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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 June 30, 2022
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 August 8, 2022 was 226,144,634.

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, 2021, filed with the Securities and Exchange Commission ("SEC") on December 23, 2021, including, among other things, risks associated with:

- the initiation, timing, progress and results of our past, current and planned 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 ongoing novel coronavirus ("COVID-19") global pandemic. 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)

	June 30, 2022	September 30, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 26,021,429	$ 14,477,324
Prepaid expenses and other current assets	11,491,956	7,030,823
Total current assets	37,513,385	21,508,147
Property and equipment, net	40,906	163,625
Operating lease right-of-use assets, net	80,924	111,429
Equity method investment	812,156	853,660
Other assets	140,356	174,590
Total assets	$ 38,587,727	$ 22,811,451
Liabilities, convertible preferred stock and stockholders' equity		
Current liabilities:		
Current portion of long-term debt	$ 10,459,372	$ 904,200
Current portion of finance lease liabilities	14,354	26,464
Current portion of operating lease liabilities	38,203	42,854
Accounts payable	2,480,871	2,196,349
Accrued expenses	3,580,535	1,725,721
Income taxes payable	1,856,629	1,856,629
Total current liabilities	18,429,964	6,752,217
Long-term debt	—	10,885,854
Finance lease liabilities	7,349	16,018
Operating lease liabilities	—	26,995
Warrant liability	68,319	522,918
Total liabilities	18,505,632	18,204,002
Commitments and contingencies (Note 9)		
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; 325,000,000 shares authorized; 225,942,719 and 176,461,628 shares issued and outstanding at June 30, 2022 and September 30, 2021, respectively	2,259,427	1,764,616
Additional paid-in capital	412,413,161	345,726,087
Accumulated deficit	(394,590,493)	(342,883,254)
Total stockholders' equity	20,082,095	4,607,449
Total liabilities, convertible preferred stock and stockholders' equity	$ 38,587,727	$ 22,811,451

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 June 30,		Nine months ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 11,249,191	$ 8,545,279	$ 33,341,333	$ 29,023,253
General and administrative	5,774,769	2,929,717	15,741,888	9,267,962
Loss from operations	(17,023,960)	(11,474,996)	(49,083,221)	(38,291,215)
Loss on equity method investment	11,805	435,346	41,504	435,346
Interest expense, net	356,947	256,873	1,126,808	666,945
Loss on extinguishment of debt	—	—	1,025,402	—
Change in fair value of unsecured convertible promissory note	376,963	—	882,903	—
Change in fair value of warrant liability	(229,714)	29,332	(454,599)	363,476
Loss before income taxes	(17,539,961)	(12,196,547)	(51,705,239)	(39,756,982)
Income tax expense	—	—	2,000	2,000
Net loss	$ (17,539,961)	$ (12,196,547)	$ (51,707,239)	$ (39,758,982)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.08)	$ (0.07)	$ (0.25)	$ (0.27)
Weighted average shares outstanding, basic and diluted	220,497,826	168,420,675	209,108,090	146,860,652

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

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

	Stockholders' Equity (Deficit)				
	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity (Deficit)
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
Issuance of common stock in connection with exercise of warrants	—	—	—	—	—
Sale of common stock, net of issuance costs	149,977	1,500	290,001	—	291,501
Stock-based compensation expense	—	—	1,367,874	—	1,367,874
Net loss	—	—	—	(17,539,961)	(17,539,961)
Balance at June 30, 2022	225,942,719	$ 2,259,427	$ 412,413,161	$ (394,590,493)	$ 20,082,095

	Stockholders' Equity (Deficit)				
	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance at October 1, 2020	127,183,109	$ 1,271,831	$ 291,274,366	$ (289,719,906)	$ 2,826,291
Stock-based compensation expense	—	—	1,154,641	—	1,154,641
Net loss	—	—	—	(14,455,914)	(14,455,914)
Balance at December 31, 2020	127,183,109	$ 1,271,831	$ 292,429,007	$ (304,175,820)	$ (10,474,982)
Issuance of common stock in connection with exercise of warrants	3,815,304	38,153	3,547,656	—	3,585,809
Sale of common stock, net of issuance costs	42,607,394	426,074	39,091,045	—	39,517,119
Stock-based compensation expense	—	—	1,129,747	—	1,129,747
Net loss	—	—	—	(13,106,521)	(13,106,521)
Balance at March 31, 2021	173,605,807	$ 1,736,058	$ 336,197,455	$ (317,282,341)	$ 20,651,172
Sale of common stock, net of issuance costs	1,207,519	12,075	3,084,152	—	3,096,227
Stock-based compensation expense	—	—	1,198,384	—	1,198,384
Net loss	—	—	—	(12,196,547)	(12,196,547)
Balance at June 30, 2021	174,813,326	$ 1,748,133	$ 340,479,991	$ (329,478,888)	$ 12,749,236

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

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

	Nine months ended June 30,	
	2022	**2021**
OPERATING ACTIVITIES		
Net loss	$ (51,707,239)	$ (39,758,982)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	153,224	211,466
Loss on extinguishment of debt	1,025,402	—
Non-cash interest expense	1,199,697	640,215
Stock-based compensation	6,334,717	3,482,772
Change in fair value of unsecured convertible promissory note	882,903	—
Change in fair value of warrant liability	(454,599)	363,476
Gain on settlement of lease termination obligation	—	(552,340)
Loss on equity method investment	41,504	435,346
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(4,461,133)	(6,904,417)
Other assets	—	298,523
Operating lease liability	(31,646)	(140,272)
Accounts payable	284,522	194,029
Accrued expenses	308,776	(3,532,940)
Net cash used in operating activities	(46,423,872)	(45,263,124)
FINANCING ACTIVITIES		
Proceeds from the sale of common stock, net of issuance costs	60,675,552	42,514,237
Proceeds from debt	10,000,000	10,000,000
Payment of debt issuance costs	—	(8,032)
Proceeds from exercise of common stock warrants	188,100	3,585,809
Proceeds from exercise of stock options	17,750	—
Payments of finance lease obligations	(20,779)	(23,098)
Repayment of debt	(12,292,646)	(3,649,743)
Payment of financing costs	(600,000)	—
Net cash provided by financing activities	57,967,977	52,419,173
Net increase in cash and cash equivalents	11,544,105	7,156,049
Cash and cash equivalents at beginning of period	14,477,324	12,535,986
Cash and cash equivalents at end of period	$ 26,021,429	$ 19,692,035
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 1,556,088	$ 17,915
Supplemental schedule of non-cash financing activities:		
Deferred offering costs amortization	$ 34,234	$ 82,654

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 pre-commercial 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.

The Company has been actively monitoring the ongoing COVID-19 pandemic and its impact globally. Given the Company's current infrastructure needs and current strategy, the Company was able to transition to remote working with limited impact on productivity as shelter-in-place and similar government orders were imposed. 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").

The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition will depend on future developments that are highly uncertain, including any new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19. Management believes the financial results for the nine months ended June 30, 2022 were not significantly impacted by COVID-19.

2. Liquidity

The Company has incurred recurring losses and negative cash flows from operations since its inception and has an accumulated deficit of $394,590,493 as of June 30, 2022. As of June 30, 2022, the Company had $10,847,966 of principal and accrued interest due under an unsecured promissory note maturing on January 1, 2023. 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 June 30, 2022 will be sufficient to fund its operations into the first calendar quarter of 2023. Additional financing will be needed by the Company to fund its operations in the future and to commercially develop ONS-5010 and any other product candidates. Management is currently evaluating different strategies to obtain the required funding for future operations such as continuing to access capital through the current ATM Offering (as defined below) and negotiating a potential extension of maturity for notes that are scheduled to mature in January 2023. Refer to Note 10 for further details on the ATM Offering. These strategies may also include, but are not limited to, 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 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 June 30, 2022 and its results of operations for the three and nine months ended June 30, 2022 and 2021, cash flows for the nine months ended June 30, 2022 and 2021, and stockholders' equity (deficit) for the three and nine months ended June 30, 2022 and 2021. Operating results for the nine months ended June 30, 2022 are not necessarily indicative of the results that may be expected for the full year ending September 30, 2022. 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, 2021 included in the Company's Annual Report on Form 10-K filed with the SEC on December 23, 2021.

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, including as a result of the ongoing COVID-19 pandemic, 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.

Fair value option

As permitted under ASC 825, *Financial Instruments* ("ASC 825") the Company has elected the fair value option to account for its convertible promissory note (Note 8). In accordance with ASC 825, the Company records the convertible promissory note at fair value with changes in fair value recorded in the consolidated statements of operations.

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 June 30,		Nine months ended June 30,	
	2022	2021	2022	2021
Net loss attributable to common stockholders	$ (17,539,961)	$ (12,196,547)	$ (51,707,239)	$ (39,758,982)
Common stock shares outstanding (weighted average)	220,497,826	168,420,675	209,108,090	146,860,652
Basic and diluted net loss per share	$ (0.08)	$ (0.07)	$ (0.25)	$ (0.27)

The following potentially dilutive securities (in common stock equivalents) have been excluded from the computation of diluted weighted-average shares outstanding as of June 30, 2022, and 2021, as they would be antidilutive:

	As of June 30,	
	2022	2021
Performance-based stock units	2,470	2,470
Performance-based stock options	700,000	—
Stock options	20,099,581	12,010,781
Common stock warrants	6,812,794	5,129,460

Recently issued accounting pronouncements

In January 2020, FASB issued ASU 2020-01, *Investments-Equity Securities (Topic 321), Investments-Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815)*, which, generally, provides guidance for investments in entities accounted for under the equity method of accounting. ASU 2020-01 is effective for public companies with fiscal years beginning after December 15, 2020 and for all other entities the amendments are effective for fiscal years beginning after December 15, 2021, including interim periods therein. The Company adopted ASU 2020-01 on October 1, 2021 and the adoption of this standard did not have a material impact on the Company's consolidated financial condition, results of operations, cash flows and financial statement disclosures.

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) — Accounting for Convertible Instruments and Contracts in an Entity's Own Equity.* The ASU simplifies accounting for convertible instruments by removing major separation models required under current GAAP. Consequently, more convertible debt instruments will be reported as a single liability instrument with no separate accounting for embedded conversion features. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception, which will permit more equity contracts to qualify for it. The ASU also simplifies the diluted net income per share calculation in certain areas. The new guidance is effective for annual and interim periods beginning after December 15, 2021, and early adoption is permitted for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. The Company is currently evaluating the new standard, but adoption is not expected to have a material impact on its consolidated financial condition, results of operations, cash flows and financial statement disclosures.

4. Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 - Quoted prices in active markets for identical assets or liabilities.

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:

	June 30, 2022		
	(Level 1)	(Level 2)	(Level 3)
Liabilities			
Warrant liability	$ —	$ —	$ 68,319

	September 30, 2021		
	(Level 1)	(Level 2)	(Level 3)
Liabilities			
Warrant liability	$ —	$ —	$ 522,918

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 nine months ended June 30, 2022:

	Unsecured Convertible Promissory Note	Warrants
Balance at October 1, 2021	$ —	$ 522,918
Fair value at issuance date	12,051,581	—
Change in fair value	882,903	(454,599)
Repayment	(12,934,484)	—
Balance at June 30, 2022	$ —	$ 68,319

As further described in Note 8, the Company elected the fair value option to account for its amended unsecured convertible promissory note. The fair value of the amended unsecured convertible promissory note at issuance was estimated using a discounted cash flow model. Significant estimates in the cash flow model include the discount rate and the probability and timing of redemption.

The warrants issued in connection with the convertible senior secured notes originally issued pursuant to a certain Note and Warrant Purchase Agreement dated December 22, 2017 are classified as liabilities on the accompanying 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:

	June 30, 2022	September 30, 2021
Risk-free interest rate	2.96 %	0.62 %
Remaining contractual term of warrant (years)	2.6	3.4
Expected volatility	100.3 %	124.7 %
Annual dividend yield	— %	— %
Fair value of common stock (per share)	$ 1.02	$ 2.17

Fair Value of Other Financial Instruments

At June 30, 2022, the fair value and carrying value of the unsecured promissory note included in long-term debt on the consolidated balance sheet on June 30, 2022 was $10,647,000 and $10,459,372, respectively. The estimated fair value was based on discounted expected future cash flows using the prevailing interest rate that is a Level 3 input under the fair value hierarchy.

5. Property and Equipment, Net

Property and equipment, net, consists of:

	June 30, 2022	September 30, 2021
Laboratory equipment	$ 1,067,351	$ 1,067,351
Less: accumulated depreciation	(1,026,445)	(903,726)
	$ 40,906	$ 163,625

Depreciation expense was $40,906 for the three months ended June 30, 2022 and 2021, and $122,719 and $122,718 for the nine months ended June 30, 2022 and 2021, respectively.

6. Equity Method Investment

In connection with the execution of a stock purchase agreement with Syntone Ventures LLC (“Syntone Ventures”), the U.S. 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.

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7. Accrued Expenses

Accrued expenses consists of:

	June 30, 2022	September 30, 2021
Compensation	$ 1,324,246	$ 753,808
Research and development	1,455,024	808,780
Interest payable	—	12,909
Professional fees	586,649	—
Other accrued expenses	214,616	150,224
	$ 3,580,535	$ 1,725,721

8. Debt

Debt consists of:

	June 30, 2022	September 30, 2021
Unsecured promissory note	$ 10,847,966	10,938,145
Paycheck Protection Program term loan	—	904,200
Total debt	10,847,966	11,842,345
Less: unamortized loan costs	(388,594)	(52,291)
Total debt, net of unamortized loan costs	10,459,372	11,790,054
Less: current portion	(10,459,372)	(904,200)
Long-term debt	$ —	$ 10,885,854

Unsecured convertible promissory note

On November 5, 2020, the Company received $10,000,000 in net proceeds from the issuance of an unsecured promissory note with a face amount of $10,220,000, which was amended in November 2021 and became convertible. Debt issuance costs totaling $228,032 were recorded as debt discount and were deducted from the principal in the accompanying consolidated balance sheets. The debt discount was amortized as a component of interest expense over the 14-month term of the underlying debt using the effective interest method. The note bore interest at a rate of 7.5% per annum and was due to mature January 1, 2022. On November 16, 2021, the Company 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 note for shares of the Company's common stock beginning July 1, 2022, subject to certain limitations. The amendment was accounted for as an extinguishment of the old promissory note. As a result, the Company recorded a loss on debt extinguishment of $1,025,402, which is the difference between the fair value of the amended promissory note and the net carrying value of the old promissory note, which includes $26,488 of unamortized debt discount and lender fees of $552,633. The amended promissory note included redemption options whereby beginning on July 1, 2022, the holder had the option to redeem up to $2,000,000 of outstanding principal and accrued and unpaid interest per calendar month for shares of the Company's common stock at a redemption price equal to 75% of the lowest closing bid price in the three trading days immediately preceding the date the holder delivers written notice. The Company elected to account for the amended promissory note at fair value (Note 4) and was not required to bifurcate the redemption options as derivatives.

The Company prepaid the note in full on June 30, 2022 by paying 105% of the outstanding balance. The total payment was $12,934,484, which included interest of $1,546,038.

Unsecured promissory note

On November 16, 2021, the Company received $10,000,000 in net proceeds from the issuance of an unsecured promissory note with a face amount of $10,220,000. Debt issuance costs totaling $820,000 were recorded as debt discount and are

deducted from the principal in the accompanying consolidated balance sheets. The debt discount is amortized as a component of interest expense over the term of the underlying debt using the effective interest method. The note bears interest at a rate of 9.5% per annum compounding daily and matures January 1, 2023. The Company may prepay all or a portion of the note at any time by paying 105% of the outstanding balance elected for pre-payment.

During the three months ended June 30, 2022 and 2021, the Company recognized $436,593 and $242,816, respectively, of interest expense related to the unsecured promissory notes of which $179,228 and $48,801, respectively, are related to the amortization of debt discount. During the nine months ended June 30, 2022 and 2021, the Company recognized $1,199,697 and $640,215, respectively, of interest expense related to the unsecured promissory notes of which $457,208 and $125,229, respectively, are related to the amortization of debt discount.

Paycheck Protection Program term loan

On May 4, 2020, the Company received $904,200 in proceeds from a loan granted pursuant to the PPP of the CARES Act. The PPP term loan is evidenced by a promissory note containing the terms and conditions for repayment of the PPP term loan. The PPP term loan provides for an initial six-month deferral of payments and any amount owed on the loan has a two-year maturity (May 2022), with an interest rate of 1% per annum. Commencing October 15, 2021, the Company began to pay the lender equal monthly payments of principal and interest as required to fully amortize any principal amount outstanding on the PPP term loan as of October 15, 2021 by May 2, 2022. The loan was fully repaid on May 2, 2022. Aggregate interest expense on the PPP loan for the three months ended June 30, 2022 and 2021 was $131 and $2,279, respectively, and for the nine months ended June 30, 2022 and 2021 was $2,726 and $6,763, respectively.

9. Commitments and Contingencies

Litigation

On July 20, 2020, Laboratorios Liomont S.A. de C.V. (“Liomont”), filed a complaint against the Company in the U.S. District Court of the Southern District of New York alleging certain breach of contract claims under the June 25, 2014 strategic development, license and supply agreement relating to the biosimilar development program for ONS-3010 and ONS-1045 claiming $3,000,000 in damages. On March 30, 2021, the Company entered into a confidential settlement agreement with Liomont, and the complaint was dismissed on April 11, 2021. The Company agreed to make an initial settlement payment of $625,000 that was paid in April 2021; and an additional payment of $750,000, which was accrued at March 31, 2022 and paid in April 2022. There are no remaining future financial obligations.

Leases

Corporate office

In March 2021, the Company assigned its Monmouth Junction, New Jersey corporate office lease to a third party and does not have remaining future obligations. In March 2021, the Company entered into a new 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.

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The components of lease cost for the three and nine months ended June 30, 2022 and 2021 are as follows:

	Three months ended June 30, 2022	2021	Nine months ended June 30, 2022	2021
Lease cost:				
Amortization of right-of-use assets	$ —	$ —	$ —	$ —
Interest on lease liabilities	723	1,210	2,547	3,997
Total finance lease cost	723	1,210	2,547	3,997
Operating lease cost	11,217	8,413	33,650	95,663
Total lease cost	$ 11,940	$ 9,623	$ 36,197	$ 99,660

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

	June 30, 2022	September 30, 2021
Operating leases:		
Right-of-use asset	$ 80,924	$ 111,429
Operating lease liabilities	38,203	69,849
Finance leases:		
Right-of-use asset	$ —	$ —
Financing lease liabilities	21,703	42,482
Weighted-average remaining lease term (years):		
Operating leases	1.8	2.6
Finance leases	1.3	1.7
Weighted-average discount rate:		
Operating leases	7.5%	7.5%
Finance leases	11.8%	9.5%

Other information related to leases for the nine months ended June 30, 2022 and 2021 are as follows:

	Nine months ended June 30, 2022	2021
Cash paid for amounts included in the measurement of lease obligations:		
Operating cash flows from finance leases	$ 2,547	$ 3,997
Operating cash flows from operating leases	34,791	147,187
Financing cash flows from finance leases	20,779	23,098
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	$ —	$ 128,473

Future minimum lease payments under non-cancelable leases as of June 30, 2022 are as follows for the years ending September 30:

	Operating leases	Finance leases
2022 (remaining three months)	$ 11,861	$ 6,279
2023	27,675	13,149
2024	—	4,383
Total undiscounted lease payments	$ 39,536	$ 23,811
Less: Imputed interest	1,333	2,108
Total lease obligations	$ 38,203	$ 21,703

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10. Common Stock and Stockholders' Equity (Deficit)

Common stock

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 and Investments ("GMS Ventures"), the Company's largest stockholder and strategic partner, 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 "Agreement") 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 from time to time through Wainwright as sales agent (the "ATM Offering"). The Company filed a prospectus supplement, dated March 26, 2021, with the Securities and Exchange Commission pursuant to which the Company may offer and sell shares of common stock having an aggregate offering price of up to 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 June 30, 2022, $127,763 of such deferred costs are included in other assets on the consolidated balance sheets.

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

During the nine months ended June 30, 2022, the Company sold 3,440,416 shares of common stock under the ATM Offering and generated $6,929,743 in gross proceeds. The Company paid fees to the Agent and other issuance costs of $222,249.

Common stock warrants

As of June 30, 2022, 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
April 13, 2025	(i)	145,686	$ 12.00
May 31, 2025	(i)	62,437	$ 12.00
February 24, 2025		172,864	$ 1.27
February 26, 2024		1,747,047	$ 0.9535
June 22, 2025		191,268	$ 1.51875
January 28, 2026		2,116,364	$ 1.25000
November 23, 2026		2,100,000	$ 1.56250
		6,812,794	

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(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 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.

During the nine months ended June 30, 2022, warrants to purchase an aggregate of 400,360 shares of common stock with a weighted average exercise price of $12.00 expired; and warrants to purchase an aggregate of 15,675 shares of common stock with a weighted average exercise price of $12.00 were exercised for cash.

11. 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 June 30, 2022, 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.

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 34,565,837. As of June 30, 2022, 13,571,604 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 share of RSU over its vesting period.

The Company recorded stock-based compensation expense in the following expense categories of its statements of operations for the three and nine months ended June 30, 2022 and 2021:

	Three months ended June 30,		Nine months ended June 30,	
	2022	2021	2022	2021
Research and development	$ 205,410	$ 239,231	$ 2,278,067	$ 707,442
General and administrative	1,162,464	959,153	4,056,650	2,775,330
	$ 1,367,874	$ 1,198,384	$ 6,334,717	$ 3,482,772

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Stock options

As of June 30, 2022 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, 2021	16,110,015	$ 1.46		
Granted	4,014,566	1.60		
Exercised	(25,000)	0.71		$ 38,960
Balance at June 30, 2022	20,099,581	1.49	8.5	$ 2,768,083
Exercisable	6,748,589	1.35	8.0	$ 1,275,638
Vested and expected to vest at June 30, 2022	20,099,581	$ 1.49	8.5	$ 2,768,083

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 nine months ended June 30, 2022 and 2021 was $1.23 and $0.57 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:

	Nine months ended June 30,	
	2022	2021
Risk-free interest rate	1.77 %	0.40 %
Expected term (years)	6.0	6.0
Expected volatility	95.2 %	95.4 %
Expected dividend yield	—	—

As of June 30, 2022, there was $12,368,234 of unrecognized compensation expense that is expected to be recognized over a weighted-average period of 2.85 years.

Performance-based stock options

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

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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 June 30, 2022 and changes during the nine 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, 2021	1,000,000	$ 2.42		
Granted	1,900,000	1.44		
Forfeited or expired	(2,200,000)	1.89		
Balance at June 30, 2022	700,000	$ 1.44	9.48	$ —
Exercisable	700,000	$ 1.44	9.48	$ —
Vested and expected to vest at June 30, 2022	700,000	$ 1.44	9.48	$ —

The weighted average grant date fair value of the performance stock options awarded during the nine months ended June 30, 2022 was $1.03 per option. During the nine months ended June 30, 2022, an aggregate of 700,000 performance-based stock options vested as a result of achieving one of the set performance conditions related to the Company's BLA submission that resulted in the Company recognizing stock-based compensation expense of $718,950 during the nine months ended June 30, 2022. During the nine months ended June 30, 2022, an aggregate of 2,200,000 performance-based stock options were forfeited because certain performance conditions were not achieved. As of June 30, 2022, there were no remaining performance conditions. 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:

	Nine months ended June 30, 2022
Risk-free interest rate	1.26 %
Expected term (years)	5.22
Expected volatility	91.46 %
Expected dividend yield	—

There were no performance-based stock options granted during the nine months ended June 30, 2021.

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 nine months ended June 30, 2022:

	Number of PSUs	Base Price Per PSU	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at October 1, 2021	2,470	$ 49.97		
Forfeitures	—	—		
Balance at June 30, 2022	2,470	49.97	3.0	$ —
Vested and exercisable at June 30, 2022	2,470	49.97	3.0	$ —
Vested and expected to vest at June 30, 2022	2,470	$ 49.97	3.0	$ —

Restricted stock

In connection with the consulting agreements entered into by the Company and four former principals of MTTR, in March 2020, the Company issued an aggregate of 7,244,739 shares of its common stock. Refer to Note 12 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 nine months ended June 30, 2022 as a result of the Company achieving certain performance conditions related to the Company's BLA submission that make it probable that the repurchase rights will lapse. During the three months ended 2021, the Company recognized compensation expense related to the restricted stock of $151,764. During the nine months ended June 30, 2022 and 2021, the Company recognized compensation expense related to the restricted stock of $2,003,946 and $455,293, respectively. As of June 30, 2022, there was no unrecognized compensation expense related to the restricted stock.

12. 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 Operating 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 Operating Officer and Chief Commercial Officer, respectively, pursuant to the strategic partnership agreement until such agreement, as amended, was terminated effective March 19,

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2020. The Company began compensating Mr. Dagnon and Mr. Evanson directly as consultants effective March 19, 2020 pursuant to their respective consulting agreements with the Company, which became effective March 19, 2020 following stockholder approval of the share issuances contemplated therein.

On 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 11 for the accounting of the restricted stock issued and compensation expense recognized.

During the three months ended June 30, 2022 and 2021, MTTR and its four principals under the strategic partnership agreement and the subsequent individual consulting agreements earned an aggregate $58,069 and $271,583, respectively, and $471,435 and $812,808 during the nine months ended June 30, 2022 and 2021, respectively, which includes monthly consulting fees and expense reimbursement, but excludes stock-based compensation related to restricted stock (Note 11). As of June 30, 2022 and September 30, 2021, an aggregate $18,333 and $89,762, respectively, was due to the former MTTR principals as consultants, which is included in accounts payable in the accompanying consolidated balance sheets.

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, 2021 and 2020 included in our Annual Report on Form 10-K for the year ended September 30, 2021, filed with the Securities and Exchange Commission, or SEC, on December 23, 2021.

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, 2021, filed with the SEC on December 23, 2021, 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 pre-commercial 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 U.S. and up to 10 years of regulatory exclusivity in the EU.

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 have confirmed the additional information necessary to re-submit the BLA for ONS-5010 by September 2022. ONS-5010 is our sole product candidate in active clinical development.

Our BLA 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 ("BCVA") score was met and was both highly statistically significant and clinically relevant. In the intent-to-treat ("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 ("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. 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 are available for the initial ONS-5010 BLA submission with the FDA. In March 2021 we reported that the results from NORSE THREE provided 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 plan to submit for regulatory approval in multiple other markets beginning in late 2022 in Europe 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 at least 50% of all wet AMD prescriptions in the United States.

Going Concern

Through June 30, 2022 we have funded substantially all of our operations with $408.8 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 current cash resources of $26.0 million as of June 30, 2022 are expected to fund our operations into the first calendar quarter of 2023. We will need to raise additional capital and, if we are not successful in raising additional capital or entering into one or more licensing and/or co-development rights agreements for ONS-5010, 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.

We do not have any products approved for sale and we have only generated revenue from our collaboration agreements. We have incurred operating losses and negative operating cash flows since inception and there is no assurance that we will ever achieve profitable operations, and if achieved, that profitable operations will be sustained. Our net loss for the nine months ended June 30, 2022 was $51.7 million. In addition, development activities, clinical and preclinical testing and commercialization of our product candidates will require significant additional financing.

We have incurred recurring losses and negative cash flows from operations since inception. As of June 30, 2022, we had substantial indebtedness that included $10.8 million of principal and accrued interest under an unsecured promissory note maturing on January 1, 2023. As a result, there is substantial doubt about our ability to continue as a going concern. We

will need to raise additional capital to fund our planned future operations, commence clinical trials, receive approval for and commercialize ONS-5010, or to develop other product candidates. We plan to finance our future operations with a combination of proceeds from our ATM facility, renegotiation of the maturity date for existing unsecured notes, 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 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.

Impacts of the COVID-19 Pandemic

We continue to monitor the ongoing COVID-19 global pandemic, which has resulted in travel and other restrictions to reduce the spread of the disease. To date, we have experienced only minor disruptions from the ongoing COVID-19 pandemic, including a brief delay in patient enrollment and recruitment in NORSE TWO in 2020 at the beginning of the pandemic due to local clinical trial site protocols designed to protect staff and patients. Given our current infrastructure needs and current strategy, we were able to transition to remote working with limited impact on productivity. We have confirmed with the Ophthalmic Division of the FDA that it considers both approved and investigational treatments for sight-threatening conditions such as wet AMD not to be elective, and that as such they should continue during the COVID-19 restrictions. All clinical and chemistry, manufacturing and control, or CMC, activities are currently active.

All three of our clinical trials required to support our BLA submission are now complete. To date, we have not experienced any significant disruptions to patient follow-up in NORSE SEVEN, but the clinical trial protocol accounts for potential delayed or missed visits for any reason, including COVID-19 related interruptions. The FDA has provided guidance in the event of COVID-19 related disruptions, and we intend to confer with the FDA and follow the appropriate guidance in the event that any of our ongoing or planned future clinical trials experience an unusually high number of delayed or missed patient visits due to COVID-19.

The safety, health and well-being of all patients, medical staff and our internal and external teams is paramount and is our primary focus. As the pandemic evolves, we are aware that the potential exists for further disruptions to our projected timelines. We are in close communication with our clinical teams and key vendors and are prepared to take action should the pandemic worsen and impact our business in the future.

The ultimate impact of the ongoing COVID-19 pandemic is highly uncertain and subject to change. We do not yet know the full extent of any impacts the evolving COVID-19 pandemic may have on our business, operations, financial position and our CMC, clinical and regulatory activities. To the extent the evolving effects of the COVID-19 pandemic adversely affect our business and financial condition, it may also have the effect of heightening many of the other risks and uncertainties described under “Risk Factors” in our Annual Report on Form 10-K for the year ended September 30, 2021 that we filed with the SEC on December 23, 2021.

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 will be 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 April 2013 we entered into three commercial license agreements with Selexis S.A., or Selexis, for 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 for our legacy biosimilar product candidates 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. As of June 30, 2022, we have paid Selexis (or its assignees) an aggregate of approximately $0.4 million under the commercial license agreements.

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.

Loss on Equity Method Investment

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

Interest Expense

Interest expense consists of cash paid and non-cash interest expense related to our unsecured notes with current and former stockholders, unsecured promissory notes, equipment loans, finance leases and other finance obligations.

Loss on Extinguishment of Debt

Loss on extinguishment of debt is related to an unsecured promissory note amendment during the period that was accounted for as an extinguishment of the old promissory note.

Change in Fair Value of Unsecured Promissory Note

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

Change in Fair Value of Warrant Liability

Warrants to purchase our common stock that were issued in conjunction with the convertible senior secured notes originally issued December 2017 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.

Income Taxes

Since inception, we have not recorded any U.S. federal or state income tax benefits (excluding the sale of New Jersey state net operating losses "NOLs" and research and development "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, 2021, we had federal and state NOL carryforwards of $282.4 million and $118.2 million, respectively, that will begin to expire in 2030 and 2039, respectively. As of September 30, 2021, 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, 2021, we also had federal research and development tax credit carryforwards of $8.1 million and $0.8 million, respectively, which 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, our ability to utilize NOLs could be further limited by Section 382 of the Code. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Code. Our NOLs are also subject to international regulations, which could restrict our ability to utilize our NOLs. Furthermore, our ability to utilize NOLs of companies that we may acquire in the future may be subject to limitations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

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

Results of Operations

Comparison of Three Months Ended June 30, 2022 and 2021

	Three months ended June 30,		
	2022	2021	Change
Operating expenses:			
Research and development	$ 11,249,191	$ 8,545,279	$ 2,703,912
General and administrative	5,774,769	2,929,717	2,845,052
Loss from operations	(17,023,960)	(11,474,996)	(5,548,964)
Loss on equity method investment	11,805	435,346	(423,541)
Interest expense, net	356,947	256,873	100,074
Change in fair value of convertible promissory note	376,963	—	376,963
Change in fair value of warrant liability	(229,714)	29,332	(259,046)
Net loss	$ (17,539,961)	$ (12,196,547)	$ (5,343,414)

Research and development expenses

The following table summarizes our research and development expenses by functional area for the three months ended June 30, 2022 and 2021:

	Three months ended June 30,	
	2022	2021
ONS-5010 development	$ 10,104,255	$ 7,411,262
Compensation and related benefits	692,188	411,695
Stock-based compensation	205,410	239,230
Other research and development	247,338	483,092
Total research and development expenses	$ 11,249,191	$ 8,545,279

Research and development expenses for the three months ended June 30, 2022 increased by $2.7 million compared to the three months ended June 30, 2021. The increase was primarily due to an increase in ONS-5010 development costs of $2.7 million related to ongoing work in support of our BLA submission.

General and administrative expenses

The following table summarizes our general and administrative expenses by type for the three months ended June 30, 2022 and 2021:

	Three months ended June 30,	
	2022	2021
Professional fees	$ 2,421,043	$ 1,162,616
Compensation and related benefits	1,273,405	305,015
Stock-based compensation	1,162,464	959,153
Facilities, fees and other related costs	917,857	502,933
Total general and administrative expenses	$ 5,774,769	$ 2,929,717

General and administrative expenses for the three months ended June 30, 2022 increased by $2.8 million compared to the three months ended June 30, 2021. The increase compared to the prior period was due to an increase in professional fees of $1.2 million related to our ongoing pre-launch preparations in anticipation of the potential approval of our BLA for ONS-5010, a $1.0 million increase in compensation and related benefits due to an increase in headcount, increase in stock-based compensation expenses of $0.2 million primarily as a result of increased stock grants during the fiscal year, and an increase in allocated business insurance and travel related expenses of $0.4 million.

Interest expense

Interest expense increased by $0.1 million to $0.4 million for the three months ended June 30, 2022, as compared to $0.3 million for the three months ended June 30, 2021. The increase was primarily related to a new unsecured promissory note issued in November 2021.

Change in fair value of unsecured promissory note

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

Comparison of Nine Months Ended June 30, 2022 and 2021

	Nine months ended June 30,		
	2022	2021	Change
Operating expenses:			
Research and development	$ 33,341,333	$ 29,023,253	$ 4,318,080
General and administrative	15,741,888	9,267,962	6,473,926
Loss from operations	(49,083,221)	(38,291,215)	(10,792,006)
Loss on equity method investment	41,504	435,346	(393,842)
Interest expense, net	1,126,808	666,945	459,863
Loss on extinguishment of debt	1,025,402	—	1,025,402
Change in fair value of convertible promissory note	882,903	—	882,903
Change in fair value of warrant liability	(454,599)	363,476	(818,075)
Loss before income taxes	(51,705,239)	(39,756,982)	(11,948,257)
Income tax expense	2,000	2,000	—
Net loss	$ (51,707,239)	$ (39,758,982)	$ (11,948,257)

Research and Development Expenses

The following table summarizes our research and development expenses by functional area for the nine months ended June 30, 2022 and 2021:

	Nine months ended June 30,	
	2022	2021
ONS-5010 development	$ 25,204,351	$ 25,635,197
Compensation and related benefits	1,725,498	1,165,430
Stock-based compensation	2,278,066	707,442
Other research and development	4,133,418	1,515,184
Total research and development expenses	$ 33,341,333	$ 29,023,253

Research and development expenses for the nine months ended June 30, 2022 increased by $4.3 million compared to the nine months ended June 30, 2021. The increase was primarily due to an increase in other research and development related to BLA submission fees of $3.1 million incurred during the period and an increase in stock-based compensation expense of $1.6 million primarily as a result of vested equity grants during the 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 nine months ended June 30, 2022 and 2021:

	Nine months ended June 30,	
	2022	2021
Professional fees	$ 5,773,737	$ 4,107,749
Compensation and related benefits	2,842,071	863,646
Stock-based compensation	4,056,650	2,775,330
Facilities, fees and other related costs	3,069,430	1,521,237
Total general and administrative expenses	$ 15,741,888	$ 9,267,962

General and administrative expenses for the nine months ended June 30, 2022 increased by $6.5 million compared to the nine months ended June 30, 2021. The increase was due to a $1.3 million increase in stock-based compensation primarily as a result of vested equity grants during the period related to the achievement of a milestone for performance-based stock options for some of our executives, increased compensation and related benefits of $2.0 million due to increased

headcount, a $1.7 million increase in professional fees primarily related to our ongoing pre-launch preparations in anticipation of the potential approval of our BLA for ONS-5010, and a $1.5 million increase in facilities, fees and other expenses associated with increased business insurance premiums and a gain recorded after the assignment of our Monmouth Junction, New Jersey corporate office lease in 2021.

Interest Expense

Interest expense increased by $0.5 million to $1.1 million for the nine months ended June 30, 2022, as compared to $0.7 million for the nine months ended June 30, 2021. The increase was primarily related to a new unsecured promissory note issued in November 2021.

Loss on extinguishment of debt

We recognized a $1.0 million loss on extinguishment related to an unsecured promissory note amendment during the period that was accounted for as an extinguishment of the old promissory note.

Change in Fair Value of Warrant Liability

During the nine months ended June 30, 2022, we recorded a gain of $0.5 million related to the decrease in the fair value of our common stock warrant liability associated with the warrants issued in connection with the senior secured notes originally issued December 2017, which resulted from a decrease in the price of our common stock.

During the nine months ended June 30, 2021, we recorded a loss of $0.4 million related to an increase in the fair value of our common stock warrant liability associated with the warrants issued in connection with the senior secured notes originally issued December 2017, which resulted from an increase in the price of our common stock.

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 June 30, 2022, we have funded substantially all of our operations with $408.8 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. 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, 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 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 Note for shares of our common stock beginning July 1, 2022, subject to certain limitations. On June 30, 2022, we prepaid the note in full by paying 105% of the outstanding balance. The total payment was $12,934,484, which included interest of $1,546,038.

On November 16, 2021, we received $10.0 million in net proceeds from the issuance of an unsecured promissory note, or 2021 Note, with a face amount of $10.2 million. The note bears interest at a rate of 9.5% per annum, matures January 1, 2023 and includes 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.

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 at the public offering price per share. 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 nine months ended June 30, 2022, we sold 3,440,416 shares of common stock under, and generated $6.7 million in net proceeds from, the ATM Offering after payment of fees to the sales agent of $0.2 million.

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 June 30, 2022, we had an accumulated deficit of $394.6 million. In addition, $10.8 million of principal and accrued interest under an unsecured promissory note, which bears interest compounding daily and mature January 1, 2023. As a result, there is substantial doubt about our ability to continue as a going concern. Our current cash resources of $26.0 million as of June 30, 2022 are expected to fund our operations into the first 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.

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, we are not able to resubmit our BLA on the expected timeframe, 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, laboratory and related supplies, 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 $26.0 million as of June 30, 2022 can fund our operations into the first 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. We plan to finance our future operations with a combination of proceeds from our ATM facility, renegotiation of the maturity date for existing unsecured notes, 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:

	Nine months ended June 30,	
	2022	2021
Net cash used in operating activities	$ (46,423,872)	$ (45,263,124)
Net cash provided by financing activities	57,967,977	52,419,173

Operating Activities

During the nine months ended June 30, 2022, we used $46.4 million of cash in operating activities resulting primarily from our net loss of $51.7 million. This use of cash was partially offset by $9.2 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 outflow of $3.9 million from changes in our operating assets and liabilities was primarily due to an increase in prepaid expenses of $4.5 million for prepayments associated with ONS-5010 development costs partially offset by an increase in accounts payable and accrued expenses of $0.6 million.

During the nine months ended June 30, 2021, we used $45.3 million of cash in operating activities resulting primarily from our net loss of $39.8 million. This use of cash was partially offset by $4.6 million of non-cash items such as stock-based compensation, non-cash interest expense, change in fair value of warrant liability, gain on settlement of lease termination obligation, loss on equity method investment and depreciation and amortization expense. The net cash outflow of $10.1 million from changes in our operating assets and liabilities was primarily due to an increase in prepaid expenses of $6.9 million for prepayments associated with ONS-5010 development costs, a decrease in accrued expenses of $3.5 million primarily due to the settlement of lease termination obligation and payments to sites for accrued costs, and $0.1 million of payments for operating leases. These outflows were partially offset by an increase in accounts payable of $0.3 million and a decrease in other assets of $0.3 million.

Financing Activities

During the nine months ended June 30, 2022, net cash provided by financing activities was $58.0 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 exercise of common stock warrants, $6.7 million in net proceeds from the sale of common stock under the ATM Offering and $9.4 million in net proceeds from the issuance of an unsecured promissory note with a face amount of $10.2 million in November 2021. We also made $12.3 million in debt and finance lease obligation payments.

During the nine months ended June 30, 2021, net cash provided by financing activities was $52.4 million, primarily attributable to $39.5 million in net proceeds from the registered direct offering and concurrent private placements in February 2021 for an aggregate of 42,607,394 shares of our common stock and accompanying 2,116,364 warrants to purchase shares of our common stock, $3.0 million in net proceeds from the sale of common stock under the ATM Offering and $10.0 million in net proceeds from the issuance of an unsecured promissory note with a face amount of $10.2 million in November 2020. Additionally, we received $3.6 million in net proceeds from common stock warrants exercised. We also made $3.7 million in debt and finance lease obligation payments.

Description of Indebtedness

On November 16, 2021, we received $10.0 million in net proceeds from the issuance of an unsecured promissory note, or 2021 Note, with a face amount of $10.2 million. The note bears interest at a rate of 9.5% per annum compounding daily, matures January 1, 2023, and includes 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.

While the unsecured notes are outstanding, we agreed to keep adequate public information available, maintain our Nasdaq listing, and refrain from undertaking certain "Variable Security Issuances" without the noteholders' consent, subject to certain limited exempt issuances, in addition to other negative covenants. The unsecured notes provide that in the event of default if we breach our negative covenants under the purchase agreements, undertake certain "Fundamental Transactions" (as defined therein), along with other customary events of default, in addition to providing for a default rate of 14%, the noteholder has the right to increase the outstanding balance by 5%.

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, 2021, filed with the SEC on December 23, 2021 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 third fiscal quarter ended June 30, 2022. We have not experienced any material impact to our internal control over financial reporting despite the fact that our employees are working remotely due to the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 situation on our internal controls to minimize the impact on their design and operating effectiveness.

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 June 30, 2022, 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, 2021 filed with the SEC on December 23, 2021.

The ongoing armed conflict between Russia and Ukraine could adversely affect our business, financial condition and results of operations.

On February 24, 2022, Russian military forces launched a military action in Ukraine, and sustained conflict and disruption in the region is likely. The length, impact, and outcome of this ongoing military conflict is highly unpredictable and could lead to significant market and other disruptions, including significant volatility in commodity prices and supply of energy resources, instability in financial markets, supply chain interruptions, political and social instability, trade disputes or trade barriers, changes in consumer or purchaser preferences, as well as an increase in cyberattacks and espionage.

Russia's recognition of two separatist republics in the Donetsk and Luhansk regions of Ukraine and subsequent military action against Ukraine have led to substantial expansion of sanction programs imposed by the United States, the European Union, the United Kingdom, Canada, Switzerland, Japan, and other countries against Russia, Belarus, the Crimea Region of Ukraine, the so-called Donetsk People's Republic, and the so-called Luhansk People's Republic, including, among others:

- blocking sanctions against some of the largest state-owned and private Russian financial institutions (and their subsequent removal from the Society for Worldwide Interbank Financial Telecommunication payment system) and certain Russian businesses, some of which have significant financial and trade ties to the European Union;
- blocking sanctions against Russian and Belarusian individuals, including the Russian President, other politicians, and those with government connections or involved in Russian military activities; and
- blocking of Russia's foreign currency reserves as well as expansion of sectoral sanctions and export and trade restrictions, limitations on investments and access to capital markets, and bans on various Russian imports.

In retaliation against new international sanctions and as part of measures to stabilize and support the volatile Russian financial and currency markets, the Russian authorities also imposed significant currency control measures aimed at restricting the outflow of foreign currency and capital from Russia, imposed various restrictions on transacting with non-Russian parties, banned exports of various products, and imposed other economic and financial restrictions. The situation is rapidly evolving, and additional sanctions by Russia on the one hand, and by the other countries on the other hand, could adversely affect the global economy, financial markets, energy supply and prices, certain critical materials and metals, supply chains, and global logistics and could adversely affect our business, financial condition, and results of operations.

We are actively monitoring the situation in Ukraine and Russia and assessing its impact on our business, including our business partners and customers. To date, we have not experienced any material interruptions in our infrastructure, supplies, technology systems, or networks needed to support our operations. We have no way to predict the progress or outcome of the military conflict in Ukraine or its impacts in Ukraine, Russia, Belarus, Europe, or the U.S. The extent and duration of the military action, sanctions, and resulting market disruptions could be significant and could potentially have substantial impact on the global economy and our business, operations, operating results and financial condition as well as our ability to raise additional capital when needed on acceptable terms for an unknown period of time. Any such disruption may also magnify the impact of other risks described in our Annual Report on Form 10-K for the fiscal year ended September 30, 2021.

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

Not applicable.

Item 3. Defaults Upon Senior Securities

Not applicable.

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	Second Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Company's current report on Form 8-K filed with the SEC on March 26, 2021).
10.1	Amended and Restated Investor Rights Agreement dated April 21, 2022, by and between Outlook Therapeutics, Inc. and GMS Ventures and Investments (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K filed with the SEC on April 22, 2022).
10.2	Amended and Restated Executive Employment Agreement by and between Lawrence Kenyon and Outlook Therapeutics, Inc. dated June 2, 2022 (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K filed with the SEC on June 7, 2022).
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 - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL 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 (formatted as inline XBRL and contained in Exhibit 101)

* 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.

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: August 10, 2022

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: August 10, 2022

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: August 10, 2022

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 June 30, 2022, 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: August 10, 2022

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

Date: August 10, 2022

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."