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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 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 August 12, 2020 was 127,183,109.

Outlook Therapeutics, Inc.
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In this report, unless otherwise stated or as the context otherwise requires, references to "Outlook Therapeutics," "Outlook," "the Company," "we," "us," "our" and similar references refer to Outlook Therapeutics, Inc. and its consolidated subsidiaries. The Outlook logo, LYTENAVA and other trademarks or service marks of Outlook Therapeutics, Inc. appearing in this report are the property of Outlook Therapeutics, Inc. This report also contains registered marks, trademarks and trade names of other companies. All other trademarks, registered marks and trade names appearing in this report are the property of their respective holders. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this report, including statements regarding our future financial condition, business strategy and plans, and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “believe,” “may,” “could,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “seek,” “plan,” “expect,” “should,” “would,” “potentially” or the negative of these terms or similar expressions in this report.

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of known and unknown risks, uncertainties and assumptions, including risks described in the section titled “Risk Factors” contained in our annual report on Form 10-K for the year ended September 30, 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)

	June 30, 2020	September 30, 2019
Assets		
Current assets:		
Cash	$ 23,953,080	$ 8,015,528
Prepaid expenses and other current assets	4,282,298	4,986,033
Assets held for sale	—	500,000
Total current assets	28,235,378	13,501,561
Property and equipment, net	368,155	3,175,960
Operating lease right-of-use assets, net	206,229	—
Other assets	1,433,198	457,476
Total assets	$ 30,242,960	$ 17,134,997
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Convertible senior secured notes	$ —	$ 6,699,000
Current portion of long-term debt	422,131	1,026,168
Current portion of finance lease liabilities	41,213	192,290
Current portion of operating lease liabilities	181,585	—
Stockholder notes	3,612,500	3,612,500
Accounts payable	5,008,923	2,277,817
Accrued expenses	7,328,154	4,622,988
Income taxes payable	1,859,434	1,859,434
Total current liabilities	18,453,940	20,290,197
Long-term debt	544,924	50,285
Finance lease liabilities	49,162	3,365,790
Operating lease liabilities	48,394	—
Warrant liability	181,098	255,734
Other liabilities	—	3,942,948
Total liabilities	19,277,518	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 June 30, 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; 126,360,064 shares issued and outstanding at June 30, 2020 and 28,609,995 shares issued and outstanding at September 30, 2019	1,263,601	286,100
Additional paid-in capital	289,500,131	238,064,947
Accumulated deficit	(279,798,290)	(254,480,408)
Total stockholders' equity (deficit)	10,965,442	(16,129,361)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 30,242,960	$ 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 June 30,		Nine months ended June 30,	
	2020	2019	2020	2019
Collaboration revenues	$ —	$ 583,848	$ —	$ 2,292,586
Operating expenses:				
Research and development	8,488,143	4,342,539	18,718,659	16,349,946
General and administrative	3,286,739	1,834,545	7,580,638	6,587,691
Impairment of property and equipment	104,296	50,927	527,624	2,962,064
	11,879,178	6,228,011	26,826,921	25,899,701
Loss from operations	(11,879,178)	(5,644,163)	(26,826,921)	(23,607,115)
Interest expense, net	443,624	1,081,779	1,737,440	3,256,505
(Gain) loss on extinguishment of debt	(6,164,284)	423,686	1,896,296	607,240
Change in fair value of redemption feature	—	—	(1,796,982)	—
Change in fair value of warrant liability	127,506	(1,931,244)	(74,636)	(2,265,836)
Loss before income taxes	(6,286,024)	(5,218,384)	(28,589,039)	(25,205,024)
Income tax benefit	(3,271,157)	(777,500)	(3,271,157)	(777,500)
Net loss	(3,014,867)	(4,440,884)	(25,317,882)	(24,427,524)
Beneficial conversion feature upon issuance of Series A-1 convertible preferred stock	—	—	—	(61,365)
Series A-1 convertible preferred stock dividends and related settlement	—	(158,128)	(166,133)	(462,907)
Deemed dividend upon modification of warrants	—	—	(3,140,009)	(829,530)
Deemed dividend upon amendment of the terms of the Series A-1 convertible preferred stock	—	—	(10,328,118)	—
Net loss attributable to common stockholders	$ (3,014,867)	$ (4,599,012)	$ (38,952,142)	$ (25,781,326)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.03)	$ (0.20)	$ (0.69)	$ (1.74)
Weighted average shares outstanding, basic and diluted	90,757,825	23,007,077	56,089,036	14,787,010

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

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

	Convertible Preferred Stock Series A-1		Stockholders' Equity (Deficit)				
			Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance at April 1, 2020	—	$ —	89,751,192	$ 897,512	$ 255,361,229	$ (276,783,423)	$ (20,524,682)
Issuance of common stock in connection with conversion of senior secured notes and interest	—	—	12,201,461	122,015	7,872,479	—	7,994,494
Sale of common stock, net of issuance costs	—	—	24,407,411	244,074	24,907,703	—	25,151,777
Stock-based compensation expense	—	—	—	—	1,358,720	—	1,358,720
Net loss	—	—	—	—	—	(3,014,867)	(3,014,867)
Balance at June 30, 2020	—	$ —	126,360,064	$ 1,263,601	$ 289,500,131	$ (279,798,290)	$ 10,965,442

	Convertible Preferred Stock Series A-1		Stockholders' Equity (Deficit)				
			Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance at April 1, 2019	63,250	$5,039,195	11,759,630	$117,596	$ 211,739,503	$(239,943,261)	$ (28,086,162)
Proceeds from exercise of common stock warrants	—	—	6,133,398	61,334	(56,984)	—	4,350
Sale of common stock in public offering, net of issuance costs	—	—	10,340,000	103,400	26,053,103	—	26,156,503
Series A-1 convertible preferred stock dividends and related settlement	1,581	158,128	—	—	(158,128)	—	(158,128)
Stock-based compensation expense	—	—	—	—	(31,265)	—	(31,265)
Net loss	—	—	—	—	—	(4,440,884)	(4,440,884)
Balance at June 30, 2019	64,831	$5,197,323	28,233,028	$282,330	$ 237,546,229	$(244,384,145)	$ (6,555,586)

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	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance at October 1, 2019	66,451	$ 5,359,404	28,609,995	$ 286,100	$ 238,064,947	$ (254,480,408)	$ (16,129,361)
Issuance of common stock in connection with exercise of warrants	—	—	13,003,414	130,034	1,008,866	—	1,138,900
Issuance of common stock in connection with conversion of stockholder notes and interest	—	—	1,475,258	14,753	1,533,673	—	1,548,426
Issuance of common stock in connection with conversion of senior secured notes and interest	—	—	12,201,461	122,015	7,872,479	—	7,994,494
Issuance of vested restricted stock units	—	—	109	1	(1)	—	—
Sale of common stock, net of issuance costs	—	—	34,466,467	344,665	34,004,060	—	34,348,725
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	—	—	—	—	2,022,736	—	2,022,736
Net loss	—	—	—	—	—	(25,317,882)	(25,317,882)
Balance at June 30, 2020	—	$ —	126,360,064	$ 1,263,601	$ 289,500,131	$ (279,798,290)	$ 10,965,442

	Convertible Preferred Stock		Stockholders' Equity (Deficit)				
	Series A-1		Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Deficit)
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	—	—	6,134,307	61,343	(56,993)	—	4,350
Private placement sale of common stock, net of issuance 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
Sale of common stock in public offering, net of issuance costs	—	—	10,340,000	103,400	26,053,103	—	26,156,503
Series A-1 convertible preferred stock dividends and related settlement	4,628	462,907	—	—	(462,907)	—	(462,907)
Stock-based compensation expense	—	—	—	—	1,108,766	—	1,108,766
Accrued directors fees settled in fully vested stock options	—	—	—	—	49,121	—	49,121
Net loss	—	—	—	—	—	(24,427,524)	(24,427,524)
Balance at June 30, 2019	64,831	$5,197,323	28,233,028	$ 282,330	$ 237,546,229	$(244,384,145)	$ (6,555,586)

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

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

	Nine months ended June 30,	
	2020	**2019**
OPERATING ACTIVITIES		
Net loss	$ (25,317,882)	$ (24,427,524)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	473,920	2,473,005
Loss on extinguishment of debt	1,896,296	607,240
Non-cash interest expense	235,636	1,314,321
Stock-based compensation	2,022,736	1,108,766
Change in fair value of redemption feature	(1,796,982)	—
Change in fair value of warrant liability	(74,636)	(2,265,836)
Impairment of property and equipment	527,624	2,962,064
Loss on lease termination	680,017	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	676,564	(2,779,990)
Other assets	(84,120)	(109,096)
Operating lease liability	(122,193)	—
Accounts payable	900,030	(1,935,958)
Accrued expenses	215,175	(1,090,468)
Deferred revenue	—	(2,277,586)
Other liabilities	55,587	73,531
Net cash used in operating activities	(19,712,228)	(26,347,531)
INVESTING ACTIVITIES		
Purchase of property and equipment	—	(437,306)
Investment in joint venture	(900,000)	—
Net cash used in investing activities	(900,000)	(437,306)
FINANCING ACTIVITIES		
Proceeds from the sale of common stock, net of offering costs	34,739,271	45,964,820
Proceeds from debt	904,200	—
Proceeds from exercise of common stock warrants	1,138,900	4,350
Payments of finance lease obligations	(196,959)	(470,295)
Repayment of debt	(35,632)	(6,404,597)
Net cash provided by financing activities	36,549,780	39,094,278
Net increase in cash	15,937,552	12,309,441
Cash at beginning of period	8,015,528	1,717,391
Cash at end of period	$ 23,953,080	$ 14,026,832
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 910,503	$ 2,710,376
Accrued interest settled by conversion into common stock	$ 1,531,004	$ 1,393
Supplemental schedule of non-cash investing activities:		
Purchases of property and equipment in accounts payable and accrued expenses	$ —	$ 1,048,286
Supplemental schedule of non-cash financing activities:		
Senior secured notes principal converted into common stock	$ 7,033,950	$ 400,575
Unsecured notes principal converted into common stock	$ 977,966	$ —
Issuance of capital lease obligations in connection with purchase of property and equipment	$ —	$ 48,683
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	$ 462,907
Deferred offering costs and common stock issuance costs in accounts payable and accrued expenses	$ 390,546	$ —
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 nine months ended June 30, 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. As of June 30, 2020, the Company had $3.6 million of unsecured notes that were due on demand as of such date and $0.9 million loan granted pursuant to the Paycheck Protection Program (the "PPP") of the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), which matures on May 2, 2022. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying unaudited interim consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The unaudited interim consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

On July 16, 2020, the Company received $1.0 million in proceeds in connection with a securities purchase agreement entered into on June 22, 2020 with Syntone Ventures LLC ("Syntone"), a U.S. affiliate of Syntone Technologies Group Co. Ltd., a People's Republic of China ("PRC") entity, the Company's strategic partner for ONS-5010 in China, in a private placement pursuant to which the Company issued and sold 823,045 shares of its common stock at a purchase price of $1.215 per share.

Management believes that the Company's existing cash as of June 30, 2020, and the $1.0 million proceeds received in July 2020 from the Syntone private placement pursuant to the June 2020 securities purchase agreement will be sufficient to fund its operations through the first quarter of fiscal 2021. 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 June 30, 2020 and its results of operations for the three and nine months ended June 30, 2020 and 2019, cash flows for the nine months ended June 30, 2020 and 2019, and convertible preferred stock and stockholders' equity for the three and nine months ended June 30, 2020 and 2019. Operating results for the three and nine months ended June 30, 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 June 30,		Nine months ended June 30,	
	2020	2019	2020	2019
Net loss attributable to common stockholders	$ (3,014,867)	$ (4,599,012)	$ (38,952,142)	$ (25,781,326)
Common stock outstanding (weighted average)	90,757,825	23,007,077	56,089,036	14,787,010
Basic and diluted net loss per share	$ (0.03)	$ (0.20)	$ (0.69)	$ (1.74)

The following potentially dilutive securities (in common stock equivalents) have been excluded from the computation of diluted weighted-average shares outstanding as of June 30, 2020 and 2019, as they would be antidilutive:

	As of June 30,	
	2020	2019
Series A-1 convertible preferred stock	—	1,225,172
Convertible senior secured notes	—	767,605
Convertible unsecured notes	—	149,573
Performance-based stock units	2,470	16,131
Restricted stock units	—	3,750
Stock options	2,238,470	605,452
Common stock warrants	7,051,857	16,067,923

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 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 Company may enter into leases with an initial term of 12 months or less (“Short-Term Leases”). For Short-Term Leases,

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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 June 30, 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 and the adoption of this standard did not have a material impact on the Company's financial statements.

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.

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- 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:

	June 30, 2020		
	(Level 1)	(Level 2)	(Level 3)
Liabilities			
Warrant liability	$ —	$ —	$ 181,098

	September 30, 2019		
	(Level 1)	(Level 2)	(Level 3)
Liabilities			
Warrant liability	$ —	$ —	$ 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. During the three months ended June 30, 2020, the remaining outstanding principal and accrued interest on the senior secured notes were exchanged for shares of its common stock and as a result, the Company wrote off the redemption feature liability as a gain on extinguishment of debt.

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 nine months ended June 30, 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	(74,636)	(1,796,982)
Write off due to extinguishment of senior secured notes	—	(6,467,469)
Balance at June 30, 2020	$ 181,098	$ —

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

	June 30, 2020	September 30, 2019
Risk-free interest rate	0.36 %	1.56 %
Remaining contractual life of warrant	4.63 years	5.38 years
Expected volatility	92.1 %	89.0 %
Annual dividend yield	0 %	0 %
Fair value of common stock	$ 1.29 per share	$ 1.49 per share

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

5. Property and Equipment, Net

Property and equipment, net, consists of:

	June 30, 2020	September 30, 2019
Laboratory equipment	$ 1,067,351	$ 1,067,351
Leasehold improvements	—	160,086
Land and building	—	3,000,000
	1,067,351	4,227,437
Less: accumulated depreciation and amortization	(699,196)	(1,051,477)
	$ 368,155	$ 3,175,960

Depreciation and amortization expense was $50,959 and $833,387 for the three months ended June 30, 2020 and 2019, respectively, and $178,510 and $2,473,005 for the nine months ended June 30, 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 was due to mature in February 2028 and the effective interest rate on the corporate office lease was 43.9%. At September 30, 2019, $475,000 of accumulated amortization was related to capital leases.

Impairment charges

During the three and nine months ended June 30, 2020, the Company recorded an impairment charge of $104,296 and $527,624, respectively, 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 9 for further details.

During the three and nine months ended June 30, 2019, the Company wrote off certain construction in progress and laboratory equipment with a carrying amount of $50,927 and $2,962,064, 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 development and manufacturing of ONS-5010.

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6. Other Assets

Other assets consist of:

	June 30, 2020	September 30, 2019
Advance to PRC joint venture	$ 900,000	$ —
Other assets	533,198	457,476
	$ 1,433,198	$ 457,476

In connection with the Syntone stock purchase agreement, on May 22, 2020, the Company and Syntone entered into a joint venture agreement pursuant to which they agreed to form a PRC joint venture that will be 80% owned by Syntone and 20% owned by the Company. Once formed, the Company intends to enter into a royalty-free license with the PRC joint venture for the development, commercialization and manufacture of the Company's product candidate, ONS-5010 in the greater China market, which includes Hong Kong, Taiwan and Macau.

The Company made the initial investment of $900,000 in June 2020. The Company expects to be required to make an additional capital contribution to the PRC joint venture of approximately $2.1 million, which will be made within four years after the establishment date in accordance with the development plan contemplated in the license agreement or on such other terms within such four-year period.

7. Accrued Expenses

Accrued expenses consists of:

	June 30, 2020	September 30, 2019
Compensation	$ 402,212	$ 919,394
Severance and related costs	29,803	505,570
Research and development	2,642,922	1,692,040
Interest payable	1,412	934,145
Professional fees	157,353	419,216
Lease termination obligation	3,954,717	—
Other accrued expenses	139,735	152,623
	$ 7,328,154	$ 4,622,988

8. Debt

Senior secured notes

	June 30, 2020	September 30, 2019
Convertible senior secured notes	$ —	$ 6,699,000

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

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The new senior secured notes were substantially similar to the Old Senior Notes, as amended through the date of the Exchange Agreement, bore interest at a rate of 12.0% per annum and would have matured December 31, 2020 (subject to extension to June 30, 2021 at the Company's option upon payment of an extension fee equal to 3% of the outstanding balance and being in compliance with applicable Nasdaq listing requirements). The new senior secured notes were convertible, at the option of the holder, beginning April 1, 2020, into shares of the Company's common stock at a conversion price equal to 90% of the two lowest closing bid prices in the 20 trading days immediately preceding such conversion, subject to a floor price of $0.232 per share. The conversion feature was determined to be a redemption feature and was bifurcated from the debt instrument. The estimated fair value of the redemption feature was $8,264,451 at issuance (see Note 4). The Exchange Agreement was accounted for as an extinguishment of debt.

The Company recognized a loss on extinguishment of convertible senior secured notes for the Exchange Agreement during the nine months ended June 30, 2020 of $8,060,580, which amount was equal to the excess fair value of the notes and bifurcated redemption feature over the notes' net carrying value.

During the three months ended June 30, 2020, the holder of the new senior secured notes converted the entire outstanding principal and accrued interest totaling $7,994,494 for 12,201,461 shares of the Company's common stock at an average conversion price of $0.66 per share. As of June 30, 2020, there are no longer any new senior secured notes outstanding. The Company recognized a $6,164,284 gain on extinguishment of the new senior secured notes exchanged for shares of common stock during the three and nine months ended June 30, 2020 primarily due to the redemption feature liability and write-off of unamortized debt discount.

Aggregate interest expense on the Old Senior Notes and the new senior secured notes for the three months ended June 30, 2020 and 2019 was $269,437 and $526,615, respectively, and $819,498 and $1,689,533 for the nine months ended June 30, 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.

Other Indebtedness

The Company has other outstanding debt consisting of unsecured notes, a PPP term loan and equipment loans.

	June 30, 2020	September 30, 2019
Unsecured notes	$ —	$ 977,966
Paycheck Protection Program term loan	904,200	—
Equipment loans	62,855	98,487
	967,055	1,076,453
Less: current portion	(422,131)	(1,026,168)
Long-term debt	$ 544,924	$ 50,285

Unsecured notes

On March 7, 2019, the Company entered into a forbearance and exchange agreement with Iliad Research and Trading, L.P., a Utah limited partnership (the "Lender"). Concurrently with the execution of this agreement, the Lender purchased two stockholder notes issued by the Company previously in the original principal amount of $1,000,000 with an aggregate outstanding balance as of March 7, 2019 of $1,947,133, including accrued interest. The stockholder notes were accruing

interest at the rate of 2.5% per month. The Lender agreed to refrain and forbear from bringing any action to collect under the stockholder notes until March 7, 2020 and to reduce the interest rates currently in effect to 12.0% per annum simple interest during such forbearance period. The Company also agreed to, at Lender's election, repay or exchange the stockholder notes (or portions thereof) for shares of the Company's common stock at an exchange rate of $13.44 per share or, beginning September 2019, at 95% of the average of the two lowest closing bid prices in the prior twenty trading days, as applicable.

During the nine months ended June 30, 2020, the remaining unsecured notes with an aggregate carrying amount of $977,966 and accrued interest of $570,460 were exchanged for 1,475,258 shares of the Company’s common stock at an average exchange price of $1.05. As of June 30, 2020, these unsecured notes were no longer outstanding.

Paycheck Protection Program term loan

On May 4, 2020, the Company received $904,200 in proceeds from a loan granted pursuant to the PPP of the CARES Act. The PPP term loan is evidenced by a promissory note containing the terms and conditions for repayment of the PPP term loan. The PPP term loan provides for an initial six-month deferral of payments and any amount owed on the loan has a two-year maturity (May 2022), with an interest rate of 1% per annum. Commencing December 15, 2020, the Company is required to pay the lender equal monthly payments of principal and interest as required to fully amortize any principal amount outstanding on the PPP term loan as of December 15, 2020 by May 2, 2022. The Company has the right to prepay any amounts outstanding under this loan at any time and from time to time, in whole or in part, without penalty.

During the three months ended June 30, 2019, the Company recognized interest expense related to other indebtedness of $3,480 and $33,552, respectively, and $21,634 and $181,061 for the nine months ended June 30, 2020 and 2019, respectively.

9. Leases

Corporate office and warehouse leases

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

In connection with the lease termination, the Company recorded a liability of $981,987 at May 11, 2020, the cease-use date, that represents the undiscounted future termination payments as the termination period is less than a year. The Company derecognized the assets and liabilities associated with the financing lease and recorded a charge of $680,017 to general and administrative expense.

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At June 30, 2020, the lease termination obligation of $731,987 is included in accounts payable on the consolidated balance sheets. A rollforward of the charges incurred to general and administrative expense for the nine months ended June 30, 2020:

	Balance October 1, 2019	Expensed / Accrued Expense	Cash Payments	Non-cash Adjustments	Balance June 30, 2020
Lease termination payments	$ —	$ 981,987	$ (250,000)	$ —	$ 731,987
Assets and liabilities derecognition	—	(842,514)	—	842,514	—
Other charges	—	540,544	(540,544)		—
	$ —	$ 680,017	$ (790,544)	$ 842,514	$ 731,987

Equipment leases

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

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

The components of lease cost for the three and nine months ended June 30, 2020 are as follows:

	Three months ended June 30, 2020	Nine months ended June 30, 2020
Finance lease cost:		
Amortization of right-of-use assets	$ 32,967	$ 182,967
Interest on lease liabilities	165,191	903,278
Total finance lease cost	198,158	1,086,245
Operating lease cost	43,625	130,875
Total lease cost	$ 241,783	$ 1,217,120

Amounts reported in the consolidated balance sheets for leases where the Company is the lessee as of June 30, 2020 were as follows:

	June 30, 2020
Operating leases:	
Right-of-use asset	$ 206,229
Operating lease liabilities	229,979
Finance leases:	
Right-of-use asset	$ —
Financing lease liabilities	90,375
Weighted-average remaining lease term (years):	
Operating leases	1.3
Finance leases	2.3
Weighted-average discount rate:	
Operating leases	9.0%
Finance leases	8.1%

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Other information related to leases for the nine months ended June 30, 2020 are as follows:

	Nine months ended June 30, 2020
Cash paid for amounts included in the measurement of lease obligations:	
Operating cash flows from finance leases	$ 903,278
Operating cash flows from operating leases	140,625
Financing cash flows from finance leases	196,959
Right-of-use assets obtained in exchange for lease obligations:	
Operating leases	$ —
Finance leases	—

Future minimum lease payments under non-cancelable leases as of June 30, 2020 are as follows for the years ending September 30:

	Operating leases	Finance leases
2020 (remaining three months)	$ 46,875	$ 19,864
2021	195,000	34,869
2022	—	29,605
2023	—	13,149
2024	—	4,383
Total undiscounted lease payments	$ 241,875	$ 101,870
Less: Imputed interest	11,896	11,495
Total lease obligations	$ 229,979	$ 90,375

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.

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At June 30, 2020, the lease termination obligation of $3,954,717 is included in accrued expenses on the consolidated balance sheets. A roll forward of the charges incurred to general and administrative expense for the nine months ended June 30, 2020 is as follows:

	Balance October 1, 2019	Expensed / Accrued Expense	Cash Payments	Balance June 30, 2020
Lease termination payments	$ 3,909,448	$ 495,269	$ (450,000)	$ 3,954,717

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 $7.7 million in gross 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.

In June 2020, the Company issued, in a private placement, an aggregate of 16,000,000 shares of common stock to Syntone, pursuant to a stock purchase agreement entered into on May 22, 2020, at a purchase price of $1.00 per share, for aggregate gross proceeds to the Company of $16.0 million.

In June 2020, the Company issued, in a registered direct offering, an aggregate of 8,407,411 shares of common stock at a purchase price of $1.215 per share, for aggregate gross proceeds to the Company of approximately $10.2 million. In connection with the registered direct offering, the Company issued placement agent warrants to purchase up to an aggregate of 588,519 shares of common stock, at an exercise price of $1.51875 per share and a 5-year term.

During the nine months ended June 30, 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

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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.

During the nine months ended June 30, 2020, the Company issued 1,661 shares of Series A-1 to settle the related dividends that were due on a quarterly basis. At June 30, 2020, there were no shares of Series A-1 outstanding.

Common stock warrants

As of June 30, 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
June 22, 2025	588,519	$ 1.5188
	7,051,857	

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.

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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 nine months ended June 30, 2020 was $3,140,009, 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 nine months ended June 30, 2020, warrants to purchase an aggregate of 15,085,240 shares of common stock with a weighted averaged exercise price of $0.232 were exercised for an aggregate 13,003,414 shares of the Company's common stock; and warrants to purchase an aggregate of 80,797 shares of common stock with a weighted averaged exercise price of $0.08 expired. In aggregate, 10,157,050 of the exercised warrants were April 2019 Warrants, described above, exercised pursuant to the net exercise provisions therein, as amended.

11. Stock-Based Compensation

2011 Equity Incentive Plan

The Company’s 2011 Equity Compensation Plan (the “2011 Plan”) provided for the Company to sell or issue restricted common stock, RSUs, performance-based awards (“PSUs”), cash-based awards or to grant stock options for the purchase of common stock to officers, employees, consultants and directors of the Company. The 2011 Plan was administered by 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 June 30, 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 June 30, 2020, 1,614,404 shares remained available for grant under the 2015 Plan.

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

The Company recorded stock-based compensation expense in the following expense categories of its statements of operations for the three and nine months ended June 30, 2020 and 2019:

	Three months ended June 30,		Nine months ended June 30,	
	2020	2019	2020	2019
Research and development	$ 915,974	$ (207,015)	$ 1,064,912	$ 4,957
General and administrative	442,746	175,750	957,824	1,103,809
	$ 1,358,720	$ (31,265)	$ 2,022,736	$ 1,108,766

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

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Stock options

As of June 30, 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	1,115,810	1.00	
Forfeited	(267,339)	2.74	
Balance at June 30, 2020	2,238,470	2.32	9.2
Vested and exercisable	551,799	3.34	8.9
Vested and expected to vest at June 30, 2020	2,238,470	$ 2.32	9.2

As of June 30, 2020, the aggregate intrinsic value of options outstanding was $388,541. The aggregate intrinsic value represents the total amount by which the fair value of the common stock subject to options exceeds the exercise price of the related options.

The weighted average grant date fair value of the options awarded to employees for the nine months ended June 30, 2020 and 2019 was $0.71 and $4.70 per option, respectively. The fair value of the options was estimated on the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions:

	Nine months ended June 30,	
	2020	2019
Risk-free interest rate	1.08 %	2.46 %
Expected life (years)	5.73	6.00
Expected volatility	89.3 %	89.5 %
Expected dividend yield	—	—

As of June 30, 2020, there was $2,110,777 of unrecognized compensation expense that is expected to be recognized over a weighted-average period of 2.72 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 nine months ended June 30, 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 June 30, 2020	2,470	49.97	4.0
Vested and exercisable at June 30, 2020	2,470	49.97	4.0
Vested and expected to vest at June 30, 2020	2,470	$ 49.97	4.0

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Restricted stock units

The following table summarizes the activity related to RSUs during the nine months ended June 30, 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 June 30, 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 nine months ended June 30, 2020, the Company recognized compensation expense related to the restricted stock of $1,070,404, and $1,149,387, respectively. As of June 30, 2020, there was $2,762,772 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 nine months ended June 30, 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

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began compensating Mr. Dagnon and Mr. Evanson directly as consultants effective March 19, 2020 pursuant to their respective consulting agreements with the Company, which became effective March 19, 2020 following stockholder approval of the share issuances contemplated therein. Mr. Dagnon and Mr. Evanson have also agreed to provide consulting services to an affiliate of BioLexis pursuant to a separate arrangement.

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

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

MTTR and its four principals under the strategic partnership agreement and the subsequent individual consulting agreements earned an aggregate $242,603 and $573,983 during the three months ended June 30, 2020 and 2019, respectively; and $1,023,374 and $1,154,894 during the nine months ended June 30, 2020 and 2019, respectively, which includes monthly consulting fees and expense reimbursement, but excludes stock-based compensation related to restricted stock (Note 11). As of June 30, 2020, an aggregate $89,762 was due to the former MTTR principals as consultants, which is included in accounts payable in the accompanying consolidated balance sheets. As of September 30, 2019, $365,301 was due to MTTR which is included in accrued expenses in the accompanying consolidated balance sheets.

13. Subsequent Events

Syntone Purchase Agreement

On July 16, 2020, the Company received $1.0 million in proceeds in connection with a securities purchase agreement entered into on June 22, 2020 with Syntone, in a private placement pursuant to which the Company issued and sold 823,045 shares of its common stock at a purchase price of $1.215 per share.

Stock options grants

In July 2020, the Company granted 1,581,256 stock options with a weighted average exercise price of $1.57 and grant date fair value of $1.14.

Litigation

On July 20, 2020, Laboratorios Liomont S.A. de C.V. (“Liomont”), filed a complaint against the Company in the U.S. District Court of the Southern District of New York alleging certain breach of contract claims under the June 25, 2014 strategic development, license and supply agreement relating to the biosimilar development program for ONS-3010 and ONS-1045. According to the complaint, Liomont is claiming $3,000,000 damages due. The Company disputes the claims in the Liomont complaint, believes they are without merit, and intends to defend against these claims vigorously.

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, United Kingdom, Europe, Japan and other markets for the treatment of wet age-related macular degeneration, or wet AMD, diabetic macular edema, or DME, and branch retinal vein occlusion, or BRVO.

ONS-5010 (LYTENAVA (bevacizumab-vikg)) 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 clinical program for ONS-5010 in wet AMD involves three clinical trials, which we refer to as NORSE 1, NORSE 2 and NORSE 3, the first two evaluating ONS-5010 against ranibizumab (LUCENTIS) and NORSE 3 an open label safety study to complete the necessary safety population. Enrollment in the NORSE 1 trial is complete with 61 patients enrolled at nine trial sites in Australia. The endpoint for NORSE 1 is 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. 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. The NORSE 1 study was designed to provide the initial safety data to open our IND with the U.S. FDA. We expect to report top line data for NORSE 1 later in August 2020.

The NORSE 2 Phase 3 study began enrolling wet AMD patients in July 2019. Enrollment in NORSE 2 is complete with a total of 227 patients enrolled at 39 clinical trial sites 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 monthly compared to LUCENTIS dosed using the alternative PIER clinical trial dosing regimen. Initial top line data from

NORSE 2 is expected in July 2021. The ongoing COVID-19 pandemic is not expected to impact the completion of the NORSE 2 trial at this time. See "—Impacts of the COVID-19 Pandemic" below for more information.

We plan to initiate the NORSE 3 clinical trial in the third calendar quarter of 2020. 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 three 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, United Kingdom, Europe and Japan, as well as other markets. Because there are no approved bevacizumab products for the treatment of retinal diseases in such major markets, we are developing ONS-5010 as a standard 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 unapproved bevacizumab. Off-label use of unapproved bevacizumab is currently estimated to account for at least 50% of all wet AMD prescriptions in the United States.

Going Concern

Through June 30, 2020, we have funded substantially all of our operations with $278.1 million in proceeds from the sale and issuance of our equity and debt securities. We have also received $29.0 million pursuant to our previous collaboration and licensing agreements.

In June 2020, we closed the private placement of 16,000,000 shares of common stock to Syntone Ventures LLC, or Syntone, a U.S. affiliate of Syntone Technologies Group Co. Ltd., a People's Republic of China, or PRC, entity, our strategic partner for ONS-5010 in China, pursuant to a May 2020 stock purchase agreement, at a purchase price of $1.00 per share, receiving aggregate gross proceeds of $16.0 million. In June 2020, we also issued, in a registered direct offering, an aggregate of 8,407,411 shares of common stock at a purchase price of $1.215 per share, for aggregate gross proceeds of approximately $10.2 million, and in July 2020, we closed the concurrent private placement of 823,045 shares of common stock to Syntone pursuant to a June 2020 stock purchase agreement, at a purchase price of $1.215 per share, receiving aggregate gross proceeds of $1.0 million.

Our cash resources of $24.0 million as of June 30, 2020, and the $1.0 million proceeds received in July 2020 from a private placement, are expected to fund our operations through the first quarter of fiscal 2021. 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 previous collaboration agreements. We have incurred operating losses and negative operating cash flows since inception and there is no assurance that we will ever achieve profitable operations, and if achieved, that profitable operations will be sustained. Our net loss for the nine months ended June 30, 2020 was $25.3 million. In addition, the continued development activities, clinical and preclinical testing and commercialization of our product candidates will require significant additional financing.

On May 6, 2020, we terminated our lease for office space in Cranbury, New Jersey and relocated our headquarters to Monmouth Junction, New Jersey a site previously used by us as our warehouse location. 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. As of June 30, 2020, we had substantial indebtedness that included $3.6 million unsecured notes that were due on demand as of such date and a $0.9 million loan granted pursuant to the Paycheck Protection Program, or PPP, of the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, which matures on May 2, 2022. We will need to raise substantial additional capital to fund our planned future operations, commence clinical trials, receive approval for and commercialize ONS-5010, or to develop other product candidates. We plan to finance our future operations with a combination of proceeds from potential licensing and/or marketing arrangements with pharmaceutical companies, the issuance of equity securities, 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.

Impacts of the COVID-19 Pandemic

We continue to monitor the ongoing COVID-19 global pandemic, which has resulted in travel and other restrictions to reduce the spread of the disease. To date, we have experienced only minor disruptions from the ongoing COVID-19 pandemic, including a brief delay in patient enrollment and recruitment in NORSE 2 due to local clinical trial site protocols designed to protect staff and patients. Given our current infrastructure needs and current strategy, we were able to transition to remote working with limited impact on productivity, as shelter-in-place and other types of local and state orders were imposed. We have confirmed with the Ophthalmic Division of the FDA that it considers both approved and investigational treatments for sight-threatening conditions such as wet AMD not to be elective, and that as such they should continue during the COVID-19 restrictions. All clinical and chemistry, manufacturing and control, or CMC, activities are currently active.

Both NORSE 1 and NORSE 2 have completed enrollment and NORSE 1 has also essentially completed patient follow-up activities. NORSE 2 patients continue to require monthly follow-up visits, which will continue over the next 12 months. To date, we have not experienced any significant COVID-19 disruptions to patient follow-up but the clinical trial protocol accounts for potential delayed or missed visits for any reason, including COVID-19 type interruptions. The FDA has provided guidance in the event of COVID-19 disruptions and we intend to confer with the FDA and follow the appropriate guidance in the event that NORSE 2 experiences an unusually high number of delayed or missed patient visits due to COVID-19.

The safety, health and well-being of all patients, medical staff and our internal and external teams is paramount and is our primary focus. As shelter-in-place rules 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 have entered 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.

Syntone – Private Placement and PRC Joint Venture

In May 2020, we entered into a stock purchase agreement with Syntone, pursuant to which we sold and issued, in a private placement, 16,000,000 shares of our common stock at a purchase price of $1.00 per share, for aggregate gross proceeds of $16.0 million. In connection with the entry into the stock purchase agreement, we entered into a joint venture agreement with Syntone's PRC-affiliate, pursuant to which we agreed to form a PRC joint venture that will be 80% owned by Syntone's PRC-affiliate and 20% owned by us. Once formed, we intend to enter into a royalty-free license with the PRC joint venture for the development, commercialization and manufacture of ONS-5010 in the greater China market, which includes Hong Kong, Taiwan and Macau.

We used approximately $0.9 million of the proceeds from the private placement to fund our initial capital contribution to the PRC joint venture, and expect to be required to make an additional capital contribution to the PRC joint venture of approximately $2.1 million within the next four years.

Selexis SA

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

Selexis also granted us a non-transferrable option to obtain a perpetual, non-exclusive, worldwide commercial license under the Selexis Technology to manufacture, or have manufactured, a recombinant protein produced by a cell line developed using the Selexis Technology for clinical testing and commercial sale. We exercised this option in April 2013 and entered into three commercial license agreements with Selexis for our ONS-3010, ONS-1045 (which covers ONS-5010) and ONS-1050 product candidates. We paid an upfront licensing fee to Selexis for each commercial license and also agreed to pay a fixed milestone payment for each licensed product. In addition, we are required to pay a single-digit royalty on a final product-by-final product and country-by-country basis, based on worldwide net sales of such final products by us or any of our affiliates or sub-licensees during the royalty term. At any time during the term, we have the right to terminate our royalty payment obligation by providing written notice to Selexis and paying Selexis a royalty termination fee. The initiation of our Phase 3 clinical program for ONS-5010 triggered a CHF 65,000 (approximately $0.1 million) milestone payment under the commercial license agreement, which we paid in November 2019.

As of June 30, 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 is to 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 and/or specific treatment indications 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, finance leases and other finance obligations.

Loss on Extinguishment of Debt

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

Change in fair value of redemption feature

Change in fair value of the redemption feature reflects the change in the fair value of the embedded derivative contained in the 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 was subject to re-measurement at each balance sheet date until our obligations under the new senior secured notes were satisfied.

Change in Fair Value of Warrant Liability

Warrants to purchase our common stock that were issued in conjunction with the convertible senior secured notes originally issued December 2017 are classified as liabilities and recorded at fair value. The warrants are subject to re-measurement at each balance sheet date and we recognize any change in fair value in our statements of operations. During the nine months ended June 30, 2020 and 2019, we recorded income of $0.1 million and $2.3 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 June 30, 2020 and 2019

	Three months ended June 30,		
	2020	2019	Change
Collaboration revenues	$ —	$ 583,848	$ (583,848)
Operating expenses:			
Research and development	8,488,143	4,342,539	4,145,604
General and administrative	3,286,739	1,834,545	1,452,194
Impairment of property and equipment	104,296	50,927	53,369
	11,879,178	6,228,011	5,651,167
Loss from operations	(11,879,178)	(5,644,163)	(6,235,015)
Interest expense, net	443,624	1,081,779	(638,155)
(Gain) loss on extinguishment of debt	(6,164,284)	423,686	(6,587,970)
Change in fair value of warrant liability	127,506	(1,931,244)	2,058,750
Loss before income taxes	(6,286,024)	(5,218,384)	(1,067,640)
Income tax benefit	(3,271,157)	(777,500)	(2,493,657)
Net loss	$ (3,014,867)	$ (4,440,884)	$ 1,426,017

Collaboration Revenues

The following table sets forth a summary of revenue recognized from our collaboration and licensing agreements for the three months ended June 30, 2020 and 2019, all of which was from the recognition of deferred revenues under such agreements:

	Three months ended June 30,	
	2020	2019
IPCA Collaboration	$ —	$ 128,007
Liomont Collaboration	—	84,414
Huahai Collaboration	—	371,427
	$ —	$ 583,848

There were no collaboration revenues for the three months ended June 30, 2020 as compared to $0.6 million for the three months ended June 30, 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 June 30, 2020 and 2019:

	Three months ended June 30,	
	2020	2019
ONS-5010 development	$ 6,792,319	$ 1,160,019
Compensation and related benefits	336,612	1,296,798
Stock-based compensation	915,974	(207,015)
Other research and development	443,238	2,092,737
Total research and development expenses	$ 8,488,143	$ 4,342,539

Research and development expenses for the three months ended June 30, 2020 increased by $4.1 million compared to the three months ended June 30, 2019. The increase is primarily due to an increase in ONS-5010 development costs of $5.6 million as the ONS-5010 program advanced into the NORSE 2 clinical trial in July 2019 and was partially offset by a $1.6 million decrease in other research and development expenses resulting from our decision to focus all of our efforts on ONS-5010 and to outsource the commercial manufacturing and remaining development for the ONS-5010 program.

General and Administrative Expenses

The following table summarizes our general and administrative expenses by type for the three months ended June 30, 2020 and 2019:

	Three months ended June 30,	
	2020	2019
Professional fees	$ 1,248,157	$ 754,509
Compensation and related benefits	370,431	226,166
Stock-based compensation	442,746	175,750
Facilities, fees and other related costs	1,225,405	678,120
Total general and administrative expenses	$ 3,286,739	$ 1,834,545

General and administrative expenses for the three months ended June 30, 2020 increased by $1.5 million compared to the three months ended June 30, 2019. The increase was primarily driven by a loss on lease termination of $0.7 million recognized upon termination of office, manufacturing and laboratory space located in Cranbury, New Jersey, an increase in commercial insurance costs of $0.3 million due to increased premiums, and an increase in professional fees of $0.5 million primarily from increased consulting and professional fees associated with the strategic investment by Syntone for the development and commercialization rights for ONS-5010 in China that closed in June 2020.

Impairment of Property and Equipment

During the three months ended June 30, 2020, we recorded an impairment charge of $0.1 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 June 30, 2019, we wrote off certain construction in progress and laboratory equipment with a carrying amount of $0.1 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 $0.6 million to $0.4 million for the three months ended June 30, 2020 as compared to $1.1 million for the three months ended June 30, 2019. The decrease was primarily due to the termination of the finance lease for the corporate offices in Cranbury, New Jersey and reduction of outstanding principal amount of notes and other

indebtedness, due to exchanges of such indebtedness for shares of our common stock in fiscal 2020 and partial cash repayments in fiscal 2019.

Debt Extinguishment

We recognized a $6.2 million gain on extinguishment of the new secured senior notes during the three months ended June 30, 2020, primarily due to the conversion of the notes into common stock in the third quarter of fiscal 2020 and the resulting write-off of the redemption feature liability as a gain on extinguishment of debt.

We recorded a loss on extinguishment of debt of $0.4 million during the three months ended June 30, 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.

Comparison of Nine Months Ended June 30, 2020 and 2019

	Nine months ended June 30,		
	2020	2019	Change
Collaboration revenues	$ —	$ 2,292,586	$ (2,292,586)
Operating expenses:			
Research and development	18,718,659	16,349,946	2,368,713
General and administrative	7,580,638	6,587,691	992,947
Impairment of property and equipment	527,624	2,962,064	(2,434,440)
	26,826,921	25,899,701	927,220
Loss from operations	(26,826,921)	(23,607,115)	(3,219,806)
Interest expense, net	1,737,440	3,256,505	(1,519,065)
Loss on extinguishment of debt	1,896,296	607,240	1,289,056
Change in fair value of redemption feature	(1,796,982)	—	(1,796,982)
Change in fair value of warrant liability	(74,636)	(2,265,836)	2,191,200
Loss before income taxes	(28,589,039)	(25,205,024)	(3,384,015)
Income tax benefit	(3,271,157)	(777,500)	(2,493,657)
Net loss	$ (25,317,882)	$ (24,427,524)	$ (890,358)

Collaboration Revenues

The following table sets forth a summary of revenue recognized from our collaboration and licensing agreements for the nine months ended June 30, 2020 and 2019, all of which was from the recognition of deferred revenues under such agreements:

	Nine months ended June 30,	
	2020	2019
IPCA Collaboration	$ —	$ 384,021
Liomont Collaboration	—	268,242
Huahai Collaboration	—	1,114,281
BioLexis Collaboration	—	526,042
	$ —	$ 2,292,586

There were no collaboration revenues for the nine months ended June 30, 2020 as compared to $2.3 million for the nine months ended June 30, 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 nine months ended June 30, 2020 and 2019:

	Nine months ended June 30,	
	2020	2019
ONS-5010 development	$ 15,165,085	$ 6,153,101
Compensation and related benefits	1,029,283	4,693,270
Stock-based compensation	1,064,912	4,957
Other research and development	1,459,379	5,498,618
Total research and development expenses	$ 18,718,659	$ 16,349,946

Research and development expenses for the nine months ended June 30, 2020 increased by $2.4 million compared to the nine months ended June 30, 2019. The increase was primarily driven by an increase in ONS-5010 development costs of $9.0 million as the ONS-5010 program advanced into the NORSE 2 clinical trial in July 2019. This increase was partially offset by a $4.0 million decrease in other research and development expenses and a $3.7 million decrease in compensation expenses resulting from our decision to focus all of our efforts on ONS-5010 and to outsource the commercial manufacturing and remaining development for the ONS-5010 program.

General and Administrative Expenses

The following table summarizes our general and administrative expenses by type for the nine months ended June 30, 2020 and 2019:

	Nine months ended June 30,	
	2020	2019
Professional fees	$ 2,968,390	$ 2,884,838
Compensation and related benefits	724,498	817,474
Stock-based compensation	957,824	1,103,809
Facilities, fees and other related costs	2,929,926	1,781,570
Total general and administrative expenses	$ 7,580,638	$ 6,587,691

General and administrative expenses for the nine months ended June 30, 2020 increased by $1.0 million compared to the nine months ended June 30, 2019. The increase was primarily driven by a loss on lease termination of $0.7 million recognized upon termination of office, manufacturing and laboratory space located in Cranbury, New Jersey and an increase in commercial insurance costs of $0.5 million due to increased insurance premiums in fiscal 2020.

Impairment of Property and Equipment

During the nine months ended June 30, 2020, we recorded an impairment charge of $0.5 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 nine months ended June 30, 2019, we wrote off certain construction in progress and laboratory equipment with a carrying amount of $3.0 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 $1.5 million to $1.7 million for the nine months ended June 30, 2020 as compared to $3.3 million for the nine months ended June 30, 2019. The decrease was primarily due to the termination of the finance lease for the corporate offices in Cranbury, New Jersey and the reduction of outstanding principal amount of notes and other

indebtedness, due to exchanges of such indebtedness for shares of our common stock in 2020 and partially due to repayments in fiscal 2019.

Debt Extinguishment

During the nine months ended June 30, 2020, we recorded a loss on extinguishment of $1.9 million in connection with the exchange of our old senior secured notes for new senior secured notes in December 2019 and the exchange of the remaining outstanding principal and accrued interest on senior secured notes for common stock shares during the third quarter in fiscal 2020. 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 $0.6 million during the nine months ended June 30, 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 June 30, 2020, we have funded substantially all of our operations through the receipt of $278.1 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.

In February 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, 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.

In March 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 convertible secured notes began exchanging the outstanding principal and interest per terms of the notes. The holder exchanged the entire outstanding principal and accrued interest totaling $7,994,494 for 12,201,461 shares of our common stock at an average conversion price of $0.66 per share. As of June 30, 2020, there are no longer any convertible senior secured notes outstanding.

In May 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.

In June 2020, we issued, in a private placement, an aggregate of 16,000,000 shares of common stock to Syntone, pursuant to a May 2020 stock purchase agreement, at a purchase price of $1.00 per share, for aggregate gross proceeds of $16.0 million.

In June 2020, we issued, in a registered direct offering, an aggregate of 8,407,411 shares of common stock at a purchase price of $1.215 per share, for aggregate gross proceeds of approximately $10.2 million. In connection with the registered direct offering, we issued placement agent warrants to purchase up to an aggregate of 588,519 shares of common stock, at an exercise price of $1.51875 per share and a 5-year term.

In June 2020, we also entered into a stock purchase agreement with Syntone for the sale of issue 823,045 shares of common stock at a purchase price of $1.215 per share, which we closed in July 2020, for gross proceeds of $1.0 million.

As of June 30, 2020, we had a cash balance of $24.0 million. In addition, we had substantial indebtedness that included $3.6 million unsecured notes that were due on demand as of such date and a $0.9 million loan granted pursuant to the PPP of the CARES Act, which matures on May 2, 2022. 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 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 June 30, 2020 and the $1.0 million proceeds received in July 2020 from the Syntone private placement will be sufficient to fund our operations through the first quarter of fiscal 2021. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We will need to raise substantial additional capital in order to complete our planned ONS-5010 development program. We plan to finance our future operations with a combination of proceeds from potential strategic collaborations, sale of the development and commercial rights to our drug product candidates, the issuance of equity securities, the

issuance of additional debt, and revenues from potential future product sales, if any. 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:

	Nine months ended June 30,	
	2020	**2019**
Net cash used in operating activities	$ (19,712,228)	$ (26,347,531)
Net cash used in investing activities	(900,000)	(437,306)
Net cash provided by financing activities	36,549,780	39,094,278

Operating Activities.

During the nine months ended June 30, 2020, we used $19.7 million of cash in operating activities resulting primarily from our net loss of $25.3 million, This use of cash was partially offset by $4.0 million of non-cash items such as change in fair value of redemption feature, non-cash interest expense, stock-based compensation, change in fair value of warrant liability, impairment of property and equipment, loss on extinguishment of debt, loss on lease termination, and depreciation and amortization expense. The change in our operating assets and liabilities of $1.6 million was primarily to an increase in our accounts payable of $0.9 million primarily due to remaining future lease termination payments and increased professional fees and a decrease in prepayments of $0.7 million associated with our ONS 5010 development costs from September 30, 2019 offset.

During the nine months ended June 30, 2019, we used $26.4 million of cash in operating activities resulting primarily from our net loss of $24.4 million. This use of cash was partially offset by $6.2 million of non-cash 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 of negative $8.1 million was primarily due to prepayments associated with our clinical trials and ONS-5010 development costs and payments of our accrued expenses from September 30, 2018 as well as the amortization of our deferred revenues from collaborations.

Investing Activities.

During the nine months ended June 30, 2020, we used cash of $0.9 million in investing activities for the initial investment in our PRC joint venture.

During the nine months ended June 30, 2019, we used cash of $0.4 million in investing activities for the purchase of property and equipment.

Financing Activities.

During the nine months ended June 30, 2020, net cash provided by financing activities was $36.5 million, primarily attributable to $9.4 million in net proceeds from the February 2020 registered direct offering and concurrent private placements; $16.0 million in net proceeds from the May 2020 private placement with Syntone, which closed in June 2020; and $9.3 million in net proceeds from the registered direct offering in June 2020. During the nine months ended June 30, 2020, we received $1.1 million in net proceeds from the exercise of common stock warrants and $0.9 million in proceeds from the PPP loan. We also made $0.2 million in debt and finance lease obligations payments during the nine months ended June 30, 2020.

During the nine months ended June 30, 2019, net cash provided by financing activities was $39.1 million, primarily attributable to $19.8 million in net proceeds from the November 2018 BioLexis private placement, and approximately $26.2 in net proceeds from the April 2019 public offering. In November 2018 through February 2019, we issued BioLexis an aggregate of 2,680,965 shares of our common stock for gross cash proceeds of $20.0 million. In April 2019, we completed a public offering of 10,340,000 shares of our common stock, 15-month warrants to purchase up to an aggregate of 10,340,000 shares of our common stock and five-year warrants to purchase up to an aggregate of 10,340,000 shares of our common stock for net proceeds of $26.2 million. We also made $6.9 million in debt and capital lease obligations payments during the nine months ended June 30, 2019.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of June 30, 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 third fiscal quarter ended June 30, 2020. We have not experienced any material impact to our internal control over financial reporting despite the fact that our employees are working remotely due to the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 situation on our internal controls to minimize the impact on their design and operating effectiveness.

Part II. Other Information

Item 1. Legal Proceedings

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

On July 20, 2020, Laboratorios Liomont S.A. de C.V., or Liomont, filed a complaint against us in the U.S. District Court of the Southern District of New York alleging certain breach of contract claims under our June 25, 2014 strategic development, license and supply agreement relating to the biosimilar development program for ONS-3010 and ONS-1045. According the complaint, Liomont is claiming $3,000,000 damages due. We dispute the claims in the Liomont complaint, believe they are without merit, and intend to defend against them vigorously.

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 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 developments, we have implemented work-from-home policies for all our employees. While certain of these restrictions are being lifted and phased re-openings are occurring, there can be no certainty that such policies will continue, or that new or similar restrictions will not be imposed to address continued spread of disease, The effects of these orders, government-imposed quarantines and our work-from-home policies, including the uncertainty and changing nature of such restrictions, may negatively impact productivity, disrupt our business and could further 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 COVID-19 outbreak. Patient enrollment and recruitment was 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 also materially 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 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 Program, 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.

We may need to enter into alliances with other companies that can provide capabilities and funds for the development and commercialization of our product candidates. If we are unsuccessful in forming or maintaining these alliances on favorable terms, our business could be harmed. We may also have disagreements from time to time with our partners, which could negatively impact our business or reputation.

Because we are a late clinical stage biopharmaceutical company, we have found it necessary to enter into alliances with other companies. For example, we entered into a strategic partnership agreement for consulting services for ONS-5010, pursuant to which we paid a monthly fee and agreed to share a portion of net profits, if any. We have also entered into service agreements for clinical trials, and co-development and license agreements for our biosimilar product candidates. In the future, we may also find it necessary to form other alliances or joint ventures with major pharmaceutical companies to jointly develop and/or commercialize the inactive biosimilar product candidates in our pipeline and any other product

candidates that we may develop. In such alliances, we would expect our collaboration partners to provide substantial capabilities in regulatory affairs, as well as sales and marketing. We may not be successful in entering into any such alliances. Even if we do succeed in securing such alliances, we may not be able to maintain them if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. We may also have disagreements from time to time with our collaboration partners regarding our rights and obligations under such arrangements. For example, one of our contract counterparties for our former biosimilar program recently filed a complaint claiming breach. See Item 1. “Legal Proceedings.” If we are not able to successfully resolve this or any other disagreements with our contract partners, it could negatively impact our business or reputation. Further, if we are unable to secure or maintain such alliances, we may not have the capabilities necessary to continue or complete development of our product candidates and bring them to market, which may have an adverse effect on our business.

In addition to commercialization capabilities, we may depend on our alliances with other companies to provide substantial additional funding for development and potential commercialization of our product candidates. We may not be able to obtain funding on favorable terms from these alliances, and if we are not successful in doing so, we may not have sufficient funds to develop a particular product candidate internally or to bring product candidates to market. Failure to bring ONS-5010, or any other product candidates we may develop in the future, to market will prevent us from generating sales revenue, and this will substantially harm our business. Furthermore, any delay in entering into these alliances could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market. As a result, our business and operating results may be harmed.

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	Stock Purchase Agreement between the Registrant and Syntone Ventures LLC, dated as of May 22, 2020 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on May 28, 2020).
10.2	Form of Securities Purchase Agreement, dated June 22, 2020, by and among the Registrant and 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 June 23, 2020).
10.3	Securities Purchase Agreement, dated June 22, 2020, between the Registrant and Syntone Ventures LLC (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K filed with the SEC on June 23, 2020).
10.4	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's current report on Form 8-K filed with the SEC on June 23, 2020).
10.5	Engagement letter dated June 2, 2020 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 June 23, 2020).
10.6+	Lease Termination Agreement dated, May 6, 2020 between the Registrant and Cedar Brook Corporate Center, LP.
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

\+ Filed herewith.

* 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

SIGNATURES

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

OUTLOOK THERAPEUTICS, INC.

Date: August 14, 2020

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

LEASE TERMINATION AGREEMENT

THIS LEASE TERMINATION AGREEMENT (hereinafter referred to as this "**Agreement**") is made as of the 6th day of May, 2020, by and between **CEDAR BROOK CORPORATE CENTER, LP**, a New Jersey limited partnership, whose address is 4A Cedar Brook Drive, Cranbury, New Jersey 08512 (hereinafter referred to as "**Landlord**"); and **OUTLOOK THERAPEUTICS, INC.** (f/k/a ONCOBIOLOGICS, INC**.),** a Delaware corporation, whose address is 7 Clarke Drive, Cranbury, New Jersey 08512 (hereinafter referred to as "**Tenant**").

RECITALS:

A. Landlord and Tenant have entered into that certain Lease dated June 12, 2011, for certain real property and improvements consisting of 66,249+/- square feet of space located at 7 Clarke Drive, Cranbury, New Jersey, constituting a portion of the office/industrial park known as Cedar Brook Corporate Center (as amended and modified from time to time, hereinafter referred to as the "**Lease**").·

B. Tenant has requested that Landlord agree to an early termination of the Lease, and Landlord has agreed to do so, subject to and upon the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants and conditions herein contained and for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Landlord and Tenant hereby agree as follows:

1. **Recitals**. The Recitals set forth above are incorporated and shall be deemed a part of this Agreement.

2. **Defined Terms**. All capitalized terms not expressly defined in this Agreement shall have the meanings assigned and ascribed to such terms in the Lease.

3. **Termination**. Landlord and Tenant agree that the Lease shall be terminated upon the date of satisfaction of the following conditions precedent (such date being referred to herein as the "**Lease Termination Date**"); provided, however, that in the event the Lease Termination Date has not occurred on or before May 10, 2020, this Agreement shall automatically terminate and be of no further force or effect:

(a) Tenant shall have vacated the Leased Premises in the condition prescribed by and set forth in Section 27 of the Lease and as set forth in this Agreement;

(b) to the extent transferable without cost or expense to Tenant, Tenant shall assign and transfer its rights, title and interests in and to any and all architectural and engineering drawings, plans and specifications relating to the Leased Premises, free and clear of any and all liens, claims and encumbrances, to WuXi Biologics USA LLC (hereinafter referred to as "**WuXi**") by execution and delivery of a Bill of Sale and Assignment substantially in the form of **Appendix 1** attached hereto (hereinafter referred to as the "**Bill of Sale and Assignment**");

(c) to the extent transferable without cost or expense to Tenant, Tenant shall assign and transfer its rights, title and interests in and to the furniture, fixtures and equipment located in the Leased Premises and set forth on Exhibit A of the Bill of Sale and Assignment to WuXi, free and clear of any and all liens, claims and encumbrances, by execution and delivery of the Bill of Sale and Assignment;

(d) Tenant shall have delivered to Landlord evidence reasonably satisfactory to Landlord that Tenant has complied with all applicable terms and provisions of the Industrial Site Recovery Act, N.J.S.A 13: IK-6 et seq. (hereinafter referred to as "**ISRA**"), and any other environmental law, rule or regulation in respect of the Leased Premises, including any decommissioning required thereunder (it being understood and agreed that the foregoing shall not relieve or release Tenant or Landlord from any liabilities or obligations under the Lease or otherwise in respect of any applicable provision of any environmental law,

rule or regulation);

(e) Landlord and Tenant shall have executed a lease termination certificate (hereinafter referred to as the "**Lease Termination Certificate**") in substantially the form attached hereto and made a part hereof as **Appendix 2**, evidencing the termination of the Lease in accordance with the terms, conditions and provisions of this Agreement;

(f) Concurrently with the execution of the Lease Termination Certificate, Tenant shall pay to Landlord the sum of $39,250.00; and

(g) Landlord and WuXi shall have signed a lease for all or a portion of the Leased Premises.

In the event the foregoing conditions are not satisfied on or before May 10, 2020, then, unless the parties otherwise agree in writing to extend this Agreement, Tenant shall immediately pay all Rent due under the Lease (less the amount paid under paragraph (f) above), and the Lease shall remain in full force and effect.

4. **Lease Termination Payment**. In consideration of the termination of the Lease, Tenant shall pay to Landlord a lease termination payment (hereinafter referred to as the "**Lease Termination Payment**") in the aggregate amount of $981,987.00, which Lease Termination Payment shall be payable in eight (8) installments, the first seven (7) of which installments shall each be in the amount of $125,000.00 and the final installment of which shall be in the amount of $106,987.00, with the first installment due and payable on the Lease Termination Date and each subsequent installment shall be due and payable on the first day of each of the seven (7) calendar months thereafter. In the event Tenant fails to make any installment of the Lease Termination Payment within five (5) days of its due date, the remaining balance of the Lease Termination Payment shall be immediately due and payable within five (5) business days of written request therefor by Landlord to Tenant. The acceptance by Landlord of any partial payment or any payment after any date when due shall not be deemed or constitute the waiver of any right or remedy of the Landlord hereunder or any modification of any term or provision set forth herein.

5. **Security Deposit**. Landlord and Tenant acknowledge that Landlord is currently holding the sum of $190,336.00 as a cash security deposit (hereinafter referred to as the "**Security Deposit**") pursuant to the terms, conditions and provisions of Section 37 of the Lease. The parties agree that Landlord shall continue to hold the Security Deposit thereunder as security for, and Tenant grants to Landlord a first and exclusive lien, pledge and security interest in and to the Security Deposit as collateral for, (a) Tenant's obligations under the Lease until the Lease Termination Date, (b) Tenant's obligations under this Agreement, including payment in full of the Lease Termination Payment as herein provided, and (c) Tenant's obligations under that certain Lease Termination Agreement (hereinafter referred to as the "**Building 9 LTA**") dated August 28, 2018, by and between Tenant and Cedar Brook East Corporate Center, LP with respect to the premises located at 9 Cedar Brook Drive, Cranbury, New Jersey (hereinafter collectively referred to as the "**Secured Obligations**"). Any and all Secured Obligations which are not paid in full on or before the date when due, beyond any applicable cure period therefor, shall accrue interest on the unpaid balance thereof at the annual rate of seven percent (7%) per annum until paid. Upon any default by Tenant in the payment or performance of the Secured Obligations beyond any applicable cure period therefor, Landlord shall have all rights and remedies available at law or in equity in respect of the Security Deposit, including the right, upon five (5) business days' notice, to apply the Security Deposit to payment of all or any portion of the Secured Obligations. In the event that Landlord applies all or any portion of the Security Deposit to any of the Secured Obligations in accordance with the terms, conditions or provisions of this paragraph 5, Landlord shall have no right to require that Tenant replenish all or any portion of the Security Deposit. Upon satisfaction and payment in full of the Secured Obligations in accordance with the terms thereof, including the payment of any interest accrued thereon, Landlord shall release the Security Deposit to Tenant.

6. **Lease Obligations**. All of Tenant's obligations under the Lease, including the payment of all amounts due thereunder, and all of Landlord's obligations under the Lease shall each remain in full force and effect until the Lease Termination Date. From and after the Lease Termination Date, (a)

Tenant shall have no further right, benefit or privilege under the Lease, nor any liability or obligation thereunder, except for such liabilities and obligation which, under the terms of the Lease, survive the expiration or termination thereof and (b) Landlord shall have no further right, benefit or privilege under the Lease, nor any liability or obligation thereunder, except for such liabilities and obligation which, under the terms of the Lease, survive the expiration or termination thereof.

7. **Representations**. Landlord and Tenant each represent and warrant to the other that each has the full power and authority to enter into this Agreement and to perform its obligations hereunder without the consent or approval of any other person or entity which has not already been obtained. Tenant represents and warrants that it has not assigned the Lease or sublet its interest in the Lease.

8. **Releases**.

(a) Effective as of the Lease Termination Date, Landlord shall remise, release and forever discharge Tenant, its successors and assigns, from all obligations and liability under the Lease, except as expressly set forth in this Agreement and/or the Bill of Sale and Assignment, and Landlord hereby agrees that, as of the Lease Termination Date, the Lease shall be cancelled, null and void and of no further force or effect.

(b) Effective as of the Lease Termination Date, Tenant shall remise, release and forever discharge Landlord, its successors and assigns, from all obligations and liability under the Lease, except as expressly set forth in this Agreement and/or the Bill of Sale and Assignment, and Tenant hereby agrees that, as of the Lease Termination Date, the Lease shall be cancelled, null and void and of no further force or effect.

The foregoing releases shall not affect (i) the terms, conditions and provisions of this Agreement which shall remain in full force and effect following the Lease Termination Date in accordance with the terms set forth herein, and (ii) the terms and provisions of the Lease which are expressly stated therein to survive the termination or expiration of the Lease.

9. **Captions**. The captions preceding the various paragraphs of this Agreement have been inserted solely for convenience of reference and shall not be used in construing this Agreement.

10. **Choice of Law**. This Agreement shall be governed by the laws of the State of New Jersey.

11. **Successors and Assigns**. This Agreement shall be binding upon the parties hereto, their successors and permitted assigns, and may not be altered, amended, terminated or modified except by written instrument executed by the parties hereto.

12. **Counterparts**. This Agreement may be executed in several counterparts, which shall constitute one and the same instrument. Execution of this Agreement by PDF or facsimile shall bind the parties.

13. **Entire Agreement**. This Agreement is intended by the parties as the final, complete and exclusive statement of the transactions evidenced herein. All prior or contemporaneous promises, agreements and understandings, whether oral or written, are deemed to be superseded by this Agreement, and no party is relying on any promise, agreement or understanding not set forth herein.

14. **Construction**. This Agreement has been drafted by Landlord as a matter of convenience and shall not, on such account, be interpreted against or for either party, it being understood that each of the parties has had an opportunity to submit revisions to the text hereof.

[SIGNATURES APPEAR ON THE FOLLOWING PAGE]

IN WITNESS WHEREOF the parties have hereunto set their hands and seal the day and year first above written.

LANDLORD:

CEDAR BROOK CORPORATE CENTER, LP

By: /s/ A. Joseph Stern
Name: A. Joseph Stern
Title: Partner

TENANT:

OUTLOOK THERAPEUTICS, INC. (FKA ONCOBIOLOGICS, INC.)

By: /s/ Lawrence A. Kenyon
Name: Lawrence A. Kenyon
Title: President and CEO

APPENDIX 1

BILL OF SALE AND ASSIGNMENT AGREEMENT

THIS BILL OF SALE AND ASSIGNMENT AGREEMENT (hereinafter referred to as this "**Bill of Sale**") is made as of the 11 day of May, 2020, by and between **WUXI BIOLOGICS USA LLC**, a Delaware limited liability company (hereinafter referred to as the "**Assignee**"), as the designee of CEDAR BROOK CORPORATE CENTER, LP, a New Jersey limited partnership, whose address is 4A Cedar Brook Drive, Cranbury, New Jersey 08512 (hereinafter referred to as "**Landlord**"); and **OUTLOOK THERAPEUTICS, INC.** (f/k/a ONCOBIOLOGICS, INC.), a Delaware corporation, whose address is 7 Clarke Drive, Cranbury, New Jersey 08512 (hereinafter referred to as "**Tenant**").

RECITALS:

A. Landlord and Tenant have entered into that certain Lease dated June 12, 2011, for certain real property and improvements consisting of 66,249+/- square feet of space located at 7 Clarke Drive, Cranbury, New Jersey (hereinafter referred to as the "**Leased Premises**"), constituting a portion of the office/industrial park known as Cedar Brook Corporate Center (as amended and modified from time to time, hereinafter referred to as the "**Lease**").

B. Pursuant to that certain Lease Termination Agreement dated May 10 , 2020 (the "**Termination Agreement**") by and between Tenant and Landlord, Tenant and Landlord have agreed to an early termination of the Lease, subject to and upon the terms, conditions and provisions set forth therein.

C. Pursuant to the Termination Agreement, Landlord and Tenant are concurrently herewith executing and delivering a Lease Termination Certificate pursuant to which the Lease is terminated as of the date hereof.

D. Tenant (i) has possession of those certain architectural and engineering drawings, plans and specifications relating to the Leased Premises and Tenant's planned improvements as are located in the facility manager's office located at the Leased Premises (hereinafter referred to as the "**Plans and Specs**"), and (ii) owns and has possession of the furniture, fixtures and equipment located in the Leased Premises and located in leased warehouse space located at 4260 US Route 1, Monmouth Junction, New Jersey 08852 (hereinafter referred to as the "**Off-Site Storage Facility**"), which furniture, fixtures and equipment is listed on **Exhibit A** attached hereto (hereinafter referred to as the "**Equipment**").

E. Pursuant to the Termination Agreement, Tenant has agreed to transfer, convey and assign all of its right, title and interest in, to and under the Plans and Specs and Equipment to the Assignee.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants and conditions herein contained and for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Assignee and Tenant hereby agree as follows:

Tenant by this Bill of Sale hereby grants, bargains, sells, conveys, transfers, assigns and delivers to Assignee, its successors and assigns, all of Tenant's transferable rights, title and interests in, to and under all Plans and Specs and the Equipment to the Assignee, free and clear of all liens, claims and encumbrances.

Assignee does hereby (b) accept and acquire Tenant's transferable rights, title and interests in and to the Plans and Specs and Equipment; and (b) assume and agree to discharge and perform all liabilities

and obligations arising under or associated with Assignee's use of the Plans and Specs and Equipment (hereinafter collectively referred to as the "**Assumed Liabilities**").

Tenant represents and warrants that: (a) it has possession of the Plans and Specs as are located in the facility manager's office at the Leased Premises and will provide to Assignee such hard copies as they exist and any electronic copies of the Plans and Specs which may be in Tenant's possession and control, (b) it has good, valid and legal title to, free and clear of all liens, claims and encumbrances, and the full right, power and authority to transfer, convey, assign and deliver the Equipment to the Assignee, without any requirement of payment or notice to, or consent or approval of, any other party, and (c) except for the Assumed Liabilities arising from and after the date hereof, there are no amounts, liabilities, obligations or acts of performance unpaid, owing or otherwise due in respect of the Equipment or related thereto.

TENANT MAKES NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE IN RESPECT OF THE PLANS AND SPECS AND EQUIPMENT (HEREINAFTER REFERRED TO AS THE "**ASSIGNED PROPERTIES**"), AND THE SAME ARE CONVEYED, DELIVERED, AND/OR SOLD IN "AS IS, WHERE IS" CONDITION, WITH ALL FAULTS. BY EXECUTION OF THIS BILL OF SALE, ASSIGNEE AFFIRMS THAT IT HAS NOT RELIED ON TENANT'S SKILL OR JUDGMENT TO SELECT OR FURNISH THE ASSIGNED PROPERTIES FOR ANY PARTICULAR PURPOSE, AND THAT TENANT MAKES NO WARRANTY THAT THE ASSIGNED PROPERTIES ARE FIT FOR ANY PARTICULAR PURPOSE, AND THAT THE ASSIGNED PROPERTIES ARE BEING SOLD TO ASSIGNEE WITHOUT REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS, IMPLIED OR STATUTORY

Tenant and Assignee hereby covenant and agree to sign, seal, execute and deliver, or cause to be signed, sealed, executed and delivered and to do or make, or cause to be done or made, upon reasonable request by the other party, any and all agreements, instruments, papers, acts or things supplemental, confirmatory or otherwise, as may be reasonably required by the Tenant or Assignee, respectively, for the purpose of or in connection with acquiring, or more effectively vesting in the Assignee, or evidencing the vesting in the Assignee of, the Plans and Specs and Equipment transferred, assigned or delivered hereby or hereunder. The obligations of this paragraph shall survive the transfer of the Assigned Properties.

Assignee and Tenant each represent and warrant to the other that each has the full power and authority to enter into this Bill of Sale and to perform its obligations hereunder without the consent or approval of any other person or entity which has not already been obtained.

This Bill of Sale shall be governed by the laws of the State of New Jersey. This Bill of Sale shall be binding upon the parties hereto, their successors and assigns, and may not be altered, amended, terminated or modified except by written instrument executed by the parties hereto. This Bill of Sale may be executed in several counterparts, which shall constitute one and the same instrument. Any party to this Bill of Sale may deliver an executed copy hereof by facsimile transmission to the other party hereto, and any such delivery shall have the same force and effect as any other delivery of a manually signed copy of this Bill of Sale. This Bill of Sale and the Termination Agreement is intended by the parties as the final, complete and exclusive statement of the transactions evidenced herein. All prior or contemporaneous promises, agreements and understandings, whether oral or written, are deemed to be superseded by this Bill of Sale and the Termination Agreement, and no party is relying on any promise, agreement or understanding not set forth herein or therein,

C. Certain of the Equipment will be located (a) in the Leased Premises and (b) in the Off-Site Storage Facility). Tenant's lease of the Off-Site Storage Facility will continue after the date of this Bill of Sale for at least six (6) months.

Tenant agrees, at no additional cost to Assignee, that the Equipment that is located at the Off-Site Storage Facility (hereinafter referred to as the "**Off-Site Equipment**") may continue to be stored at the Off-Site Storage Facility for up to six (6) months following the date of this Bill of Sale; provided, however, that (i) Assignee shall bear all risks of loss or damage to the Equipment from and after the date hereof, (ii) Assignee shall remove all Off-Site Equipment from the Off-Site Storage Facility within six (6) months following the date of this Bill of Sale, (iii) Tenant shall have the right to sell, transfer, assign, convey discard and or otherwise dispose of any Off-Site Equipment from and after the date which is six (6) months following the date of this Bill of Sale, all at Assignee's sole cost and expense, and (iv) from and after the date which is six (6) months from the date of this Bill of Sale, Assignee shall be deemed to have disclaimed any right, title and interest in and to any Off-Site Equipment which remains located at the Off-Site Storage Facility.

Assignee, upon reasonable prior written notice to Tenant, will be granted reasonable access during Tenant's normal business hours to the Off-Site Storage Facility to access the Off-Site Equipment. In connection with any such access, Assignee shall furnish or cause to be furnished to Tenant, and cause to be maintained and kept in effect, and without expense to Tenant, at all times that any entry is made upon the Off-Site Storage Facility, evidence of insurance against claims for personal injury (including death), and property damage, under a policy or policies of general public liability insurance of not less than $1,000,000 in respect to bodily injury (including death), and not less than $3,000,000 of excess liability insurance, naming Tenant and its landlord at the Off-Site Storage Facility as additional insureds. Each policy shall be on an occurrence basis and not on a claims made basis. Each policy shall be issued by a recognized, responsible insurance company licensed to do business in the State of New Jersey. In addition, Assignee shall furnish or cause to be furnished to Tenant, and cause to be maintained and kept in effect, and without expense to Tenant, at all times that any entry is made upon the Off-Site Storage Facility, evidence of adequate workers' compensation insurance in statutory limits to cover employees of Assignee and any of Assignee's agents and invitees which are or may become engaged in any activities at the Off-Site Storage Facility.

Assignee shall indemnify, defend and hold Tenant and its partners, members, officers, directors, shareholders, agents and employees harmless from and against all claims, liabilities, losses, penalties, damages and costs, foreseen or unforeseen, including, without limitation, reasonable legal, engineering and other professional or expert fees and expenses which any or all them may incur (hereinafter collectively referred to as "**Claims**"), resulting directly or indirectly, wholly or partly, from the access granted hereunder and the storage of the Off-Site Equipment at the Off-Site Storage Facility. Assignee releases and covenants not to sue Tenant with respect to any personal injury or property damage suffered by Tenant or its employees, representatives, agents and/or any third party (hereinafter collectively referred to as "**Damages**"), resulting directly or indirectly, wholly or partly, from the breach of this Bill of Sale or the terms, conditions and provisions of this **Paragraph 7**.

The obligations set forth in this **Paragraph 7** shall survive the execution of this Bill of Sale.

[SIGNATURES APPEAR ON THE FOLLOWING PAGE]

IN WITNESS WHEREOF the parties have hereunto set their hands and seal the day and year first above written.

WUXI BIOLOGICS USA, LLC as Assignee

By: /s/ Michelle Chen
Name: Michelle Chen
Title: Vice President, Head of Corporate Development

OUTLOOK THERAPEUTICS, INC. (FKA ONCOBIOLOGICS, INC.). Tenant

By: /s/ Lawrence A. Kenyon
Name: Lawrence A. Kenyon
Title: President & CEO

APPENDIX 2

TO THAT CERTAIN LEASE TERMINATION AGREEMENT BY AND BETWEEN CEDAR BROOK CORPORATE CENTER, LP, AS LANDLORD, AND OUTLOOK THERAPEUTICS, INC., AS TENANT, DATED AS OF MAY 1, 2020

LEASE TERMINATION CERTIFICATE

THIS LEASE TERMINATION CERTIFICATE is made as of the 10th day of May, 2020, by and between **CEDAR BROOK EAST CORPORATE CENTER, LP**, a New Jersey limited partnership, whose address is 4A Cedar Brook Drive, Cranbury, New Jersey 08512 (hereinafter referred to as "**Landlord**"); and **OUTLOOK THERAPEUTICS, INC.**, a Delaware corporation, (f/k/a ONCOBIOLOGICS, INC.) whose address is 7 Clarke Drive, Cranbury, New Jersey 08512 (hereinafter referred to as "**Tenant**").

RECITALS

D. Landlord and Tenant have entered into that certain Lease for certain real property and improvements located at 7 Clarke Drive, Cranbury, New Jersey (hereinafter referred to as the "**Leased Premises**"), constituting a portion of the office/industrial park known as Cedar Brook Corporate Center, dated June 12, 2011 (hereinafter referred to as the "**Lease**")·

E. Pursuant to that certain Lease Termination Agreement dated as of May 1, 2020 (hereinafter referred to as the "**Termination Agreement**"), Tenant and Landlord have agreed to an early termination of the Lease, subject to and upon the terms and conditions set forth therein.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant hereby agree that the Lease is hereby terminated as of the date set forth above, and, as of such date, Tenant shall have no further rights to occupancy or possession of the Leased Premises under the Lease, and Landlord and Tenant hereby reaffirm the releases set forth in Section 8 of the Termination Agreement.

This Certificate may be executed in several PDF counterparts, which shall constitute one and the same instrument.

SIGNATURES APPEAR ON A SEPARATE PAGE.

IN WITNESS WHEREOF the parties have hereunto set their hands and seal the day and year first above written.

CEDAR BROOK CORPORATE CENTER, LP, Landlord

By: /s/ A. Joseph Stern
Name: A. Joseph Stern
Title: Partner

OUTLOOK THERAPEUTICS, INC. (FKA ONCOBIOLOGICS, INC.), Tenant

By: /s/ Lawrence A. Kenyon
Name: Lawrence A. Kenyon
Title: President and CEO

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: August 14, 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 June 30, 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: August 14, 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."