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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, 2023
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.)**
485 Route 1 South Building F, Suite 320 Iselin, New Jersey	
(Address of principal executive offices)	**08830 (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 10, 2023 was 256,666,794.

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, 2022, filed with the Securities and Exchange Commission (“SEC”) on December 29, 2022, 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 the novel coronavirus (“COVID-19”) global pandemic, inflation, rising interest rates, current or potential future bank failures or political disruption such as the war between Ukraine and Russia. 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, 2023	September 30, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 43,629,102	$ 17,396,812
Prepaid expenses and other current assets	9,423,025	10,123,634
Total current assets	53,052,127	27,520,446
Operating lease right-of-use assets, net	48,581	70,360
Equity method investment	809,470	804,930
Other assets	113,850	132,015
Total assets	$ 54,024,028	$ 28,527,751
Liabilities, convertible preferred stock and stockholders' equity		
Current liabilities:		
Current portion of long-term debt	$ 31,823,000	$ 10,915,015
Current portion of finance lease liabilities	10,332	11,751
Current portion of operating lease liabilities	3,929	26,995
Accounts payable	3,619,748	3,491,485
Accrued expenses	6,214,397	3,427,900
Income taxes payable	1,856,629	1,856,629
Total current liabilities	43,528,035	19,729,775
Finance lease liabilities	—	4,267
Warrant liability	8,263	57,138
Total liabilities	43,536,298	19,791,180
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' equity:		
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; 425,000,000 shares authorized; 256,666,794 and 227,310,572 shares issued and outstanding at March 31, 2023 and September 30, 2022, respectively	2,566,667	2,273,105
Additional paid-in capital	442,173,380	415,398,984
Accumulated deficit	(434,252,317)	(408,935,518)
Total stockholders' equity	10,487,730	8,736,571
Total liabilities, convertible preferred stock and stockholders' equity	$ 54,024,028	$ 28,527,751

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,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 544,948	$ 12,219,666	$ 10,407,372	$ 22,092,142
General and administrative	6,292,982	6,689,914	12,118,586	9,967,119
Loss from operations	(6,837,930)	(18,909,580)	(22,525,958)	(32,059,261)
Loss (income) on equity method investment	16,965	6,044	(4,540)	29,699
Interest (income) expense, net	(187,794)	418,327	2,260,797	769,861
Loss on extinguishment of debt	—	—	577,659	1,025,402
Change in fair value of promissory notes	3,000	343,585	3,000	505,940
Change in fair value of warrant liability	(18,615)	25,013	(48,875)	(224,885)
Loss before income taxes	(6,651,486)	(19,702,549)	(25,313,999)	(34,165,278)
Income tax expense	2,800	2,000	2,800	2,000
Net loss	$ (6,654,286)	$ (19,704,549)	$ (25,316,799)	$ (34,167,278)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.03)	$ (0.09)	$ (0.10)	$ (0.17)
Weighted average shares outstanding, basic and diluted	256,666,794	219,067,900	241,877,917	203,443,077

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

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

	Stockholders' Equity				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at October 1, 2022	227,310,572	$2,273,105	$ 415,398,984	$(408,935,518)	$ 8,736,571
Sale of common stock, net of issuance costs	29,356,222	293,562	23,998,598	—	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	256,666,794	2,566,667	440,789,975	(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	256,666,794	$2,566,667	$ 442,173,380	$(434,252,317)	$ 10,487,730

	Stockholders' Equity				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at October 1, 2021	176,461,628	$ 1,764,616	$ 345,726,087	$(342,883,254)	$ 4,607,449
Issuance of common stock in connection with exercise of stock options	25,000	250	17,500	—	17,750
Sale of common stock, net of issuance costs	47,773,974	477,740	56,979,163	—	57,456,903
Stock-based compensation expense	—	—	1,204,048	—	1,204,048
Net loss	—	—	—	(14,462,729)	(14,462,729)
Balance at December 31, 2021	224,260,602	2,242,606	403,926,798	(357,345,983)	48,823,421
Issuance of common stock in connection with exercise of warrants	15,675	157	187,943	—	188,100
Sale of common stock, net of issuance costs	1,516,465	15,164	2,877,750	—	2,892,914
Stock-based compensation expense	—	—	3,762,795	—	3,762,795
Net loss	—	—	—	(19,704,549)	(19,704,549)
Balance at March 31, 2022	225,792,742	$ 2,257,927	$ 410,755,286	$(377,050,532)	$ 35,962,681

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,	
	2023	**2022**
OPERATING ACTIVITIES		
Net loss	$ (25,316,799)	$ (34,167,278)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	21,779	101,953
Loss on extinguishment of debt	577,659	1,025,402
Non-cash interest expense	2,529,830	763,104
Stock-based compensation	2,775,798	4,966,843
Change in fair value of promissory notes	3,000	505,940
Change in fair value of warrant liability	(48,875)	(224,885)
(Income) loss on equity method investment	(4,540)	29,699
Interest paid on debt	(1,158,609)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	713,199	(1,092,452)
Operating lease liabilities	(23,066)	(20,749)
Accounts payable	128,263	1,963,638
Accrued expenses	2,786,497	824,155
Net cash used in operating activities	(17,015,864)	(25,324,630)
FINANCING ACTIVITIES		
Proceeds from the sale of common stock, net of issuance costs	24,297,734	60,382,548
Proceeds from debt	30,000,000	10,000,000
Proceeds from exercise of common stock warrants	—	188,100
Proceeds from exercise of stock options	—	17,750
Payments of finance lease obligations	(5,686)	(13,728)
Repayment of debt	(10,220,000)	(703,267)
Payment of financing costs	(823,894)	(600,000)
Net cash provided by financing activities	43,248,154	69,271,403
Net increase in cash and cash equivalents	26,232,290	43,946,773
Cash and cash equivalents at beginning of year	17,396,812	14,477,324
Cash and cash equivalents at end of period	$ 43,629,102	$ 58,424,097
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 1,159,008	$ 22,017
Supplemental schedule of non-cash financing activities:		
Deferred offering costs amortization	$ 5,573	$ 32,731

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.

All development activities are currently active in support of the Company's Biologics License Application ("BLA") registration program for ONS-5010 for wet age-related macular degeneration ("wet AMD"). In fiscal year 2022, the Company submitted the BLA and received confirmation from the U.S. Food and Drug Administration ("FDA") that the BLA had been accepted for filing with a goal date of August 29, 2023 for a review decision by the FDA. Additionally, the Company submitted a Marketing Authorization Application ("MAA") with the European Medicines Agency ("EMA"), which has been validated for review with an estimated decision date expected in early 2024.

2. Liquidity

The Company has incurred recurring losses and negative cash flows from operations since its inception and has an accumulated deficit of $434,252,317 as of March 31, 2023. As of March 31, 2023, the Company had $35,056,257 of principal, accrued interest and exit fees due under an unsecured convertible promissory note issued in December 2022 (the "December 2022 Note"), maturing on January 1, 2024. As a result, there is substantial doubt about the Company's ability to continue as a going concern. The accompanying unaudited interim consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The unaudited interim consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Management believes that the Company's existing cash and cash equivalents as of March 31, 2023 will be sufficient to fund its operations through the anticipated approval of the BLA for ONS-5010 in the third calendar quarter of 2023 and potentially through the fourth calendar quarter of 2023. As a result, 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.

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.

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

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, 2023 and its results of operations for the three and six months ended March 31, 2023 and 2022, cash flows for the six months ended March 31, 2023 and 2022, and stockholders' equity for the three and six months ended March 31, 2023 and 2022. Operating results for the six months ended March 31, 2023 are not necessarily indicative of the results that may be expected for the full year ending September 30, 2023. 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, 2022 included in the Company's Annual Report on Form 10-K filed with the SEC on December 29, 2022.

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 the ongoing COVID-19 pandemic or political disruption such as the war between Ukraine and Russia, 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 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.

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

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,	
	2023	2022	2023	2022
Net loss attributable to common stockholders	$ (6,654,286)	$ (19,704,549)	$ (25,316,799)	$ (34,167,278)
Common stock shares outstanding (weighted average)	256,666,794	219,067,900	241,877,917	203,443,077
Basic and diluted net loss per share	$ (0.03)	$ (0.09)	$ (0.10)	$ (0.17)

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, 2023 and 2022, as they would be antidilutive:

	As of March 31,	
	2023	2022
Performance-based stock units	2,470	2,470
Performance-based stock options	1,900,000	1,900,000
Stock options	22,064,850	19,783,581
Common stock warrants	7,328,549	6,812,794
Convertible debt	16,305,235 (i)	—

(i) The potentially dilutive securities related to convertible debt are calculated based on a fixed conversion price of $2.00 per share, which is subject to change as described in Note 7.

Recently issued accounting pronouncements

In August 2020, the FASB issued ASU 2020-06, *Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815 - 40)*. ASU 2020-06 eliminated the beneficial conversion and cash conversion accounting models in ASC 470-20 that required separate accounting for embedded conversion features and simplifies the settlement assessment to determine whether a contract qualifies for equity classification. In addition, the new guidance requires entities to use the if-converted method to calculate earnings per share for all convertible instruments and to include the effect of share settlement for instruments that may be settled in cash or shares. The Company adopted ASU 2020-06 on October 1, 2022 using the modified retrospective approach and applied the guidance to all financial instruments that were outstanding as of the beginning of 2022. There was no cumulative effect adjustment to the opening balance of retained earnings as a result of adopting ASU 2020-06.

There have been no other accounting pronouncements issued but not yet adopted by the Company which are expected to have a material impact on the Company's consolidated financial position, results of operations or cash flows.

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.

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

- 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, 2023		
	(Level 1)	(Level 2)	(Level 3)
Liabilities			
Unsecured convertible promissory note	$ —	$ —	$ 31,823,000
Warrant liability	—	—	8,263
Total	$ —	$ —	$ 31,831,263

	September 30, 2022		
	(Level 1)	(Level 2)	(Level 3)
Liabilities			
Unsecured convertible promissory note	$ —	$ —	$ —
Warrant liability	—	—	57,138
Total	$ —	$ —	$ 57,138

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, 2023:

	Unsecured Convertible Promissory Note	Warrants
Balance at October 1, 2022	$ —	$ 57,138
Fair value at issuance date	31,820,000	—
Change in fair value	3,000	(48,875)
Balance at March 31, 2023	$ 31,823,000	$ 8,263

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

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

The fair value of the December 2022 Note as of March 31, 2023 was estimated using a binomial lattice model with the following assumptions:

	March 31, 2023
Term (years)	0.8
Stock price	$ 1.09
Volatility	57.0 %
Risk-free rate	4.8 %
Dividend yield	— %
Credit-adjusted discount rate	23.3 %

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 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. The warrant liability is revalued each reporting period with the change in fair value recorded in the accompanying consolidated statements of operations until the warrants are exercised or expire. The fair value of the warrant liability is estimated using the Black-Scholes option pricing model using the following assumptions:

	March 31, 2023	September 30, 2022
Risk-free interest rate	4.14 %	4.23 %
Remaining contractual term of warrants (years)	1.9	2.4
Expected volatility	76.1 %	92.5 %
Annual dividend yield	— %	— %
Fair value of common stock (per share)	$ 1.09	$ 1.22

5. Equity Method Investment

In connection with the execution of a stock purchase agreement with Syntone Ventures LLC (“Syntone Ventures”), 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”), 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’s operations through voting rights or representation on Syntone’s board of directors, the Company accounts for this investment using the equity method of accounting. Upon formation of Syntone in April 2021, the Company entered into a royalty-free license with Syntone 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 expects to be required to make an additional capital contribution to Syntone of approximately $2,100,000, which will be made within four years after the establishment date in accordance with the development plan contemplated in the license agreement or on such other terms within such four-year period. The maximum exposure to a loss as a result of the Company’s involvement in Syntone is limited to the initial investment and the future capital contributions of approximately $2,100,000.

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

6. Accrued Expenses

Accrued expenses consists of:

	March 31, 2023	September 30, 2022
Compensation	$ 1,661,984	$ 1,976,252
Research and development	3,836,228	744,154
Professional fees	559,181	564,423
Other accrued expenses	157,004	143,071
	$ 6,214,397	$ 3,427,900

7. Debt

Debt consists of:

	March 31, 2023	September 30, 2022
Unsecured convertible promissory note (measured at fair value)	$ 31,823,000	$ —
Unsecured promissory note	—	11,114,518
Total debt	31,823,000	11,114,518
Less: unamortized loan costs	—	(199,503)
Total debt, net of unamortized loan costs	31,823,000	10,915,015
Less: current portion	(31,823,000)	(10,915,015)
Long-term debt	$ —	$ —

Unsecured convertible promissory 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. The December 2022 Note bears interest at 9.5% per annum and matures on January 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 will have the right to convert the December 2022 Note at the Conversion Price (as defined below). The principal amount and conversion price of the December 2022 Note are subject to adjustment upon certain triggering events. In addition, the Company has the right to convert all or any portion of the outstanding balance under the December 2022 Note into shares of common stock at the Conversion Price if certain conditions have been met at the time of conversion, including if at any time after the six-month anniversary of the closing date, the daily volume-weighted average price of the common stock on Nasdaq equals or exceeds $2.50 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

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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. Under the December 2022 Note, "Conversion Price" means, prior to a Major Trigger Event, $2.00 per share (subject to adjustment for stock splits and stock combinations), and following a Major Trigger Event, the lesser of (i) $2.00 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 $0.1756 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.

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 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 related to 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.

Unsecured promissory 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 in the accompanying consolidated balance sheet as of September 30, 2022. 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 months ended March 31, 2022, the Company recognized $418,388 of interest expense related to the November 2021 Note of which $169,857 was related to the amortization of debt discount. During the six months ended March 31, 2023 and 2022, the Company recognized $454,866 and $763,104, respectively, of interest expense related to the November 2021 Note of which $190,775 and $277,980, respectively, were related to the amortization of debt discount.

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8. Commitments and Contingencies

Leases

Corporate office

In March 2021, the Company entered into a three-year term corporate office lease in Iselin, New Jersey that commenced on April 23, 2021.

Equipment leases

The Company has equipment leases, with terms between 12 and 36 months, recorded as finance leases. The equipment leases bear interest between 4.0% and 13.0% per annum.

Certain lease agreements contain provisions for future rent increases. Payments due under the lease contracts include minimum payments that the Company is obligated to make under the non-cancelable initial terms of the leases as the renewal terms are at the Company's option. Lease expense is 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, 2023 and 2022 are as follows:

	Three months ended March 31, 2023	Three months ended March 31, 2022	Six months ended March 31, 2023	Six months ended March 31, 2022
Lease cost:				
Amortization of right-of-use assets	$ —	$ —	$ —	$ —
Interest on lease liabilities	398	849	889	1,823
Total finance lease cost	398	849	889	1,823
Operating lease cost	11,216	11,217	22,433	22,433
Total lease cost	$ 11,614	$ 12,066	$ 23,322	$ 24,256

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

	March 31, 2023	September 30, 2022
Operating leases:		
Right-of-use asset	$ 48,581	$ 70,360
Operating lease liabilities	3,929	26,995
Finance leases:		
Right-of-use asset	$ —	$ —
Financing lease liabilities	10,332	16,018
Weighted-average remaining lease term (years):		
Operating leases	1.1	1.6
Finance leases	0.8	1.3
Weighted-average discount rate:		
Operating leases	7.5%	7.5%
Finance leases	13.0%	13.0%

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Other information related to leases for the six months ended March 31, 2023 and 2022 are as follows:

	Six months ended March 31, 2023	2022
Cash paid for amounts included in the measurement of lease obligations:		
Operating cash flows from finance leases	$ 889	$ 1,823
Operating cash flows from operating leases	23,721	23,043

Future minimum lease payments under non-cancelable leases as of March 31, 2023 are as follows for the years ending September 30:

	Operating leases	Finance leases
2023 (remaining six months)	$ 3,954	$ 6,575
2024	—	4,383
Total undiscounted lease payments	3,954	10,958
Less: Imputed interest	25	626
Total lease obligations	$ 3,929	$ 10,332

9. Common Stock and Stockholders' Equity

Common stock

On March 29, 2023, following receipt of stockholder approval at the Company's 2023 annual meeting of stockholders, the number of authorized shares of common stock under the Company's Certificate of Incorporation was increased from 325,000,000 shares to 425,000,000 shares.

In December 2022, in a registered direct equity offering to certain institutional and accredited investors, including GMS Ventures and Investments ("GMS Ventures"), the Company's largest stockholder, the Company issued 28,460,831 shares of common stock at a purchase price per share of $0.8784 for $23,547,904 in net proceeds after payment of placement agent fees and other offering costs. GMS Ventures purchased an aggregate of 14,230,418 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 515,755 shares of common stock at an exercise price of $1.05 per share, which warrants have a three-year term.

In November 2021, the Company issued 46,000,000 shares of common stock in an underwritten public offering at a purchase price per share of $1.25 for $53,968,057 in net proceeds after payment of underwriter discounts and commissions and other underwriter offering costs. GMS Ventures purchased an aggregate of 16,000,000 shares of common stock in the public offering at the public offering price per share. In connection with the underwritten public offering, the Company issued the underwriter warrants to purchase up to an aggregate of 2,100,000 shares of common stock at an exercise price of $1.5625 per share, which warrants have a five-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 (the "ATM Agreement" or the "ATM Offering"), with H.C. Wainwright & Co., as sales agent ("Wainwright" or the "Agent") under which the Company may 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 are being reclassified to additional paid in capital on a pro rata basis when the Company sells common stock under the ATM Offering. As of

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March 31, 2023, $113,850 of such deferred costs are included in other assets on the unaudited interim consolidated balance sheets.

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

No shares of common stock were sold under the ATM Offering during the three months ended March 31, 2023. During the six months ended March 31, 2023, the Company sold 895,391 shares of common stock under the ATM Offering and generated $1,127,904 in gross proceeds. The Company paid fees to the Agent and other issuance costs of $38,799. During the six months ended March 31, 2022, the Company sold 3,290,439 shares of common stock under the ATM Offering and generated $6,626,696 in gross proceeds. The Company paid fees to the Agent and other issuance costs of $212,206. The Company terminated the ATM Agreement effective May 15, 2023.

Common stock warrants

As of March 31, 2023, 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)	277,128	$	12.00
February 26, 2024		1,747,047	$	0.9535
February 24, 2025		172,864	$	1.27
April 13, 2025	(i)	145,686	$	12.00
May 31, 2025	(i)	62,437	$	12.00
June 22, 2025		191,268	$	1.51875
December 28, 2025		515,755	$	1.0500
January 28, 2026		2,116,364	$	1.25
November 23, 2026		2,100,000	$	1.5625
		7,328,549		

(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.

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, 2023, PSUs representing 2,470 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.

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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 42,265,841. As of March 31, 2023, 18,106,339 shares remained available for grant under the 2015 Plan.

Stock options and RSUs are granted under the Company's 2015 Plan and generally vest over a period of one to four years from the date of grant and, in the case of stock options, have a term of 10 years. The Company recognizes the grant date fair value of each option and 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, 2023 and 2022:

	Three months ended March 31,		Six months ended March 31,	
	2023	2022	2023	2022
Research and development	$ 322,268	$ 1,820,262	$ 612,924	$ 2,072,657
General and administrative	1,061,137	1,942,533	2,162,874	2,894,186
	$ 1,383,405	$ 3,762,795	$ 2,775,798	$ 4,966,843

Stock options

As of March 31, 2023 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, 2022	20,124,581	$ 1.49		
Granted	1,940,269	1.15		
Balance at March 31, 2023	22,064,850	$ 1.46	8.0	$ 3,412,868
Vested and exercisable at March 31, 2023	11,901,123	$ 1.48	7.6	$ 2,169,900
Vested and expected to vest at March 31, 2023	22,064,850	$ 1.46	8.0	$ 3,412,868

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

The weighted average grant date fair value of the options awarded to employees for the six months ended March 31, 2023 and 2022 was $0.96 and $1.25 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,	
	2023	2022
Risk-free interest rate	3.7 %	1.6 %
Expected term (years)	5.7	6.0
Expected volatility	112.4 %	95.7 %
Expected dividend yield	—	—

As of March 31, 2023, there was $10,112,008 of unrecognized compensation expense that is expected to be recognized over a weighted-average period of 2.4 years.

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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, 2023 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, 2022	700,000	$ 1.44		
Granted	1,200,000	1.04		
Balance at March 31, 2023	1,900,000	$ 1.19	9.3	$ 60,000
Vested and exercisable at March 31, 2023	700,000	$ 1.44	8.7	$ —
Vested and expected to vest at March 31, 2023	700,000	$ 1.44	8.7	$ —

The weighted average grant date fair value of the performance stock options awarded during the six months ended March 31, 2023 and 2022, was $0.91 and $1.03 per option, respectively. As of March 31, 2023, 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,	
	2023	2022
Risk-free interest rate	3.8 %	1.3 %
Expected term (years)	10.0	5.2
Expected volatility	91.3 %	91.5 %
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.

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The following table summarizes the activity related to PSUs during the six months ended March 31, 2023:

	Number of PSUs	Base Price Per PSU	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at October 1, 2022	2,470	$ 49.97		
Forfeitures	—	—		
Balance at March 31, 2023	2,470	$ 49.97	1.8	$ —
Vested and exercisable at March 31, 2023	2,470	$ 49.97	1.8	$ —

Restricted stock

In connection with the consulting agreements entered into by the Company and four former principals of MTTR LLC ("MTTR"), in March 2020, the Company issued an aggregate of 7,244,739 shares of its common stock. Refer to Note 11 for further details on the consulting agreements and terminated strategic partnership agreement. These shares may not be sold until the earlier of (i) six months following FDA approval of ONS-5010, (ii) the date the Company publicly announces not to pursue development of ONS-5010, (iii) a change in control or (iv) January 2025. In addition, the Company has the right to repurchase the shares for $0.01 per share if the consultant terminates his agreement other than for good reason or the Company terminates the agreement for cause. The repurchase right lapses, in tiered percentages, based upon the completion of enrollment of the Company's NORSE TWO clinical trial of ONS-5010 by certain dates. The repurchase right may also lapse as to 50% or 100% of the shares if the Company enters into certain agreements pertaining to ONS-5010 that meet certain value thresholds or the Company's share price meets certain predefined targets. The repurchase right also lapses as to 100% of the shares upon the earliest to occur of (i) filing of the BLA for ONS-5010, (ii) termination of the agreement by the consultant for good reason or by the Company other than for cause, (iii) in the event of disability, or (iv) upon a change in control.

The grant date fair value of the restricted shares was $0.54 per share and equal to the closing stock price of the Company's common stock at the time of grant. Compensation expense is recognized over the shorter of the explicit service period or derived service period, which was determined to be 4.8 years at the time of grant. The compensation expense was accelerated during the year ended September 30, 2022 as a result of the Company achieving certain performance conditions related to the Company's BLA submission and the corresponding repurchase rights lapsing. During the three months ended March 31, 2022, the Company recognized compensation expense related to the restricted stock of $1,852,182. During the six months ended March 31, 2022, the Company recognized compensation expense related to the restricted stock of $2,003,946. There was no expense recognized for the three and six months ended March 31, 2023 and as of March 31, 2023, there was no unrecognized compensation expense related to the restricted stock.

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

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

Concurrently, the Company also entered into consulting agreements directly with each of the four principals of MTTR setting forth the terms of his respective compensation arrangement, as well as providing for certain transfer restrictions and repurchase rights applicable to the shares of common stock to be issued pursuant hereto. The termination agreement and the consulting agreements became effective upon stockholder approval of the share issuance on March 19, 2020. Refer to Note 10 for the accounting of the restricted stock issued and compensation expense recognized.

During the three months ended March 31, 2023 and 2022, MTTR and its four principals under the strategic partnership agreement and the subsequent individual consulting agreements earned an aggregate of $28,886 and $99,380, respectively, and $65,552 and $413,366 during the six months ended March 31, 2023 and 2022, respectively, which includes monthly consulting fees and expense reimbursement, but excludes stock-based compensation related to restricted stock (Note 10). As of September 30, 2022, an aggregate of $18,333, was due to the former MTTR principals as consultants, which is included in accounts payable in the accompanying consolidated balance sheets. As of March 31, 2023, there was no outstanding amount due to the former MTTR principals as consultants.

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.

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, 2022 and 2021 included in our Annual Report on Form 10-K for the year ended September 30, 2022, filed with the Securities and Exchange Commission, or SEC, on December 29, 2022.

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, 2022, filed with the SEC on December 29, 2022, 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, or FDA, for use in retinal indications. Our goal is to launch directly in the United States as the first and only approved ophthalmic bevacizumab for the treatment of wet age-related macular degeneration, or wet AMD, diabetic macular edema, or DME, and branch retinal vein occlusion, or BRVO. Our plans also include potentially securing a strategic partner for the United Kingdom, Europe, Japan and other markets. If approved, we expect to receive 12 years of regulatory exclusivity in the United States and up to 10 years of regulatory 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. Following receipt of further correspondence from the FDA, we confirmed the additional information necessary to re-submit the BLA for ONS-5010 and resubmitted the BLA in August 2022. In October 2022, we received confirmation from the FDA that our BLA has been accepted for filing with a goal date of August 29, 2023 for a review decision by the FDA. Additionally, in October 2022, we submitted a Marketing Authorization Application, or MAA, for ONS-5010 with the European Medicines Agency, or the EMA. On December 22, 2022 our MAA was validated for review by the EMA. The formal review process of the MAA by the EMA's Committee for Medicinal Products for Human Use, or CHMP, is now set to begin with an estimated decision date expected in early 2024. ONS-5010 is our sole product candidate in active development.

Our BLA and MAA registration program 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 ($p = 0.0043$). 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 ($p = 0.05$) 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.

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. We intend to initiate these studies following the anticipated FDA approval of our BLA for wet AMD.

Currently, the cancer drug Avastin (bevacizumab) is used off-label for the treatment of wet AMD and other retinal diseases such as DME and BRVO even though Avastin has not been approved by regulatory authorities for use in these diseases. In addition to our BLA submission in the United States, we have submitted an MAA for approval in Europe and plan to submit for regulatory approval in multiple other markets, including the United Kingdom and other major markets. 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. Off-label use of unapproved bevacizumab is currently estimated to account for approximately 50% of all wet AMD injections in the United States (approximately 3.5 million injections annually).

Going Concern

Through March 31, 2023 we have funded substantially all of our operations with $465.2 million in proceeds from the sale and issuance of our equity and debt securities. We have also received $29.0 million pursuant to our collaboration and licensing agreements through such date. Our net loss for the six months ended March 31, 2023 was $25.3 million. We also had a net loss of $34.2 million for the six months ended March 31, 2022. 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.

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. Our current cash resources of $43.6 million as of March 31, 2023 are expected to fund our operations through the anticipated approval of ONS-5010 in the third calendar quarter of 2023 and, potentially

through the fourth calendar quarter of 2023. These factors raise substantial doubt about our ability to continue as a going concern. We will need to raise substantial additional capital to fund our planned future operations, commercialize ONS-5010, if approved, commence and continue clinical trials, or develop other product candidates. We plan to finance our future operations with a combination of proceeds from potential licensing and/or marketing arrangements with pharmaceutical companies, the issuance of equity securities, including through at-the-market offering programs, and the issuance of additional debt, potential collaborations and revenues from potential future product sales, if any. There are no assurances that we will be successful in obtaining an adequate level of financing for the development and commercialization of ONS-5010 or any other current or future product candidates. If we are unable to secure adequate additional funding, our business, operating results, financial condition and cash flows may be materially and adversely affected. Our consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

Collaboration, License and Strategic Partnership Agreements

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

Syntone – PRC Joint Venture

In May 2020, we entered into a stock purchase agreement with Syntone, 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's affiliate based in the People's Republic of China, or PRC, pursuant to which we agreed to form a PRC joint venture that is 80% owned by Syntone's PRC affiliate and 20% owned by us. Upon formation of the PRC joint venture in April 2021, we entered into a royalty-free license with the PRC joint venture 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 the PRC joint venture and expect to be required to make an additional capital contribution to the PRC joint venture of approximately $2.1 million within the next four years.

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 expenses consist 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 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 and follow-up in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Product commercialization will take several years and millions of dollars in development costs.

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

General and Administrative Expenses

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

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

(Income) Loss on Equity Method Investment

(Income) loss on equity method investment represents our proportionate share for the period of the net (income) loss of our investee to which the equity method of accounting is applied.

Interest Expense

Interest expense consists of cash paid and non-cash interest expense related to our unsecured notes, unsecured promissory notes, finance leases and other finance obligations.

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 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 consolidated statements of operations.

Change in Fair Value of Warrant Liability

We issued warrants to purchase our common stock in conjunction with our old senior secured notes, which are classified as liabilities and recorded at fair value. The warrants are subject to re-measurement at each balance sheet date and we recognize any change in fair value in our statements of operations as other (income) expense.

Income Taxes

Since inception, we have not recorded any United States federal or state income tax benefits (excluding the sale of New Jersey state net operating losses, or 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, 2022, we had federal and state NOL carryforwards of $339.9 million and $175.7 million, respectively, that will begin to expire in 2030 and 2039, respectively. As of September 30, 2022, we had federal foreign tax credit carryforwards of $2.4 million available to reduce future tax liabilities, which begin to expire starting in 2023. As of September 30, 2022, we also had federal and state R&D tax credit carryforwards of $10.4 million and $0.8 million, respectively, that will begin to expire in 2032 and 2033, respectively.

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

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.

Results of Operations

Comparison of Three Months Ended March 31, 2023 and 2022

	Three months ended March 31,		
	2023	2022	Change
Operating expenses:			
Research and development	$ 544,948	$ 12,219,666	$ (11,674,718)
General and administrative	6,292,982	6,689,914	(396,932)
Loss from operations	(6,837,930)	(18,909,580)	12,071,650
Loss on equity method investment	16,965	6,044	10,921
Interest (income) expense, net	(187,794)	418,327	(606,121)
Change in fair value of promissory notes	3,000	343,585	(340,585)
Change in fair value of warrant liability	(18,615)	25,013	(43,628)
Loss before income taxes	(6,651,486)	(19,702,549)	13,051,063
Income tax expense	2,800	2,000	800
Net loss	$ (6,654,286)	$ (19,704,549)	$ 13,050,263

Research and development expenses

The following table summarizes our research and development expenses by functional area for the three months ended March 31, 2023 and 2022:

	Three months ended March 31,	
	2023	2022
ONS-5010 development	$ 3,744,704	$ 6,371,227
Compensation and related benefits	130,229	600,296
Stock-based compensation	322,268	1,820,261
Other research and development	(3,652,253)	3,427,882
Total research and development expenses	$ 544,948	$ 12,219,666

Research and development expenses for the three months ended March 31, 2023 decreased by $11.7 million compared to the three months ended March 31, 2022. The decrease was primarily due to cash refunds of waived FDA BLA submission fees of $3.9 million received during the period combined with the BLA submission fees of $3.1 million recorded in the comparable prior period when the BLA was initially submitted. Additionally, stock-based compensation expenses decreased by $1.5 million primarily as a result of the vesting of equity awards during the comparable prior period related to the achievement of a milestone for performance-based stock options for some of our executives. In addition, we experienced a decrease of $1.6 million in wet AMD clinical related expenses for ONS-5010 as a result of the completion of the NORSE clinical related activities for wet AMD in fiscal 2022, a $1.0 million decrease in ONS-5010 development costs due to completion of certain process characterization and manufacturing activities associated primarily with our BLA submission, and a $0.5 million reduction in compensation and related benefits.

General and administrative expenses

The following table summarizes our general and administrative expenses by type for the three months ended March 31, 2023 and 2022:

	Three months ended March 31,	
	2023	2022
Professional fees	$ 3,651,705	$ 2,200,563
Compensation and related benefits	650,987	938,640
Stock-based compensation	1,061,137	1,942,534
Facilities, fees and other related costs	929,153	1,608,177
Total general and administrative expenses	$ 6,292,982	$ 6,689,914

General and administrative expenses for the three months ended March 31, 2023 decreased by $0.4 million compared to the three months ended March 31, 2022. The decrease compared to the prior period was primarily due to a decrease in stock-based compensation expenses of $0.9 million because of the vesting of equity awards during the comparable prior period related to the achievement of a milestone for performance-based stock options for some of our executives, a $0.3 million reduction in compensation and related benefits, and a decrease in other administrative expenses of $0.7 million. The decreases were partially offset by an increase in professional fees of $1.5 million related to our ongoing pre-launch preparations in anticipation of the potential approval of our BLA for ONS-5010.

Interest (income) expense, net

Interest (income) expense decreased by $0.6 million to $(0.2) million income for the three months ended March 31, 2023, as compared to $0.4 million expense for the three months ended March 31, 2022. There was no interest expense recorded during the three months ended March 31, 2023 because we repaid in full the November 2021 Note in December 2022, and we elected to account for our December 2022 Note at fair value with changes in fair value being recorded in the unaudited interim consolidated statements of operations.

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.

Comparison of Six Months Ended March 31, 2023 and 2022

	Six months ended March 31,		
	2023	2022	Change
Operating expenses:			
Research and development	$ 10,407,372	$ 22,092,142	$ (11,684,770)
General and administrative	12,118,586	9,967,119	2,151,467
Loss from operations	(22,525,958)	(32,059,261)	9,533,303
(Income) loss on equity method investment	(4,540)	29,699	(34,239)
Interest expense, net	2,260,797	769,861	1,490,936
Loss on extinguishment of debt	577,659	1,025,402	(447,743)
Change in fair value of promissory notes	3,000	505,940	(502,940)
Change in fair value of warrant liability	(48,875)	(224,885)	176,010
Loss before income taxes	(25,313,999)	(34,165,278)	8,851,279
Income tax expense	2,800	2,000	800
Net loss	$ (25,316,799)	$ (34,167,278)	$ 8,850,479

Research and development expenses

The following table summarizes our research and development expenses by functional area for the six months ended March 31, 2023 and 2022:

	Six months ended March 31,	
	2023	2022
ONS-5010 development	$ 14,685,759	$ 15,100,096
Compensation and related benefits	878,427	1,033,310
Stock-based compensation	612,924	2,072,657
Other research and development	(5,769,738)	3,886,079
Total research and development expenses	$ 10,407,372	$ 22,092,142

Research and development expenses for the six months ended March 31, 2023 decreased by $11.7 million compared to the six months ended March 31, 2022. The decrease 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 of $3.1 million recorded in the comparable prior period when the BLA was initially submitted. Additionally, stock-based compensation expenses decreased by $1.5 million primarily as a result of vested equity grants during the comparable prior period related to the achievement of a milestone for performance-based stock options for some of our executives.

General and administrative expenses

The following table summarizes our general and administrative expenses by type for the six months ended March 31, 2023 and 2022:

	Six months ended March 31,	
	2023	2022
Professional fees	$ 6,421,589	$ 3,352,694
Compensation and related benefits	1,906,404	1,568,666
Stock-based compensation	2,162,874	2,894,186
Facilities, fees and other related costs	1,627,719	2,151,573
Total general and administrative expenses	$ 12,118,586	$ 9,967,119

General and administrative expenses for the six months ended March 31, 2023 increased by $2.2 million compared to the six months ended March 31, 2022. The increase compared to the prior period was primarily due to an increase in professional fees of $3.1 million related to our ongoing pre-launch preparations in anticipation of the potential approval of our BLA for ONS-5010, and a $0.3 million increase in compensation due to increased headcount to support the planned launch of ONS-5010, if approved. The increases were partially offset by a decrease in stock-based compensation expenses of $0.7 million as a result of the vesting of equity awards during the comparable prior period related to the achievement of a milestone for performance-based stock options for some of our executives and a decrease in other administrative expenses of $0.5 million.

Interest expense, net

Interest expense increased by $1.5 million to $2.3 million for the six months ended March 31, 2023, as compared to $0.8 million for the six months ended March 31, 2022. The increase was primarily related to the original issue discount on the December 2022 Note. The comparable prior period interest expense related to the November 2021 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. We recognized a $1.0 million loss on extinguishment related to an unsecured promissory note amendment during the six months ended March 31, 2022 that was accounted for as an extinguishment of the old promissory note.

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.

Change in fair value of warrant liability

During the six months ended March 31, 2023, the change in fair value of warrant liability was immaterial. During the three months ended March 31, 2022, we recorded income of $0.2 million related to the decrease in the fair value of our common stock warrant liability as a result of the decrease in the price of our common stock during the period.

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, 2023, we have funded substantially all of our operations with $465.2 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 5, 2020, we received $10.0 million in net proceeds from the issuance of an unsecured promissory note, or 2020 Note, with a face amount of $10.2 million. The 2020 Note bore interest at a rate of 7.5% per annum, and was due to mature on January 1, 2022, and included an original issue discount of $0.2 million. On November 16, 2021, we entered into a note amendment, which, among other things, (i) extended the maturity date to January 1, 2023, (ii) increased the interest rate from 7.5% per annum to 10% per annum beginning on January 1, 2022, and (iii) provided for the lender's right to redeem some or all of the outstanding balance of the 2020 Note for shares of our common stock beginning July 1, 2022, subject to certain limitations. On June 30, 2022, we prepaid the 2020 Note in full by paying 105% of the outstanding balance. The total payment was $12.9 million, which included interest of $1.5 million and other fees totaling $1.2 million.

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 may 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.

In November 2021, we issued in an underwritten public offering an aggregate of 46,000,000 shares of common stock at a purchase price per share of $1.25 for $54.0 million in net proceeds after payment of underwriter discounts and commissions and other underwriter offering costs. GMS Ventures purchased an aggregate of 16,000,000 shares of common stock in the public offering. In connection with the underwritten public offering, we issued the underwriter warrants to purchase up to an aggregate of 2,100,000 shares of common stock at an exercise price of $1.5625 per share, which warrants have a five-year term.

During the six months ended March 31, 2023, we sold 895,391 shares of common stock pursuant to the ATM Offering, generating $1.1 million in gross proceeds. The sales agent fees paid were immaterial. During the six months ended March 31, 2022, the Company sold 3,290,439 shares of common stock under the ATM Offering and generated $6.6 million in gross proceeds and paid fees to the Agent and other issuance costs of $0.2 million.

In December 2022, in a registered direct equity offering to certain institutional and accredited investors, including GMS Ventures, our largest stockholder, we issued 28,460,831 shares of common stock at a purchase price per share of $0.8784 for $24.0 million in net proceeds after payment of placement agent fees and other offering costs. GMS Ventures purchased an aggregate of 14,230,418 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 515,755 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 $1.05 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 current holder of our outstanding unsecured promissory note that was due to mature on January 1, 2023, or the November 2021 Note. The Note has an original issue discount of $1.8 million. We received gross proceeds of $30.0 million upon the closing on December 28, 2022, after deducting the Lender's transaction costs in connection with the issuance. 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. The December 2022 Note bears interest at

9.5% per annum and matures on January 1, 2024. The December 2022 Note contains customary covenants, including a restriction on our ability to pledge certain of our assets, subject to certain exceptions, without the Lender's consent. Beginning on April 1, 2023, the Lender will have the right to convert the December 2022 Note at an initial conversion price of $2.00 per share. The principal amount and conversion price of the December 2022 Note are subject to adjustment upon certain triggering events. See "Description of Indebtedness" below for additional detail.

We evaluated whether there are conditions or events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern. As of March 31, 2023, we had an accumulated deficit of $434.3 million and $35.1 million of principal and accrued interest outstanding under an unsecured convertible promissory note, which bears interest compounding daily and matures on January 1, 2024. As a result, there is substantial doubt about our ability to continue as a going concern. Our current cash resources of $43.6 million as of March 31, 2023 are expected to fund our operations through the anticipated approval of the BLA for ONS-5010 in the third calendar quarter of 2023 and, potentially through the fourth calendar quarter of 2023.

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, while the long-term economic impact of either the COVID-19 pandemic or the war between Ukraine and Russia is difficult to assess or predict, each of these events has caused significant disruptions to the global financial markets and contributed to 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 anticipate we will incur net losses and negative cash flow from operations for the foreseeable future. We may not be able to complete the development and initiate commercialization of ONS-5010 if, among other things, the FDA does not approve our BLA when we expect, or at all, or if we are not able to enter into strategic partnerships for ONS-5010 providing for sufficient funding of our expected commercial and development costs and we are unable to obtain such funding elsewhere.

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 believe our existing cash of $43.6 million as of March 31, 2023 can fund our operations through the anticipated approval of ONS-5010 in the third calendar quarter of 2023 and, potentially through the fourth calendar quarter of 2023. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We may need to raise substantial additional capital to complete our planned ONS-5010 development and commercialization program and continue to operate as a going concern. We plan to finance our future operations with a combination of proceeds from future at-the-market offerings, 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. If we raise additional capital through the sale of equity or convertible debt securities, your ownership will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. There are no

assurances that we will be successful in obtaining an adequate level of financing for the development and commercialization of ONS-5010 or any other current or future product candidates. Alternatively, we 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.

Cash Flows

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

	Six months ended March 31,	
	2023	2022
Net cash used in operating activities	$ (17,015,864)	$ (25,324,630)
Net cash provided by financing activities	43,248,154	69,271,403
Net increase in cash	$ 26,232,290	$ 43,946,773

Operating Activities

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.

During the six months ended March 31, 2022, we used $25.3 million of cash in operating activities resulting primarily from our net loss of $34.2 million. This use of cash was partially offset by $7.2 million of non-cash items such as stock-based compensation, non-cash interest expense, change in fair value of warrant liability, change in fair value of unsecured convertible promissory note, loss on extinguishment of debt, loss on equity method investment and depreciation and amortization expense. The net cash inflow of $1.7 million from changes in our operating assets and liabilities was primarily due to an increase in accounts payable of $2.0 million primarily from activities related to our BLA submission and an increase of $0.8 million in accrued expenses. These outflows were partially offset by an increase in prepaid expenses of $1.1 million for prepayments associated with ONS-5010 development costs.

Financing Activities

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 28,460,831 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.

During the six months ended March 31, 2022, net cash provided by financing activities was $69.3 million, primarily attributable to $54.0 million in net proceeds from an underwritten public offering in November 2021 of an aggregate of 46,000,000 shares of our common stock and accompanying 2,100,000 warrants to purchase shares of our common stock, $0.2 million in net proceeds from the exercise of common stock warrants, $6.4 million in net proceeds from the sale of common stock under the ATM Offering and $9.4 million in net proceeds from issuance of an unsecured promissory note with a face amount of $10.2 million in November 2021. We also made $0.7 million in debt and finance lease obligation payments.

Description of Indebtedness

On December 22, 2022, we entered into the Securities Purchase Agreement and issued the December 2022 Note to Streeterville Capital, LLC, or the Lender. The December 2022 Note has a face value of $31.8 million and an original issue

discount of $1.8 million. The December 2022 Note bears interest at 9.5% per annum and matures on January 1, 2024. The December 2022 Note contains customary covenants, including a restriction on our ability to pledge certain of our assets, subject to certain exceptions, without the Lender's consent. Beginning on April 1, 2023, the Lender will have the right to convert the December 2022 Note at the Conversion Price (as defined below). The principal amount and Conversion Price of the December 2022 Note are subject to adjustment upon certain triggering events. In addition, the Company has the right to convert all or any portion of the outstanding balance under the December 2022 Note into shares of common stock at the Conversion Price if certain conditions have been met at the time of conversion, including if at any time after the six-month anniversary of the closing date, the daily volume-weighted average price of the common stock on Nasdaq equals or exceeds $2.50 per share (subject to adjustments for stock splits and stock combinations) for a period of 30 consecutive trading days. We may make payments (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 us 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. Under the December 2022 Note, "Conversion Price" means, prior to a Major Trigger Event, $2.00 per share (subject to adjustment for stock splits and stock combinations), and following a Major Trigger Event, the lesser of (i) $2.00 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 $0.1756 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, 2022, filed with the SEC on December 29, 2022, have not materially changed.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

As a "Smaller Reporting Company," this Item and the related disclosure is 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, 2023.

Part II. Other Information

Item 1. Legal Proceedings

We are not party to any material pending legal proceedings. From time to time, we may become involved in litigation relating to claims arising from the ordinary course of business.

Item 1A. Risk Factors

Except as set forth below, as of March 31, 2023, 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, 2022 filed with the SEC on December 29, 2022.

We will need to raise substantial additional funding to complete the development of ONS-5010 (LYTENAVA (bevacizumab-vikg)), and/or support our operations after the planned launch in late 2023, if approved by FDA, until we are able to generate sufficient revenue and continue to operate as a going concern. This additional funding may not be available on acceptable terms or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

Developing product candidates is an expensive, risky and lengthy process. We are currently advancing ONS-5010 through the regulatory approval process and additional clinical development. Our expenses may increase in connection with our ongoing activities, particularly as we continue the research and development of, continue and initiate clinical trials of, and seek marketing approval for, ONS-5010.

As of March 31, 2023, our cash and cash equivalents balance was $43.6 million. We expect that our current cash resources will be sufficient to fund our operations fund its operations through the anticipated approval of the BLA for ONS-5010 in the third calendar quarter of 2023 and, potentially through the fourth calendar quarter of 2023. Because our cash and cash equivalents will not be adequate to fund our currently planned operations through at least the next 12 months from the date the consolidated financial statements in this Quarterly Report on Form 10-Q are issued, there is substantial doubt about our ability to continue as a going concern. We will require substantial additional capital to continue to operate as a going concern and to commercialize ONS-5010. Although we continue to pursue discussions with additional potential strategic partners for ONS-5010 outside of the United States, there is no guarantee that we will be successful in reaching any such agreement, nor that such agreement, if successful, will cover the anticipated commercialization costs for ONS-5010. Our operating plan may also change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as through other collaborations, strategic alliances and licensing arrangements, or a combination of these approaches. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. We may experience difficulties in accessing the capital markets due to external factors beyond our control, such as volatility in the equity markets for emerging biotechnology companies and general economic and market conditions both in the United States and abroad. For example, our ability to raise additional capital may be adversely impacted by global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide, such as has been experienced recently due in part to, among other things, the impacts of the COVID-19 pandemic, the ongoing conflict between Russia and Ukraine, and disruptions in access to bank deposits and lending commitments due to bank failure. We cannot be certain that we will be able to obtain financing on terms acceptable to us, or at all. Our failure to obtain adequate and timely funding will adversely affect our business and our ability to develop our technology and products candidates. Moreover, the terms of any financing may negatively impact the holdings or the rights of our stockholders, and the issuance of additional securities, whether equity or debt, by us or the possibility of such issuance may cause the market price of our securities to decline. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact

our ability to conduct our business. We may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, in order to obtain necessary funding, any of which may harm our business, operating results and prospects. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or for specific strategic considerations. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our development programs or the commercialization of any product candidates. We may also be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could harm our business, financial condition and results of operations.

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

None.

Item 6. Exhibits

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's current report on Form 8-K filed with the SEC on May 19, 2016).
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's current report on Form 8-K filed with the SEC on December 6, 2018).
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's current report on Form 8-K filed with the SEC on March 18, 2019).
3.4	Certificate of Amendment to the Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's current report on Form 8-K filed with the SEC on March 26, 2021).
3.5	Certificate of Amendment of the Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed with the SEC on March 30, 2023, as subsequently amended).
3.6	Second Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Company's current report on Form 8-K filed with the SEC on March 26, 2021).
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1*	Certification of Principal Executive Officer 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, 2023

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

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, 2023

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, 2023

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, 2023, 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, 2023 By /s/ C. Russell Trenary III
C. Russell Trenary III
Chief Executive Officer

Date: May 15, 2023 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."