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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 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 May 12, 2021 was 173,605,807.

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, 2020 filed with the SEC on December 23, 2020, as amended January 28, 2021, including, among other things, risks associated with:

- the timing and the success of the design of the 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;
- 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)

	March 31, 2021	September 30, 2020
Assets		
Current assets:		
Cash	$ 37,168,854	$ 12,535,986
Prepaid expenses and other current assets	6,623,987	5,407,882
Total current assets	43,792,841	17,943,868
Property and equipment, net	245,437	327,249
Operating lease right-of-use assets, net	—	166,986
Other assets	1,073,536	1,294,448
Total assets	$ 45,111,814	$ 19,732,551
Liabilities, convertible preferred stock and stockholders' equity		
Current liabilities:		
Current portion of long-term debt	$ 11,184,734	$ 50,285
Current portion of finance lease liabilities	26,972	29,778
Current portion of operating lease liabilities	—	187,486
Stockholder notes	—	3,612,500
Accounts payable	6,332,256	2,394,818
Accrued expenses	4,497,209	7,757,310
Income taxes payable	1,856,629	1,856,629
Total current liabilities	23,897,800	15,888,806
Long-term debt	129,171	904,200
Finance lease liabilities	28,755	42,482
Warrant liability	404,916	70,772
Total liabilities	24,460,642	16,906,260
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; 173,605,807 shares issued and outstanding at March 31, 2021 and 127,183,109 shares issued and outstanding at September 30, 2020	1,736,058	1,271,831
Additional paid-in capital	336,197,455	291,274,366
Accumulated deficit	(317,282,341)	(289,719,906)
Total stockholders' equity	20,651,172	2,826,291
Total liabilities, convertible preferred stock and stockholders' equity	$ 45,111,814	$ 19,732,551

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

Outlook Therapeutics, Inc.
Consolidated Statements of Operations
(unaudited)

	Three months ended March 31,		Six months ended March 31,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 8,529,393	$ 4,383,214	$ 20,477,974	$ 10,230,516
General and administrative	4,095,891	1,957,175	6,338,245	4,293,899
Impairment of property and equipment	—	423,328	—	423,328
	12,625,284	6,763,717	26,816,219	14,947,743
Loss from operations	(12,625,284)	(6,763,717)	(26,816,219)	(14,947,743)
Interest expense, net	250,409	696,151	410,072	1,293,816
Loss on extinguishment of debt	—	—	—	8,060,580
Change in fair value of redemption feature	—	(1,759,037)	—	(1,796,982)
Change in fair value of warrant liability	228,828	(764)	334,144	(202,142)
Loss before income taxes	(13,104,521)	(5,700,067)	(27,560,435)	(22,303,015)
Income tax expense	2,000	—	2,000	—
Net loss	(13,106,521)	(5,700,067)	(27,562,435)	(22,303,015)
Series A-1 convertible preferred stock dividends and related settlement	—	—	—	(166,133)
Deemed dividend upon modification of warrants	—	(1,431,406)	—	(3,140,009)
Deemed dividend upon amendment of the terms of the Series A-1 convertible preferred stock	—	(10,328,118)	—	(10,328,118)
Net loss attributable to common stockholders	$ (13,106,521)	$ (17,459,591)	$ (27,562,435)	$ (35,937,275)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.09)	$ (0.36)	$ (0.20)	$ (0.93)
Weighted average shares outstanding, basic and diluted	150,730,191	47,895,771	136,080,637	38,849,364

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

Outlook Therapeutics, Inc.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(unaudited)

	Convertible Preferred Stock Series A-1		Stockholders' Equity (Deficit)				
			Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance at January 1, 2021	—	$ —	127,183,109	$ 1,271,831	$ 292,429,007	$ (304,175,820)	$ (10,474,982)
Issuance of common stock in connection with exercise of warrants	—	—	3,815,304	38,153	3,547,656	—	3,585,809
Sale of common stock, net of issuance costs	—	—	42,607,394	426,074	39,091,045	—	39,517,119
Stock-based compensation expense	—	—	—	—	1,129,747	—	1,129,747
Net loss	—	—	—	—	—	(13,106,521)	(13,106,521)
Balance at March 31, 2021	—	$ —	173,605,807	$ 1,736,058	$ 336,197,455	$ (317,282,341)	$ 20,651,172

	Convertible Preferred Stock Series A-1		Stockholders' Equity (Deficit)				
			Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance at October 1, 2020	—	$ —	127,183,109	$1,271,831	$ 291,274,366	$(289,719,906)	$ 2,826,291
Issuance of common stock in connection with exercise of warrants	—	—	3,815,304	38,153	3,547,656	—	3,585,809
Sale of common stock, net of issuance costs	—	—	42,607,394	426,074	39,091,045	—	39,517,119
Stock-based compensation expense	—	—	—	—	2,284,388	—	2,284,388
Net loss	—	—	—	—	—	(27,562,435)	(27,562,435)
Balance at March 31, 2021	—	$ —	173,605,807	$ 1,736,058	$ 336,197,455	$ (317,282,341)	$ 20,651,172

	Convertible Preferred Stock Series A-1		Stockholders' Equity (Deficit)				
			Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance at January 1, 2020	68,112	$ 5,525,537	38,430,924	$384,309	$ 239,766,786	$(271,083,356)	$ (30,932,261)
Issuance of common stock in connection with exercise of warrants	—	—	4,657,852	46,579	1,034,043	—	1,080,622
Sale of common stock, net of issuance costs	—	—	10,059,056	100,591	9,096,357	—	9,196,948
Conversion of Series A-1 convertible preferred stock to common stock	(68,112)	(5,525,537)	29,358,621	293,586	5,231,951	—	5,525,537
Issuance of restricted common stock to former principals of MTTR, LLC (Note 12)	—	—	7,244,739	72,447	(72,447)	—	—
Stock-based compensation expense	—	—	—	—	304,539	—	304,539
Net loss	—	—	—	—	—	(5,700,067)	(5,700,067)
Balance at March 31, 2020	—	$ —	89,751,192	$897,512	$ 255,361,229	$(276,783,423)	$ (20,524,682)

	Convertible Preferred Stock Series A-1		Stockholders' Equity (Deficit)				
			Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance at October 1, 2019	66,451	$ 5,359,404	28,609,995	$286,100	$ 238,064,947	$(254,480,408)	$ (16,129,361)
Issuance of common stock in connection with exercise of warrants	—	—	13,003,414	130,034	1,008,866	—	1,138,900
Issuance of common stock in connection with conversion of stockholder notes	—	—	1,475,258	14,753	1,533,673	—	1,548,426
Sale of common stock, net of issuance costs	—	—	10,059,056	100,591	9,096,357	—	9,196,948
Issuance of vested restricted stock units	—	—	109	1	(1)	—	—
Series A-1 convertible preferred stock dividends and related settlement	1,661	166,133	—	—	(166,133)	—	(166,133)
Conversion of Series A-1 convertible preferred stock to common stock	(68,112)	(5,525,537)	29,358,621	293,586	5,231,951	—	5,525,537
Issuance of restricted common stock to former principals of MTTR, LLC (Note 12)	—	—	7,244,739	72,447	(72,447)	—	—
Stock-based compensation expense	—	—	—	—	664,016	—	664,016
Net loss	—	—	—	—	—	(22,303,015)	(22,303,015)
Balance at March 31, 2020	—	$ —	89,751,192	$897,512	$ 255,361,229	$(276,783,423)	$ (20,524,682)

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

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

	Six months ended March 31,	
	2021	2020
OPERATING ACTIVITIES		
Net loss	$ (27,562,435)	$ (22,303,015)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	163,283	351,623
Loss on extinguishment of debt	—	8,060,580
Non-cash interest expense	392,028	135,787
Stock-based compensation	2,284,388	664,016
Change in fair value of redemption feature	—	(1,796,982)
Change in fair value of warrant liability	334,144	(202,142)
Impairment of property and equipment	—	423,328
Gain on settlement of lease termination obligation	(552,340)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,323,108)	229,616
Other assets	137,579	(83,358)
Operating lease liability	(91,721)	(80,572)
Accounts payable	3,685,278	1,028,736
Accrued expenses	(2,537,903)	(233,806)
Other liabilities	—	49,455
Net cash used in operating activities	(25,070,807)	(13,756,734)
FINANCING ACTIVITIES		
Proceeds from the sale of common stock, net of offering costs	39,779,507	9,457,400
Proceeds from debt	10,000,000	—
Payment of debt issuance costs	(8,032)	—
Proceeds from exercise of common stock warrants	3,585,809	1,138,900
Payments of finance lease obligations	(16,533)	(178,757)
Repayment of debt	(3,637,076)	(23,414)
Net cash provided by financing activities	49,703,675	10,394,129
Net increase (decrease) in cash	24,632,868	(3,362,605)
Cash at beginning of period	12,535,986	8,015,528
Cash at end of period	$ 37,168,854	$ 4,652,923
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 10,490	$ 718,521
Supplemental schedule of non-cash financing activities:		
Unsecured notes and accrued interest converted into common stock	$ —	$ 1,548,426
Issuance of exchange notes at estimated fair value	$ —	$ 7,050,206
Issuance of redemption feature at estimated fair value	$ —	$ 8,264,451
Series A-1 convertible preferred stock dividends and related settlement	$ —	$ 166,133
Deferred offering costs and common stock issuance costs in accounts payable and accrued expenses	$ 262,388	$ 260,452

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 clinical and chemistry, manufacturing and control activities are currently active for NORSE TWO, the Company's remaining clinical trials under its 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 six months ended March 31, 2021 were not significantly impacted by COVID-19.

2. Liquidity

The Company has incurred substantial losses and negative cash flows from operations since its inception. As of March 31, 2021, the Company had $10.5 million of principal and accrued interest due under an unsecured promissory note maturing on January 1, 2022, and a $0.9 million 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 as of March 31, 2021 will be sufficient to fund its operations through November 2021. 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 ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

In the opinion of management, the accompanying unaudited interim consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company's financial position as of March 31, 2021 and its results of operations for the three and six months ended March 31, 2021 and 2020, cash flows for the six months ended March 31, 2021 and 2020, and convertible preferred stock and stockholders' equity (deficit) for the three and six months ended March 31, 2021 and 2020. Operating results for the three and six months ended March 31, 2021 are not necessarily indicative of the results that may be expected for the full year ending September 30, 2021. 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, 2020 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on December 23, 2020 and amended on January 28, 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.

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. Dilutive common stock equivalents potentially include warrants, stock options and non-vested restricted stock unit ("RSU") awards using the treasury stock method. For all periods presented, there is no difference in the number of shares used to compute basic and diluted shares due to the Company's loss.

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

	Three months ended March 31,		Six months ended March 31,	
	2021	2020	2021	2020
Net loss attributable to common stockholders	$ (13,106,521)	$ (17,459,591)	$ (27,562,435)	$ (35,937,275)
Common stock outstanding (weighted average)	150,730,191	47,895,771	136,080,637	38,849,364
Basic and diluted net loss per share	$ (0.09)	$ (0.36)	$ (0.20)	$ (0.93)

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

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

	As of March 31,	
	2021	2020
Performance-based stock units	2,470	2,470
Stock options	12,010,781	2,218,551
Common stock warrants	5,129,460	6,463,338

Recently issued and adopted accounting pronouncements

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820)*: *Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"), which removes and modifies some existing disclosure requirements and adds others. ASU 2018-13 modifies the disclosure requirements for fair value measurements and removes the requirement to disclose (1) the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, (2) the policy for timing of transfers between levels, and (3) the valuation processes for Level 3 fair value measurements. ASU 2018-13 requires disclosure of changes in unrealized gains and losses for the period included in other comprehensive income (loss) for recurring Level 3 fair value measurements held at the end of the reporting period and the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. The Company adopted ASU 2018-13 on October 1, 2020 and the adoption of this standard did not have a material impact to the Company's financial statements.

4. Fair Value Measurements

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

- Level 1 - Quoted prices in active markets for identical assets or liabilities.
- Level 2 - Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The asset's or liability's fair value measurement level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. Valuation techniques used need to maximize the use of observable inputs and minimize the use of unobservable inputs.

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

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

	March 31, 2021		
	(Level 1)	(Level 2)	(Level 3)
Liabilities			
Warrant liability	$ —	$ —	$ 404,916

	September 30, 2020		
	(Level 1)	(Level 2)	(Level 3)
Liabilities			
Warrant liability	$ —	$ —	$ 70,772

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 redemption feature for the six months ended March 31, 2021:

	Warrants
Balance at October 1, 2020	$ 70,772
Change in fair value	334,144
Balance at March 31, 2021	$ 404,916

The warrants issued in connection with the convertible senior secured notes (see Note 8) 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:

	March 31, 2021	September 30, 2020
Risk-free interest rate	0.60 %	0.24 %
Remaining contractual life of warrant	3.9 years	4.4 years
Expected volatility	98.8 %	94.7 %
Annual dividend yield	— %	— %
Fair value of common stock	$ 2.25 per share	$ 0.72 per share

Fair Value of Other Financial Instruments

The fair value and carrying value of the PPP loan included in long-term debt on the consolidated balance sheets on March 31, 2021, was $868,000 and $904,200, respectively. The fair value and carrying value of the unsecured promissory note included in long-term debt on the consolidated balance sheets on March 31, 2021, was $10,546,000 and $10,383,996, respectively. The estimated fair values were based on discounted expected future cash flows using prevailing interest rates that are Level 3 inputs under the fair value hierarchy.

5. Property and Equipment, Net

Property and equipment, net, consists of:

	March 31, 2021	September 30, 2020
Laboratory equipment	$ 1,067,351	$ 1,067,351
Less: accumulated depreciation and amortization	(821,914)	(740,102)
	$ 245,437	$ 327,249

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Depreciation expense was $40,906 and $63,775 for the three months ended March 31, 2021 and 2020, respectively and $81,812 and $127,551 for the six months ended March 31, 2021 and 2020, respectively.

6. Other Assets

Other assets consist of:

	March 31, 2021	September 30, 2020
Investment in PRC joint venture	$ 900,000	$ 900,000
Other assets	173,536	394,448
	$ 1,073,536	$ 1,294,448

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, Syntone Biopharma Ltd, that will be 80% owned by Syntone PRC and 20% owned by the Company. Upon formation of the PRC joint venture in April 2021, the Company 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.

The Company made the initial investment of $900,000 in June 2020. The Company expects to be required to make an additional capital contribution to the PRC joint venture of approximately $2.1 million, 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.

7. Accrued Expenses

Accrued expenses consists of:

	March 31, 2021	September 30, 2020
Compensation	$ 854,263	$ 579,618
Severance and related costs	—	9,521
Research and development	3,167,136	2,890,333
Interest payable	8,175	3,691
Professional fees	326,335	132,085
Lease termination obligation	—	3,971,111
Other accrued expenses	141,300	170,951
	$ 4,497,209	$ 7,757,310

8. Debt

Debt consists of:

	March 31, 2021	September 30, 2020
Unsecured promissory note	$ 10,535,601	$ —
Paycheck Protection Program term loan	904,200	904,200
Equipment loans	25,709	50,285
Total debt	11,465,510	954,485
Less: unamortized loan costs	(151,605)	—
Total debt, net of unamortized loan costs	11,313,905	954,485
Less: current portion	(11,184,734)	(50,285)
Long-term debt	$ 129,171	$ 904,200

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Unsecured promissory note

On November 5, 2020, the Company received $10.0 million in net proceeds from issuance of an unsecured promissory note with face amount of $10.2 million. Debt issuance costs totaling $228,032 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 14-month term of the underlying debt using the effective interest method. The note bears interest at a rate of 7.5% per annum and matures 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. During the three and six months ended March 31, 2021, the Company recognized $242,819, and $392,028, respectively, of interest expense related to the unsecured promissory note.

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 is required 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 and six months ended March 31, 2021 was $2,205, and $4,484, respectively.

Senior secured notes

In December 2019, the Company entered into an exchange agreement with the holders of its $7,254,077 outstanding aggregate principal amount and accrued interest of senior secured notes (the “Old Senior Notes”) originally issued pursuant to the certain Note and Warrant Purchase Agreement dated December 22, 2017, as amended on April 13, 2017, November 5, 2018, and June 28, 2019 (the “Exchange Agreement”). Pursuant to the Exchange Agreement, the holders of the Old Senior Notes exchanged the entire outstanding principal and accrued interest for new senior secured notes having an aggregate outstanding original principal amount of $7,589,027 which included an aggregate exchange fee of $334,950.

The new senior secured notes were substantially similar to the Old Senior Notes, as amended through the date of the Exchange Agreement, bore interest at a rate of 12.0% per annum and would have matured December 31, 2020 (subject to extension to June 30, 2021 at the Company’s option upon payment of an extension fee equal to 3% of the outstanding balance and being in compliance with applicable Nasdaq listing requirements). The new senior secured notes were convertible, at the option of the holder, beginning April 1, 2020, into shares of the Company’s common stock at a conversion price equal to 90% of the two lowest closing bid prices in the 20 trading days immediately preceding such conversion, subject to a floor price of $0.232 per share. The conversion feature was determined to be a redemption feature and was bifurcated from the debt instrument. The estimated fair value of the redemption feature was $8,264,451 at issuance. The Exchange Agreement was accounted for as an extinguishment of debt. The Company recognized a loss on extinguishment of convertible senior secured notes for the Exchange Agreement during the three months ended December 31, 2019 of $8,060,580, which amount was equal to the excess fair value of the notes and bifurcated redemption feature over the notes’ net carrying value.

The fair value of the redemption feature was estimated by using a Monte Carlo simulation model and a with-and-without perspective, where the fair value of debt instrument was measured with the derivative and without the derivative and the difference is the implied fair value of the redemption feature. The value of the debt instrument with the redemption feature depended on the daily stock price path followed by the Company’s common stock price. This model simulated daily common stock prices from the issuance date through the maturity date for the debt instrument. At issuance, the Company utilized a volatility estimate of 130% based upon the observed historical volatility of both the Company and peer group for 1-year and 2-year periods. Risk-free interest rate was based upon US treasury yields.

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During the year ended September 30, 2020, the holder of the new senior secured notes converted the entire outstanding principal and accrued interest and as of September 30, 2020, there were no longer any new senior secured notes outstanding.

Aggregate interest expense on the Old Senior Notes and the new senior secured notes for the three and six months ended March 31, 2020 was $348,541, and $550,062, respectively.

Unsecured notes

On March 7, 2019, the Company entered into a forbearance and exchange agreement with Iliad Research and Trading, L.P., a Utah limited partnership (the "Lender"). Concurrently with the execution of this agreement, the Lender purchased two stockholder notes issued by the Company previously in the original principal amount of $1,000,000 with an aggregate outstanding balance as of March 7, 2019 of $1,947,133, including accrued interest. The stockholder notes were accruing interest at the rate of 2.5% per month. The Lender agreed to refrain and forbear from bringing any action to collect under the stockholder notes until March 7, 2020 and to reduce the interest rates currently in effect to 12.0% per annum simple interest during such forbearance period. The Company also agreed to, at Lender's election, repay or exchange the stockholder notes (or portions thereof) for shares of the Company's common stock at an exchange rate of $13.44 per share or, beginning September 2019, at 95% of the average of the two lowest closing bid prices in the prior twenty trading days, as applicable.

During the three months ended December 31, 2019, the remaining unsecured notes with an aggregate carrying amount of $977,966 and accrued interest of $570,460 were exchanged for 1,475,258 shares of the Company's common stock at an average exchange price of $1.10. As of December 31, 2019, these unsecured notes were no longer outstanding. During the six months ended March 31, 2020, the Company recognized $12,997 of interest expense related to the unsecured notes. No interest expense related to the unsecured notes was recognized during the three months ended March 31, 2020.

Stockholder notes

	March 31, 2021	September 30, 2020
Restricted stock repurchase notes	$ —	$ 800,000
Common stock repurchase note	—	2,812,500
	—	3,612,500
Less: current portion	—	(3,612,500)
	$ —	$ —

The Company previously repurchased shares of its restricted stock in exchange for notes in the amount of $800,000 that did not bear interest and were due on demand. These notes were paid in full in November 2020.

The Company had a $2,812,500 note payable related to the previous repurchase of common stock that did not bear interest and was due on demand. This note was paid in full in November 2020.

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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 recorded in accounts payable at March 31, 2021, and paid in April 2021; and an additional payment of $750,000, which is contingent upon the occurrence of certain future events.

Leases

Corporate office and warehouse leases

In March 2021, the Company assigned its Monmouth Junction, New Jersey corporate office lease to a third party and as of March 31, 2021, did not have remaining future obligations. Upon assignment, the Company recognized a gain of $10,250. 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. The future minimum lease payments for the new lease total $135,535.

On May 6, 2020, the Company terminated its lease agreement for approximately 66,000 square feet of office, manufacturing and laboratory space located in Cranbury, New Jersey, which previously served as its headquarters, and relocated its corporate office to Monmouth Junction, New Jersey, a site previously used as a warehouse location. The Company’s Monmouth Junction, New Jersey lease matures in September 2021. In consideration for the termination of the Cranbury lease, the Company agreed to make payments to the landlord totaling $981,987, payable in eight monthly installments commencing May 1, 2020. In November 2020 the remaining portion of the liability was paid in full. On September 30, 2020, the lease termination obligation was included in accounts payable on the consolidated balance sheet.

A rollforward of the charges incurred to general and administrative expense for the six months ended March 31, 2021 is as follows:

	Balance October 1, 2020	Expensed / Accrued Expense	Cash Payments	Non-cash Adjustments	Balance March 31, 2021
Lease termination payments	$ 356,987	$ —	$ (356,987)	$ —	$ —

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

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

	Three months ended March 31, 2021	Three months ended March 31, 2020	Six months ended March 31, 2021	Six months ended March 31, 2020
Finance lease cost:				
Amortization of right-of-use assets	$ —	$ 75,000	$ —	$ 150,000
Interest on lease liabilities	1,005	361,033	2,787	733,256
Total finance lease cost	1,005	436,033	2,787	883,256
Operating lease cost	43,625	43,625	87,250	87,250
Total lease cost	$ 44,630	$ 479,658	$ 90,037	$ 970,506

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

	March 31, 2021	September 30, 2020
Operating leases:		
Right-of-use asset	$ —	$ 166,986
Operating lease liabilities	—	187,486
Finance leases:		
Right-of-use asset	$ —	$ —
Financing lease liabilities	55,727	72,260
Weighted-average remaining lease term (years):		
Operating leases	—	1.0
Finance leases	2.2	2.4
Weighted-average discount rate:		
Operating leases	—	9.0%
Finance leases	9.0%	8.5%

Other information related to leases for the six months ended March 31, 2021 are as follows:

	Six months ended March 31, 2021	Six months ended March 31, 2020
Cash paid for amounts included in the measurement of lease obligations:		
Operating cash flows from finance leases	$ 2,787	$ 713,364
Operating cash flows from operating leases	97,500	93,750
Financing cash flows from finance leases	16,533	178,757
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	$ —	$ —
Finance leases	—	—

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

	Finance leases
2021 (remaining six months)	15,551
2022	29,605
2023	13,149
2024	4,383
Total undiscounted lease payments	$ 62,688
Less: Imputed interest	6,961
Total lease obligations	$ 55,727

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Office and laboratory lease termination obligation

In August 2018, the Company entered into a lease termination agreement effective September 1, 2018, to terminate the lease for unutilized office and laboratory space in Cranbury, New Jersey. In consideration for the termination of the lease, the Company agreed to make payments to the landlord totaling up to $5.8 million, which included (i) $287,615 upon execution of the termination agreement, (ii) $50,000 per month for up to 30 months, commencing September 1, 2018, and (iii) a $4.0 million payment, in any event, on or before February 1, 2021. The Company and landlord agreed that the $174,250 security deposit will be used to pay the 7th, 8th, 9th and a portion of the 10th monthly payments. In November 2020, the Company fully settled the remaining lease termination payments for a one-time cash payment of $3,250,000 and $190,336 security deposit from the terminated Cranbury, New Jersey corporate office lease. Upon settlement, the Company recognized a gain of $542,090 in general and administrative expenses which represented the difference between the carrying value of the liability at the time of settlement and the settlement amounts.

A roll forward of the charges incurred to general and administrative expense for the six months ended March 31, 2021 is as follows:

	Balance October 1, 2020	Expensed / Accrued Expense	Cash Payments	Non-cash Adjustments	Balance March 31, 2021
Lease termination payments	$ 3,971,111	$ 111,315	$ (3,540,336)	$ (542,090)	$ —

10. Common Stock, Convertible Preferred Stock and Stockholders' Equity (Deficit)

Common stock

In February 2021, the Company issued in an underwritten public offering, including partial exercise of the underwriters' overallotment option, an aggregate of 38,593,767 shares of common stock at a purchase price per share of $1.00 for $36.0 million 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 8,360,000 shares of common stock in the public offering at the public offering price per share. In a separate concurrent private placement, the Company issued 3,000,000 shares of common stock to Syntone Ventures at a purchase price of $1.00 per share for aggregate gross proceeds of $3.0 million.

Following partial exercise of the underwriters' overallotment option subsequent to the initial closing, and pursuant to the Investor Rights Agreement dated as of September 11, 2017 and as amended, by and among the Company, BioLexis and GMS Ventures, the Company sold an additional 1,013,627 shares of common stock to GMS Ventures in a private placement for aggregate gross proceeds to the Company of $1.0 million at the public offering price per share of $1.00.

In connection with the underwritten public offering (including the partial exercise of the overallotment option) the Company issued the underwriter warrants to purchase up to an aggregate of 2,116,364 shares of common stock at an exercise price of $1.25 per share, which warrants have a 5-year term.

On March 24, 2021, following receipt of stockholder approval at the Company's 2021 annual meeting of stockholders, the number of authorized shares of common stock was increased from 200,000,000 shares to 325,000,000 shares.

In February 2020, the Company issued, in a registered direct offering, an aggregate of 7,598,426 shares of common stock and, in a concurrent private placement to the same investors, warrants to purchase up to an aggregate of 3,799,213 shares of common stock at a combined purchase price per share and accompanying warrant of $1.016 for approximately $6.7 million in net proceeds after payment of placement agent fees and other offering costs. In a separate concurrent private placement, the Company issued 2,460,630 shares of common stock and warrants to purchase up to an aggregate of 1,230,315 shares of common stock to GMS Ventures, at a combined purchase price per share and accompanying warrant

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of $1.016 for $2.5 million. The warrants issued were exercisable immediately at an exercise price of $0.9535 per share and will expire four years from the issuance date.

In connection with the registered direct offering and concurrent private placement of warrants to those investors, the Company issued placement agent warrants to purchase up to an aggregate of 531,890 shares of common stock, on substantially the same terms as the concurrent private placement warrants, at an exercise price of $1.27 per share and a 5-year term.

Effective March 19, 2020, following approval of the Company's stockholders, the Company issued an aggregate of 7,244,739 shares of its common stock to the four former principals (who include two of its named executive officers, Messrs. Dagnon and Evanson) of MTTR, LLC ("MTTR") pursuant to their respective consulting agreements that were entered into on January 27, 2020 concurrent with the termination agreement and mutual release with MTTR to terminate the strategic partnership agreement. Refer to Note 11 for the accounting of the restricted stock issued and Note 12 for further details on the terminated MTTR strategic partnership agreement.

During the six months ended March 31, 2020, the Company issued 109 shares of common stock, respectively, upon the vesting of RSUs.

Series A-1 convertible preferred stock

A total of 200,000 shares of Series A-1 Convertible Preferred Stock (the "Series A-1") were authorized for issuance under the Certificate of Designation of Series A-1 Convertible Preferred Stock of the Company (the "Certificate of Designation"). The shares of Series A-1 had a stated value of $100.00 per share, and ranked senior to all junior securities (as defined in the Certificate of Designation).

On March 23, 2020, the Company issued 29,358,621 shares of its common stock upon conversion of all 68,112 shares of Series A-1 outstanding by BioLexis, pursuant to an agreement entered on January 27, 2020 with BioLexis, whereby the effective conversion rate of the Series A-1 was increased from the $18.89797 per share to $431.03447263 per share, (or an effective conversion rate of $0.232 per share) following stockholder approval of the amended terms on March 19, 2020.

The amendment to the Series A-1 was deemed an extinguishment for accounting purposes. The excess fair value of common stock received over the net carrying value of the Series A-1 was $10,328,118 and reflected as a deemed dividend in the consolidated statements of operations for purposes of presenting net loss attributable to common stockholders when calculating basic and diluted loss per share. As of March 31, 2021 and September 30, 2020, there were no shares of Series A-1 outstanding.

The Series A-1 accrued dividends at a rate of 10% per annum, compounded quarterly, payable quarterly at the Company's option in cash or in kind in additional shares of Series A-1. During the six months ended March 31, 2020, the Company issued 1,661 shares of Series A-1 to settle the related dividends that were due on a quarterly basis.

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Common stock warrants

As of March 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		416,666	$ 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	$ 1.5188
January 28, 2026		2,116,364	$ 1.2500
		5,129,460	

(i) The warrants were issued in connection with the convertible senior secured notes (see Note 8) 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.

On December 23, 2019, the Company amended the terms of its outstanding 15-month warrants and five-year warrants issued April 12, 2019 (the “April 2019 Warrants”), which originally had an exercise price of $2.90 per share of the Company’s common stock. The exercise price of all outstanding April 2019 Warrants was reduced to $0.2320 per share and the exercise period was amended such that all April 2019 Warrants expire on December 24, 2019. Immediately prior to expiration, all then unexercised April 2019 Warrants were automatically net exercised pursuant to the amended provisions.

The estimated change in fair value of warrants amended during the three and six months ended March 31, 2020 was $1,431,406 and $3,140,009, respectively, and reflected as a deemed dividend in the consolidated statements of operations for purposes of presenting net loss attributable to common stockholders when calculating basic and diluted loss per share.

During the six months ended March 31, 2021, warrants to purchase an aggregate of 3,641,507 shares of common stock with a weighted averaged exercise price of $0.9847 were exercised for aggregate gross proceeds to the Company of $3,585,809. In addition, warrants to purchase an aggregate of 397,251 shares of common stock with a weighted averaged exercise price of $1.51875 were exercised on a cashless basis.

During the six months ended March 31, 2020, warrants to purchase an aggregate of 15,085,240 shares of common stock with a weighted averaged exercise price of $0.232 were exercised for an aggregate 13,003,414 shares of the Company's common stock; and warrants to purchase an aggregate of 80,797 shares of common stock with a weighted averaged exercise price of $0.08 expired. In aggregate, 10,157,050 of the exercised warrants were April 2019 Warrants, described above, exercised pursuant to the net exercise provisions therein, as amended.

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

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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 March 31, 2021, PSUs representing 2,470 shares of the Company's common stock were outstanding under the 2011 Plan. In light of 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 March 31, 2021, 15,657,586 shares remained available for grant under the 2015 Plan.

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

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

	Three months ended March 31,		Six months ended March 31,	
	2021	2020	2021	2020
Research and development	$ 228,240	$ 41,148	$ 468,211	$ 148,938
General and administrative	901,507	263,391	1,816,177	515,078
	$ 1,129,747	$ 304,539	$ 2,284,388	$ 664,016

Stock options

As of March 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, 2020	3,762,143	$ 2.01		
Granted	8,361,645	0.74		
Forfeited or expired	(113,007)	0.73		
Balance at March 31, 2021	12,010,781	1.14	9.3	$ 15,228,082
Vested and exercisable	1,726,016	1.93	8.8	$ 1,739,158
Vested and expected to vest at March 31, 2021	12,010,781	$ 1.14	9.3	

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

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The weighted average grant date fair value of the options awarded to employees for the six months ended March 31, 2021 and 2020 was $0.56 and $0.72 per option, respectively. The fair value of the options was estimated on the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions:

	Six months ended March 31,	
	2021	2020
Risk-free interest rate	0.39 %	1.13 %
Expected life (years)	6.01	5.71
Expected volatility	95.4 %	89.2 %
Expected dividend yield	—	—

As of March 31, 2021, there was $5,851,014 of unrecognized compensation expense that is expected to be recognized over a weighted-average period of 2.58 years.

Performance-based stock units

The Company has issued PSUs, which generally have a ten-year life 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 March 31, 2021:

	Number of PSUs	Base Price Per PSU	Weighted Average Remaining Contractual Term (Years)
Balance at October 1, 2020	2,470	$ 49.97	
Forfeitures	—	—	
Balance at March 31, 2021	2,470	49.97	3.8
Vested and exercisable at March 31, 2021	2,470	49.97	3.8
Vested and expected to vest at March 31, 2021	2,470	$ 49.97	3.8

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 2 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 March 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 and six months ended March 31, 2021, the Company recognized compensation expense related to the restricted stock of $151,764 and $303,529, respectively. During the three and six months ended March 31, 2020, the Company recognized compensation expense related to the restricted stock of $78,984. As of March 31, 2021, there was $2,307,477 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. Mr. Dagnon and Mr. Evanson have also agreed to provide consulting services to an affiliate of BioLexis pursuant to a separate arrangement.

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

Concurrently, the Company also entered into consulting agreements directly with each of the four principals of MTTR setting forth the terms of his respective compensation arrangement, as well as providing for certain transfer restrictions and repurchase rights applicable to the shares of common stock to be issued pursuant hereto. The termination agreement, and the consulting agreements, became effective upon stockholder approval of the share issuance on March 19, 2020. Refer to Note 11 for the accounting of the restricted stock issued and compensation expense recognized.

During the three months ended March 2021 and 2020, MTTR and its four principals under the strategic partnership agreement and the subsequent individual consulting agreements earned an aggregate $73,572 and $169,347, respectively; and $541,225 and $780,911 during the six months ended March 31, 2021 and 2020, respectively, which includes monthly consulting fees and expense reimbursement, but excludes stock-based compensation related to restricted stock (Note 11). As of March 31, 2021, and September 30, 2020 an aggregate $90,476 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.

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, 2020 and 2019 included in our Annual Report on Form 10-K for the year ended September 30, 2020, filed with the Securities and Exchange Commission, or SEC, on December 23, 2020, as amended January 28, 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 difference include, but are not limited to, those discussed under the caption "Risk Factors" in our Annual Report on Form 10-K for the year ended September 30, 2020, filed with the SEC on December 23, 2020, and as amended January 28, 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 late clinical-stage biopharmaceutical company working to develop 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 or through a strategic partner as the first and only approved bevacizumab in the United States, United Kingdom, Europe, Japan and other markets for the treatment of wet age-related macular degeneration, or wet AMD, diabetic macular edema, or DME, and branch retinal vein occlusion, or BRVO.

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 to ranibizumab (LUCENTIS) that completed enrollment in July 2020. Topline results are expected in the third calendar quarter of 2021. 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 Biologics License Application, or BLA, filing with the FDA. In March 2021 we reported that the results 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 either been completed or are fully enrolled.

In addition, we have received agreements 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. 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 to evaluate ONS-5010 to treat DME. We intend to initiate these studies in 2021 after the completion of NORSE TWO.

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. Off-label use of unapproved bevacizumab is currently estimated to account for at least 50% of all wet AMD treatments in the United States each year. If the ONS-5010 clinical program is successful, it will support our plans to submit for regulatory approval in multiple markets including the United States, United Kingdom, Europe and Japan, as well as 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.

Going Concern

Through March 31, 2021, we have funded substantially all of our operations with $331.9 million in proceeds from the sale and issuance of our equity and debt securities. We have also received $29.0 million pursuant to our previous collaboration and licensing agreements.

In February 2021, we closed an underwritten public offering of our common stock for net proceeds of $36.0 million. We also entered into a securities purchase agreement with Syntone Ventures LLC, or Syntone Ventures, for the sale of an additional $3.0 million of shares which concurrent private placement closed in February 2021. Following partial exercise of the underwriters' overallotment option, in a separate concurrent private placement, we entered into a securities purchase agreement with GMS Ventures and Investments, or GMS Ventures, an affiliate of BioLexis Pte. Ltd., our largest stockholder, for additional proceeds of $1.0 million.

In February 2021, warrants to purchase an aggregate of 3,641,507 shares of common stock with a weighted averaged exercise price of $0.9847 were exercised for aggregate gross proceeds of $3.6 million.

Our current cash resources of $37.2 million as of March 31, 2021, are expected to fund our operations through November 2021. 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 six months ended March 31, 2021 was $27.6 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 March 31, 2021, we had substantial indebtedness that included $10.5 million of principal and accrued interest under an unsecured promissory note maturing on January 1, 2022, and $0.9 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 March 2020 in patient enrollment and recruitment in NORSE TWO 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 have completed enrollment and NORSE ONE and NORSE THREE have also completed patient follow-up activities. NORSE TWO patients continue to require monthly follow-up visits, which will continue over the next three months. To date, we have not experienced any significant COVID-19 disruptions to patient follow-up but the clinical trial protocol accounts 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 NORSE TWO experiences 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 shelter-in-place rules 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 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, 2020 that we filed with the SEC on December 23, 2020 and amended January 28, 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 joint venture agreement with Syntone Ventures’ People’s Republic of China, or PRC, based-affiliate, pursuant to which we agreed to form a PRC joint venture, Syntone Biopharma Ltd, that is 80% owned by Syntone Ventures’ 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 March 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 U.S. Food and Drug Administration, or 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.

Interest Expense

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

Loss on Extinguishment of Debt

Loss on extinguishment of debt consists of modifications to senior secured notes that are deemed to be substantially different from the existing notes and the exchange of senior secured notes for our shares of common stock.

Change in Fair Value of Redemption Feature

Change in fair value of the redemption feature reflects the change in the fair value of the embedded derivative contained in the senior secured notes issued in December 2019, as a result of the fact that such notes were convertible into a variable number of shares of our common stock and at a discount that is deemed to be substantial. This embedded derivative was recorded at fair value and was subject to re-measurement at each balance sheet date until our obligations under the senior secured notes were satisfied.

Change in Fair Value of Warrant Liability

Warrants to purchase our common stock that were issued in conjunction with the convertible senior secured notes originally issued December 2017 are classified as liabilities and recorded at fair value. The warrants are subject to re-measurement at each balance sheet date and we recognize any change in fair value in our statements of operations.

Income Taxes

Since inception, we have not recorded any U.S. federal or state income tax benefits (excluding the sale of New Jersey state net operating losses, or NOLs, and research and development, or R&D tax credits) for the net losses we have incurred in each year or on our earned R&D tax credits, due to our uncertainty of realizing a benefit from those items. As of September 30, 2020, we had federal and state NOL carryforwards of $236.5 million and $72.3 million, respectively, that will begin to expire in 2030 and 2038, respectively. As of September 30, 2020, 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, 2020, we also had federal research and development tax credit carryforwards of $6.6 million and $0.3 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 March 31, 2021 and 2020

	Three months ended March 31,		
	2021	2020	Change
Operating expenses:			
Research and development	$ 8,529,393	$ 4,383,214	$ 4,146,179
General and administrative	4,095,891	1,957,175	2,138,716
Impairment of property and equipment	—	423,328	(423,328)
	12,625,284	6,763,717	5,861,567
Loss from operations	(12,625,284)	(6,763,717)	(5,861,567)
Interest expense, net	250,409	696,151	(445,742)
Change in fair value of redemption feature	—	(1,759,037)	1,759,037
Change in fair value of warrant liability	228,828	(764)	229,592
Loss before income taxes	(13,104,521)	(5,700,067)	(7,404,454)
Income tax expense	2,000	—	2,000
Net loss	$ (13,106,521)	$ (5,700,067)	$ (7,406,454)

Research and Development Expenses

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

	Three months ended March 31,	
	2021	2020
ONS-5010 development	$ 7,440,604	$ 3,610,551
Compensation and related benefits	383,883	285,368
Stock-based compensation	228,240	41,148
Other research and development	476,666	446,147
Total research and development expenses	$ 8,529,393	$ 4,383,214

Research and development expenses for the three months ended March 31, 2021 increased by $4.1 million compared to the three months ended March 31, 2020. The increase was primarily driven by an increase in ONS-5010 development costs of $3.8 million as we initiated enrollment and completed our NORSE THREE clinical trial in fiscal 2021, and continued the necessary process characterization and manufacturing scale up activities with external partners to support our planned BLA filing for wet AMD.

General and Administrative Expenses

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

	Three months ended March 31,	
	2021	2020
Professional fees	$ 1,531,809	$ 768,785
Compensation and related benefits	263,901	(74,257)
Stock-based compensation	901,507	263,391
Facilities, fees and other related costs	1,398,674	999,256
Total general and administrative expenses	$ 4,095,891	$ 1,957,175

General and administrative expenses for the three months ended March 31, 2021 increased by $2.1 million compared to the three months ended March 31, 2020. The increase was primarily due to a $1.0 million increase in compensation and related benefits, including stock-based compensation, due to stock options granted in fiscal 2021 to employees and directors, combined with a reversal of previously accrued compensation cost in the prior year period, a $0.8 million increase in professional fees, primarily related to licensing efforts for ONS-5010 during the period, and $0.6 million in litigation settlement related costs included in facilities, fees and other costs.

Impairment of Property and Equipment

During the three months ended March 31, 2020, we recorded an impairment charge of $0.4 million primarily due to the write-off of assets held for sale after we determined that the carrying amount of these assets was not recoverable as result of the May 2020 termination of our remaining lease for office, manufacturing and laboratory space in Cranbury, New Jersey and relocation of our corporate headquarters to our former warehouse space in Monmouth Junction, New Jersey.

Change in Fair Value of Warrant Liability

During the three months ended March 31, 2021, we recorded a loss of $0.2 million related to an increase in the fair value of our common stock warrant liability associated with the warrants issued in connection with the senior secured notes originally issued December 2017 which resulted from an increase in the price of our common stock.

During the three months ended March 31, 2020, the change in fair value of our common stock warrant liability associated with the warrants issued in connection with the senior secured notes originally issued December 2017 was immaterial.

Interest Expense

Interest expense decreased by $0.4 million to $0.3 million for the three months ended March 31, 2021 as compared to $0.7 million for the three months ended March 31, 2020. The decrease was primarily due to termination of the finance lease for our former corporate offices in Cranbury, New Jersey and the reduction of outstanding principal amount of notes and other indebtedness due to exchanges of such indebtedness for shares of our common stock in 2020.

Comparison of Six Months Ended March 31, 2021 and 2020

	Six months ended March 31,		
	2021	2020	Change
Operating expenses:			
Research and development	$ 20,477,974	$ 10,230,516	$ 10,247,458
General and administrative	6,338,245	4,293,899	2,044,346
Impairment of property and equipment	—	423,328	(423,328)
	26,816,219	14,947,743	11,868,476
Loss from operations	(26,816,219)	(14,947,743)	(11,868,476)
Interest expense, net	410,072	1,293,816	(883,744)
Loss on extinguishment of debt	—	8,060,580	(8,060,580)
Change in fair value of redemption feature	—	(1,796,982)	1,796,982
Change in fair value of warrant liability	334,144	(202,142)	536,286
Loss before income taxes	(27,560,435)	(22,303,015)	(5,257,420)
Income tax expense	2,000	—	2,000
Net loss	$ (27,562,435)	$ (22,303,015)	$ (5,259,420)

Research and Development Expenses

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

	Six months ended March 31,	
	2021	2020
ONS-5010 development	$ 18,223,935	$ 8,372,766
Compensation and related benefits	753,735	692,671
Stock-based compensation	468,211	148,938
Other research and development	1,032,093	1,016,141
Total research and development expenses	$ 20,477,974	$ 10,230,516

Research and development expenses for the six months ended March 31, 2021 increased by $10.2 million compared to the six months ended March 31, 2020. The increase was primarily driven by an increase in ONS-5010 development costs of $9.9 million as we initiated enrollment and completed our NORSE THREE clinical trial in fiscal 2021, and continued the necessary process characterization and manufacturing scale up activities with external partners to support our planned BLA filing for wet AMD.

General and Administrative Expenses

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

	Six months ended March 31,	
	2021	2020
Professional fees	$ 2,945,133	$ 1,720,233
Compensation and related benefits	558,631	354,068
Stock-based compensation	1,816,177	515,078
Facilities, fees and other related costs	1,018,304	1,704,520
Total general and administrative expenses	$ 6,338,245	$ 4,293,899

General and administrative expenses for the six months ended March 31, 2021 increased by $2.0 million compared to the six months ended March 31, 2020. The increase was due to a $1.3 million increase in stock-based compensation due to stock options granted in fiscal 2021 to employees and directors, a $1.2 million increase in professional fees, which was

primarily related to licensing efforts for ONS-5010 during the period, and $0.6 million in litigation settlement related costs included in facilities, fees and other costs, which increases were partially offset by decreased rent expenses of $0.5 million and a $0.6 million gain recorded from a settlement of a lease termination obligation associated with our terminated lease for an unutilized office and laboratory space in Cranbury, New Jersey.

Interest Expense

Interest expense decreased by $0.9 million to $0.4 million for the six months ended March 31, 2021 as compared to $1.3 million for the six months ended March 31, 2020. The decrease was primarily due to the termination of the finance lease for our former corporate offices in Cranbury, New Jersey and the reduction of outstanding principal amount of notes and other indebtedness due to exchanges of such indebtedness for shares of our common stock in 2020.

Debt Extinguishment

During the six months ended March 31, 2020, we recorded a loss on extinguishment of $8.1 million in connection with the exchange of our old senior secured notes for new senior secured notes in December 2019. The new senior secured notes were considered substantially different from the old notes, as such they qualified for extinguishment accounting.

Change in Fair Value of Warrant Liability

During the six months ended March 31, 2021, we recorded a loss of $0.3 million related to an increase in the fair value of our common stock warrant liability associated with the warrants issued in connection with the senior secured notes originally issued December 2017 which resulted from an increase in the price of our common stock.

During the six months ended March 31, 2020, we recorded a gain of $0.2 million related to the decrease in the fair value of our common stock warrant liability associated with the warrants issued in connection with the senior secured notes originally issued December 2017 which resulted from a decrease in the price of our common stock.

Liquidity and Capital Resources

We have not generated any revenue from product sales. Since inception, we have incurred net losses and negative cash flows from our operations. Through March 31, 2021, we have funded substantially all of our operations through the receipt of $331.9 million net proceeds from the 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.

In November 2020, we received $10.0 million in net proceeds from issuance of an unsecured promissory note with face amount of $10.2 million. The note bears interest at a rate of 7.5% per annum and matures January 1, 2022. 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 February 2021, we closed an underwritten public offering of our common stock for net proceeds of $36.0 million. We also entered into a securities purchase agreement with Syntone Ventures, for the sale of an additional $3.0 million of shares which concurrent private placement closed in February 2021. Following partial exercise of the underwriters' overallotment option, in a separate concurrent private placement, we issued an additional $1.0 million of shares of common stock to GMS Ventures at a purchase price of $1.00 per share.

In February 2021, warrants to purchase an aggregate of 3,641,507 shares of common stock with a weighted averaged exercise price of $0.9847 were exercised for aggregate gross proceeds of $3.6 million.

As of March 31, 2021, we had a cash balance of $37.2 million. In addition, we had substantial indebtedness that included $10.5 million of principal and accrued interest under an unsecured promissory note maturing on January 1, 2022, and a $0.9 million loan granted pursuant to the PPP of the CARES Act, which matures on May 2, 2022. These factors raise substantial doubt about our ability to continue as a going concern. Our 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. 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 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 can be no assurance that these future funding efforts will be successful. 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.

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 advancing ONS-5010 through clinical trials to support the filing of a BLA with 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, our clinical trials are not successful or 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 a licensing deal for ONS-5010 providing for sufficient funding of our expected 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 March 31, 2021 of $37.2 million is expected to fund our operations through November 2021. 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 will need to raise substantial additional capital in order to complete our planned ONS-5010 development 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:

	Six months ended March 31,	
	2021	**2020**
Net cash used in operating activities	$ (25,070,807)	$ (13,756,734)
Net cash provided by financing activities	49,703,675	10,394,129

Operating Activities.

During the six months ended March 31, 2021, we used $25.1 million of cash in operating activities resulting primarily from our net loss of $27.6 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, gain on settlement of lease termination obligation, and depreciation and amortization expense. The net cash outflow of $0.1 million from changes in our operating assets and liabilities was primarily to an increase in our accounts payable of $3.7 million primarily due to clinical trial costs and ONS 5010 development costs and a decrease in other assets of $0.1 million. These inflows were partially offset by a decrease in accrued expenses of $2.5 million primarily due to the settlement of lease termination obligation and payments to sites for accrued costs, $0.1 million of payments for operating leases, and an increase in prepaid expenses of $1.3 million for prepayments associated with our clinical trials and ONS 5010 development costs.

During the six months ended March 31, 2020, we used $13.8 million of cash in operating activities resulting primarily from our net loss of $22.3 million, This use of cash was partially offset by $7.6 million of non-cash items such as change in fair value of redemption feature, non-cash interest expense, stock-based compensation, change in fair value of warrant liability, loss on disposal of property and equipment, loss on extinguishment of debt and depreciation and amortization expense. The change in our operating assets and liabilities of $0.9 million was primarily to an increase in our accounts payable associated with our clinical trials and ONS 5010 development costs from September 30, 2019.

Financing Activities.

During the six months ended March 31, 2021, net cash provided by financing activities was $49.7 million, primarily attributable to $39.8 million in net proceeds from the registered direct offering and concurrent private placements in February 2021 for an aggregate of 42,607,394 shares of our common stock and accompanying 2,116,364 warrants to purchase shares of our common stock and $10.0 million in net proceeds from issuance of an unsecured promissory note with face amount of $10.2 million in November 2020. Additionally, we received $3.6 million in net proceeds from common stock warrants exercised. We also made $3.7 million in debt and finance lease obligations payments.

During the six months ended March 31, 2020, net cash provided by financing activities was $10.4 million, primarily attributable to $9.5 million in net proceeds from the registered direct offering and concurrent private placements in February 2020 for an aggregate of 10,059,056 shares of our common stock and accompanying 5,029,528 warrants to purchase shares of our common stock. During the six months ended March 31, 2020, we received $1.1 million in net proceeds from common stock warrants exercised. We also made $0.2 million in debt and capital lease obligations 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 $10,220,000 for $10,000,000 in cash proceeds. The unsecured note bears interest at a rate of 7.5% per annum compounding daily, matures January 1, 2022, and includes an original issue discount of $200,000, along with $20,000 for the noteholder's fees, costs and other transaction expenses incurred in connection with the purchase and sale of the note. 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.

While the unsecured note is 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 note provides that it is an event of default if we breach our negative covenants under the purchase agreement, undertake certain "Fundamental Transactions" (as defined therein), along with other customary events of default, in addition to providing for a default rate of 14%, and gives the noteholder the right to increase the outstanding balance by 5% in the event of default.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of March 31, 2021.

Contractual Obligations and Commitments

Not applicable.

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, 2020, filed with the SEC on December 23, 2020, as amended January 28, 2021, have not materially changed.

JOBS Act Accounting Election

The JOBS Act, permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

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 second fiscal quarter ended March 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

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

On July 20, 2020, Laboratorios Liomont S.A. de C.V., or Liomont, filed a complaint against us in the U.S. District Court of the Southern District of New York alleging certain breach of contract claims under our 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, we entered into a confidential settlement agreement with Liomont and the complaint was dismissed on April 11, 2021. See Note 9 to the unaudited condensed consolidated financials included elsewhere in this quarterly report on Form 10-Q for more information.

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	Form of underwriter warrant (incorporated by reference to Exhibit 4.1 to the Registrant's current report on Form 8-K filed with the SEC on February 2, 2021).
10.2	Securities Purchase Agreement, dated January 28, 2021, by and between the Company and Syntone Ventures LLC (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K filed with the SEC on February 2, 2021).
10.3	Securities Purchase Agreement, dated February 9, 2021, by and between the Company and GMS Ventures and Investments (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K filed with the SEC on February 11, 2021).
10.4	At The Market Offering Agreement between the Company and H.C. Wainwright & Co. dated March 26, 2021 (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K filed with the SEC on March 26, 2021).
31.1	Certification of Principal Executive Officer and 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

* 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: May 14, 2021

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

Exhibit 31.1

CERTIFICATIONS

I, Lawrence A. Kenyon, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Outlook Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: May 14, 2021

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

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Outlook Therapeutics, Inc. (the "Company") for the period ended March 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 14, 2021

By /s/ Lawrence A. Kenyon
Lawrence A. Kenyon
Chief Executive Officer and 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."