, LLC ("Syntone"), the Company issued 714,286 shares of common stock and accompanying warrants to purchase 1,071,429 shares of common stock for $5,000,000 in gross proceeds pursuant to a securities purchase agreement entered in January 2024. The warrants have an exercise price of $7.70 per share of common stock and will expire on April 15, 2029.

Management does not believe that the existing cash and cash equivalents as of March 31, 2024, combined with the proceeds from the Syntone private placement in April 2024, 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 and additional financing will be needed by the Company to fund its operations in the future and to commercially develop ONS-5010 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, continuing to access capital through at-the-market offering agreements (refer to Note 9 for further details), proceeds from potential licensing and/or marketing arrangements or collaborations with pharmaceutical or other companies, the issuance of equity securities, the issuance of additional debt, and revenues from potential future product sales, if any. There can be no assurance that these future funding efforts will be successful.

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

However, management does believe that the existing cash and cash equivalents as of March 31, 2024, combined with $5,000,000 of gross proceeds from the Syntone private placement that closed in April 2024, when combined with the expected proceeds from the full exercise of warrants to purchase shares of common stock (subject to meeting the requirements for calling the associated warrants), would be sufficient to support the Company's operations through 2025. For further details on the warrants to purchase shares of common stock, refer to Note 9. The Company's consolidated financial statements do not include any adjustments that might be necessary if it is unable to continue as a going concern.

The Company's future operations are highly dependent on a combination of factors, including (i) the timely and successful completion of additional financing discussed above; (ii) the Company's ability to successfully begin marketing of its product candidates or complete revenue-generating partnerships with other companies; (iii) the success of its research and 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, 2024 and its results of operations for the three and six months ended March 31, 2024 and 2023, cash flows for the six months ended March 31, 2024 and 2023, and stockholders' equity for the three and six months ended March 31, 2024 and 2023. Operating results for the six months ended March 31, 2024 are not necessarily indicative of the results that may be expected for the full year ending September 30, 2024. 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, 2023 included in the Company's Annual Report on Form 10-K filed with the SEC on December 22, 2023.

Reverse stock-split

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

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 inflation, high interest rates or ongoing overseas conflict, actual results may materially vary from these estimates. Estimates and assumptions are periodically reviewed, and the

effects of revisions are reflected in the unaudited interim consolidated financial statements in the period they are determined to be necessary.

Net loss per share

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

For purposes of calculating diluted loss per common share, the denominator includes both the weighted average common shares outstanding and the number of common stock equivalents if the inclusion of such common stock equivalents would be dilutive. Potentially dilutive securities include convertible debt, warrants, performance-based stock options and units, stock options and non-vested restricted stock unit ("RSU") awards using the treasury stock method. For all periods presented, there is no difference in the number of shares used to compute basic and diluted shares due to the Company's loss.

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

	Three months ended March 31,		Six months ended March 31,	
	2024	2023	2024	2023
Net loss attributable to common stockholders	$ (114,288,943)	$ (6,654,286)	$ (125,467,182)	$ (25,316,799)
Common stock shares outstanding (weighted average)	14,270,289	12,833,330	13,638,126	12,093,889
Basic and diluted net loss per share	$ (8.01)	$ (0.52)	$ (9.20)	$ (2.09)

The following potentially dilutive securities (in common stock equivalents) have been excluded from the computation of diluted weighted-average shares outstanding as of March 31, 2024 and 2023, as they would be antidilutive:

	As of March 31,	
	2024	2023
Performance-based stock units	123	123
Performance-based stock options	669,000	95,000
Stock options	1,959,565	1,103,242
Common stock warrants	13,136,193	366,410
Convertible debt	2,304,391 (i)	815,262 (ii)

(i) The calculation for potentially dilutive securities pertaining to convertible debt is as follows: $12,000,000 of outstanding principal and accrued interest as of March 31, 2024, is converted at a rate of $7.00, and the remaining amount is converted based on a fixed conversion price of $40.00 per share, which is subject to change as described in Note 7.

(ii) The potentially dilutive securities related to convertible debt are calculated based on a fixed conversion price of $40.00 per share, which is subject to change as described in Note 7.

Recently issued accounting pronouncements

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

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

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. ASU 2023-09 which is intended to improve income tax disclosure requirements by requiring (1) consistent categories and greater disaggregation of information in the rate reconciliation and (2) the disaggregation of income taxes paid by jurisdiction. The guidance makes several other changes to the income tax disclosure requirements. The guidance in ASU 2023-09 will be effective for annual reporting periods in fiscal years beginning after December 15, 2024. The Company is currently evaluating the impact that the adoption of ASU 2023-09 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, 2024		
	(Level 1)	(Level 2)	(Level 3)
Liabilities			
Unsecured convertible promissory note	$ —	$ —	$ 44,745,000
Warrant liability	—	—	139,184,543
Total	$ —	$ —	$ 183,929,543

	September 30, 2023		
	(Level 1)	(Level 2)	(Level 3)
Liabilities			
Unsecured convertible promissory note	$ —	$ —	$ 35,551,000
Warrant liability	—	—	6,219
Total	$ —	$ —	$ 35,557,219

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

The table presented below is a summary of changes in the fair value of the Company's Level 3 valuation for the warrant liability and unsecured convertible promissory note for the six months ended March 31, 2024:

	Unsecured Convertible Promissory Note	Warrants
Balance at October 1, 2023	$ 35,551,000	$ 6,219
Issued in connection with sale of common stock	—	89,510,165
Promissory note maturity extension fee added to outstanding balance	2,681,847	—
Principal and accrued interest converted to common stock	(3,000,000)	—
Change in fair value	9,512,153	49,668,159
Balance at March 31, 2024	$ 44,745,000	$ 139,184,543

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

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

	March 31, 2024	September 30, 2023
Term (years)	1.3	0.3
Stock price	$ 11.94	$ 4.40
Volatility	167.0 %	71.0 %
Risk-free rate	4.9 %	5.5 %
Dividend yield	— %	— %
Credit-adjusted discount rate	21.7 %	22.8 %

The warrants issued in connection with the convertible senior secured notes originally issued pursuant to that certain Note and Warrant Purchase Agreement dated December 22, 2017 and warrants issued in connection with a private placement that closed on March 18, 2024 are classified as liabilities on the accompanying unaudited interim consolidated balance sheets. The warrants related to the Note and Warrant Purchase Agreement dated December 22, 2017 are classified as liabilities as the warrants include cash settlement features at the option of the holders under certain circumstances. The warrants issued in connection with a private placement that closed on March 18, 2024 are classified as liabilities as the Company assessed that they are not indexed to the Company's own stock and must be classified as liabilities. For further details on the evaluation refer to Note 9.

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, 2024	September 30, 2023
Risk-free interest rate	4.21 %	5.30 %
Remaining contractual term of warrants (years)	5.0	1.4
Expected volatility	135.4 %	158.3 %
Annual dividend yield	— %	— %
Fair value of common stock (per share)	$ 11.94	$ 4.40

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5. Equity Method Investment

In connection with the execution of a stock purchase agreement with Syntone Ventures LLC, 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 in the greater China market, which includes Hong Kong, Taiwan and Macau.

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

6. Accrued Expenses

Accrued expenses consists of:

	March 31, 2024	September 30, 2023
Compensation	$ 1,139,963	$ 919,970
Professional fees	1,215,594	165,192
Research and development	544,562	1,234,192
Other accrued expenses	215,271	426,386
	$ 3,115,390	$ 2,745,740

7. Debt

Debt consists of:

	March 31, 2024	September 30, 2023
Unsecured convertible promissory note (measured at fair value)	$ 44,745,000	$ 35,551,000
Less: current portion	(44,745,000)	(35,551,000)
Long-term debt	$ —	$ —

December 2022 Note

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

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

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The December 2022 Note bore interest at 9.5% per annum through April 1, 2024. The December 2022 Note contains customary covenants, including a restriction on the Company's ability to pledge certain of the Company's assets, subject to certain exceptions, without the Lender's consent. Beginning on April 1, 2023, the Lender had the right to convert the December 2022 Note at the Conversion Price (as defined below). The principal amount and conversion price of the December 2022 Note were subject to adjustment upon certain triggering events. In addition, the Company had the right to convert all or any portion of the outstanding balance under the December 2022 Note into shares of common stock at the Conversion Price if certain conditions have been met at the time of conversion, including if at any time after the six-month anniversary of the closing date, the daily volume-weighted average price of the common stock on Nasdaq equals or exceeds $50.00 per share (subject to adjustments for stock splits and stock combinations) for a period of 30 consecutive trading days. Payments may be made by the Company (i) in cash, (ii) in shares of common stock, with the number of shares being equal to the portion of the applicable payment amount divided by the Conversion Price (as defined below), or (iii) a combination of cash and shares of common stock. Any payments made by the Company in cash, including prepayments or repayment at maturity, will be subject to an additional fee of 7.5%. Upon the occurrence of certain events described in the December 2022 Note, including, among others, the Company's failure to pay amounts due and payable under the December 2022 Note, events of insolvency or bankruptcy, failure to observe covenants contained in the Securities Purchase Agreement and the December 2022 Note, breaches of representations and warranties in the Securities Purchase Agreement, and the occurrence of certain transactions without the Lender's consent (each such event, a "Trigger Event"), the Lender shall have the right, subject to certain exceptions, to increase the balance of the December 2022 Note by 10% for a Major Trigger Event (as defined in the December 2022 Note) and 5% for a Minor Trigger Event (as defined in the December 2022 Note). If a Trigger Event is not cured within ten (10) trading days of written notice thereof from the Lender, it will result in an event of default (such event, an "Event of Default"). Following an Event of Default, the Lender may accelerate the December 2022 Note such that all amounts thereunder become immediately due and payable, and interest shall accrue at a rate of 22% annually until paid. Prior to April 1, 2024, under the December 2022 Note, "Conversion Price" meant, prior to a Major Trigger Event, $40.00 per share (subject to adjustment for stock splits and stock combinations), and following a Major Trigger Event, the lesser of (i) $40.00 per share (subject to adjustment for stock splits and stock combinations), and (ii) 90% multiplied by the lowest closing bid price of the Company's common stock in the three trading days prior to the date on which the conversion notice is delivered. If the Conversion Price is below $3.51 per share, the Company will be required to satisfy a conversion notice from the Lender in cash. Subject to certain exceptions, while the December 2022 Note is outstanding, the Lender will have a consent right on any future variable rate transactions or any debt and a 10% participation right in any future debt or equity financings.

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

Under the Note Amendment, the initial conversion price with respect to $15,000,000 in aggregate principal amount of the December 2022 Note was changed to $7.00, the price per share in the private placement that closed on March 18, 2024. Effective April 1, 2024, the December 2022 Note bears interest at the prime rate (as published in the Wall Street Journal) plus 3% (subject to a floor of 9.5%) and the Company has an obligation to repay at least $3,000,000 of the outstanding balance of the December 2022 Note for each calendar quarter beginning with the second calendar quarter of 2024 (subject to adjustment for conversions by the Lender and to payment of an exit fee as set forth in the Note Amendment) and continuing until the December 2022 Note is repaid in full. As of March 31, 2024, the December 2022 Note was classified as current on the unaudited interim consolidated balance sheets as the Lender has the right to convert the December 2022 Note into equity until the entire outstanding balance has been paid off.

During the three and six months ended March 31, 2024, an aggregate of principal and accrued interest totaling $3,000,000 of the December 2022 Note was converted into 428,571 shares of the Company's common stock.

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The Company elected to account for the December 2022 Note at fair value (Note 4) and was not required to bifurcate the conversion option as a derivative and as a result the original issue discount of $1,820,000 and debt issuance costs were written off upon election to fair value and accounted for as interest. During the six months ended March 31, 2023, the Company recognized $2,074,964 of interest expense related to the December 2022 Note, consisting of the original issue discount of $1,820,000 and other third-party debt issuance costs of $254,964 as the Company elected the fair value option.

During the three and six months ended March 31, 2024, the Company recorded $3,156,847 of interest expense in both periods, respectively. This interest expense was associated with the fees incurred for extending the debt.

November 2021 Note

On November 16, 2021, the Company received $10,000,000 in net proceeds from the issuance of the November 2021 Note with a face amount of $10,220,000. Debt issuance costs totaling $820,000 were recorded as debt discount and were deducted from the principal. The debt discount was amortized as a component of interest expense over the term of the underlying debt using the effective interest method. The November 2021 Note bore interest at a rate of 9.5% per annum compounding daily and was set to mature on January 1, 2023. The Company could prepay all or a portion of the November 2021 Note at any time by paying 105% of the outstanding balance elected for pre-payment.

As discussed above, the November 2021 Note was cancelled using proceeds from the December 2022 Note issued to the same lender. The total repayment was $11,947,539, which represented 105% of the outstanding balance and included $1,158,609 of interest expense. The transaction has been accounted for as an extinguishment of the November 2021 Note. As a result, the Company recorded a loss on debt extinguishment of $577,659, which included $8,729 of unamortized debt discount, and prepayment fees of $568,930.

During the three and six months ended March 31, 2023, the Company recognized $418,388 and $454,866 of interest expense, respectively, related to the November 2021 Note of which $169,857 and $190,775, respectively, was related to the amortization of debt discount. During the three and six months ended March 31, 2024, no interest expense was recognized.

8. Commitments and Contingencies

Litigation

On November 3, 2023, a securities class action lawsuit was filed against the Company and certain of its officers in the United States District Court for the District of New Jersey. The class action complaint alleges violations of the Securities Exchange Act of 1934, as amended, or the Exchange Act, in connection with allegedly false and misleading statements made by the Company related to the Company's BLA during the period from December 29, 2022 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 as a treatment for wet AMD and that the Company and/or their manufacturing partner had deficient CMC controls for ONS-5010, which remained unresolved at the time the Company's BLA was re-submitted to the FDA and, as a result, the FDA was unlikely to approve the Company's BLA, and that the Company's stock price dropped when such information was disclosed. The plaintiffs in the class action complaint seek damages and interest, and an award of reasonable costs, including attorneys' fees.

The pending lawsuit 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 lawsuit and any other related lawsuits is necessarily uncertain. The Company could be forced to expend significant resources in the defense of the pending lawsuit 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 lawsuit is currently at an early stage, and the Company cannot be certain how long it may take to resolve the pending lawsuit 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 lawsuit 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 lawsuit and any other related lawsuits. It is possible that the Company could, in the future, incur judgments or enter into settlements of claims for monetary damages.

Leases

Corporate office

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

In March 2024, the Company entered into a five-year term corporate office lease for its new corporate headquarters in Iselin, New Jersey that commenced on May 1, 2024. The Company did not recognize a right-of-use asset and related operate lease liability as of March 31, 2024 because the lease had not commenced.

Equipment leases

As of March 31, 2024, all equipment leases had expired. The Company had equipment leases, with terms between 12 and 36 months, recorded as finance leases. The equipment leases bore interest between 4.0% and 13.0% per annum. Certain lease agreements contained provisions for future rent increases. Payments due under the lease contracts included minimum payments that the Company was obligated to make under the non-cancelable initial terms of the leases as the renewal terms are at the Company's option. Lease expense was recorded as research and development or general and administrative based on the use of the leased asset.

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

	Three months ended March 31,		Six months ended March 31,	
	2024	2023	2024	2023
Lease cost:				
Amortization of right-of-use assets	$ —	$ —	$ —	$ —
Interest on lease liabilities	12	398	116	889
Total finance lease cost	12	398	116	889
Operating lease cost	11,217	11,216	22,433	22,433
Total lease cost	$ 11,229	$ 11,614	$ 22,549	$ 23,322

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

	March 31, 2024	September 30, 2023
Operating leases:		
Right-of-use asset	$ 3,739	$ 26,172
Operating lease liabilities	—	—
Finance leases:		
Right-of-use asset	$ —	$ —
Financing lease liabilities	—	4,267
Weighted-average remaining lease term (years):		
Operating leases	0.1	0.6
Finance leases	—	0.3
Weighted-average discount rate:		
Operating leases	7.5%	7.5%
Finance leases	—	13.0%

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

	Six months ended March 31, 2024	2023
Cash paid for amounts included in the measurement of lease obligations:		
Operating cash flows from finance leases	$ 116	$ 889
Operating cash flows from operating leases	—	23,721
Financing cash flows from finance leases	4,267	5,686

As of March 31, 2024, there were no remaining future minimum lease payments under non-cancelable leases.

9. Common Stock and Stockholders' Equity

Common stock

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

On March 18, 2024, in a private placement (the "Private Placement") pursuant to a securities purchase agreement entered in January 2024 with certain institutional and accredited investors, including GMS Ventures and Investments ("GMS Ventures"), the Company's largest stockholder, the Company issued an aggregate of 8,571,423 shares of common stock and warrants to purchase an aggregate of 12,857,133 shares of common stock at a purchase price per share of $7.00 per share and accompanying warrant to purchase one and one-half shares of common stock for $55,498,311 in net proceeds after payment of placement agent fees and other offering costs. GMS Ventures purchased an aggregate of 2,305,714 shares of common stock and warrants to purchase an aggregate of 3,458,571 shares of common stock in the Private Placement. The Warrants have an exercise price of $7.70 per share of common stock and will expire on March 18, 2029.

The Company evaluated the equity classification for the common stock warrants and considered the conditions as prescribed within ASC 815-40, *Derivatives and Hedging, Contracts in an Entity's own Equity* ("ASC 815-40"). The Company determined that the warrants did not meet the "fixed for fixed" settlement provision set forth in Step 2 of the indexation guidance and as a result they are not indexed to the Company's own stock and must be classified as liabilities. The warrants were measured at fair value at issuance and recorded as a liability and will be remeasured to fair value at each subsequent reporting date, with changes in fair value recorded in current earnings. The net proceeds from the Private Placement were allocated first to the warrants at fair value, with the residual amount recorded as common stock at par

value. The Company will continue to classify such warrants as liabilities until they are exercised, expire, or are no longer required to be classified as liabilities.

As the fair value of the warrants upon issuance was more than the proceeds of the Private Placement, there are no proceeds allocated to additional paid in capital. The excess fair value of the warrants over the net proceeds was $34,097,568 in the aggregate and was recorded as warrant related expenses in the unaudited interim consolidated statement of operations.

In December 2022, in a registered direct equity offering to certain institutional and accredited investors, including GMS Ventures, the Company issued 1,423,041 shares of common stock at a purchase price per share of $17.568 for $23,208,679 in net proceeds after payment of placement agent fees and other offering costs. GMS Ventures purchased an aggregate of 711,520 shares of common stock in the registered direct equity offering. In connection with the registered direct equity offering, the Company issued to M.S. Howells & Co., the placement agent, warrants to purchase up to an aggregate of 25,787 shares of common stock at an exercise price of $21.00 per share, which warrants have a three-year term.

H.C. Wainwright & Co. At-the-Market Offering Agreement

On March 26, 2021, the Company entered into an At-the-Market Offering Agreement with H.C. Wainwright & Co., as sales agent ("Wainwright") (the "Wainwright ATM Agreement" or the "Wainwright ATM Offering"), under which the Company could issue and sell shares of its common stock having an aggregate offering price of up to $40,000,000 from time to time through Wainwright. The Company incurred financing costs of $197,654, which were capitalized and reclassified to additional paid in capital on a pro rata basis when the Company sold common stock under the Wainwright ATM Offering.

Under the Wainwright ATM Agreement, the Company paid Wainwright a commission equal to 3.0% of the aggregate gross proceeds of any sales of common stock under the Wainwright ATM Agreement. The Company terminated the Wainwright ATM Agreement effective May 15, 2023. As a result, the Company wrote off unamortized deferred costs under the Wainwright ATM Agreement effective as of the termination date.

No shares of common stock were sold under the Wainwright ATM Offering during the three months ended March 31, 2023. During the six months ended March 31, 2023, the Company sold 44,769 shares of common stock under the Wainwright ATM Offering and generated $1,089,105 in net proceeds. The Company paid fees to Wainwright and other issuance costs of $38,799.

BTIG, LLC At-the-Market Offering Agreement

On May 16, 2023, the Company entered into an At-the-Market Sales Agreement with BTIG, LLC ("BTIG") as sales agent (as amended, the "BTIG ATM Agreement" or the "BTIG ATM Offering"), under which the Company may issue and sell shares of its common stock having an aggregate offering price of up to $100,000,000 from time to time through BTIG. The Company incurred financing costs of $353,688, which were capitalized and are being reclassified to additional paid in capital on a pro rata basis when the Company sells common stock under the BTIG ATM Offering. As of March 31, 2024, $331,512 of such deferred costs are included in other assets on the unaudited interim consolidated balance sheets.

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

No shares of common stock were sold under the BTIG ATM Offering during the three and six months ended March 31, 2024.

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Common stock warrants

As of March 31, 2024, shares of common stock issuable upon the exercise of outstanding warrants were as follows:

Expiration Date		Shares of common stock issuable upon exercise of warrants	Exercise Price Per Share
December 22, 2024	(i)	13,850	$ 240.00
February 24, 2025		8,642	$ 25.40
April 13, 2025	(i)	7,284	$ 240.00
May 31, 2025	(i)	3,121	$ 240.00
June 22, 2025		9,563	$ 30.38
December 28, 2025		25,787	$ 21.00
January 28, 2026		12,576	$ 25.00
February 2, 2026		93,238	$ 25.00
November 23, 2026		104,999	$ 31.25
March 18, 2029	(ii)	12,857,133	$ 7.70
		13,136,193	

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

(ii) The warrants were issued in connection with a private placement that closed on March 18, 2024 and 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 above for further details.

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 $1.00 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, 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.

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10. Stock-Based Compensation

2011 Equity Incentive Plan

The Company's 2011 Equity Compensation Plan (the "2011 Plan") provided for the Company to sell or issue restricted common stock, RSUs, performance-based awards ("PSUs"), cash-based awards or to grant stock options for the purchase of common stock to officers, employees, consultants and directors of the Company. The 2011 Plan was administered by the board of directors or, at the discretion of the board of directors, by a committee of the board. As of March 31, 2024, PSUs representing 123 shares of the Company's common stock were outstanding under the 2011 Plan. Effective with the December 2015 adoption of the 2015 Equity Incentive Plan, (the "2015 Plan"), no future awards under the 2011 Plan will be granted.

2015 Equity Incentive Plan

In December 2015, the Company adopted the 2015 Plan. The 2015 Plan provides for the grant of stock options, stock appreciation rights, restricted stock awards, RSU awards, performance stock awards and other forms of equity compensation to Company employees, directors and consultants. The aggregate number of shares of common stock authorized for issuance pursuant to the Company's 2015 Plan is 2,503,677. As of March 31, 2024, there were no shares available for grant under the 2015 Plan.

Stock options and RSUs are granted under the Company's 2015 Plan and generally vest over a period of one to four years from the date of grant and, in the case of stock options, have a term of 10 years. The Company recognizes the grant date fair value of each option and 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, 2024 and 2023:

	Three months ended March 31,		Six months ended March 31,	
	2024	2023	2024	2023
Research and development	$ 236,960	$ 322,268	$ 468,376	$ 612,924
General and administrative	1,073,547	1,061,137	2,114,742	2,162,874
	$ 1,310,507	$ 1,383,405	$ 2,583,118	$ 2,775,798

Stock options

As of March 31, 2024, options to purchase common stock of the Company outstanding under the 2015 Plan were as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at October 1, 2023	1,197,774	$ 28.72		
Granted	799,729	6.70		
Forfeited	(29,605)	27.93		
Expired	(8,333)	33.60		
Balance at March 31, 2024	1,959,565	$ 19.72	8.2	$ 4,219,550
Exercisable at March 31, 2024	875,865	$ 27.62	7.0	$ 383,313
Vested and expected to vest at March 31, 2024	1,959,565	$ 19.72	8.2	$ 4,219,550

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.

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The weighted average grant date fair value of the options awarded to employees for the six months ended March 31, 2024 and 2023 was $6.06 and $19.20 per option, respectively. The fair value of the options was estimated on the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions:

	Six months ended March 31,	
	2024	2023
Risk-free interest rate	4.3 %	3.7 %
Expected term (years)	6.0	5.7
Expected volatility	131.3 %	112.4 %
Expected dividend yield	—	—

As of March 31, 2024, there was $10,784,269 of unrecognized compensation expense that is expected to be recognized over a weighted-average period of 1.6 years.

Performance-based stock options

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

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

A summary of the activity under the performance share option plan as of March 31, 2024 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 October 1, 2023	35,000	$ 28.80		
Granted	634,000	6.78		
Balance at March 31, 2024	669,000	$ 7.93	9.9	$ 3,271,440
Exercisable at March 31, 2024	35,000	$ 28.80	7.7	$ —
Vested and expected to vest at March 31, 2024	669,000	$ 7.93	9.9	$ 3,271,440

The vesting of the performance-based stock options is conditional upon FDA approval of ONS-5010. 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, 2024 as the performance conditions were not deemed probable of being met. The weighted average grant date fair value of the performance stock options awarded during the six months ended March 31, 2024, was $6.52 per option. As of March 31, 2024, the Company assessed that the performance conditions related to the performance options granted were not probable of achievement. The assessment was based on the relevant facts and circumstances and therefore

no compensation costs were recognized. 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,	
	2024	2023
Risk-free interest rate	4.3 %	3.8 %
Expected term (years)	10.0	10.0
Expected volatility	125.6 %	91.3 %
Expected dividend yield	—	—

Performance-based stock units

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

The following table summarizes the activity related to PSUs during the six months ended March 31, 2024:

	Number of PSUs	Exercise Price Per PSU	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at October 1, 2023	123	$ 999.40		
Forfeitures	—	—		
Balance at March 31, 2024	123	$ 999.40	0.3	$ —
Exercisable at March 31, 2024	123	$ 999.40	0.3	$ —
Vested and expected to vest at March 31, 2024	123	$ 999.40	0.3	$ —

11. Related-Party Transactions

MTTR – strategic partnership agreement (ONS-5010)

In February 2018, the Company entered into a strategic partnership agreement with MTTR to advise on regulatory, clinical and commercial strategy and assist in obtaining approval of ONS-5010.

In November 2018, the board of directors of the Company appointed Mr. Terry Dagnon as Chief Operations Officer and Mr. Jeff Evanson as Chief Commercial Officer. Both Mr. Dagnon and Mr. Evanson initially provided services to the Company pursuant to the February 2018 strategic partnership agreement with MTTR, as amended. Mr. Dagnon and Mr. Evanson were both principals in MTTR. Both Mr. Dagnon and Mr. Evanson were compensated directly by MTTR for services provided to the Company as the Company's Chief Operations Officer and Chief Commercial Officer, respectively, pursuant to the strategic partnership agreement until such agreement, as amended, was terminated effective March 19, 2020. The Company began compensating Mr. Dagnon and Mr. Evanson directly as consultants effective March 19, 2020 pursuant to their respective consulting agreements with the Company, which became effective March 19, 2020 following stockholder approval of the share issuances contemplated therein.

On December 21, 2021, the Company entered into employment agreements with each of Mr. Dagnon and Mr. Evanson, which superseded and replaced their prior consulting agreements. Pursuant to their new employment agreements, each of Mr. Dagnon and Mr. Evanson will receive a base salary of $450,000 and a discretionary annual cash bonus with a target amount equal to 50% of his respective base salary. In connection with their entry into the employment agreements, each of Mr. Dagnon and Mr. Evanson received a grant of 800,000 options to purchase common stock, one quarter of which will vest on the first anniversary of the grant and the remainder of which will vest in monthly installments over the succeeding three years, subject to their continued service through each vesting date. In addition, each of Mr. Dagnon and Mr. Evanson

received a performance grant of 200,000 options to purchase common stock, which will vest upon the Company's achievement of certain milestones. An aggregate of 200,000 performance-based stock options vested as a result of achieving the performance condition related to the Company's BLA submission.

Mr. Dagnon transitioned from Chief Operations Officer to Senior Advisor on December 6, 2023, as part of the Company's strategic organizational realignment program.

During the three months ended March 31, 2024 and 2023, MTTR and its four principals under the strategic partnership agreement and the subsequent individual consulting agreements earned an aggregate of $60,000 and $28,886, respectively, and $120,000 and $65,552 during the six months ended March 31, 2024 and 2023, respectively, which includes monthly consulting fees and expense reimbursement. There were no amounts payable to the former MTTR principals at March 31, 2024 and September 30, 2023.

12. Subsequent Events

Unsecured convertible promissory note conversions

In April and May 2024, an aggregate of principal and accrued interest totaling $4,750,000 of the December 2022 Note was converted into 678,570 shares of the Company's common stock. For further details on the December 2022 Note, refer to Note 7.

Restated Certificate of Incorporation

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

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, 2023 and 2022 included in our Annual Report on Form 10-K for the year ended September 30, 2023, filed with the Securities and Exchange Commission, or SEC, on December 22, 2023.

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, 2023, filed with the SEC on December 22, 2023, and elsewhere in this report. See "Special Note Regarding Forward-Looking Statements." Forward-looking statements are based on our management's current beliefs and assumptions and based on information currently available to our management. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments.

Overview

We are a biopharmaceutical company working to launch the first ophthalmic formulation of bevacizumab approved by the U.S. Food and Drug Administration (FDA), the European Commission in the European Union (EU), and the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom (UK), for use in retinal indications. Our initial goal is to launch directly in the United States, EU and UK as the first and only approved ophthalmic bevacizumab for the treatment of retina conditions, including wet age-related macular degeneration, or wet AMD., diabetic macular edema, or DME, and branch retinal vein occlusion, or BRVO. Our plans also include seeking approval and launching the product in Japan and other markets. Outside of the United States, we are currently assessing options to commercialize either directly or through a strategic partner. If approved, we expect to receive 12 years of regulatory exclusivity in the United States and up to 10 years of market exclusivity in the European Union.

Bevacizumab is a full-length, humanized anti-VEGF (Vascular Endothelial Growth Factor) recombinant monoclonal antibody, or mAb, that inhibits VEGF and associated angiogenic activity. In March 2022, we submitted a BLA with the FDA for ONS-5010/LYTENAVA™ (bevacizumab-vikg), an investigational ophthalmic formulation of bevacizumab, which we have developed to be administered as an intravitreal injection for the treatment of wet AMD and other retinal diseases. In May 2022, we voluntarily withdrew our BLA to provide additional information requested by the FDA. We re-submitted the BLA to the FDA for ONS-5010 on August 30, 2022, and in October 2022, we received confirmation from the FDA that our BLA had been accepted for filing with a goal date of August 29, 2023 for a review decision by the FDA. On August 29, 2023, we received a Complete Response Letter, or CRL, in which the FDA concluded it could not approve the BLA during this review cycle due to several chemical, manufacturing and control, or CMC, issues, open observations from pre-approval manufacturing inspections, and a lack of substantial evidence. At subsequent Type A meetings with the FDA, we learned that the FDA requires the successful completion of an additional adequate and well-controlled clinical trial evaluating ONS-5010, as well as additional requested CMC data indicated in the CRL to approve ONS-5010 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. In December 2023, we submitted a Special Protocol Assessment, or SPA, to the FDA for this study (NORSE EIGHT) seeking confirmation that, if successful, it will address the FDA's requirement for a second adequate and well-controlled clinical trial to support our planned resubmission of the ONS-5010 BLA. In January 2024,

we received confirmation that the FDA has reviewed and agreed upon the NORSE EIGHT trial protocol pursuant to the SPA. If the NORSE EIGHT trial is successful, it would satisfy the FDA's requirement for a second adequate and well-controlled clinical trial to address fully the clinical deficiency identified in the CRL. In addition, through a Type A meeting and additional interactions, we have identified the approaches needed to resolve the CMC comments in the CRL. We are working to address the open CMC items and have scheduled a series of Type C and Type D meetings with the FDA to help to resolve these comments prior to reporting top line results from NORSE EIGHT in the fourth quarter of calendar 2024.

Separately, in October 2022 we submitted a Marketing Authorization Application, or MAA, for ONS-5010 with the EMA. On December 22, 2022, our MAA was validated for review by the EMA. The MAA was submitted as a 'full-mixed marketing authorization application' based on Article 8.3 of Directive 2001/83/EC. On March 22, 2024, the EMA's Committee for Medicinal Products for Human Use, or CHMP issued a positive opinion concerning the authorization of ONS-5010/LYTENAVA™ (bevacizumab gamma), an investigational ophthalmic formulation of bevacizumab for the treatment of wet age-related macular degeneration (wet AMD) in the EU. The CHMP's positive opinion supports the grant of marketing authorization by the European Commission for ONS-5010 MAA. The European Commission is expected to make a decision within approximately 67 days following the CHMP opinion. The decision will apply automatically in all 27 EU Member States, and, within 30 days, also to Iceland, Norway and Liechtenstein. Additionally, in April 2024, we submitted a MAA to the MHRA in the UK seeking approval of ONS-5010/LYTENAVA™ (bevacizumab gamma) for the treatment of wet AMD. The submission was completed under the new International Recognition Procedure (IRP), which allows the MHRA to rely on an authorization received for the same product from one of MHRA's specified Reference Regulators (RRs) when considering an application for marketing authorization in the UK. These RRs include a positive opinion by the EMA's CHMP concerning an application for grant of marketing authorization for the same product in the EU. The IRP is available for new UK MAAs of a medicinal product (having the same qualitative and quantitative composition, and the same pharmaceutical form) that has previously been authorized by a Reference Regulator (RR). In this case this is the EMA.

Our BLA and MAA submissions for ONS-5010 in wet AMD involved three clinical trials, which we refer to as NORSE ONE, NORSE TWO and NORSE THREE. The study design for our clinical program to evaluate ONS-5010 as an ophthalmic formulation of bevacizumab was reviewed at an end of Phase 2 meeting with the FDA in April 2018, and we filed our investigational new drug application, or IND, with the FDA in the first quarter of calendar 2019. In August 2020, we reported achieving the anticipated safety and efficacy and positive proof-of-concept topline results from NORSE ONE, a clinical experience study. NORSE TWO is our pivotal Phase 3 clinical trial comparing ONS-5010 (bevacizumab-vikg) to ranibizumab (LUCENTIS). The topline results reported from NORSE TWO in August 2021 showed that ONS-5010 met the primary and key secondary endpoint for efficacy with clinically impactful change observed for treated patients. The NORSE TWO primary endpoint difference in proportion of subjects gaining at least 15 letters in Best Corrected Visual Acuity, or BCVA, score was met and was both highly statistically significant and clinically relevant. In the intent to treat, or ITT, primary dataset, the percentage of patients who gained at least 15 letters who were treated with ONS-5010, was 41.7%, and the percentage of patients who gained at least 15 letters who were treated with ranibizumab was 23.1% ($p = 0.0052$). The primary endpoint was also statistically significant and clinically relevant in the secondary per protocol, or PP, dataset ($p = 0.04$) where the percentages were almost identical, at 41.0% with ONS-5010, and 24.7% with ranibizumab. The key secondary endpoint BCVA score change from baseline to month 11 in the primary ITT dataset was also highly statistically significant and clinically relevant ($p = 0.0035$). A mean change of 11.2 letters in BCVA score was observed with ONS-5010, and with ranibizumab the mean change was 5.8 letters. The results were also statistically significant in the secondary PP dataset ($p = 0.01$) with a mean change with ONS-5010 of 11.1 letters versus 7.0 letters with ranibizumab. Additionally, the majority of ONS-5010 subjects maintained or gained BCVA during the study (defined as change from baseline in BCVA ≥ 0), with at least 80% of ONS-5010 subjects maintaining BCVA each month. Results were also positive for the remaining NORSE TWO secondary endpoints with 56.5% ($p = 0.0016$) of ONS-5010 subjects gaining ≥ 10 letters of vision and 68.5% ($p = 0.0116$) of ONS-5010 subjects gaining ≥ 5 letters of vision. NORSE THREE is an open-label safety study we conducted to ensure the adequate number of safety exposures to ONS-5010 were available for the initial ONS-5010 BLA submission with the FDA. In March 2021, we reported that the results from NORSE THREE showed a positive safety profile for ONS-5010.

As agreed to with the FDA in the SPA, NORSE EIGHT is a randomized, controlled, parallel-group, masked, non-inferiority study of approximately 400 newly diagnosed, wet AMD subjects randomized in a 1:1 ratio to receive 1.25 mg ONS-5010 or 0.5 mg ranibizumab intravitreal injections. Subjects will receive injections at Day 0 (randomization), Week

4, and Week 8 visits. The primary endpoint will be mean change in BCVA from baseline to week 8. The first subject was enrolled in NORSE EIGHT in January 2024 and over 30% of the required subjects have been enrolled to date. We expect NORSE EIGHT topline results and potential resubmission of the ONS-5010 BLA by the end of calendar year 2024.

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

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

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

Going Concern

Through March 31, 2024 we have funded substantially all of our operations with $526.7 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, 2024 was $125.5 million. We also had a net loss of $25.3 million for the six months ended March 31, 2023. We have not generated any revenue from product sales. We anticipate incurring additional losses until such time, if ever, that we can generate significant sales of ONS-5010 or any other product candidate we may develop.

On April 15, 2024, in a private placement with Syntone Ventures, LLC (“Syntone”), the Company issued 714,286 shares of common stock and accompanying warrants to purchase 1,071,429 shares of common stock for $5.0 million in gross proceeds pursuant to a securities purchase agreement entered in January 2024. The warrants have an exercise price of $7.70 per share of common stock and will expire on April 15, 2029.

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, 2024, combined with the proceeds from the Syntone private placement in April 2024, 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. However, management does believe that the existing cash and cash equivalents as of March 31, 2024, combined with $5.0 million proceeds from the Syntone private placement that closed in April 2024, when combined with the expected proceeds from the full exercise of warrants to purchase shares of common stock (subject to meeting the requirements for calling the associated warrants), would be sufficient to support the Company’s operations through 2025. For further details on the warrants to purchase shares of common stock, refer to Note 9 of the unaudited consolidated interim financial statements included elsewhere in this Quarterly Report on Form 10-Q. The Company’s consolidated financial statements do not include any adjustments that might be necessary if it is unable to continue as a going concern.

Recent Developments

Effective on March 14, 2024, the Company amended its amended and restated certificate of incorporation to implement a one-for-twenty reverse stock split of its common stock. As a result of the reverse stock split, the Company made corresponding adjustments to the share amounts under its employee incentive plans, outstanding options, and common

stock warrant agreements with third parties. The disclosure of common shares and per common share data in this Quarterly Report on Form 10-Q reflect the reverse stock split for all periods presented.

In April and May 2024, an aggregate of principal and accrued interest totaling $4.8 million of the unsecured convertible promissory note was converted into 678,570 shares of the Company's common stock. For further details on the unsecured convertible promissory note, refer to Note 7 to the unaudited consolidated interim financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Collaboration, License and Strategic Partnership Agreements

From time to time, we enter into collaboration and license agreements for the research and development, manufacture and/or commercialization of our products and/or product candidates. These agreements generally provide for non-refundable upfront license fees, development and commercial performance milestone payments, cost sharing, royalty payments and/or profit sharing. We have also licensed rights to our inactive biosimilar program product candidates (ONS-3010, ONS-1045 and ONS-1050) in other markets.

Syntone – PRC Joint Venture

In May 2020, we entered into a stock purchase agreement with Syntone Ventures LLC, or Syntone Ventures, the United States-based affiliate of Syntone Technologies Group Co. Ltd., or Syntone PRC, pursuant to which we sold and issued in June 2020, in a private placement, 16,000,000 shares of our common stock at a purchase price of $1.00 per share, for aggregate gross proceeds of $16.0 million. In connection with the entry into the stock purchase agreement, we entered into a joint venture agreement with Syntone PRC pursuant to which we agreed to form a People's Republic of China, or PRC joint venture, Beijing Syntone Biopharma Ltd, or Syntone JV, that is 80% owned by Syntone PRC and 20% owned by us. Upon formation of Syntone JV in April 2021, we entered into a royalty-free license with Syntone JV for the development, commercialization and manufacture of ONS-5010 in the greater China market, which includes Hong Kong, Taiwan and Macau.

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

Selexis SA

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

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

Components of our Results of Operations

Research and Development Expenses

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

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

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

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

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

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

General and Administrative Expenses

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

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

Loss (income) on Equity Method Investment

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

Interest Expense (Income), Net

Interest expense (income), net consists of cash paid and non-cash interest expense related to our senior secured notes, equipment loans, lease liabilities and other finance obligations, net of de minimis amount of interest income.

Loss on Extinguishment of Debt

Loss on extinguishment of debt is related to the prepayment and cancellation or amendment of promissory notes during the period that was accounted for as an extinguishment.

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.

Warrant Related Expenses

The warrant related expense relates to the excess of the fair value of the warrants upon issuance over the proceeds of the private placement that closed on March 18, 2024. The excess fair value of the warrants over the net proceeds was recorded in the unaudited interim consolidated statement of operations.

Change in Fair Value of Warrant Liability

We issued warrants to purchase our common stock in conjunction with convertible senior secured notes issued pursuant to a certain Note and Warrant Purchase Agreement dated December 22, 2017. Additionally, we issued warrants in connection with a private placement that closed on March 18, 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

During the years ended September 30, 2023 and 2022, we had no accruals for foreign withholding taxes in connection with our collaboration and licensing agreements. We did not sell any NOLs or unused research and development tax credits during the years ended September 30, 2023 and 2022.

Since inception, we have not recorded any U.S. federal or state income tax benefits (excluding the sale of New Jersey state NOLs and research and development, or R&D, tax credits) for the net losses we have incurred in each year or on our earned R&D tax credits, due to our uncertainty of realizing a benefit from those items. As of September 30, 2023, we had federal and state NOL carryforwards of $371.7 million and $207.5 million, respectively, that will begin to expire in 2030 and 2039, respectively. As of September 30, 2023, we had federal foreign tax credit carryforwards of $1.6 million available to reduce future tax liabilities, which began to expire in 2023. As of September 30, 2023, we also had federal and state R&D tax credit carryforwards of $11.2 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 August 16, 2022, President Biden signed the Inflation Reduction Act, or the IRA. The IRA contains a number of tax related provisions including a 15% minimum corporate income tax on certain large corporations as well as an excise tax on stock repurchases, both provisions are effective for tax years beginning after December 31, 2022. We are in the process of evaluating the IRA, but do not expect it to have a material impact on our consolidated financial statements.

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

Results of Operations

Comparison of Three Months Ended March 31, 2024 and 2023

	Three months ended March 31,		
	2024	2023	Change
Operating expenses:			
Research and development	$ 13,508,934	$ 544,948	$ 12,963,986
General and administrative	5,431,041	6,292,982	(861,941)
Loss from operations	(18,939,975)	(6,837,930)	(12,102,045)
Loss on equity method investment	30,595	16,965	13,630
Interest expense (income), net	3,084,035	(187,794)	3,271,829
Change in fair value of promissory notes	8,519,153	3,000	8,516,153
Warrant related expenses	34,097,568	—	34,097,568
Change in fair value of warrant liability	49,614,817	(18,615)	49,633,432
Loss before income taxes	(114,286,143)	(6,651,486)	(107,634,657)
Income tax expense	2,800	2,800	—
Net loss	$ (114,288,943)	$ (6,654,286)	$ (107,634,657)

Research and development expenses

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

	Three months ended March 31,	
	2024	2023
ONS-5010 development	$ 12,371,350	$ 3,744,704
Compensation and related benefits	665,018	130,229
Stock-based compensation	236,960	322,268
Other research and development	235,606	(3,652,253)
Total research and development expenses	$ 13,508,934	$ 544,948

Research and development expenses for the three months ended March 31, 2024 increased by $13.0 million compared to the three months ended March 31, 2023. The increase was due to an increase in development expenses amounting to $8.6 million, which was primarily related to conducting the NORSE EIGHT clinical trial. Additionally, the increase was driven by cash refunds of waived FDA BLA submission fees of $3.9 million received during the three months ended March 31, 2023, which was recorded as a reduction of expense in the prior year.

General and administrative expenses

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

	Three months ended March 31,	
	2024	2023
Professional fees	$ 1,776,559	$ 3,651,705
Compensation and related benefits	1,423,392	650,987
Stock-based compensation	1,073,547	1,061,137
Facilities, fees and other related costs	1,157,543	929,153
Total general and administrative expenses	$ 5,431,041	$ 6,292,982

General and administrative expenses for the three months ended March 31, 2024 decreased by $0.9 million when compared to the three months ended March 31, 2023. The decrease was due to a $1.9 million decrease in professional fees primarily due to the discontinuing of commercial launch activities following receipt of the CRL in August 2023. This decrease was partially offset by a $0.8 million increase in compensation and benefits, mainly due to increased headcount and cost of living adjustments awarded employees during the three months ended March 31, 2024.

Interest expense (income), net

Interest expense (income), net changed by $3.3 million, from income of $0.2 million to an expense of $3.1 million. The increase was primarily due to convertible promissory note maturity extension fees incurred during the period.

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 notes. We record the promissory notes at fair value with changes in fair value recorded in the unaudited interim consolidated statements of operations.

Warrant related expenses

During the quarter ended on March 31, 2024, we recognized charges associated with warrants issued during the quarter, which were categorized as liabilities. These expenses amounted to the difference between the fair value of the warrants and the net proceeds received from a private placement that closed on March 18, 2024. For further details on warrants to purchase shares of common stock, refer to Note 9 of the unaudited consolidated interim financial statements included herein.

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 a private placement that closed on March 18, 2024. These warrants are categorized as liabilities and recorded at fair value. The warrants are subject to re-measurement at each balance sheet date, and we recognize any change in fair value in our statements of operations. The increase was primarily due to the change in fair value of warrants during the quarter ended March 31, 2024 due to the increase in the price per share of common stock from the date of issuance to March 31, 2024.

Comparison of Six Months Ended March 31, 2024 and 2023

	Six months ended March 31,		
	2024	2023	Change
Operating expenses:			
Research and development	$ 18,038,292	$ 10,407,372	$ 7,630,920
General and administrative	11,224,805	12,118,586	(893,781)
Loss from operations	(29,263,097)	(22,525,958)	(6,737,139)
Loss (income) on equity method investment	28,047	(4,540)	32,587
Interest expense, net	2,895,358	2,260,797	634,561
Loss on extinguishment of debt	—	577,659	(577,659)
Change in fair value of promissory notes	9,512,153	3,000	9,509,153
Warrant related expenses	34,097,568	—	34,097,568
Change in fair value of warrant liability	49,668,159	(48,875)	49,717,034
Loss before income taxes	(125,464,382)	(25,313,999)	(100,150,383)
Income tax expense	2,800	2,800	—
Net loss	$ (125,467,182)	$ (25,316,799)	$ (100,150,383)

Research and development expenses

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

	Six months ended March 31,	
	2024	2023
ONS-5010 development	$ 15,784,424	$ 14,685,759
Compensation and related benefits	1,328,629	878,427
Stock-based compensation	468,376	612,924
Other research and development	456,863	(5,769,738)
Total research and development expenses	$ 18,038,292	$ 10,407,372

Research and development expenses for the six months ended March 31, 2024 increased by $7.6 million compared to the six months ended March 31, 2023. The increase was primarily due to cash refunds of waived FDA BLA submission fees of $6.2 million received during the period combined with the BLA submission fees and an increase in ONS-5010 development costs related to clinical trial costs for NORSE EIGHT. Additionally, ONS-5010 development expenses increased by $1.1 million primarily driven by NORSE EIGHT clinical trial costs incurred during the period.

General and administrative expenses

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

	Six months ended March 31,	
	2024	2023
Professional fees	$ 3,919,228	$ 6,421,589
Compensation and related benefits	3,400,879	1,906,404
Stock-based compensation	2,114,742	2,162,874
Facilities, fees and other related costs	1,789,956	1,627,719
Total general and administrative expenses	$ 11,224,805	$ 12,118,586

General and administrative expenses for the six months ended March 31, 2024 decreased by $0.9 million compared to the six months ended March 31, 2023. The decrease was due to a decrease in professional fees by $2.5 million primarily due to the discontinuing of commercial launch activities following receipt of the CRL in August 2023 partially offset by a $1.5 million increase in compensation and benefits, mainly due to increased headcount and cost of living adjustments awarded employees during the six months ended March 31, 2024.

Interest expense (income), net

Interest expense, net for the six months ended March 31, 2024 increased by $0.6 million compared to March 31, 2023. The increase was primarily due to convertible promissory note maturity extension fees incurred during the period compared to $2.5 million incurred in comparative period relating to the recognition of the original issue discount on the December 2022 Note during the six months ended March 31, 2023 after we elected the fair value option to account for the December 2022 Note.

Loss on extinguishment of debt

Loss on extinguishment of debt of $0.6 million was recorded related to the prepayment and cancellation of a promissory note during the six months ended March 31, 2023 that was accounted for as an extinguishment.

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 notes. We record the promissory notes at fair value with changes in fair value recorded in the unaudited interim consolidated statements of operations.

Warrant related expenses

During the quarter ended on March 31, 2024, we recognized charges associated with warrants issued during the quarter, which were categorized as liabilities. These expenses amounted to the difference between the fair value of the warrants and the net proceeds received from a private placement that closed on March 18, 2024. For further details on warrants to purchase shares of common stock, refer to Note 9 of the unaudited consolidated interim financial statements included herein.

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 a private placement that closed on March 18, 2024. These warrants are categorized as liabilities and recorded at fair value. The warrants are subject to re-measurement at each balance sheet date, and we recognize any change in fair value in our statements of operations. The increase was primarily due to the change in fair value of warrants during the six months ended March 31, 2024 due to the increase in the price per share of common stock from the date of issuance to March 31, 2024.

Liquidity and Capital Resources

We have not generated any revenue from product sales. Since inception, we have incurred net losses and negative cash flows from our operations. Through March 31, 2024, we have funded substantially all of our operations with $526.7 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 or any other product candidate we may develop. We will need additional financing to fund our operations and to commercially develop ONS-5010 or any other product candidate we may develop and to continue as a going concern. Management is currently evaluating various strategic opportunities to obtain the required funding for future operations. These strategies may include but are not limited to potential licensing and/or marketing arrangements or collaborations with pharmaceutical

or other companies, the issuance of equity securities, including through an at-the-market offering program, the issuance of additional debt, and revenues from potential future product sales, if any. Alternatively, we may be required to, among other things, modify our clinical trial plans for ONS-5010 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 November 16, 2021, we received $10.0 million in net proceeds from the issuance of the November 2021 Note, with a face amount of $10.2 million. The November 2021 Note bore interest at a rate of 9.5% per annum, was due to mature January 1, 2023 and included an original issue discount of $0.2 million. We could prepay all or a portion of the note at any time by paying 105% of the outstanding balance elected for pre-payment. On December 28, 2022, we prepaid the November 2021 Note in full by paying 105% of the outstanding balance. The total payment was $11.9 million, which included interest of $1.2 million and a prepayment fee of $0.6 million.

On March 26, 2021, the Company entered into an At-the-Market Offering Agreement with H.C. Wainwright & Co., as sales agent ("Wainwright") (the "Wainwright ATM Agreement" or the "Wainwright ATM Offering"), under which the Company could issue and sell shares of its common stock having an aggregate offering price of up to $40.0 million from time to time through Wainwright. The Company terminated the Wainwright ATM Agreement effective May 15, 2023. As a result, the Company wrote off unamortized deferred costs under the Wainwright ATM Agreement effective as of the termination date.

No shares of common stock were sold under the Wainwright ATM Offering during the three months ended March 31, 2023. During the six months ended March 31, 2023, the Company sold 44,769 shares of common stock under the Wainwright ATM Offering and generated $1.1 million in net proceeds, and the issuance costs were immaterial.

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

No shares of common stock were sold under the BTIG ATM Offering during the six months ended March 31, 2024.

In December 2022, in a registered direct equity offering to certain institutional and accredited investors, including GMS Ventures, our largest stockholder, we issued 1,423,041 shares of common stock at a purchase price per share of $17.568 for $23.2 million in net proceeds after payment of placement agent fees and other offering costs. GMS Ventures purchased an aggregate of 711,520 shares of common stock in the registered direct equity offering. In connection with the registered direct equity offering, we issued to M.S. Howells & Co., as placement agent for certain accredited investors in the offering, warrants to purchase up to an aggregate of 25,787 shares of common stock, which will be exercisable commencing on the one-year anniversary of the closing of the offering at an exercise price of $21.00 per share, which warrants have a three-year term.

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, or the Lender, the holder of our November 2021 Note. The December 2022 Note has an original issue discount of $1.8 million. A portion of the proceeds from the December 2022 Note were used to repay in full the remaining outstanding principal and accrued interest on the November 2021 Note, which was cancelled upon repayment. We received net proceeds of $18.1 million upon the closing on December 28, 2022, after deducting the Lender's transaction costs in connection with the issuance and November 2021 Note repayment. In December 2023, the Company extended the maturity of the December 2022 Note from January 1, 2024 to April 1, 2024. The Company incurred a $475 thousand extension fee. The December 2022 Note bore interest at 9.5% per annum through April 1, 2024. On January 22, 2024, the Company entered into an amendment to the December 2022 Note (the "Note Amendment") with the Lender, which became effective on April 1, 2024 after satisfaction of certain closing conditions, including various required stockholder approvals and the closing of the private placement that closed on March 18, 2024. The maturity of the December 2022 Note was extended to July 1, 2025. An

extension fee of $2.7 million (calculated as 7.5% of the outstanding balance of the December 2022 Note) was added to the outstanding balance on March 18, 2024. Under the Note Amendment, the initial conversion price with respect to $15.0 million in aggregate principal amount of the December 2022 Note was changed to $7.00, the price per share in the private placement that closed on March 18, 2024 and the remaining aggregate principal amount is converted at a price of $40.00 per share. Effective April 1 2024, the December 2022 Note bears interest at the prime rate (as published in the Wall Street Journal) plus 3% (subject to a floor of 9.5%) and the Company has an obligation to repay at least $3.0 million of the outstanding balance of the December 2022 Note for each calendar quarter beginning with the second calendar quarter of 2024 (subject to adjustment for conversions by the Lender and to payment of an exit fee as set forth in the December 2022 Note) and continuing until the December 2022 Note is repaid in full. The December 2022 Note contains customary covenants, including a restriction on the Company's ability to pledge certain of the Company's assets, subject to certain exceptions, without the Lender's consent. See "Description of Indebtedness" below for additional detail.

During the six months ended March 31, 2024, an aggregate of principal and accrued interest totaling $3.0 million of the December 2022 Note was converted into 428,571 shares of our common stock. In April and May 2024, an aggregate of principal and accrued interest totaling $4.8 million of the December 2022 Note was converted into 678,570 shares of our common stock.

In March 2024, in a private placement pursuant to a securities purchase agreement entered in January 2024 with certain institutional and accredited investors, including GMS Ventures, our largest stockholder, we issued an aggregate of 8,571,423 shares of common stock and warrants to purchase an aggregate of 12,857,133 shares of common stock at a purchase price per share of $7.00 per share and accompanying warrant to purchase one and one-half shares of common stock for $55.5 million in net proceeds after payment of placement agent fees and other offering costs. GMS Ventures purchased an aggregate of 2,305,714 shares of common stock and warrants to purchase an aggregate of 3,458,571 shares of common stock in the Private Placement. The warrants have an exercise price of $7.70 per share of common stock and will expire on March 18, 2029.

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, 2024, combined with $5.0 million proceeds from the Syntone private placement that closed in April 2024, 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. However, management does believe that the existing cash and cash equivalents as of March 31, 2024, combined with $5.0 million proceeds from the Syntone private placement that closed in April 2024, when combined with the expected proceeds from the full exercise of warrants to purchase shares of common stock (subject to meeting the requirements for calling the associated warrants), would be sufficient to support our operations through 2025. For further details on the warrants to purchase shares of common stock, refer to Note 9 of the unaudited consolidated interim financial statements included elsewhere in this Quarterly Report on Form 10-Q. Our consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

Our future operations are highly dependent on a combination of factors, including: (i) the timely and successful completion of additional financing discussed above; (ii) our ability to successfully begin marketing of our product candidates or complete revenue-generating partnerships with other companies; (iii) the success of our research and development; (iv) the development of competitive therapies by other biotechnology and pharmaceutical companies; and, ultimately; (v) regulatory approval and market acceptance of our proposed future products. Additionally, the global financial markets have experienced significant disruptions due to various macroeconomic factors, including, among other things, the impacts of ongoing overseas conflict, resulting in a general global economic slowdown. Furthermore, inflation rates, particularly in the United States and the United Kingdom, have increased recently to levels not seen in decades. In addition, the U.S. Federal Reserve has raised, and is expected to further raise, interest rates in response to concerns about inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may further increase economic uncertainty and heighten these risks. Moreover, the recent closures of Silicon Valley Bank, Signature Bank and First Republic Bank have resulted in broader financial institution liquidity risk and concerns. If other banks and financial institutions fail or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our cash, cash equivalents and investments may be threatened and our ability to raise additional capital could be substantially impaired. If the disruptions and slowdown deepen or persist, we may not

be able to access additional capital on favorable terms, or at all, which could in the future negatively affect our ability to pursue our business strategy.

Funding Requirements

We plan to focus in the near term on supporting the review of our BLA submission for ONS-5010 with the FDA and to prepare for the potential launch of LYTENAVA™, if approved, to support the generation of commercial revenues. We anticipate we will incur net losses and negative cash flow from operations for the foreseeable future. We may not be able to initiate commercialization of ONS-5010 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 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, 2024, combined with $5.0 million proceeds from the Syntone private placement that closed in April 2024, are sufficient to fund our operations through one year from the date of this Quarterly Report on Form 10-Q. However, management does believe that the existing cash and cash equivalents as of March 31, 2024, combined with $5.0 million proceeds from the Syntone private placement that closed in April 2024, when combined with the expected proceeds from the full exercise of warrants to purchase shares of common stock (subject to meeting the requirements for calling the associated warrants), would be sufficient to support our operations through 2025. For further details on the warrants to purchase shares of common stock, refer to Note 9 of the unaudited consolidated interim financial statements included herein. Our consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

We plan to finance our future operations with a combination of proceeds from potential strategic collaborations, sale of the development and commercial rights to our drug product candidates, the issuance of equity securities, the issuance of additional debt, and revenues from potential future product sales, if any. If we raise additional capital through the sale of equity or convertible debt securities, your ownership will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. 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 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 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,	
	2024	2023
Net cash used in operating activities	$ (32,299,606)	$ (17,015,864)
Net cash provided by financing activities	56,136,733	43,248,154
Net increase in cash and cash equivalents	$ 23,837,127	$ 26,232,290

Operating Activities

During the six months ended March 31, 2024, we used $32.3 million of cash in operating activities resulting primarily from our net loss of $125.5 million. This use of cash was partially offset by $98.6 million of non-cash items such as stock-based compensation, non-cash interest expense, change in fair value of promissory notes, warrant related expense, change in fair value of warrant liability, loss on equity method investment and depreciation and amortization expense. The net cash outflow of $5.5 million from changes in our operating assets and liabilities was primarily due to a decrease in accounts

payable and accrued expenses of $2.5 million, and an increase in prepaid expenses of $3.0 million for timing of payments associated with ONS-5010 development costs relating to clinical trial and drug development costs.

During the six months ended March 31, 2023, we used $17.0 million of cash in operating activities resulting primarily from our net loss of $25.3 million. This use of cash was partially offset by $5.9 million of non-cash items such as stock-based compensation, non-cash interest expense, change in fair value of warrant liability, loss on extinguishment of debt, income on equity method investment and depreciation and amortization expense. We also paid interest on debt of $1.2 million during the period. The net cash inflow of $3.6 million from changes in our operating assets and liabilities was primarily due to an increase in accounts payable and accrued expenses of $2.9 million, and a decrease in prepaid expenses of $0.7 million for timing of payments associated with ONS-5010 development costs.

Financing Activities

During the six months ended March 31, 2024, net cash provided by financing activities was $56.1 million, primarily attributable to $56.1 million in net proceeds from a private placement in March 2024 of an aggregate 8,571,423 common stock shares and warrants to purchase an aggregate of 12,857,133 shares of common stock.

During the six months ended March 31, 2023, net cash provided by financing activities was $43.2 million, primarily attributable to $23.2 million in net proceeds from a registered direct equity offering in December 2022 of an aggregate of 1,423,041 shares of our common stock, $1.1 million in net proceeds from the sale of common stock under the ATM Offering and $30.0 million in net proceeds from the issuance of an unsecured convertible promissory note with a face amount of $31.8 million in December 2022. We also made $10.2 million in debt and finance lease obligation payments and a $0.8 million payment of financing costs.

Description of Indebtedness

On December 22, 2022, we entered into the Securities Purchase Agreement and issued the December 2022 Note to the Lender. The December 2022 Note, which was amended in December 2023, has a face value of $31.8 million and an original issue discount of $1.8 million. In December 2023, the Company extended the maturity of the December 2022 Note from January 1, 2024 to April 1, 2024. On January 22, 2024, the Company entered into an amendment to the December 2022 Note with the Lender, which became effective on April 1, 2024 after satisfaction of certain closing conditions, including various required stockholder approvals and the closing of the private placement that closed on March 18, 2024. Effective April 1, 2024, the initial conversion price with respect to $15,000,000 in aggregate principal amount of the December 2022 Note was changed to $7.00, the price per share in the private placement that closed on March 18, 2024 and bears interest at the prime rate (as published in the Wall Street Journal) plus 3% (subject to a floor of 9.5%) and the Company has an obligation to repay at least $3,000,000 of the outstanding balance of the December 2022 Note for each calendar quarter beginning with the second calendar quarter of 2024 (subject to adjustment for conversions by the Lender and to payment of an exit fee as set forth in the December 2022 Note) and continuing until the December 2022 Note is repaid in full.

The December 2022 Note contains customary covenants, including a restriction on the Company's ability to pledge certain of the Company's assets, subject to certain exceptions, without the Lender's consent. Beginning on April 1, 2023, the Lender had the right to convert the December 2022 Note at the Conversion Price (as defined below). The principal amount and conversion price of the December 2022 Note were subject to adjustment upon certain triggering events. In addition, the Company had the right to convert all or any portion of the outstanding balance under the December 2022 Note into shares of common stock at the Conversion Price if certain conditions have been met at the time of conversion, including if at any time after the six-month anniversary of the closing date, the daily volume-weighted average price of the common stock on Nasdaq equals or exceeds $50.00 per share (subject to adjustments for stock splits and stock combinations) for a period of 30 consecutive trading days. Payments may be made by the Company (i) in cash, (ii) in shares of common stock, with the number of shares being equal to the portion of the applicable payment amount divided by the Conversion Price (as defined below), or (iii) a combination of cash and shares of common stock. Any payments made by the Company in cash, including prepayments or repayment at maturity, will be subject to an additional fee of 7.5%. Upon the occurrence of certain events described in the December 2022 Note, including, among others, the Company's failure to pay amounts due and payable under the December 2022 Note, events of insolvency or bankruptcy, failure to observe covenants contained in the Securities Purchase Agreement and the December 2022 Note, breaches of representations and warranties

in the Securities Purchase Agreement, and the occurrence of certain transactions without the Lender's consent (each such event, a "Trigger Event"), the Lender shall have the right, subject to certain exceptions, to increase the balance of the December 2022 Note by 10% for a Major Trigger Event (as defined in the December 2022 Note) and 5% for a Minor Trigger Event (as defined in the December 2022 Note). If a Trigger Event is not cured within ten (10) trading days of written notice thereof from the Lender, it will result in an event of default (such event, an "Event of Default"). Following an Event of Default, the Lender may accelerate the December 2022 Note such that all amounts thereunder become immediately due and payable, and interest shall accrue at a rate of 22% annually until paid. Prior to April 1, 2024, under the December 2022 Note, "Conversion Price" meant, prior to a Major Trigger Event, $40.00 per share (subject to adjustment for stock splits and stock combinations), and following a Major Trigger Event, the lesser of (i) $40.00 per share (subject to adjustment for stock splits and stock combinations), and (ii) 90% multiplied by the lowest closing bid price of the Company's common stock in the three trading days prior to the date on which the conversion notice is delivered. If the Conversion Price is below $3.51 per share, the Company will be required to satisfy a conversion notice from the Lender in cash. Subject to certain exceptions, while the December 2022 Note is outstanding, the Lender will have a consent right on any future variable rate transactions or any debt and a 10% participation right in any future debt or equity financings.

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, 2023, filed with the SEC on December 22, 2023, 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(f) under the Exchange Act) that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting during our second fiscal quarter ended March 31, 2024.

Part II. Other Information

Item 1. Legal Proceedings

On November 3, 2023, a securities class action lawsuit was filed against us and certain of our officers in the United States District Court for the District of New Jersey. The class action complaint alleges violations of the Exchange Act in connection with allegedly false and misleading statements made by us related to our BLA during the period from December 29, 2022 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 as a treatment for wet AMD and that we and/or our manufacturing partner had deficient CMC controls for ONS-5010, which remained unresolved at the time our BLA was re-submitted to the FDA and, as a result, the FDA was unlikely to approve our BLA, and that our stock price dropped when such information was disclosed. The plaintiffs in the class action complaint seek damages and interest, and an award of reasonable costs, including attorneys' fees.

The pending lawsuit 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 lawsuit and any other related lawsuits is necessarily uncertain. We could be forced to expend significant resources in the defense of the pending lawsuit 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 lawsuit is currently at an early stage, and we cannot be certain how long it may take to resolve the pending lawsuit 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 lawsuit 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 lawsuit and any other related lawsuits. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages.

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

Item 1A. Risk Factors

As of March 31, 2024, there have been no material changes to the risk factors that were previously disclosed in Item 1A in the Company's Form 10-K for the year ended September 30, 2023 filed with the SEC on December 22, 2023.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

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

On May 13, 2024, the Company filed a Certificate of Elimination to its Certificate of Incorporation, as then amended, with the Secretary of State of the State of Delaware to eliminate from the Certificate of Incorporation all matters set forth in the

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

Item 6. Exhibits

Exhibit Number	Description
3.1	Restated Certificate of Incorporation.
3.2	Certificate of Elimination of the Series A Convertible Preferred Stock, Series B Convertible Preferred Stock and Series A-1 Convertible Preferred Stock.
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).
10.1	Amendment, dated April 12, 2024, to Sales Agreement, dated May 16, 2023, by and between the Company and BTIG (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K filed with the SEC on April 12, 2024).
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 and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS**	Inline XBRL Instance Document.
101.SCH***	Inline XBRL Taxonomy Extension Schema Document.
101.CAL***	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF***	Inline XBRL Definition Linkbase Document.
101.LAB***	Inline XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE***	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104**	Cover Page Interactive Data File.

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

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

*** Submitted electronically with the report.

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, 2024

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

RESTATED
CERTIFICATE OF INCORPORATION
OF
OUTLOOK THERAPEUTICS, INC.

(Originally incorporated on October 22, 2015 under the name Oncobiologics, Inc.)

I.

The name of this corporation is Outlook Therapeutics, Inc. (the "***Company***").

II.

The address of the registered office of this Company in the State of Delaware is 800 North State Street, Suite 304, City of Dover, County of Kent, 19901, and the name of the registered agent of this Company in the State of Delaware at such address is United Corporate Services, Inc.

III.

The purpose of the Company is to engage in any lawful act or activity for which a corporation may be organized under the Delaware General Corporation Law ("***DGCL***").

IV.

A. The Company is authorized to issue two classes of stock to be designated, respectively, "Common Stock" and "Preferred Stock." The total number of shares which the Company is authorized to issue is seventy million (70,000,000) shares. Sixty million (60,000,000) shares shall be Common Stock, each having a par value of one cent ($0.01). Ten million (10,000,000) shares shall be Preferred Stock, each having a par value of one cent ($0.01).

B. The Preferred Stock may be issued from time to time in one or more series. The Board of Directors of the Company is hereby expressly authorized to provide for the issue of all or any number of the shares of the Preferred Stock in one or more series, and to fix the number of shares and to determine or alter for each such series, such voting powers, full or limited, or no voting powers, and such designation, preferences, and relative, participating, optional, or other rights and such qualifications, limitations, or restrictions thereof, as shall be stated and expressed in the resolution or resolutions adopted by the Board of Directors providing for the issuance of such shares and as may be permitted by the DGCL. The Board of Directors is also expressly authorized to increase or decrease the number of shares of any series subsequent to the issuance of shares of that series, but not below the number of shares of such series then outstanding. In case the number of shares of any series shall be decreased in accordance with the foregoing sentence, the shares constituting such decrease shall resume the status that they had prior to the adoption of the resolution originally fixing the number of shares of such series. The number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the voting power of the stock of the Company entitled to vote thereon, without a separate vote of the holders of the Preferred Stock, or of any series thereof, unless a vote of any such holders is required pursuant to the terms of any certificate of designation filed with respect to any series of Preferred Stock.

V.

For the management of the business and for the conduct of the affairs of the Company, and in further definition, limitation and regulation of the powers of the Company, of its directors and of its stockholders or any class thereof, as the case may be, it is further provided that:

A.

1. The management of the business and the conduct of the affairs of the Company shall be vested in the Board of Directors. The number of directors which shall constitute the Board of Directors shall be fixed exclusively by resolutions adopted by a majority of the authorized number of directors constituting the Board of Directors.

2. BOARD OF DIRECTORS

a. Subject to the rights of the holders of any series of Preferred Stock to elect additional directors under specified circumstances, the directors shall be divided into three classes designated as Class I, Class II and Class III, respectively. The Board of Directors is authorized to assign members of the Board of Directors already in office to such classes at the time the classification becomes effective. At the first annual meeting of stockholders following the initial classification of the Board of Directors, the term of office of the Class I directors shall expire and Class I directors shall be elected for a full term of three years. At the second annual meeting of stockholders following such initial classification, the term of office of the Class II directors shall expire and Class II directors shall be elected for a full term of three years. At the third annual meeting of stockholders following such initial classification, the term of office of the Class III directors shall expire and Class III directors shall be elected for a full term of three years. At each succeeding annual meeting of stockholders, directors shall be elected for a full term of three years to succeed the directors of the class whose terms expire at such annual meeting.

b. Notwithstanding the foregoing provisions of this section, each director shall serve until his successor is duly elected and qualified or until his earlier death, resignation or removal. No decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.

3. REMOVAL OF DIRECTORS.

a. Subject to the rights of any series of Preferred Stock to elect additional directors under specified circumstances, neither the Board of Directors nor any individual director may be removed without cause.

b. Subject to any limitations imposed by applicable law, any individual director or directors may be removed with cause by the affirmative vote of the holders of a majority of the voting power of all then-outstanding shares of capital stock of the Company entitled to vote generally at an election of directors.

4. VACANCIES. Subject to any limitations imposed by applicable law and subject to the rights of the holders of any series of Preferred Stock, any vacancies on the Board of Directors resulting from death, resignation, disqualification, removal or other causes and any newly created directorships resulting from any increase in the number of directors, shall, unless the Board of Directors determines by resolution that any such vacancies or newly created directorships shall be filled by the stockholders and except as otherwise provided by applicable law, be filled only by the affirmative vote of a majority of the directors then in office, even though less than a quorum of the Board of Directors, and not by the

stockholders. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the director for which the vacancy was created or occurred and until such director's successor shall have been elected and qualified.

B.

1. Bylaw Amendments. The Board of Directors is expressly empowered to adopt, amend or repeal the Bylaws of the Company. The stockholders shall also have power to adopt, amend or repeal the Bylaws of the Company; provided, however, that, in addition to any vote of the holders of any class or series of stock of the Company required by law or by this Restated Certificate of Incorporation, such action by stockholders shall require the affirmative vote of the holders of at least sixty-six and two-thirds percent (66 2/3%) of the voting power of all of the then-outstanding shares of the capital stock of the Company entitled to vote generally in the election of directors, voting together as a single class.

2. The directors of the Company need not be elected by written ballot unless the Bylaws so provide.

3. No action shall be taken by the stockholders of the Company except at an annual or special meeting of stockholders called in accordance with the Bylaws, and no action shall be taken by the stockholders by written consent or electronic transmission.

4. Advance notice of stockholder nominations for the election of directors and of business to be brought by stockholders before any meeting of the stockholders of the Company shall be given in the manner provided in the Bylaws of the Company.

VI.

A. The liability of the directors for monetary damages shall be eliminated to the fullest extent permitted by applicable law.

B. To the fullest extent permitted by applicable law, the Company is authorized to provide indemnification of (and advancement of expenses to) directors, officers and agents of the Company (and any other persons to which applicable law permits the Company to provide indemnification) through Bylaw provisions, agreements with such agents or other persons, vote of stockholders or disinterested directors or otherwise in excess of the indemnification and advancement otherwise permitted by such applicable law. If applicable law is amended after approval by the stockholders of this Article VI to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director to the Company shall be eliminated or limited to the fullest extent permitted by applicable law as so amended.

C. Any repeal or modification of this Article VI shall only be prospective and shall not affect the rights or protections or increase the liability of any director under this Article VI in effect at the time of the alleged occurrence of any act or omission to act giving rise to liability or indemnification.

VII.

Unless the Company consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (A) any derivative action or proceeding brought on behalf of the Company; (B) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Company to the Company or the Company's stockholders; (C) any action asserting a claim against the Company arising pursuant to any provision of the DGCL, this Restated Certificate of Incorporation or the Bylaws of the Company; or (D) any action asserting

a claim against the Company governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of capital stock of the Company shall be deemed to have notice of and to have consented to the provisions of this Article VII.

VIII.

A. The Company reserves the right to amend, alter, change or repeal any provision contained in this Restated Certificate of Incorporation, in the manner now or hereafter prescribed by statute, except as provided in paragraph B. of this Article VIII, and all rights conferred upon the stockholders herein are granted subject to this reservation.

B. Notwithstanding any other provisions of this Restated Certificate of Incorporation or any provision of law which might otherwise permit a lesser vote or no vote, but in addition to any affirmative vote of the holders of any particular class or series of capital stock of the Company required by law or by this Restated Certificate of Incorporation or any certificate of designation filed with respect to a series of Preferred Stock, the affirmative vote of the holders of at least sixty-six and two-thirds percent (66 2/3%) of the voting power of all of the then-outstanding shares of capital stock of the Company entitled to vote generally in the election of directors, voting together as a single class, shall be required to alter, amend or repeal Articles V, VI, VII or VIII.

* * * *

IN WITNESS WHEREOF, this Restated Certificate of Incorporation which only restates and integrates and does not further amend the provisions of the Amended and Restated Certificate of Incorporation of this Company as heretofore amended or supplemented, there being no discrepancies between those provisions and the provisions of this Restated Certificate of Incorporation, and it having been duly adopted by the Company's Board of Directors in accordance with Section 245 of the Delaware General Corporation Law, has been executed by its duly authorized officer this 13th day of May, 2024.

OUTLOOK THERAPEUTICS, INC.

By: /s/ Lawrence A. Kenyon
Name: Lawrence A Kenyon
Title: Chief Financial Officer, Treasurer and Secretary

17857553

CERTIFICATE OF ELIMINATION
OF THE
SERIES A CONVERTIBLE PREFERRED STOCK,
SERIES B CONVERTIBLE PREFERRED STOCK
AND
SERIES A-1 CONVERTIBLE PREFERRED STOCK
OF
OUTLOOK THERAPEUTICS, INC.

Outlook Therapeutics, Inc., a Delaware corporation (the "***Company***"), does hereby certify as follows:

FIRST: Pursuant to Section 151(g) of the Delaware General Corporation Law (the "***DGCL***") and the authority conferred upon the Board of Directors of the Company (the "***Board***") in accordance with the Company's Amended and Restated Certificate of Incorporation (as amended, the "***Charter***"), the Board adopted the following resolutions with respect to the Company's Series A Convertible Preferred Stock, Series B Convertible Preferred Stock and Series A-1 Convertible Preferred Stock, which resolutions have not been amended or rescinded:

RESOLVED, that none of the authorized shares of the Company's Series A Convertible Preferred Stock, Series B Convertible Preferred Stock and Series A-1 Convertible Preferred Stock are outstanding and none will be issued subject to their respective Certificates of Designation filed with the Secretary of State of the State of Delaware on September 8, 2017 (with respect to the Series A Convertible Preferred Stock and the Series B Convertible Preferred Stock) and July 18, 2018, as amended on March 19, 2020 (with respect to the Series A-1 Convertible Preferred Stock);

RESOLVED FURTHER, that the Chief Executive Officer and Chief Financial Officer, or any other officer or officers of the Company authorized by such officer (individually, an "***Authorized Officer***" and, collectively, the "***Authorized Officers***") be, and each of them hereby is, authorized and directed, for and on behalf of the Company, to execute on behalf of the Company a Certificate of Elimination of the Company's Series A Convertible Preferred Stock, Series B Convertible Preferred Stock and Series A-1 Convertible Preferred Stock (the "***Certificate of Elimination***") and to file such Certificate of Elimination with the Secretary of State of the State of Delaware, and to take such further actions (including paying any fees) and to make such filings with the Secretary of State of the State of Delaware as may be deemed necessary or appropriate with respect to the Certificate of Elimination.

RESOLVED FURTHER, that when the Certificate of Elimination setting forth these resolutions becomes effective, it shall have the effect of eliminating from the Company's Amended and Restated Certificate of Incorporation, as amended, all matters set forth in the Certificates of Designation with respect to such Series A Convertible Preferred Stock, Series B Convertible Preferred Stock and Series A-1 Convertible Preferred Stock, and all such shares of preferred stock shall be returned to the status of authorized but unissued shares of preferred stock, par value $0.01 per share, of the Company, without designation as to series.

SECOND: In accordance with Section 151(g) of the DGCL, upon the effectiveness of this Certificate of Elimination, all matters set forth in the respective Certificates of Designation for the Series A Convertible Preferred Stock, Series B Convertible Preferred Stock and Series A-1 Convertible Preferred Stock, are hereby eliminated from the Charter.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the Company has caused this Certificate of Elimination of the Series A Convertible Preferred Stock, Series B Convertible Preferred Stock and Series A-1 Convertible Preferred Stock of the Company to be signed by its duly authorized officer this 13th day of May, 2024.

OUTLOOK THERAPEUTICS, INC.

By: /s/ Lawrence A. Kenyon
Name: Lawrence A. Kenyon
Title: Chief Financial Officer, Treasurer and Secretary

Exhibit 31.1

CERTIFICATIONS

I, C. Russell Trenary III, 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. The registrant's other certifying officer and I are 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. The registrant's other certifying officer and I have disclosed, based on our 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, 2024

By: /s/ C. Russell Trenary III
C. Russell Trenary III
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. The registrant's other certifying officer and I are 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. The registrant's other certifying officer and I have disclosed, based on our 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, 2024

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, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers 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, 2024 By /s/ C. Russell Trenary III
C. Russell Trenary III
Chief Executive Officer

Date: May 15, 2024 By /s/ Lawrence A. Kenyon
Lawrence A. Kenyon
Chief Financial Officer

"This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Outlook Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing."