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, 2020
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.)**
4260 U.S. Route 1 Monmouth Junction, New Jersey	**08852**
(Address of principal executive offices)	**(Zip Code)**

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	OTLK	Nasdaq Stock Market LLC
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 13, 2020 was 91,377,648.

Outlook Therapeutics, Inc.
Table of Contents

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, 2019 filed with the SEC on December 19, 2019 and risks disclosed in Part II, Item 1A of this quarterly report, 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;
- 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;
- 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, and uncertainty regarding the overall effect that it may ultimately have on our clinical trials and otherwise. 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, 2020	September 30, 2019
Assets		
Current assets:		
Cash	$ 4,652,923	$ 8,015,528
Prepaid expenses and other current assets	4,833,089	4,986,033
Assets held for sale	—	500,000
Total current assets	9,486,012	13,501,561
Property and equipment, net	523,409	3,175,960
Operating lease right-of-use assets, net	244,600	—
Finance lease right-of-use assets, net	2,375,000	—
Other assets	540,834	457,476
Total assets	$ 13,169,855	$ 17,134,997
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Convertible senior secured notes	$ 7,185,993	$ 6,699,000
Current portion of long-term debt	49,364	1,026,168
Current portion of finance lease liabilities	52,851	192,290
Current portion of operating lease liabilities	175,853	—
Stockholder notes	3,612,500	3,612,500
Accounts payable	3,306,553	2,277,817
Accrued expenses	7,463,091	4,622,988
Income taxes payable	1,859,434	1,859,434
Total current liabilities	23,705,639	20,290,197
Long-term debt	25,709	50,285
Redemption feature	6,467,469	—
Finance lease liabilities	3,346,381	3,365,790
Operating lease liabilities	95,747	—
Warrant liability	53,592	255,734
Other liabilities	—	3,942,948
Total liabilities	33,694,537	27,904,954
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 at March 31, 2020 and 66,451 shares issued and outstanding at September 30, 2019	—	5,359,404
Total convertible preferred stock	—	5,359,404
Stockholders' equity (deficit):		
Preferred stock, par value $0.01 per share: 7,300,000 shares authorized, no shares issued and outstanding	—	—
Series B convertible preferred stock, par value $0.01 per share: 1,500,000 shares authorized, no shares issued	—	—
Common stock, par value $0.01 per share; 200,000,000 shares authorized; 89,751,192 shares issued and outstanding at March 31, 2020 and 28,609,995 shares issued and outstanding at September 30, 2019	897,512	286,100
Additional paid-in capital	255,361,229	238,064,947
Accumulated deficit	(276,783,423)	(254,480,408)
Total stockholders' equity (deficit)	(20,524,682)	(16,129,361)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 13,169,855	$ 17,134,997

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,	
	2020	2019	2020	2019
Collaboration revenues	$ —	$ 641,140	$ —	$ 1,708,738
Operating expenses:				
Research and development	4,383,214	5,935,884	10,230,516	12,007,406
General and administrative	1,957,175	1,849,158	4,293,899	4,753,146
Impairment of property and equipment	423,328	561,735	423,328	2,911,138
	6,763,717	8,346,777	14,947,743	19,671,690
Loss from operations	(6,763,717)	(7,705,637)	(14,947,743)	(17,962,952)
Interest expense, net	696,151	1,053,877	1,293,816	2,174,726
Loss on extinguishment of debt	—	183,554	8,060,580	183,554
Change in fair value of redemption feature	(1,759,037)	—	(1,796,982)	—
Change in fair value of warrant liability	(764)	1,301,728	(202,142)	(334,592)
Net loss	(5,700,067)	(10,244,796)	(22,303,015)	(19,986,640)
Beneficial conversion feature upon issuance of Series A-1 convertible preferred stock	—	(61,365)	—	(61,365)
Series A-1 convertible preferred stock dividends and related settlement	—	(154,271)	(166,133)	(304,779)
Deemed dividend upon modification of warrants	(1,431,406)	(829,530)	(3,140,009)	(829,530)
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	$(17,459,591)	$(11,289,962)	$(35,937,275)	$(21,182,314)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.36)	$ (0.98)	$ (0.93)	$ (1.98)
Weighted average shares outstanding, basic and diluted	47,895,771	11,529,033	38,849,364	10,677,020

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		Stockholders' Equity (Deficit)				
	Series A-1		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
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
Issuance of restricted common stock to MTTR, LLC principals (Note 12)	—	—	7,244,739	72,447	(72,447)	—	—
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
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		Stockholders' Equity (Deficit)				
	Series A-1		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance at January 1, 2019	61,708	$4,884,924	10,636,421	$ 106,365	$ 203,237,836	$(229,698,465)	$(26,354,264)
Proceeds from exercise of common stock warrants	—	—	358	3	(3)	—	—
Private placement sale of common stock, net of costs	—	—	1,072,156	10,721	7,986,738	—	7,997,459
Issuance of vested restricted stock units	—	—	301	3	(3)	—	—
Issuance of common stock in connection with conversion of senior secured notes	—	—	50,394	504	401,464	—	401,968
Series A-1 convertible preferred stock dividends and related settlement	1,542	154,271	—	—	(154,271)	—	(154,271)
Stock-based compensation expense	—	—	—	—	267,742	—	267,742
Net loss	—	—	—	—	—	(10,244,796)	(10,244,796)
Balance at March 31, 2019	63,250	$5,039,195	11,759,630	$ 117,596	$ 211,739,503	$(239,943,261)	$(28,086,162)

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		Stockholders' Equity (Deficit)				
	Series A-1		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
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
Issuance of vested restricted stock units	—	—	109	1	(1)	—	—
Sale of common stock, net of issuance costs	—	—	10,059,056	100,591	9,096,357	—	9,196,948
Issuance of restricted common stock to MTTR, LLC principals (Note 12)	—	—	7,244,739	72,447	(72,447)	—	—
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
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)

	Convertible Preferred Stock		Stockholders' Equity (Deficit)				
	Series A-1		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance at October 1, 2018	60,203	$4,734,416	9,027,491	$ 90,275	$ 190,672,166	$(216,307,363)	$(25,544,922)
Cumulative effect of adoption of ASU 2014-09 (Topic 606)	—	—	—	—	—	(3,649,258)	(3,649,258)
Proceeds from exercise of common stock warrants	—	—	909	9	(9)	—	—
Private placement sale of common stock, net of costs	—	—	2,680,390	26,804	19,781,513	—	19,808,317
Issuance of vested restricted stock units	—	—	446	4	(4)	—	—
Issuance of common stock in connection with conversion of senior secured notes	—	—	50,394	504	401,464	—	401,968
Series A-1 convertible preferred stock dividends and related settlement	3,047	304,779	—	—	(304,779)	—	(304,779)
Stock-based compensation expense	—	—	—	—	1,140,031	—	1,140,031
Accrued directors fees settled in fully vested stock options	—	—	—	—	49,121	—	49,121
Net loss	—	—	—	—	—	(19,986,640)	(19,986,640)
Balance at March 31, 2019	63,250	$5,039,195	11,759,630	$ 117,596	$ 211,739,503	$(239,943,261)	$(28,086,162)

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,	
	2020	**2019**
OPERATING ACTIVITIES		
Net loss	$ (22,303,015)	$ (19,986,640)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	351,623	1,639,618
Loss on extinguishment of debt	8,060,580	183,554
Non-cash interest expense	135,787	895,255
Stock-based compensation	664,016	1,140,031
Change in fair value of redemption feature	(1,796,982)	—
Change in fair value of warrant liability	(202,142)	(334,592)
Impairment of property and equipment	423,328	2,911,138
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	229,616	(71,433)
Other assets	(83,358)	42,527
Operating lease liability	(80,572)	—
Accounts payable	1,028,736	233,164
Accrued expenses	(233,806)	(778,391)
Deferred revenue	—	(1,693,738)
Other liabilities	49,455	(221,287)
Net cash used in operating activities	(13,756,734)	(16,040,794)
INVESTING ACTIVITIES		
Purchase of property and equipment	—	(286,569)
Net cash used in investing activities	—	(286,569)
FINANCING ACTIVITIES		
Proceeds from the sale of common stock, net of offering costs	9,457,400	19,808,317
Proceeds from exercise of common stock warrants	1,138,900	—
Payments of finance lease obligations	(178,757)	(415,697)
Repayment of debt	(23,414)	(4,627,180)
Net cash provided by financing activities	10,394,129	14,765,440
Net decrease in cash	(3,362,605)	(1,561,923)
Cash at beginning of period	8,015,528	1,717,391
Cash at end of period	$ 4,652,923	$ 155,468
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 718,521	$ 1,681,746
Accrued interest settled by conversion into common stock	$ —	$ 1,393
Supplemental schedule of noncash investing activities:		
Purchases of property and equipment in accounts payable and accrued expenses	$ —	$ 1,095,266
Supplemental schedule of noncash financing activities:		
Carrying amount of senior secured notes converted into common stock	$ —	$ 400,575
Issuance of capital lease obligations in connection with purchase of property and equipment	$ —	$ 48,682
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	$ —
Change in fair value of convertible senior secured notes warrants recorded as debt discount	$ —	$ 1,466,710
Series A-1 convertible preferred stock dividends and related settlement	$ 166,133	$ 304,779
Deferred offering costs and common stock issuance costs in accounts payable and accrued expenses	$ 260,452	$ 74,975
Accrued directors' fees settled in fully vested stock options	$ —	$ 49,121

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, and 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 Monmouth Junction, 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 both NORSE 1 and NORSE 2, the Company's two clinical trials under its Phase 3 program for ONS-5010.

The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19. Management believes the financial results for the three months ended March 31, 2020 were not significantly impacted by COVID-19.

2. Liquidity

The Company has incurred substantial losses and negative cash flows from operations since its inception and has a stockholders' deficit of $20.5 million as of March 31, 2020. As of March 31, 2020, the Company had substantial indebtedness that included $7.8 million outstanding aggregate principal amount and accrued interest of convertible senior secured notes that mature on December 31, 2020 and $3.6 million unsecured notes that were due on demand as of such date. 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.

On December 11, 2019, the Company received approval from the New Jersey Economic Development Authority's Technology Business Tax Certificate Transfer Program to sell approximately $3.6 million of its unused New Jersey net operating losses ("NOLs") and research and development tax credits ("R&D credits"). The Company received approximately $3.3 million of proceeds from the sale of the New Jersey NOLs and R&D credits in May 2020.

Commencing in April 2020, following receipt of necessary stockholder approval, the holder of the convertible senior secured notes began exchanging the outstanding principal and accrued interest from those notes for the Company's common stock per the terms of the notes. The holder exchanged $831,932 of principal and accrued interest for an aggregate 1,626,456 shares of the Company's common stock between April 1, 2020 and May 13, 2020.

On May 4, 2020, the Company received $0.9 million in proceeds from a loan granted pursuant to the Paycheck Protection Program (the "PPP") of the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act").

Management believes that the Company's existing cash as of March 31, 2020, the $3.3 million of proceeds from the sale of New Jersey NOLs and R&D credits, and the $0.9 million proceeds from a loan granted pursuant to the PPP received in May 2020 will be sufficient to fund its operations through August 2020, excluding any repayment of debt. Substantial additional financing will be needed by the Company to fund its operations in the future and to commercially develop its 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: payments from potential strategic research and development partners, licensing and/or marketing arrangements with pharmaceutical companies, private placements of equity and/or

debt securities, sale of its development stage product candidates to third parties and public offerings of equity and/or debt securities. 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.

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, 2020 and its results of operations for the three and six months ended March 31, 2020 and 2019, cash flows for the six months ended March 31, 2020 and 2019, and convertible preferred stock and stockholders' equity for the three and six months ended March 31, 2020 and 2019. Operating results for the three and six months ended March 31, 2020 are not necessarily indicative of the results that may be expected for the full year ending September 30, 2020. 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, 2019 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on December 19, 2019.

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.

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

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,	
	2020	2019	2020	2019
Net loss attributable to common stockholders	$ (17,459,591)	$ (11,289,962)	$(35,937,275)	$(21,182,314)
Common stock outstanding (weighted average)	47,895,771	11,529,033	38,849,364	10,677,020
Basic and diluted net loss per share	$ (0.36)	$ (0.98)	$ (0.93)	$ (1.98)

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, 2020 and 2019, as they would be antidilutive:

	As of March 31,	
	2020	2019
Series A-1 convertible preferred stock	—	1,195,295
Convertible senior secured notes	—	957,482
Convertible unsecured notes	—	147,347
Performance-based stock units	2,470	16,131
Restricted stock units	—	7,156
Stock options	2,218,551	541,746
Common stock warrants	6,463,338	5,660,949

Recently issued and adopted accounting pronouncements

On October 1, 2019, the Company adopted ASU No. 2016-02, *Leases* (“ASC 842” or “ASU 2016-02”) issued by the FASB in February 2016 which was subsequently supplemented by clarifying guidance to improve financial reporting of leasing transactions. The new lease accounting guidance requires lessees to recognize lease liabilities and right-of-use assets on the balance sheet for all leases with initial terms longer than 12 months and provides enhanced disclosures on key information of leasing arrangements. The guidance allowed companies to apply the requirements retrospectively, either to all prior periods presented or through a cumulative adjustment in the year of adoption.

The Company adopted the new standard effective October 1, 2019 using the modified retrospective transition method using the package of practical expedients and a discount rate of 9% and elected to not apply the standard in the comparative periods presented in the year of adoption. The Company has implemented the internal controls to monitor and record historical and future lease arrangements and required disclosures. For all existing operating leases as of September 30, 2019, the Company recorded right of use assets of $352,172 and corresponding lease liabilities of $318,672 with an offset to other liabilities of $33,500 to eliminate deferred rent on the consolidated balance sheets. The Company recorded right of use assets of $2,525,000 and corresponding finance lease liabilities of $3,558,080 for leases previously classified as capital leases. This did not include an existing lease termination obligation of $3,909,448 pertaining to a lease for premises that had been leased in Cranbury, New Jersey for a planned office and laboratory expansion that did not materialize, and which prior termination remained unchanged as a result of the transition. Refer to Note 9 for the Company’s lease disclosures.

At lease commencement, the Company records a lease liability based on the present value of lease payments over the expected lease term including any options to extend the lease that the Company is reasonably certain to exercise. The Company calculates the present value of lease payments using an incremental borrowing rate as the Company’s leases do not provide an implicit interest rate. The Company’s incremental borrowing rate for a lease is the rate of interest it would have to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms. At the lease commencement date, the Company records a corresponding right-of-use lease asset based on the lease liability, adjusted for any lease incentives received and any initial direct costs paid to the lessor prior to the lease commencement date. The

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

Company may enter into leases with an initial term of 12 months or less (“Short-Term Leases”). For Short-Term Leases, the Company records the rent expense on a straight-line basis and does not record the leases on the consolidated balance sheet. The Company had no Short-Term Leases as of March 31, 2020.

After lease commencement, the Company measures its leases as follows: (i) the lease liability based on the present value of the remaining lease payments using the discount rate determined at lease commencement and (ii) the right-of-use lease asset based on the re-measured lease liability, adjusted for any unamortized lease incentives received, any unamortized initial direct costs and the cumulative difference between rent expense and amounts paid under the lease agreement. Any lease incentives received, and any initial direct costs are amortized on a straight-line basis over the expected lease term. Rent expense is recorded on a straight-line basis over the expected lease term.

The adoption of the new lease accounting standard did not have a material impact on the Company’s results of operations or cash flows.

On October 1, 2019, the Company adopted ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting Compensation*, issued by the FASB in June 2018. The amendments in this ASU expanded the scope of *Compensation—Stock Compensation* (“Topic 718”) to include share-based payment transactions for acquiring goods and services from nonemployees. The amendments specified that Topic 718 applied to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor’s own operations by issuing share-based payment awards. The Company applied the new guidance to share-based payments entered after October 1, 2019.

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 ASU is effective for all entities for fiscal years beginning after December 15, 2019, including interim periods therein. Early adoption is permitted for any eliminated or modified disclosures upon issuance of this ASU. The Company is currently evaluating the impact of the adoption of this standard.

Reclassifications

Certain reclassifications have been made to the prior year financial statements to conform to the current year presentation.

4. Fair Value Measurements

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

- Level 1 - Quoted prices in active markets for identical assets or liabilities.
- Level 2 - Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

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

- Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

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

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

	March 31, 2020		
	(Level 1)	(Level 2)	(Level 3)
Liabilities			
Redemption feature	$ —	$ —	$6,467,469
Warrant liability	—	—	53,592
	$ —	$ —	$6,521,061

	September 30, 2019		
	(Level 1)	(Level 2)	(Level 3)
Liabilities			
Redemption feature	$ —	$ —	$ —
Warrant liability	—	—	255,734
	$ —	$ —	$ 255,734

The Company evaluated a redemption feature within the senior secured notes issued in December 2019 and determined bifurcation of the redemption feature was required. The redemption feature is accounted for as a derivative instrument and re-measured at each reporting period until the redemption feature is exercised, expires, or otherwise settled.

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, 2020:

	Warrants	Redemption Feature
Balance at October 1, 2019	$ 255,734	$ —
Addition of feature on December 20, 2019	—	8,264,451
Change in fair value	(202,142)	(1,796,982)
Balance at March 31, 2020	$ 53,592	$ 6,467,469

The warrants issued in connection with the convertible senior secured notes (see Note 7) are classified as liabilities on the accompanying consolidated balance sheet 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, 2020	September 30, 2019
Risk-free interest rate	0.37 %	1.56 %
Remaining contractual life of warrant	4.88 years	5.38 years
Expected volatility	90.2 %	89.0 %
Annual dividend yield	0 %	0 %
Fair value of common stock	$ 0.60 per share	$ 1.49 per share

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

The fair value of the redemption feature is estimated by using a Monte Carlo simulation model and a with-and-without perspective, where the fair value of debt instrument is 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 depends on the daily stock price path followed by the Company's common stock price. This model simulates daily common stock prices from the issuance date thru 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.

5. Property and Equipment, Net

Property and equipment, net, consists of:

	March 31, 2020	September 30, 2019
Laboratory equipment	$1,067,351	$ 1,067,351
Leasehold improvements	160,086	160,086
Land and building	—	3,000,000
	1,227,437	4,227,437
Less: accumulated depreciation and amortization	(704,028)	(1,051,477)
	$ 523,409	$ 3,175,960

Depreciation and amortization expense was $63,775 and $816,541 for the three months ended March 31, 2020 and 2019, respectively and $127,551 and $1,639,618 for the six months ended March 31, 2020 and 2019, respectively.

On October 1, 2019, the Company adopted ASC 842, which resulted in the reclassification of property and equipment under capital leases to finance lease right-of-use assets separately disclosed on the consolidated balance sheets. Refer to Note 9 for the Company's lease disclosures.

At September 30, 2019, $3,000,000 represented the Company's corporate office lease that was classified as a capital lease. The Company's corporate office lease matures in February 2028 and the effective interest rate on the corporate office lease is 43.9%. At September 30, 2019, $475,000 of accumulated amortization related to capital leases.

Impairment charge

During the three and six months ended March 31, 2020, the Company recorded an impairment charge of $423,328 primarily due to the write-off of assets held for sale after the Company determined that the carrying amount of these assets was not recoverable as result of a lease termination agreement entered into in May 2020. Refer to Note 13 for further details.

During the three and six months ended March 31, 2019, the Company wrote off certain construction in progress and laboratory equipment with a carrying amount of $561,735 and $2,911,138, respectively. The Company determined that the carrying amount of these assets was not recoverable and was less than the fair value less the cost to sell due to the Company changing its operations to outsource the manufacturing of ONS-5010.

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

6. Accrued Expenses

Accrued expenses consists of:

	March 31, 2020	September 30, 2019
Compensation	$ 347,094	$ 919,394
Severance and related costs	121,357	505,570
Research and development	2,256,275	1,692,040
Interest payable	235,878	934,145
Professional fees	423,757	419,216
Lease termination obligation	3,938,994	—
Other accrued expenses	139,736	152,623
	$7,463,091	$ 4,622,988

7. Debt

Senior secured notes

	March 31, 2020	September 30, 2019
Convertible senior secured notes	$7,589,027	$ 6,699,000
Unamortized debt discount	(403,034)	—
	$7,185,993	$ 6,699,000

In December 2019, the Company entered into an exchange agreement with the holders of its approximately $7.3 million 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 $7.6 million, which includes an aggregate exchange fee of approximately $0.3 million.

The new senior secured notes are substantially similar to the Old Senior Notes, as amended through the date of the Exchange Agreement, bear interest at a rate of 12.0% per annum and will mature 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 are 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. In the event the conversion price is lower than the floor price for 20 consecutive trading days, the Company is required to make a cash redemption equal to $350,000 (provided that it shall not be required to make more than one redemption in any calendar month, nor shall a trading day where the conversion price is lower than the floor price be included in more than one 20-trading day period). 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 $8.3 million at issuance (see Note 4).

The Exchange Agreement was accounted for as an extinguishment of debt. Loss on extinguishment of convertible senior secured notes recognized during the six months ended March 31, 2020 was $8.1 million and equal to the excess fair value of the notes and bifurcated redemption feature over the notes' net carrying value.

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

Aggregate interest expense on the Old Senior Notes and the new senior secured notes for the three months ended March 31, 2020 and 2019 was $348,541 and $561,485, respectively, and $550,062 and $1,162,917 for the six months ended March 31, 2020 and 2019, respectively.

Stockholder notes

The Company previously repurchased shares of its restricted stock in exchange for notes in the amount of $800,000 that do not bear interest and are due on demand.

The Company has a $2,812,500 note payable related to the previous repurchase of common stock that does not bear interest and is due on demand.

8. Other Indebtedness

The Company has other outstanding debt consisting of equipment loans and unsecured notes.

	March 31, 2020	September 30, 2019
Unsecured notes	$ —	$ 977,966
Equipment loans	75,073	98,487
	75,073	1,076,453
Less: current portion	(49,364)	(1,026,168)
Long-term debt	$ 25,709	$ 50,285

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.

In September 2019, the Lender began exchanging the outstanding principal and accrued interest from those notes for the Company’s common stock per the terms of the March 2019 forbearance and exchange agreement. During the six months ended March 31, 2020, the remaining unsecured notes with a 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 a weighted average exchange price of $1.10. As of March 31, 2020, these unsecured notes were no longer outstanding.

During the three months ended March 31, 2019, the Company recognized interest expense related to the unsecured notes of $63,576 and $12,997 and $136,576 for the six months ended March 31, 2020 and 2019, respectively. No interest expense related to the unsecured notes was recognized during the three months ended March 31, 2020.

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

9. Leases

Corporate office and warehouse leases

At March 31, 2020, the Company had leases for its corporate office and a warehouse space in the State of New Jersey. The Company entered into a lease termination agreement for its corporate office lease on May 6, 2020. Refer to Note 13 for additional details on the corporate office lease termination and related accounting. The terminated corporate office lease had a maturity date in February 2028 with two five-year renewal options. The Company's warehouse lease matures in September 2021.

Equipment leases

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

Certain lease agreements contain provisions for future rent increases. Payments due under the lease contracts include minimum payments that the Company is obligated to make under the non-cancelable initial terms of the leases as the renewal terms are at the Company's option. Lease expense is included in research and development or general and administrative based on the use of the lease asset.

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

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

Amounts reported in the consolidated balance sheets for leases where the Company is the lessee as of March 31, 2020 were as follows:

	March 31, 2020
Operating leases:	
Right-of-use asset	$ 244,600
Operating lease liabilities	271,600
Finance leases:	
Right-of-use asset	$ 2,375,000
Financing lease liabilities	3,399,232
Weighted-average remaining lease term (years):	
Operating leases	1.6
Finance leases	7.7
Weighted-average discount rate:	
Operating leases	9.0%
Finance leases	43.0%

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

Other information related to leases for the six months ended March 31, 2020 are as follows:

	Six months ended March 31, 2020
Cash paid for amounts included in the measurement of lease obligations:	
Operating cash flows from finance leases	$ 713,364
Operating cash flows from operating leases	93,750
Financing cash flows from finance leases	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, 2020 are as follows for the years ending September 30:

	Operating leases	Finance leases
2020 (remaining six months)	$ 93,750	$ 746,636
2021	195,000	1,492,390
2022	—	1,535,809
2023	—	1,564,028
2024	—	1,597,371
Thereafter	—	5,753,515
Total undiscounted lease payments	$ 288,750	$ 12,689,749
Less: Imputed interest	17,150	9,290,517
Total lease obligations	$ 271,600	$ 3,399,232

Future minimum rental payments under non-cancelable leases prior to adoption of ASC 842, Leases, as of September 30, 2019 were as follows:

	Operating leases	Finance leases
2020	$ 187,500	$ 1,608,067
2021	195,000	1,506,592
2022	—	1,535,809
2023	—	1,564,027
2024	—	1,593,291
Thereafter	—	5,691,492
Total undiscounted lease payments	$ 382,500	$ 13,499,278
Less: Imputed interest	—	9,941,198
Total lease obligations	$ 382,500	$ 3,558,080

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 includes (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. The Company may pay the final $4.0 million payment at any time, whereupon the Company's obligation to make the remaining monthly payments terminates.

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

At March 31, 2020, the lease termination obligation of $3,938,994 is included in accrued expenses on the consolidated balance sheets. A roll forward of the charges incurred to general and administrative expense for the six months ended March 31, 2020 is as follows:

	Balance October 1, 2019	Expensed / Accrued Expense	Cash Payments	Balance March 31, 2020
Lease termination payments	$ 3,909,448	$ 329,546	$ (300,000)	$ 3,938,994

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

Common stock

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 and Investments, an affiliate of BioLexis Pte. Ltd. ("BioLexis"), the Company's controlling stockholder and strategic partner, at a combined purchase price per share and accompanying warrant 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 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, 2019, the Company issued an aggregate of 2,680,390 shares of the Company's common stock for gross cash proceeds of $20.0 million ($19.8 million net of issuance costs) pursuant to a November 5, 2018 private placement agreement with BioLexis.

During the six months ended March 31, 2020 and 2019, the Company issued 109 and 446 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") have been 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 have a stated value of $100.00 per share, and rank senior to all junior securities (as defined in the Certificate of Designation).

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. The Series A-1 was also entitled to dividends on an as-if-converted basis in the same form as any dividends actually paid on shares of common stock or other securities. The initial conversion rate was subject to appropriate adjustment in the event of a stock split, stock dividend, combination,

reclassification or other recapitalization affecting the common stock. The holders of the Series A-1 had the right to vote on matters submitted to a vote of the Company's stockholders on an as-converted basis, voting with the Company's other stockholders as a single class. In addition, without the prior written consent of a majority of the outstanding shares of Series A-1, the Company could not take certain actions, including amending its certificate of incorporation or bylaws, or issuing securities ranking pari passu or senior to the Series A-1.

On March 23, 2020, the Company issued 29,358,621 shares of its common stock upon conversion of the 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.

At March 31, 2020, there were no shares of Series A-1 outstanding. 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.

Common stock warrants

As of March 31, 2020, 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	277,128	$ 12.00
April 13, 2025	145,688	$ 12.00
May 31, 2025	62,438	$ 12.00
February 24, 2025	531,890	$ 1.27
February 26, 2024	5,029,528	$ 0.9535
	6,463,338	

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.

On January 27, 2020, the Company amended the exercise price of its outstanding warrants to purchase an aggregate 4,657,852 shares of its common, all of which were held by BioLexis to $0.232 per share. BioLexis exercised all such warrants for cash payment of approximately $1.1 million on January 29, 2020.

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, 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

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

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. Of these exercised warrants, 10,157,050 of them 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 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, 2020, 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 4,022,526. As of March 31, 2020, 1,634,323 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, 2020 and 2019:

	Three months ended March 31,		Six months ended March 31,	
	2020	2019	2020	2019
Research and development	$ 41,148	$ 120,763	$ 148,938	$ 211,972
General and administrative	263,391	146,979	515,078	928,059
	$ 304,539	$ 267,742	$ 664,016	$1,140,031

During the six months ended March 31, 2019, the Company awarded stock options with a fair value of $49,121 as settlement for directors fees accrued as of September 30, 2018.

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

Stock options

As of March 31, 2020, 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)
Balance at October 1, 2019	1,389,999	$ 3.46	
Granted	1,040,810	1.00	
Forfeited	(212,258)	2.87	
Balance at March 31, 2020	2,218,551	2.36	9.4
Vested and exercisable	377,985	4.03	9.1
Vested and expected to vest at March 31, 2020	2,218,551	$ 2.36	9.4

As of March 31, 2020, the aggregate intrinsic value of options outstanding was $29,177. The aggregate intrinsic value represents the total amount by which the fair value of the common stock subject to options exceeds the exercise price of the related options.

The weighted average grant date fair value of the options awarded to employees for the six months ended March 31, 2020 and 2019 was $0.72 and $6.36 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,	
	2020	2019
Risk-free interest rate	1.13 %	2.79 %
Expected life (years)	5.71	5.87
Expected volatility	89.2 %	88.8 %
Expected dividend yield	—	—

As of March 31, 2020, there was $2,431,719 of unrecognized compensation expense that is expected to be recognized over a weighted-average period of 2.84 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 six months ended March 31, 2020:

	Number of PSUs	Base Price Per PSU	Weighted Average Remaining Contractual Term (Years)
Balance at October 1, 2019	15,691	$ 49.97	
Forfeitures	(13,221)	50.60	
Balance at March 31, 2020	2,470	49.97	4.3
Vested and exercisable at March 31, 2020	2,470	49.97	4.3
Vested and expected to vest at March 31, 2020	2,470	$ 49.97	4.3

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

Restricted stock units

The following table summarizes the activity related to RSUs during the six months ended March 31, 2020:

	Number of RSUs	Weighted Average Grant Date Fair Value
Balance at October 1, 2019	109	$ 96.00
Vested and settled	(109)	96.00
Balance at March 31, 2020	—	$ —

Restricted stock

In connection with the consulting agreements entered into by the Company and four principals of MTTR, 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. The 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 biologics license application for ONS-5010, (ii) termination of the agreement by the consultant for good reason or by the Company other than for cause. (iii) in the event of disability, or (iv) upon a change in control.

The grant date fair value of the restricted shares was $0.54 per share and equal to the closing stock price of the Company's common stock at the time of grant. Compensation expense is recognized over the shorter of the explicit service period or derived service period which was determined to be 4.8 years at the time of grant. 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, 2020, the Company recognized compensation expense related to the restricted stock of $78,984. As of March 31, 2020, there was $3,833,176 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 six months ended March 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, whch 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.

MTTR and its four principals under the strategic partnership agreement and the subsequent individual consulting agreements earned an aggregate $169,347 and $290,431 during the three months ended March 31, 2020 and 2019, respectively; and $780,771 and $580,911 during the six months ended March 31, 2020 and 2019, respectively, which includes monthly consulting fees and expense reimbursement. As of March 31, 2020, no amounts were due to MTTR. As of September 30, 2019, amount due to MTTR was $365,301 which is included in accrued expenses in the accompanying consolidated balance sheets.

13. Subsequent Events

Corporate office lease termination

On May 6, 2020, the Company entered into a lease termination agreement with the landlord, Cedar Brook Corporate Center, LP, a New Jersey limited partnership, to terminate that certain lease dated June 12, 2011 for approximately 66,000 square feet of office, manufacturing and laboratory space located in Cranbury, New Jersey that served as the Company's headquarters. The termination of the lease is expected to reduce cash needs by approximately $14.0 million over the remaining life of the original lease through February 2028. In consideration for the termination of the lease, the Company agreed to make payments to landlord totaling approximately $1.0 million (payable in eight monthly installments commencing May 1, 2020), with late payments subject to an additional 7% per annum until paid in full.

In the third quarter of fiscal year 2020, the Company will write off the finance lease right-of-use asset and finance lease liability associated with the corporate office lease. The estimated loss on lease termination is $0.6 million.

Paycheck Protection Program term loan

On May 4, 2020, the Company received $0.9 million in proceeds from a loan granted pursuant to the PPP of the CARES Act. The PPP loan is evidenced by a promissory note containing the terms and conditions for repayment of the PPP loan.The PPP 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. 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.

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, 2019 and 2018 included in our Annual Report on Form 10-K for the year ended September 30, 2019, filed with the Securities and Exchange Commission, or SEC, on December 19, 2019.

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, 2019, filed with the SEC on December 19, 2019, 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 as the first and only approved bevacizumab in the United States, 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)) is an investigational ophthalmic formulation of bevacizumab under development 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 Phase 3 program for ONS-5010 in wet AMD involves two clinical trials, which we refer to as NORSE 1 and NORSE 2, evaluating ONS-5010 against ranibizumab (LUCENTIS). Enrollment in the NORSE 1 trial is complete with 61 patients enrolled at nine trial sites in Australia. The endpoint for NORSE 1 has been changed from the difference in mean change from baseline visual acuity to the proportion of participants who gain at least 15 letters in the best corrected visual acuity, or BCVA, at 11 months for ONS-5010 dosed on a monthly basis compared to LUCENTIS dosed using the alternative PIER clinical trial dosing regimen of three monthly doses followed by quarterly dosing. This change was made with agreement from the FDA and now aligns with the endpoint for our NORSE 2 study. While not designed as a pivotal study, NORSE 1 is one of two studies agreed upon with the FDA in April 2018 and will provide initial safety and efficacy data relating to ONS-5010 in wet AMD patients. We expect to report top line data from NORSE 1 in August 2020. The ongoing COVID-19 pandemic is not expected to impact the completion of the NORSE 1 trial at this time. See "—Impacts of the COVID-19 Pandemic" below for more information.

The NORSE 2 study began enrolling wet AMD patients in July 2019. NORSE 2 is expected to enroll a total of approximately 220 patients at more than 40 clinical trial sites and is being conducted in the United States. The primary

endpoint for NORSE 2 is the difference in proportion of participants who gain at least 15 letters in BCVA at 11 months for ONS-5010 dosed on a monthly basis compared to LUCENTIS dosed using the alternative PIER clinical trial dosing regimen. NORSE 2 continues to screen, enroll and treat patients, subject to additional COVID-19 safety protocols for both patients and staff at trial sites. Due to these additional safety protocols, some sites temporarily shut down and patient enrollment slowed. Due to local conditions at the various clinical trial sites, which have varying degrees of "shelter-in-place" and other similar government orders mandating various restrictions, enrollment in NORSE 2 is expected to be completed no later than the end of August 2020. Enrollment patterns in NORSE 2 are approaching pre-COVID-19 pandemic rates.

Subsequent to the completion of enrollment in NORSE 2 in 2020, we plan to initiate the NORSE 3 clinical trial. NORSE 3 is an open-label safety study that will be conducted to ensure the adequate number of safety exposures to ONS-5010 are available for the initial regulatory filings. Approximately 180 patients are expected to be enrolled in several different vascular and inflammatory retinal diseases where an anti-VEGF drug can be used as a therapeutic option. Patients in NORSE 3 will receive four doses of ONS-5010 over three months.

In addition to NORSE 1 and NORSE 2 for wet AMD, 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 4, a registration clinical trial to treat branch retinal vein occlusion or BRVO, and NORSE 5 and NORSE 6, two registration clinical trials to treat diabetic macular edema, or DME.

Currently, the cancer drug Avastin (bevacizumab) is used off-label for the treatment of wet AMD and other retinal diseases such as DME and BRVO even though Avastin has not been approved by regulatory authorities for use in these diseases. If the ONS-5010 clinical program is successful, it will support our plans to submit for regulatory approval in multiple markets in 2021 including the United States, 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 Biologics License Application, or 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 bevacizumab. Off-label use of bevacizumab is currently estimated to account for at least 50% of all wet AMD prescriptions in the United States.

Going Concern

Through March 31, 2020, we have funded substantially all of our operations with $251.7 million in proceeds from the sale and issuance of our equity and debt securities. We have also received $29.0 million pursuant to our collaboration and licensing agreements.

Our cash resources of $4.7 million as of March 31, 2020, the $3.3 million of proceeds from the sale of our New Jersey net operating losses, or NOLs, and research and development, or R&D, credits, and the $0.9 million proceeds from a loan granted pursuant to the Paycheck Protection Program, or PPP, of the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, we received in May 2020, are expected to fund our operations through August 2020 excluding any unscheduled repayment of debt. To provide additional working capital, we continue to engage in active discussions with global and regional pharmaceutical companies for licensing and/or co-development rights to ONS-5010. If we are not successful in raising additional capital or entering into one or more licensing and/or co-development rights agreements, 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, 2020 was $22.3 million. In addition, development activities, clinical and preclinical testing and commercialization of our product candidates will require significant additional financing.

In December 2019, we received approval from the New Jersey Economic Development Authority's Technology Business Tax Certificate Transfer Program to sell approximately $3.6 million of our unused New Jersey NOLs and R&D credits. We received approximately $3.3 million of proceeds from the sale of the New Jersey NOLs and R&D credits in May 2020.

In February 2020, we raised approximately $9.2 million of net proceeds through the sale of shares of our common stock in a public offering, and the sale of warrants and common stock in concurrent private placements. In addition, on March 19, 2020, following stockholder approval, the termination of the strategic license agreement with MTTR, LLC, or MTTR, became effective, as did the consulting agreements entered into with each of the four principals of MTTR, including two of our executive officers, Mr. Terry Dagnon and Mr. Jeff Evanson. Accordingly, our monthly payments have been reduced from $105,208 under the MTTR strategic license to approximately $90,000 per the consulting agreements.

In April 2020, the holder of our outstanding convertible senior secured notes began exchanging the outstanding principal and accrued interest from those notes for shares of our common stock per their terms. The holder exchanged $831,932 of principal and accrued interest for an aggregate 1,626,456 shares of our common stock between April 1, 2020 and May 13, 2020.

On May 4, 2020, we received $0.9 million in proceeds from a loan granted pursuant to the PPP of the CARES Act and on May 6, 2020, we terminated our lease for office space in Cranbury, New Jersey and will use space, as needed, at our warehouse in Monmouth Junction, New Jersey as our corporate headquarters. We expect that the termination of the Cranbury office lease will reduce our cash needs by approximately $14.0 million over the remaining life of the original lease, through February 2028.

We have incurred recurring losses and negative cash flows from operations since inception and had a stockholders' deficit at March 31, 2020 of $20.5 million. As of March 31, 2020, we had substantial indebtedness that included $7.8 million outstanding aggregate principal amount and accrued interest of senior secured notes that mature on December 31, 2020 and $3.6 million of unsecured notes that are due on demand. 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, 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. These matters raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

Capital Structure Changes

In December 2019, we also began implementing additional steps to improve our balance sheet and simplify our capitalization structure, which carried into the second fiscal quarter of 2020.

On December 23, 2019, we amended the terms of our outstanding 15-month warrants and five-year warrants issued April 12, 2019, which originally had an exercise price of $2.90 per share and had anti-dilution price protection features. As amended, the exercise price of all outstanding warrants was reduced to $0.2320 per share and the exercise period was amended such that all of the warrants issued April 2019 expired at 5:00 P.M., Eastern time on December 24, 2019. As a result of this amendment, such warrants to purchase an aggregate of 10,408,250 shares of common stock issued April 2019 were exercised in full for an aggregate 8,327,642 shares pursuant to the amended terms and are no longer outstanding. Of these exercised warrants, 10,157,050 were exercised pursuant to the net exercise provisions therein, as amended.

On January 27, 2020, we also amended the exercise price of our outstanding warrants to purchase an aggregate 4,657,852 shares of our common stock (originally issued in October 2017, May 2018 and June 2018), all of which were held by BioLexis Pte. Ltd., or BioLexis, our controlling stockholder, to $0.232 per share (from $7.20 to $7.80 per share). BioLexis exercised all such warrants for a cash payment of approximately $1.1 million on January 29, 2020.

In addition, on March 19, 2020, our stockholders approved an agreement with BioLexis dated January 27, 2020, whereby we agreed to amend the terms of our Series A-1 Preferred Convertible Preferred Stock, par value $0.01 per share, or the Series A-1 Preferred, and the issuance of our common stock pursuant to such amended terms, and BioLexis agreed to promptly convert its shares of Series A-1 Preferred pursuant to such amended terms, and in any event, within five business days of stockholder approval thereof. As amended, the effective conversion rate was increased from $18.89797 per share to $431.03447263 per share, which, resulted in the issuance of 29,358,621 shares upon conversion of the 68,112 shares of Series A-1 Preferred outstanding on March 23, 2020. The Series A-1 Preferred ranked senior to our common equity and had protective provisions, as well as a redemption premium of $37.5 million and a liquidation preference of $40.9 million, all of which were eliminated upon the conversion to common stock.

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. Although, to date, we have experienced only minor disruptions due to the ongoing COVID-19 pandemic, we have experienced slight delays in our ongoing clinical trials, including in patient enrollment and recruitment due to local clinical trial site protocols designed to protect staff and patients. However, 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. All clinical and chemistry, manufacturing and control, or CMC, activities are currently active for both NORSE 1 and NORSE 2. 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. We now expect our U.S. based NORSE 2 clinical trial to complete enrollment by August 2020, instead of May 2020 as previously reported. Our Australian based NORSE 1 clinical trial remains unaffected with the planned top line data release on schedule for August 2020. The initial disruptions to our NORSE 2 clinical trial sites appear to have been overcome and enrollment patterns are approaching pre COVID-19 pandemic levels.

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 are lifted 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. See also the section titled “Risk Factors” herein for additional information on risks and uncertainties related to the ongoing COVID-19 pandemic. 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, 2019 that we filed with the SEC on December 19, 2019.

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.

MTTR, LLC - ONS 5010

In February 2018, we entered into a strategic partnership agreement with MTTR, LLC, or MTTR, to advise on regulatory, clinical and commercial strategy and assist in obtaining approval of ONS-5010, our bevacizumab therapeutic product candidate for ophthalmic indications. Under the terms of the agreement, we paid MTTR a $58,333 monthly consulting fee through December 2018. Beginning January 2019, the monthly fee increased to $105,208 per month, and then, after launch of ONS-5010 in the United States, was to have increased to $170,833 per month (the amount of which would have been reduced by 50% in the event net sales of ONS-5010 were below a certain threshold million per year). We also agreed to pay MTTR a tiered percentage of the net profits of ONS-5010 ranging in the low- to mid-teens, with the ability to credit

monthly fees paid to MTTR. In March 2018, we amended the MTTR agreement and agreed to pay a one-time fee of $268,553 to MTTR by September 2020 if certain regulatory milestones are achieved earlier than anticipated.

In June 2019, we entered into a further amendment of our strategic partnership agreement with MTTR pursuant to which we increased the aggregate monthly payments to MTTR under the existing agreement from $105,208 to $170,724 through December 2019 by adding an additional monthly retainer of $115,916, and an offset of $50,000 to the existing monthly retainer while the additional monthly retainer is in effect.

On January 27, 2020, we entered into a termination agreement and mutual release with MTTR to terminate the strategic partnership agreement. Pursuant to the agreement, we agreed (x) to issue to the four principals of MTTR (who include two of our named executive officers, Messrs. Dagnon and Evanson), an aggregate of 7,244,739 shares of our 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. The termination agreement became effective upon stockholder approval of the share issuance, which occurred at our annual stockholders meeting on March 19, 2020.

As contemplated by the termination agreement, on January 27, 2020, we also entered into consulting agreements directly with each of the four principals of MTTR setting forth the terms of each respective compensation arrangement, as well as providing for certain transfer restrictions and repurchase rights applicable to the shares of our common stock to be issued pursuant thereto. The consulting agreements also became effective on March 19, 2020 following stockholder approval of the share issuances in the consulting agreements. The consulting agreements include the payment of monthly fees for services based on an agreed number of hours, and provide that the issued shares may generally not be sold until the earlier of (i) six months following FDA approval of ONS-5010, (ii) the date we publicly announce not to pursue development of ONS-5010, (iii) a “Change of Control” as defined therein or (iv) January 2025, subject to limited exceptions, including a pro rata exception if BioLexis disposes of any of its shares to an unaffiliated third party for consideration. We also have the right to repurchase such shares for $0.01 per share if the consultant terminates his agreement other than for good reason (as defined therein), or we terminate the agreement for cause (as defined therein). The repurchase right also lapses in tiered percentages (15%-40%) tied to completion of enrollment of our NORSE 2 clinical trial of ONS-5010 by certain dates. It also lapses as to 50% or 100% of the shares if we enter into agreements pertaining to ONS-5010 that meet certain value thresholds, or our 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 (as defined therein) or by us other than for cause (as defined therein), (iii) in the event of disability (as defined therein), or (iv) upon a “Change of Control” as defined therein.

MTTR and its four principals under the strategic partnership agreements and the subsequent individual consulting agreements earned an aggregate $780,771 and $580,911 during the six months ended March 31, 2020 and 2019, respectively, which includes monthly consulting fees and expense reimbursement. During the three and six months ended March 31, 2020, we recognized compensation expense related to the issuance of the restricted stock to the MTTR principals of $78,984.

Selexis SA

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

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

right to terminate our royalty payment obligation by providing written notice to Selexis and paying Selexis a royalty termination fee. The initiation of our Phase 3 clinical program for ONS-5010 triggered a CHF 65,000 (approximately $0.1 million) milestone payment under the commercial license agreement, which we paid in November 2019.

As of March 31, 2020, we have paid Selexis an aggregate of approximately $0.5 million under the commercial license agreements.

Components of our Results of Operations

Collaboration Revenue

To date, we have derived revenue only from activities pursuant to our emerging market collaboration and licensing agreements related to our inactive biosimilar development program. We have not generated any revenue from commercial product sales. For the foreseeable future, we expect all of our revenue, if any, will be generated from our collaboration and licensing agreements. If any of our product candidates currently under development are approved for commercial sale, we may generate revenue from product sales, or alternatively, we may choose to select a collaborator to commercialize our product candidates.

We consider milestones payments from our collaboration agreements as a form of variable consideration that results in such amounts being recognized over the estimated performance period. All remaining deferred revenue under our collaboration agreements was fully recognized in fiscal 2019 as all future development would be completed by our partners without any further assistance by us.

Research and Development Expenses

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

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

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

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

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

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 new 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 is subject to re-measurement at each balance sheet date until our obligations under the new senior secured notes are 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. During the six months ended March 31, 2020 and 2019, we recorded income of $0.2 million and $0.3 million, respectively, 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.

Income Taxes

On December 11, 2019, we received approval from the New Jersey Economic Development Authority's Technology Business Tax Certificate Transfer Program to sell approximately $3.6 million of our unused New Jersey NOLs and R&D credits. We received approximately $3.3 million of proceeds from the sale of the New Jersey NOLs and R&D credits in May 2020.

Since inception, we have not recorded any U.S. federal or state income tax benefits (excluding the sale of New Jersey state NOLs and R&D credits) for the net losses we have incurred in each year or on our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. As of September 30, 2019, we had federal and state NOL carryforwards of $202.7 million and $71.8 million, respectively that will begin to expire in 2030 and 2037, respectively. As of September 30, 2019, 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, 2019, we also had federal research and development tax credit carryforwards of $7.0 million, which begin to expire in 2032.

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, if any, 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, 2020 and 2019

	Three months ended March 31,		
	2020	2019	Change
Collaboration revenues	$ —	$ 641,140	$ (641,140)
Operating expenses:			
Research and development	4,383,214	5,935,884	(1,552,670)
General and administrative	1,957,175	1,849,158	108,017
Impairment of property and equipment	423,328	561,735	(138,407)
	6,763,717	8,346,777	(1,583,060)
Loss from operations	(6,763,717)	(7,705,637)	941,920
Interest expense, net	696,151	1,053,877	(357,726)
Loss on extinguishment of debt	—	183,554	(183,554)
Change in fair value of redemption feature	(1,759,037)	—	(1,759,037)
Change in fair value of warrant liability	(764)	1,301,728	(1,302,492)
Net loss	$ (5,700,067)	$ (10,244,796)	$ 4,544,729

Collaboration Revenues

The following table sets forth a summary of revenue recognized from our collaboration and licensing agreements for the three months ended March 31, 2020 and 2019, all of which was from the recognition of deferred revenues under such agreements:

	Three months ended March 31,	
	2020	2019
IPCA Collaboration	$ —	$ 128,007
Liomont Collaboration	—	84,414
Huahai Collaboration	—	371,427
BioLexis Collaboration	—	57,292
	$ —	$ 641,140

There were no collaboration revenues for the three months ended March 31, 2020 as compared to $0.6 million for the three months ended March 31, 2019. The decrease is due to the full recognition of IPCA Laboratories Limited, or IPCA, Liomont, S.A. de C.V., or Liomont, and Zhejiang Huahai Pharmaceutical Co., Ltd., or Huahai, deferred revenue during the fourth quarter of fiscal 2019, after we determined that we had no further performance obligations on these collaboration arrangements.

Research and Development Expenses

The following table summarizes our research and development expenses by functional area for the three months ended March 31, 2020 and 2019:

	Three months ended March 31,	
	2020	2019
ONS-5010 development	$ 3,610,551	$ 2,622,113
Compensation and related benefits	285,368	1,511,822
Stock-based compensation	41,148	120,763
Other research and development	446,147	1,681,186
Total research and development expenses	$ 4,383,214	$ 5,935,884

Research and development expenses for the three months ended March 31, 2020 decreased by $1.6 million compared to the three months ended March 31, 2019. The decrease is primarily due to our decision in 2019 to outsource the commercial manufacturing and remaining development for the ONS-5010 program, resulting in lower compensation and related benefits, of an aggregate of $1.3 million (including stock-based compensation) and other research and development expenses of $1.2 million. This reduction in expenses was partially offset by an increase in ONS-5010 development costs of $1.0 million as the ONS-5010 program advanced into the NORSE 2 clinical trial in July 2019.

General and Administrative Expenses

The following table summarizes our general and administrative expenses by type for the three months ended March 31, 2020 and 2019:

	Three months ended March 31,	
	2020	2019
Professional fees	$ 768,785	$ 649,355
Compensation and related benefits	(74,257)	430,126
Stock-based compensation	263,391	146,979
Facilities, fees and other related costs	999,256	622,698
Total general and administrative expenses	$ 1,957,175	$ 1,849,158

General and administrative expenses for the three months ended March 31, 2020 decreased by $0.1 million compared to the three months ended March 31, 2019. The decrease was primarily due to lower compensation and related benefits of $0.4 million resulting from reversal of previously accrued compensation cost. This reduction in expenses was primarily

offset by increased facilities and other general administrative costs of $0.4 million due to the reallocation of facilities costs to administrative functions upon the closure of our manufacturing and laboratory capabilities in 2019.

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 warehouse space in Monmouth Junction, New Jersey.

During the three months ended March 31, 2019, we wrote off certain construction in progress and laboratory equipment with a carrying amount of $0.6 million. We determined that the carrying amount of these assets was not recoverable and was less than the fair value less the cost to sell due to change in our operations to focus solely on developing and commercializing ONS-5010.

Interest Expense

Interest expense decreased by $0.4 million to $0.7 million for the three months ended March 31, 2020 as compared to $1.1 million for the three months ended March 31, 2019. The decrease was primarily due to repayment of notes in fiscal 2019.

Debt Extinguishment

We recorded a loss on extinguishment of debt of $0.2 million during the three months ended March 31, 2019 in connection with a forbearance and exchange agreement in March 2019 pursuant to which a third party purchased two stockholder notes previously issued in an aggregate original principal amount of $1.0 million with an aggregate outstanding balance of $1.9 million, including accrued interest. There was no debt extinguishment during the three months ended March 31, 2020.

Comparison of Six Months Ended March 31, 2020 and 2019

	Six months ended March 31,		
	2020	2019	Change
Collaboration revenues	$ —	$ 1,708,738	$ (1,708,738)
Operating expenses:			
Research and development	10,230,516	12,007,406	(1,776,890)
General and administrative	4,293,899	4,753,146	(459,247)
Impairment of property and equipment	423,328	2,911,138	(2,487,810)
	14,947,743	19,671,690	(4,723,947)
Loss from operations	(14,947,743)	(17,962,952)	3,015,209
Interest expense, net	1,293,816	2,174,726	(880,910)
Loss on extinguishment of debt	8,060,580	183,554	7,877,026
Change in fair value of redemption feature	(1,796,982)	—	(1,796,982)
Change in fair value of warrant liability	(202,142)	(334,592)	132,450
Net loss	$ (22,303,015)	$ (19,986,640)	$ (2,316,375)

Collaboration Revenues

The following table sets forth a summary of revenue recognized from our collaboration and licensing agreements for the six months ended March 31, 2020 and 2019, all of which was from the recognition of deferred revenues under such agreements:

	Six months ended March 31,	
	2020	2019
IPCA Collaboration	$ —	$ 256,014
Liomont Collaboration	—	183,828
Huahai Collaboration	—	742,854
BioLexis Collaboration	—	526,042
	$ —	$ 1,708,738

There were no collaboration revenues for the six months ended March 31, 2020 as compared to $1.7 million for the six months ended March 31, 2019. The decrease is due to the full recognition of IPCA, Liomont, and Huahai, deferred revenue during the fourth quarter of fiscal 2019, after we determined that we had no further performance obligations on these collaboration arrangements.

Research and Development Expenses

The following table summarizes our research and development expenses by functional area for the six months ended March 31, 2020 and 2019:

	Six months ended March 31,	
	2020	2019
ONS-5010 development	$ 8,372,766	$ 4,993,082
Compensation and related benefits	692,671	3,396,471
Stock-based compensation	148,938	211,972
Other research and development	1,016,141	3,405,881
Total research and development expenses	$ 10,230,516	$ 12,007,406

Research and development expenses for the six months ended March 31, 2020 decreased by $1.8 million compared to the six months ended March 31, 2019. The decrease is primarily due to our decision to outsource the commercial manufacturing and remaining development for the ONS-5010 program, which resulted in lower compensation and related benefits, of an aggregate of $2.8 million, and other research and development expenses of $2.4 million . This reduction in expenses was partially offset by an increase in ONS-5010 development costs of $3.4 million as the ONS-5010 program advanced into the NORSE 2 clinical trial in July 2019.

General and Administrative Expenses

The following table summarizes our general and administrative expenses by type for the six months ended March 31, 2020 and 2019:

	Six months ended March 31,	
	2020	2019
Professional fees	$ 1,720,233	$ 2,130,329
Compensation and related benefits	354,068	591,307
Stock-based compensation	515,078	928,059
Facilities, fees and other related costs	1,704,520	1,103,451
Total general and administrative expenses	$ 4,293,899	$ 4,753,146

General and administrative expenses for the six months ended March 31, 2020 decreased by $0.4 million compared to the six months ended March 31, 2019. The decrease was primarily due to an aggregate $0.6 million decrease in compensation and related benefits and stock-based compensation primarily from reversal of previously accrued compensation cost and lower stock options expense, plus reduced professional fees of $0.4 million, which decreased due to lower advisory

services fees. The reduction in expenses was partially offset by increase in facilities and other general administrative costs of $0.6 million due to the reallocation of facilities costs to administrative functions following our decision to outsource manufacturing and remaining development functions in 2019.

Impairment of Property and Equipment

During the six 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 warehouse space in Monmouth Junction, New Jersey.

During the six months ended March 31, 2019, we wrote off certain construction in progress and laboratory equipment with a carrying amount of $2.9 million. We determined that the carrying amount of these assets as of March 31, 2019 was not recoverable and was less than the fair value less the cost to sell due to change in our operations to focus solely on developing and commercializing ONS-5010.

Interest Expense

Interest expense decreased by $0.9 million to $1.3 million for the six months ended March 31, 2020 as compared to $2.2 million for the six months ended March 31, 2019. The decrease was primarily due to repayment of notes in fiscal 2019.

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.

We recorded a loss on extinguishment of debt of $0.2 million during the six months ended March 31, 2019 in connection with a forbearance and exchange agreement in March 2019 pursuant to which a third party purchased two stockholder notes previously issued in an aggregate original principal amount of $1.0 million with an aggregate outstanding balance of $1.9 million, including accrued interest.

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, 2020, we have funded substantially all of our operations through the receipt of $251.7 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 December 2019, we received approval from the New Jersey Economic Development Authority's Technology Business Tax Certificate Transfer Program to sell approximately $3.6 million of our unused New Jersey NOLs and R&D credits. We received approximately $3.3 million of proceeds from the sale of the New Jersey NOLs and R&D credits in May 2020.

On February 26, 2020, we 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 concurrent private placement, on February 26, 2020, we 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 and Investments, an affiliate of BioLexis, our controlling stockholder and strategic partner at a combined purchase price per share and accompanying warrant of $1.016 for approximately $2.5 million. The warrants issued in both concurrent private placements 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, we issued placement agent warrants to purchase up to an aggregate of 531,890 shares of common stock, on substantially the same terms as the registered direct offering and concurrent private placement warrants, at an exercise price of $1.27 per share and a 5-year term.

On March 19, 2020, following stockholder approval, the termination of the strategic license agreement with MTTR, LLC, or MTTR, became effective, as did the consulting agreements entered into with each of the four principals of MTTR, including two of our executive officers, Mr. Terry Dagnon and Mr. Jeff Evanson. Accordingly, our monthly payments have been reduced from $105,208 under the MTTR strategic license to approximately $90,000 per the consulting agreements.

Commencing April 2020, and following stockholder approval in March 2020, the holder of the convertible senior secured notes issued December 2019 began exchanging the outstanding principal and accrued interest from those notes for our common stock per the terms of the notes. The holder exchanged $831,932 of outstanding principal and accrued interest for an aggregate 1,626,456 shares of our common stock between April 1, 2020 and May 13, 2020.

On May 4, 2020, we received $0.9 million in proceeds from a loan granted pursuant to the PPP of the CARES Act, or the PPP loan. The PPP loan is evidenced by a promissory note containing the terms and conditions for repayment of the PPP loan. In accordance with the requirements of the CARES Act, we intend to use the proceeds primarily for payroll costs, and to make lease and utility payments. The PPP loan is subject to the terms and conditions applicable to all loans made pursuant to the PPP as administered by the Small Business Administration, or SBA, under the CARES Act. The PPP loan provides for an initial six-month deferral of payments and any amount owed on the loan has a two-year maturity and bears interest at a rate of 1% per annum. We have 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.

As of March 31, 2020, we had a stockholders' deficit of $20.5 million and a cash balance of $4.7 million. In addition, we have $7.8 million outstanding aggregate principal amount and accrued interest of senior secured notes that become due in December 2020, $3.6 million unsecured notes, which are due on demand as of such date. These matters 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 our product candidates currently in development. We will need substantial additional financing to fund our operations and to commercially develop our product candidates. Management is currently evaluating various strategic opportunities to obtain the required funding for future operations. These strategies may include, but are not limited to payments from potential strategic research and development, licensing and/or marketing arrangements with pharmaceutical companies and private placements and/or public offerings of equity and/or debt securities. There can be no assurance that these future funding efforts will be successful.

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.

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, manufacturing and facility costs, external research and development services, legal and other regulatory expenses, and administrative and overhead costs. Our future funding requirements will be heavily determined by the resources needed to support development of our lead product candidate.

We believe our existing cash as of March 31, 2020 including proceeds from the sale of our New Jersey NOLs and R&D credits of approximately $3.3 million, and $0.9 million in proceeds from a loan granted pursuant to the PPP received in May 2020 will fund our operations through August 2020 excluding any unscheduled repayment of debt. 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. Our ability to raise additional funds may be adversely impacted by recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. 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,	
	2020	**2019**
Net cash used in operating activities	$(13,756,734)	$(16,040,794)
Net cash used in investing activities	—	(286,569)
Net cash provided by financing activities	10,394,129	14,765,440

Operating Activities.

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 noncash 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.

During the six months ended March 31, 2019, we used $16.1 million of cash in operating activities resulting from our net loss of $20.0 million and the change in our operating assets and liabilities of $2.5 million. This use of cash was partially offset by $6.4 million of noncash items such as 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 was primarily due to payments of our accrued expenses from September 30, 2018 as well as the amortization of our deferred revenues from collaborations.

Investing Activities.

During the six months ended March 31, 2019, we used cash of $0.3 million in investing activities for the purchase of property and equipment.

Financing Activities.

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.

During the six months ended March 31, 2019, net cash provided by financing activities was $14.8 million, primarily attributable to $19.8 million in net proceeds from the November 2018 BioLexis private placement. In November 2018 through February 2019, we closed the sale of this private placement for an aggregate of 2,680,390 shares of our common stock for gross cash proceeds of $20.0 million. We also made $5.0 million in debt and capital lease obligations payments.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of March 31, 2020.

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, 2019, filed with the SEC on December 19, 2019, 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, 2020.

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. 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.

Item 1A. Risk Factors

Except as stated below, there have been no material changes to our risk factors as previously disclosed in Part I, Item 1A. included in our Annual Report on Form 10-K for the fiscal year ended September 30, 2019.

Our business could be adversely affected by the effects of health pandemics or epidemics, including the ongoing COVID-19 global pandemic, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations, or materially affect our operations, including at our headquarters in New Jersey, which is currently subject to a state executive order mandating shelter-in-place, and at our clinical trial sites, as well as the business or operations of our manufacturers, CROs or other third parties with whom we conduct business.

Our business could be adversely affected by the effects of health pandemics or epidemics, including the ongoing of COVID-19 global pandemic, which was declared by the World Health Organization as a global pandemic, and is resulting in travel and other restrictions to reduce the spread of the disease, including a New Jersey executive order, and several other state and local orders across the country, which, among other things, direct individuals to shelter at their places of residence, direct businesses and governmental agencies to cease non-essential operations at physical locations, prohibit certain non-essential gatherings, and order cessation of non-essential travel. As a result of these recent developments, we have implemented work-from-home policies for all our employees. The effects of these orders, government-imposed quarantines and our work-from-home policies may negatively impact productivity, disrupt our business and could delay our ONS-5010 clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which could disrupt our supply chain.

In addition, our ongoing clinical trials are being affected by the recent COVID-19 outbreak. Patient enrollment and recruitment is delayed due to local clinical trial site protocols designed to protect staff and patients from COVID-19 infection, and some patients may not be able to comply with clinical trial protocols if quarantines or other restrictions impede patient movement or interrupt healthcare services. Similarly, our ability to retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, could be disrupted, which would adversely impact our clinical trial operations.

The spread of COVID-19, which has caused a broad impact globally, may materially also adversely affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic, may be difficult to assess or predict, it is currently resulting in significant disruption of global financial markets. This disruption, if sustained or recurrent, could make it more difficult for us to access capital, which could in the future negatively affect our liquidity. In

addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The COVID-19 pandemic continues to rapidly evolve. The ultimate impact of the COVID-19 outbreak or a similar health pandemic or epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. These effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

In addition, 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 elsewhere in the section entitled "Risk Factors" in our Annual Report on Form 10-K for the year ended September 30, 2019, filed with the SEC on December 19, 2019.

Our common stock may be delisted from Nasdaq and begin trading in the over-the-counter markets if we are not successful in regaining compliance with Nasdaq's continued listing standards, which may negatively impact the price of our common stock and our ability to access the capital markets.

On March 27, 2020, we received written notification from The Nasdaq Stock Market LLC, or Nasdaq, indicating that as of March 27, 2020, we were not in compliance with Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market, as the minimum bid price of our listed securities was less than $1.00 per share for the previous 30 consecutive business days.

Under Nasdaq Listing Rule 5810(c)(3)(A), we have a period of 180 calendar days to regain compliance with the rule. However, as a result of COVID-19, effective April 16, 2020, Nasdaq tolled the compliance period through June 30, 2020, and as such, we have until December 7, 2020 to regain compliance with the minimum bid-price. To regain compliance, during this compliance period, the minimum bid price of our listed securities must close at $1.00 per share or more for a minimum of 10 consecutive trading days. If we are unable to regain compliance during the compliance period, we anticipate that we will receive a delisting determination from Nasdaq, following which we anticipate requesting a hearing to remain on The Nasdaq Capital Market. If granted, such request will ordinarily suspend such delisting determination until a decision by Nasdaq subsequent to the hearing. We intend to actively monitor the minimum bid price of our listed securities and, as appropriate, will consider available options to resolve the deficiencies and regain compliance with the Nasdaq Listing Rules, including effecting a reverse stock split.

If we are not successful in regaining compliance, we anticipate that our common stock would begin trading on the over-the-counter market. Delisting from Nasdaq and trading on the over-the-counter market could adversely affect the liquidity of our common stock. Stocks traded on the over-the-counter market generally have limited trading volume and exhibit a wider spread between the bid/ask quotation, as compared to securities listed on a national securities exchange. Consequently, you may not be able to liquidate your investment in the event of an emergency or for any other reason.

If our common stock is delisted from the Nasdaq, we could face significant material adverse consequences, including:

- A limited availability of market quotations for our common stock;
- A reduced amount of news and analyst coverage for our company;
- A decreased ability to issue additional securities or obtain additional financing in the future;
- Reduced liquidity for our stockholders;
- Potential loss of confidence by partners and employees; and
- Loss of institutional investor interest and fewer business development opportunities.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Unused federal net operating losses,or NOLs, for taxable years beginning before January 1, 2018 may be carried forward to offset future taxable income, if any, until such unused NOLs expire. Under legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, or the Tax Act, as modified by legislation enacted on March 27, 2020, entitled the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, federal NOLs incurred in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of such federal

NOLs in taxable years beginning after December 31, 2020 is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We may have experienced ownership changes in the past and may experience ownership changes in the future as a result of subsequent shifts in our stock ownership (some of which shifts are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income will be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows or results of operations.

We may not be entitled to forgiveness of our recently received Paycheck Protection Progam, or PPP, loan, and our application for the PPP loan could in the future be determined to have been impermissible or could result in damage to our reputation.

On May 4, 2020, we received proceeds of $0.9 million from a loan under the PPP of the CARES Act, which we intend to use to maintain payroll and make lease and utility payments. The PPP loan matures on May 2, 2022 and bears annual interest at a rate of 1% per annum. Commencing December 15, 2020, we are required to pay the lender equal monthly payments of principal and interest as required to fully amortize by May 2, 2022 any principal amount outstanding on the PPP loan as of December 15, 2020. A portion of the PPP loan may be forgiven upon documentation of expenditures in accordance with the Small Business Administration, or SBA, requirements and in compliance with the CARES Act. We will be required to repay any portion of the outstanding principal that is not forgiven, along with accrued interest, in accordance with the amortization schedule described above, and we cannot provide any assurance that we will be eligible for loan forgiveness or that any amount of the PPP loan will ultimately be forgiven by the SBA.

To obtain the PPP loan, we were required to certify, among other things, that the current economic uncertainty made the request necessary to support our ongoing operations. We made this certification in good faith after analyzing, among other things, our financial situation and access to alternative forms of capital, and believe that we satisfied all eligibility criteria, and that our receipt of the PPP loan is consistent with the broad objectives of the PPP. However, recent guidance stated that it is unlikely that a public company with substantial market value and access to capital markets will be able to make the required certification in good faith. The lack of clarity regarding loan eligibility under the PPP has resulted in significant media coverage and controversy with respect to public companies applying for and receiving loans. If, despite our good-faith belief that we satisfy all eligibility requirements for the PPP loan, we could be subject to penalties, including significant civil, criminal and administrative penalties, and be required to repay the PPP loan in its entirety if we were later determined to have violated any of the laws or governmental regulations that apply to us in connection with the loan, such as the False Claims Act, or it is otherwise determined that we were ineligible to receive the PPP loan. In addition, our receipt of the PPP loan may result in adverse publicity and damage to our reputation, and a review or audit by the SBA or other government entity or claims under the False Claims Act could consume significant financial and management resources.

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 Registrant's current report on Form 8-K filed with the SEC on May 19, 2016).
3.2	Certificate of Designation of Series A-1 Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed with the SEC on July 19, 2018).
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed with the SEC on December 6, 2018).
3.4	Certificate of Amendment to the Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed with the SEC on March 18, 2019).
3.5	Certificate of Amendment to the Certificate of Designation of Series A-1 Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed with the SEC on March 24, 2020).
3.6	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Registrant's current report on Form 8-K filed with the SEC on May 19, 2016).
3.7	Amendment to the Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed with the SEC on November 29, 2016).
10.1	Amendment to Warrants to Purchase Common Stock between the Registrant and BioLexis Pte. Ltd., dated as of January 27, 2020 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on January 31, 2020).
10.2	Agreement to Amend Series A-1 Convertible Preferred between the Registrant and BioLexis Pte. Ltd., dated as of January 27, 2020 (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K filed with the SEC on January 31, 2020).
10.3	Termination Agreement and Mutual Release between the Registrant and MTTR LLC, dated as of January 27, 2020 (incorporated by reference to Exhibit 10.3 to the Registrant's current report on Form 8-K filed with the SEC on January 31, 2020).
10.4** #	Consulting Agreement between the Registrant and The Dagnon Group LLC, dated as of January 27, 2020 (incorporated by reference to Exhibit 10.4 to the Registrant's current report on Form 8-K filed with the SEC on January 31, 2020).
10.5** #	Consulting Agreement between the Registrant and Scott Three Consulting, LLC, dated as of January 27, 2020 (incorporated by reference to Exhibit 10.5 to the Registrant's current report on Form 8-K filed with the SEC on January 31, 2020).
10.6	Global Amendment, dated as of January 29, 2020 (incorporated by reference to Exhibit 10.6 to the Registrant's current report on Form 8-K filed with the SEC on January 31, 2020).
10.7	Form of Securities Purchase Agreement, dated February 24, 2020, by and among the Registrant and the purchasers named therein (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on February 24, 2020).
10.8	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's current report on Form 8-K filed with the SEC on February 24, 2020).
10.9	Securities Purchase Agreement by and between the Registrant and GMS Ventures and Investments, dated February 24, 2020 (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K filed with the SEC on February 24, 2020).
10.10	Form of warrant issued to GMS Ventures and Investments (incorporated by reference to Exhibit 4.2 to the Registrant's current report on Form 8-K filed with the SEC on February 24, 2020).
10.11	Engagement letter dated December 10, 2019 by and between the Registrant and H.C. Wainwright & Co. LLC (incorporated by reference to Exhibit 10.3 to the Registrant's current report on Form 8-K filed with the SEC on February 24, 2020).
10.12	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.3 to the Registrant's current report on Form 8-K filed with the SEC on February 24, 2020).

10.13	Fourth Amendment to Investor Rights Agreement dated September 11, 2017 by and between the Registrant and BioLexis Pte. Ltd. (formerly GMS Tenshi Holdings Pte. Limited) by and between the Registrant, BioLexis and GMS Ventures and Investments dated February 24, 2020 (incorporated by reference to Exhibit 10.4 to the Registrant's current report on Form 8-K filed with the SEC on February 24, 2020).
31.1	Certification of Principal Executive and Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive and 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

* This certification is being furnished solely to accompany this Quarterly Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

** Certain portions of this exhibit (indicated by "[***]") have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed.

# Indicates management contract or compensatory plan.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

OUTLOOK THERAPEUTICS, INC.

Date: May 15, 2020

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; and

(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 15, 2020

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, 2020, 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 15, 2020

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."