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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 December 31, 2021
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
Series A Warrants	OTLKW	Nasdaq Stock Market LLC

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

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

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

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

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

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

The number of shares of the registrant's common stock, $0.01 par value per share, outstanding as of February 11, 2022 was 224,276,277.

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 “believe,” “may,” “could,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “seek,” “plan,” “expect,” “should,” “would,” “potentially” 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 current clinical trials 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 if we successfully complete clinical trials;
- 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 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)

	December 31, 2021	September 30, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 70,150,924	$ 14,477,324
Prepaid expenses and other current assets	7,316,327	7,030,823
Total current assets	77,467,251	21,508,147
Property and equipment, net	122,718	163,625
Operating lease right-of-use assets, net	101,468	111,429
Equity method investment	830,005	853,660
Other assets	156,702	174,590
Total assets	$ 78,678,144	$ 22,811,451
Liabilities, convertible preferred stock and stockholders' equity		
Current liabilities:		
Current portion of long-term debt (includes debt measured at fair value of $12,213,936 at December 31, 2021)	$ 12,716,269	$ 904,200
Current portion of finance lease liabilities	22,460	26,464
Current portion of operating lease liabilities	44,011	42,854
Accounts payable	2,545,503	2,196,349
Accrued expenses	2,763,646	1,725,721
Income taxes payable	1,856,629	1,856,629
Total current liabilities	19,948,518	6,752,217
Long-term debt	9,604,391	10,885,854
Finance lease liabilities	13,221	16,018
Operating lease liabilities	15,573	26,995
Warrant liability	273,020	522,918
Total liabilities	29,854,723	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; 224,260,602 and 176,461,628 shares issued and outstanding at December 31, 2021 and September 30, 2021, respectively	2,242,606	1,764,616
Additional paid-in capital	403,926,798	345,726,087
Accumulated deficit	(357,345,983)	(342,883,254)
Total stockholders' equity	48,823,421	4,607,449
Total liabilities, convertible preferred stock and stockholders' equity	$ 78,678,144	$ 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 December 31,	
	2021	**2020**
Operating expenses:		
Research and development	$ 9,872,476	$ 11,948,581
General and administrative	3,277,205	2,242,354
Loss from operations	(13,149,681)	(14,190,935)
Loss on equity method investment	23,655	—
Interest expense, net	351,534	159,663
Loss on extinguishment of debt	1,025,402	—
Change in fair value of unsecured convertible promissory note	162,355	—
Change in fair value of warrant liability	(249,898)	105,316
Net loss	$ (14,462,729)	$ (14,455,914)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.08)	$ (0.12)
Weighted average shares outstanding, basic and diluted	188,157,921	121,749,555

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 Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance at October 1, 2021	176,461,628	$ 1,764,616	$ 345,726,087	$ (342,883,254)	$ 4,607,449
Issuance of common stock in connection with exercise of stock options	25,000	250	17,500	—	17,750
Sale of common stock, net of issuance costs	47,773,974	477,740	56,979,163	—	57,456,903
Stock-based compensation expense	—	—	1,204,048	—	1,204,048
Net loss	—	—	—	(14,462,729)	(14,462,729)
Balance at December 31, 2021	224,260,602	$ 2,242,606	$ 403,926,798	$ (357,345,983)	$ 48,823,421

	Stockholders' Equity (Deficit)				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
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)

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

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

	Three months ended December 31,	
	2021	**2020**
OPERATING ACTIVITIES		
Net loss	$ (14,462,729)	$ (14,455,914)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	50,868	81,116
Loss on extinguishment of debt	1,025,402	—
Non-cash interest expense	344,716	149,210
Stock-based compensation	1,204,048	1,154,641
Change in fair value of unsecured convertible promissory note	162,355	—
Change in fair value of warrant liability	(249,898)	105,316
Gain on settlement of lease termination obligation	—	(732,426)
Loss on equity method investment	23,655	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(285,504)	28,339
Other assets	—	137,579
Operating lease liability	(10,265)	(45,335)
Accounts payable	169,169	939,353
Accrued expenses	1,037,925	(686,527)
Net cash used in operating activities	(10,990,258)	(13,324,648)
FINANCING ACTIVITIES		
Proceeds from the sale of common stock, net of issuance costs	57,654,776	—
Proceeds from debt	10,000,000	10,000,000
Proceeds from exercise of stock options	17,750	—
Payments of finance lease obligations	(6,801)	(10,080)
Repayment of debt	(401,867)	(3,624,774)
Payment of financing costs	(600,000)	(8,032)
Net cash provided by financing activities	66,663,858	6,357,114
Net increase (decrease) in cash and cash equivalents	55,673,600	(6,967,534)
Cash and cash equivalents at beginning of period	14,477,324	12,535,986
Cash and cash equivalents at end of period	$ 70,150,924	$ 5,568,452
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 20,155	$ 10,722
Supplemental schedule of non-cash financing activities:		
Common stock issuance costs in accounts payable	$ 179,985	$ —
Deferred offering costs amortization	$ 17,888	$ —

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 late clinical-stage 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 novel coronavirus ("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 as a result of 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 three months ended December 31, 2021 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 $357,345,983 as of December 31, 2021. As of December 31, 2021, the Company had $22,056,670 of principal and accrued interest due under unsecured promissory notes maturing on January 1, 2023, and a $502,333 loan granted pursuant to the Paycheck Protection Program (the "PPP") of the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), which matures on May 2, 2022. These factors raise 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 December 31, 2021 will be sufficient to fund its operations through the anticipated approval of the ONS-5010 BLA expected in the first calendar quarter of 2023. Substantial 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. These strategies may include but are not limited to proceeds from potential licensing and/or marketing arrangements with pharmaceutical companies, the issuance of equity securities, and the issuance of additional debt, potential collaborations 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 complete revenue-generating partnerships with pharmaceutical 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 December 31, 2021 and its results of operations for the three months ended December 31, 2021 and 2020, cash flows for the three months ended December 31, 2021 and 2020, and stockholders' equity (deficit) for the three months ended December 31, 2021 and 2020. Operating results for the three months ended December 31, 2021, 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 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 December 31,	
	2021	2020
Net loss attributable to common stockholders	$ (14,462,729)	$ (14,455,914)
Common stock shares outstanding (weighted average)	188,157,921	121,749,555
Basic and diluted net loss per share	$ (0.08)	$ (0.12)

The following potentially dilutive securities (in common stock equivalents) have been excluded from the computation of diluted weighted-average shares outstanding as of December 31, 2021 and 2020, as they would be antidilutive:

	As of December 31,	
	2021	2020
Performance-based stock units	2,470	2,470
Performance-based stock options	1,900,000	—
Stock options	17,904,189	11,977,677
Common stock warrants	7,228,829	7,051,854

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 all entities with fiscal years beginning after December 15, 2021, including interim periods therein. The Company is currently evaluating the impact of adopting this guidance to its consolidated financial statements.

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.
- 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.

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

- 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:

	December 31, 2021		
	(Level 1)	(Level 2)	(Level 3)
Liabilities			
Unsecured convertible promissory note	$ —	$ —	$ 12,213,936
Warrant liability	—	—	273,020
	$ —	$ —	$ 12,486,956

	September 30, 2021		
	(Level 1)	(Level 2)	(Level 3)
Liabilities			
Unsecured convertible promissory note	$ —	$ —	$ —
Warrant liability	—	—	522,918
	$ —	$ —	$ 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 three months ended December 31, 2021:

	Unsecured Convertible Promissory Note	Warrants
Balance at October 1, 2021	$ —	$ 522,918
Fair value at issuance date	12,051,581	—
Change in fair value	162,355	(249,898)
Balance at December 31, 2021	$ 12,213,936	$ 273,020

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 and at December 31, 2021 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:

	December 31, 2021	September 30, 2021
Risk-free interest rate	0.99 %	0.62 %
Remaining contractual term of warrant (years)	3.1	3.4
Expected volatility	128.3 %	124.7 %
Annual dividend yield	— %	— %
Fair value of common stock (per share)	$ 1.36	$ 2.17

Fair Value of Other Financial Instruments

At December 31, 2021, the carrying value of the PPP loan approximates its fair value due to the short duration to maturity. The fair value and carrying value of the unsecured promissory note included in long-term debt on the consolidated balance sheet on December 31, 2021 was $10,157,000 and $9,604,391, 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:

	December 31, 2021	September 30, 2021
Laboratory equipment	$ 1,067,351	$ 1,067,351
Less: accumulated depreciation	(944,633)	(903,726)
	$ 122,718	$ 163,625

Depreciation expense was $40,907 and $40,906 for the three months ended December 31, 2021 and 2020, 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 which was included in other assets at September 30, 2020 and upon formation of Syntone in April 2021, the Company reclassified the investment to equity method investment in the accompanying consolidated balance sheets. The Company expects to be required to make an additional capital contribution to Syntone of approximately $2,100,000, which will be made within four years after the establishment date in accordance with the development plan contemplated in the license agreement or on such other terms within such four-year period. The maximum exposure to a loss as a result of the Company’s involvement in Syntone is limited to the initial investment and the future capital contributions of approximately $2,100,000.

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

7. Accrued Expenses

Accrued expenses consists of:

	December 31, 2021	September 30, 2021
Compensation	$ 1,044,337	$ 753,808
Research and development	1,382,966	808,780
Interest payable	223	12,909
Professional fees	189,996	—
Other accrued expenses	146,124	150,224
	$ 2,763,646	$ 1,725,721

8. Debt

Debt consists of:

	December 31, 2021	September 30, 2021
Unsecured convertible promissory note (measured at fair value)	$ 12,213,936	$ —
Unsecured promissory note	10,342,070	10,938,145
Paycheck Protection Program term loan	502,333	904,200
Total debt	23,058,339	11,842,345
Less: unamortized loan costs	(737,679)	(52,291)
Total debt, net of unamortized loan costs	22,320,660	11,790,054
Less: current portion	(12,716,269)	(904,200)
Long-term debt	$ 9,604,391	$ 10,885,854

Unsecured convertible promissory note

On November 5, 2020, the Company received $10,000,000 in net proceeds from issuance of an unsecured promissory note with face amount of $10,220,000 which was amended in November 2021. 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. 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. 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 includes redemption options whereby beginning on July 1, 2022, the holder has 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 is not required to bifurcate the redemption options as derivatives. Since the redemption options provide the lender with the right to put the total outstanding principal and interest back to the Company within one year from the balance sheet date, the entire amount is classified as a current liability. As of December 31, 2021, the aggregate unpaid principal and interest outstanding and the fair value of the amended promissory note were $11,714,600 and $12,213,936, respectively.

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Unsecured promissory note

On November 16, 2021, the Company received $10,000,000 in net proceeds from issuance of an unsecured promissory note with face amount of $10,220,000. Debt issuance costs totaling $820,000 are 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 December 31, 2021 and 2020, the Company recognized $344,716, and $149,210, respectively, of interest expense related to the unsecured promissory notes of which $108,123 and $29,291, 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 Company has the right to prepay any amounts outstanding under this loan at any time and from time to time, in whole or in part, without penalty. Aggregate interest expense on the PPP loan for the three months ended December 31, 2021, and 2020 was $1,708 and $2,279, 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 is contingent upon the occurrence of certain future events.

Leases

Corporate office

In March 2021, the Company assigned its Monmouth Junction, New Jersey corporate office lease to a third party and as of December 31, 2021, did not have remaining future obligations. In March 2021, the Company entered into a new three-year term corporate office lease in Iselin, New Jersey which 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%.

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

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renewal terms are at the Company's option. Lease expense is recorded as research and development or general and administrative based on the use of the leased asset.

The components of lease cost for the three months ended December 31, 2021 and 2020 are as follows:

	Three months ended December 31, 2021	2020
Lease cost:		
Amortization of right-of-use assets	$ —	$ —
Interest on lease liabilities	975	1,782
Total finance lease cost	975	1,782
Operating lease cost	11,217	43,625
Total lease cost	$ 12,192	$ 45,407

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

	December 31, 2021	September 30, 2021
Operating leases:		
Right-of-use asset	$ 101,468	$ 111,429
Operating lease liabilities	59,584	69,849
Finance leases:		
Right-of-use asset	$ —	$ —
Financing lease liabilities	35,681	42,482
Weighted-average remaining lease term (years):		
Operating leases	2.3	2.6
Finance leases	1.6	1.7
Weighted-average discount rate:		
Operating leases	7.5%	7.5%
Finance leases	10.0%	9.5%

Other information related to leases for the three months ended December 31, 2021 and 2020 are as follows:

	Three months ended December 31, 2021	2020
Cash paid for amounts included in the measurement of lease obligations:		
Operating cash flows from finance leases	$ 975	$ 1,782
Operating cash flows from operating leases	11,522	48,750
Financing cash flows from finance leases	6,801	10,080

Future minimum lease payments under non-cancelable leases as of December 31, 2021 are as follows for the years ending September 30:

	Operating leases	Finance leases
2022 (remaining nine months)	$ 35,130	$ 21,830
2023	27,675	13,149
2024	—	4,383
Total undiscounted lease payments	$ 62,805	$ 39,362
Less: Imputed interest	3,221	3,681
Total lease obligations	$ 59,584	$ 35,681

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10. Common Stock and Stockholders' Equity (Deficit)

Common stock

In November 2021, the Company issued in an underwritten public offering 46,000,000 shares of common stock 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"), an affiliate of BioLexis Pte. Ltd. ("BioLexis"), 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 5-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 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 December 31, 2021, $144,109 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 three months ended December 31, 2021, the Company sold 1,773,974 shares of common stock under the ATM Offering and generated $3,622,497 in gross proceeds. The Company paid fees to the Agent and other issuance costs of $115,763.

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Common stock warrants

As of December 31, 2021, shares of common stock issuable upon the exercise of outstanding warrants were as follows:

Expiration Date		Shares of common stock issuable upon exercise of warrants		Exercise Price Per Share
February 18, 2022		416,035	$	12.00
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
		7,228,829		

(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.

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. The number of shares of common stock reserved for issuance under the 2011 Plan is 106,490. As of December 31, 2021, 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 27,838,019. As of December 31, 2021, 7,839,178 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.

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The Company recorded stock-based compensation expense in the following expense categories of its statements of operations for the three months ended December 31, 2021 and 2020:

	Three months ended December 31,	
	2021	2020
Research and development	$ 252,395	$ 239,971
General and administrative	951,653	914,670
	$ 1,204,048	$ 1,154,641

Stock options

As of December 31, 2021, 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	1,819,174	1.52		
Exercised	(25,000)	0.71		
Balance at December 31, 2021	17,904,189	1.47	8.9	$ 5,685,350
Exercisable	6,260,614	1.28	8.5	$ 2,533,181
Vested and expected to vest at December 31, 2021	17,904,189	$ 1.47	8.9	$ 5,685,350

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

The weighted average grant date fair value of the options awarded to employees for the three months ended December 31, 2021 and 2020 was $1.16 and $0.54 per option, respectively. The fair value of the options was estimated on the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions:

	Three months ended December 31,	
	2021	2020
Risk-free interest rate	1.29 %	0.38 %
Expected term (years)	6.0	6.0
Expected volatility	94.3 %	95.4 %
Expected dividend yield	—	—

As of December 31, 2021, there was $12,097,871 of unrecognized compensation expense that is expected to be recognized over a weighted-average period of 3.17 years.

Performance-based stock options

The Company granted certain officers of the Company share 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 December 31, 2021, and changes during the three months then ended is 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	(1,000,000)	2.42		
Balance at December 31, 2021	1,900,000	$ 1.44	9.97	$ —
Exercisable	—	$ —	—	$ —
Vested and expected to vest at December 31, 2021	1,900,000	$ 1.44	9.97	$ —

The weighted average grant date fair value of the performance stock options awarded during the three months ended December 31, 2021, was $1.03 per option. As of December 31, 2021, the Company assessed that the performance conditions were not probable of achievement. The assessment was based on the relevant facts and circumstances and therefore no compensation costs was recognized. The fair value of the options was estimated on the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions:

	Three months ended December 31, 2021
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 three months ended December 31, 2020.

Performance-based stock units

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

The following table summarizes the activity related to PSUs during the three months ended December 31, 2021:

	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 December 31, 2021	2,470	49.97	3.0	$ —
Vested and exercisable at December 31, 2021	2,470	49.97	3.0	$ —
Vested and expected to vest at December 31, 2021	2,470	$ 49.97	3.0	$ —

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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. As of December 31, 2021, 1,811,184 shares of common stock were vested and not subject to repurchase rights.

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. Compensation expense may be accelerated when certain performance conditions become probable, and the corresponding purchase right has lapsed. During the three months ended December 31, 2021, and 2020, the Company recognized compensation expense related to the restricted stock of $151,764. As of December 31, 2021, there was $1,700,418 of 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, the Company's bevacizumab therapeutic product candidate for ophthalmic indications.

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. The Company did not pay Mr. Dagnon or Mr. Evanson any direct compensation as consultants or as employees during the three months ended December 31, 2019 nor during the period from October 1, 2019 through March 19, 2020. 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, 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.

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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 December 31, 2021 and 2020, MTTR and its four principals under the strategic partnership agreement and the subsequent individual consulting agreements earned an aggregate $313,986 and $467,653, respectively, which includes monthly consulting fees and expense reimbursement, but excludes stock-based compensation related to restricted stock (Note 11). As of December 31, 2021, and September 30, 2021 an aggregate $91,283 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, we 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.

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 "believe," "may," "could," "will," "estimate," "continue," "anticipate," "intend," "seek," "plan," "expect," "should," "would," "potentially" 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 biopharmaceutical company working to develop and 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 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.

ONS-5010 (LYTENAVA (bevacizumab-vikg)), our sole product candidate in active clinical development, is an investigational ophthalmic formulation of bevacizumab, which we are developing to be administered as an intravitreal injection for the treatment of wet AMD and other retinal diseases. Bevacizumab is a full-length, humanized anti-VEGF (Vascular Endothelial Growth Factor) recombinant monoclonal antibody, or mAb, that inhibits VEGF and associated angiogenic activity. The study design for our Phase 3 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.

Our clinical program for ONS-5010 in wet AMD involves three clinical trials, which we refer to as NORSE ONE, NORSE TWO and NORSE THREE. We reported achieving the anticipated safety and efficacy and positive proof-of-concept topline results from NORSE ONE, a clinical experience study, in August 2020. 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 BCVA 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 in BCVA was observed with ONS-5010 was 11.2 letters, 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. 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. Accordingly, all three of these clinical trials required for our planned BLA submission in the first quarter of calendar 2022 for wet AMD have been completed.

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 in 2023 following the anticipated FDA approval of our planned 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. If the ONS-5010 clinical program is successful, it will support our plans to submit for regulatory approval in multiple markets in 2022 including the United States, Europe and other markets. Because there are no approved bevacizumab products for the treatment of retinal diseases in such major markets, we are developing ONS-5010 as a standard BLA, and 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 December 31, 2021, we have funded substantially all of our operations with $405.8 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 $70.2 million as of December 31, 2021, are expected to fund our operations through the anticipated approval of the ONS-5010 BLA expected in the first calendar quarter of 2023. We will need to raise substantial 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, 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 three months ended December 31, 2021, was $14.5 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 December 31, 2021, we had substantial indebtedness that included $22.1 million of principal and accrued interest under unsecured promissory notes maturing on January 1, 2023, and $0.5 million loan granted pursuant to the Paycheck Protection Program, or PPP, of the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, which matures on May 2, 2022. We will need to raise substantial 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 potential licensing and/or marketing arrangements with pharmaceutical companies, the

issuance of equity securities, and the issuance of additional debt, potential collaborations and revenues from potential future product sales, if any. There are no assurances that we will be successful in obtaining an adequate level of financing for the development and commercialization of ONS-5010 or any other current or future product candidates. If we are unable to secure adequate additional funding, our business, operating results, financial condition and cash flows may be materially and adversely affected. Our consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

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 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, as shelter-in-place and other types of local and state orders were imposed. 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 planned BLA submission are now complete. To date, we have not experienced any significant COVID-19 disruptions to patient follow-up, but the clinical trial protocols account for potential delayed or missed visits for any reason, including COVID-19 type interruptions. The FDA has provided guidance in the event of COVID-19 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 and its resulting restrictions evolve in jurisdictions across the country, 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 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 People’s Republic of China, or PRC, based-affiliate, 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 December 31, 2021, we have paid Selexis 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 expense consists of expenses incurred in connection with the discovery and development of our product candidates. We expense research and development costs as incurred. These expenses include:

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

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

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

Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals. We may never succeed in achieving regulatory approval for any of our 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 which 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 NOLs and 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 December 31, 2021 and 2020

	Three months ended December 31,		
	2021	2020	Change
Operating expenses:			
Research and development	$ 9,872,476	$ 11,948,581	$ (2,076,105)
General and administrative	3,277,205	2,242,354	1,034,851
Loss from operations	(13,149,681)	(14,190,935)	1,041,254
Loss on equity method investment	23,655	—	23,655
Interest expense, net	351,534	159,663	191,871
Loss on extinguishment of debt	1,025,402	—	1,025,402
Change in fair value of convertible promissory note	162,355	—	162,355
Change in fair value of warrant liability	(249,898)	105,316	(355,214)
Net loss	$ (14,462,729)	$ (14,455,914)	$ (6,815)

Research and development expenses

The following table summarizes our research and development expenses by functional area for the three months ended December 31, 2021 and 2020:

	Three months ended December 31,	
	2021	2020
ONS-5010 development	$ 8,728,869	$ 10,783,331
Compensation and related benefits	433,014	369,852
Stock-based compensation	252,395	239,971
Other research and development	458,198	555,427
Total research and development expenses	$ 9,872,476	$ 11,948,581

Research and development expenses for the three months ended December 31, 2021 decreased by $2.1 million compared to the three months ended December 31, 2020. The decrease was primarily due to reduced clinical trial expenses for ONS-5010 as a result of the completion of the NORSE TWO and NORSE THREE trials, which were partially offset by the initiation of NORSE SEVEN.

General and administrative expenses

The following table summarizes our general and administrative expenses by type for the three months ended December 31, 2021 and 2020:

	Three months ended December 31,	
	2021	2020
Professional fees	$ 1,152,132	$ 1,413,324
Compensation and related benefits	630,026	294,730
Stock-based compensation	951,653	914,670
Facilities, fees and other related costs	543,394	(380,370)
Total general and administrative expenses	$ 3,277,205	$ 2,242,354

General and administrative expenses for the three months ended December 31, 2021 increased by $1.0 million compared to the three months ended December 31, 2020. The increase was primarily due to a $0.7 million gain on lease termination recognized in the prior year and a $0.3 million increase in compensation related costs from increased headcount compared to the prior year.

Interest expense

Interest expense increased by $0.2 million to $0.4 million for the three months ended December 31, 2021, as compared to $0.2 million for the three months ended December 31, 2020. The increase was primarily related to an 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 unsecured promissory note

The change in fair value relates to an amended promissory note which 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.

Liquidity and Capital Resources

We have not generated any revenue from product sales. Since inception, we have incurred net losses and negative cash flows from our operations. Through December 31, 2021, we have funded substantially all of our operations with $405.8 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 substantial 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 payments from potential strategic research and development, licensing and/or marketing arrangements with pharmaceutical companies, private placements and/or public offerings of equity and/or debt securities. Alternatively, we will be required to, among other things, make further 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 issuance of an unsecured promissory note, or 2020 Note, with face amount of $10.2 million. The note bears interest at a rate of 7.5% per annum, matures January 1, 2022, 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. On November 16, 2021, entered into a note amendment (the “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.

In October 2021 and November 2021, we sold an additional 1,773,974 shares of common stock under and generated $3.5 million in net proceeds from the ATM Offering after payment of fees to the sales agent of $0.1 million.

On November 16, 2021, we received $10.0 million in net proceeds from issuance of an unsecured promissory note, or 2021 Note, with 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 5-year term.

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 December 31, 2021, we had an accumulated deficit of $357.3 million. In addition, $22.1 million of unsecured promissory notes, which bear interest compounding daily, and mature January 1, 2023 and a $0.5 million loan granted pursuant to the PPP of the CARES Act, which matures on May 2, 2022, are outstanding as of December 31, 2021. Our current cash resources of $70.2 million as of December 31, 2021 are expected to fund our operations through the anticipated approval of the ONS-5010 BLA expected in 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 complete revenue-generating partnerships with pharmaceutical 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 plan to focus in the near term on submitting a BLA to the FDA to support the generation of commercial revenues. We anticipate we will incur net losses and negative cash flow from operations for the foreseeable future. We may not be able to complete the development and initiate commercialization of ONS-5010 if, among other things, if the FDA does not approve our application arising out of our current clinical trials 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 as of December 31, 2021 of $70.2 million is expected to fund our operations through the anticipated approval of the ONS-5010 BLA expected in 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 in order to complete our planned ONS-5010 development and commercialization program. We plan to finance our future operations with a combination of proceeds from potential strategic collaborations, sale of the development and commercial rights to our drug product candidates, the issuance of equity securities, the issuance of additional debt, and revenues from potential future product sales, if any. If we raise additional capital through the sale of equity or convertible debt securities, your ownership will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. 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 will be required to, among other things, modify our clinical trial plans for ONS-5010 in additional indications, make reductions in our workforce, scale back our plans and place certain activities on hold, discontinue our development programs, liquidate all or a portion of our assets, and/or seek protection under the provisions of the U.S. Bankruptcy Code.

Cash Flows

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

	Three months ended December 31,	
	2021	2020
Net cash used in operating activities	$ (10,990,258)	$ (13,324,648)
Net cash provided by financing activities	66,663,858	6,357,114

Operating Activities.

During the three months ended December 31, 2021, we used $11.0 million of cash in operating activities resulting primarily from our net loss of $14.5 million. This use of cash was partially offset by $2.6 million of non-cash items such as stock-based compensation, non-cash interest expense, change in fair value of warrant liability, change in fair value of unsecured convertible promissory note, loss on extinguishment of debt, loss on equity method investment and depreciation and amortization expense. The net cash inflow of $0.9 million from changes in our operating assets and liabilities was primarily due an increase in accounts payable of $0.2 million and an increase of $1.0 million in accrued expenses due to increase in NORSE SEVEN clinical trial costs. These inflows were partially offset by to an increase in prepaid expenses of $0.3 million for prepayments associated with ONS 5010 development costs.

During the three months ended December 31, 2020, we used $13.3 million of cash in operating activities resulting primarily from our net loss of $14.5 million. This use of cash was partially offset by $0.8 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, and depreciation and amortization expense. The net cash inflow of $0.4 million from changes in our operating assets and liabilities was primarily to an increase in our accounts payable of $0.9 million primarily due to clinical trial costs and ONS 5010 development costs and a decrease in other assets of $0.2 million. These inflows were

partially offset by a decrease in accrued expenses of $0.7 million primarily due to the settlement of lease termination obligation and payments to sites for accrued costs.

Financing Activities.

During the three months ended December 31, 2021, net cash provided by financing activities was $66.7 million, primarily attributable to $54.1 million in net proceeds from an underwritten public offering in November 2021 for an aggregate of 46,000,000 shares of our common stock and accompanying 2,100,000 warrants to purchase shares of our common stock, $3.5 million in net proceeds from the sale of common stock under the ATM Offering and $9.4 million in net proceeds from issuance of an unsecured promissory note with face amount of $10.2 million in November 2021. We also made $0.4 million in debt and finance lease obligations payments.

During the three months ended December 31, 2020, net cash provided by financing activities was $6.4 million, primarily attributable to $10.0 million in net proceeds from issuance of an unsecured promissory note with face amount of $10.2 million in November 2020, offset by $3.6 million in debt and finance lease obligation payments.

Description of Indebtedness

In November 2020, we entered into a note purchase agreement with Streeterville Capital, LLC, a Utah limited liability company pursuant to which we issued an unsecured promissory note in the original principal amount of $10.2 million for $10.0 million in cash proceeds which was amended in November 2021. The unsecured note included an original issue discount of $0.2 million, bore interest at a rate of 7.5% per annum compounding daily and was due to mature January 1, 2022. We may prepay all or a portion of the unsecured note at any time by paying 105% of the outstanding balance elected for pre-payment. On November 16, 2021, we entered into the 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 November 16, 2021, we received $10.0 million in net proceeds from issuance of an unsecured promissory note, or 2021 Note, with 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

Not applicable.

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 first fiscal quarter ended December 31, 2021. 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

Not applicable.

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	Executive Employment Agreement by and between Terry Dagnon and Outlook Therapeutics, Inc, dated December 21, 2021 (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K filed with the SEC on December 23, 2021).
10.2	Executive Employment Agreement by and between Jeff Evanson and Outlook Therapeutics, Inc, dated December 21, 2021 (incorporated by reference to Exhibit 10.2 to the Company's current report on Form 8-K filed with the SEC on December 23, 2021).
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	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: February 14, 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: February 14, 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: February 14, 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 December 31, 2021, 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: February 14, 2022 By /s/ C. Russell Trenary III
C. Russell Trenary III
Chief Executive Officer

Date: February 14, 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."