

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended **March 31, 2018**  
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

**ONCOBIOLOGICS, INC.**

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE  
(STATE OR OTHER JURISDICTION OF  
INCORPORATION OR ORGANIZATION)

38-3982704  
(I.R.S. EMPLOYER  
IDENTIFICATION NO.)

7 CLARKE DRIVE  
CRANBURY, NEW JERSEY  
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES)

08512  
(ZIP CODE)

**REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (609) 619-3990**

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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, outstanding as of May 14, 2018 was 32,332,568.

**Oncobiologics, Inc.**  
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**PART I. FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**Oncobiologics, Inc.**  
**Consolidated Balance Sheets**  
**(unaudited)**

	<b>March 31, 2018</b>	<b>September 30, 2017</b>
<b>Assets</b>		
Current assets:		
Cash	\$ 5,936,115	\$ 3,185,519
Prepaid and other current assets	981,590	719,087
<b>Total current assets</b>	<b>6,917,705</b>	<b>3,904,606</b>
Property and equipment, net	20,176,847	16,088,902
Other assets	692,104	740,362
<b>Total assets</b>	<b>\$ 27,786,656</b>	<b>\$ 20,733,870</b>
<b>Liabilities, convertible preferred stock and stockholders' equity (deficit)</b>		
Current liabilities:		
Senior secured notes	\$ 12,507,368	\$ -
Current portion of long-term debt	102,907	52,600
Current portion of capital lease obligations	855,233	341,120
Stockholder notes	4,612,500	4,612,500
Accounts payable	3,607,776	10,954,358
Accrued expenses	5,038,283	7,337,469
Income taxes payable	2,352,129	2,352,129
Deferred revenue	2,676,103	3,087,561
<b>Total current liabilities</b>	<b>31,752,299</b>	<b>28,737,737</b>
Senior secured notes	-	13,231,700
Long-term debt	127,787	151,110
Capital lease obligations	3,510,811	28,067
Warrant liability	1,984,179	2,274,954
Deferred revenue	3,334,543	4,466,865
Other liabilities	2,347,344	2,569,971
<b>Total liabilities</b>	<b>43,056,963</b>	<b>51,460,404</b>
Commitments (Note 8)		
Series A convertible preferred stock, par value \$0.01 per share: 1,000,000 shares authorized, 261,045 and 32,628 shares issued and outstanding at March 31, 2018 and September 30, 2017, respectively	18,294,782	2,924,441
Stockholders' equity (deficit):		
Preferred stock, par value \$0.01 per share: 7,500,000 shares authorized, no shares issued and outstanding at March 31, 2018 and September 30, 2017, respectively	-	-
Series B convertible preferred stock, par value \$0.01 per share: 1,500,000 shares authorized, 1,500,000 and no shares issued and outstanding at March 31, 2018 and September 30, 2017, respectively	2,661,972	-
Common stock, par value \$0.01 per share; 200,000,000 shares authorized; 25,740,458 and 24,933,944 shares issued and outstanding at March 31, 2018 and September 30, 2017, respectively	257,405	249,339
Additional paid-in capital	159,191,316	152,315,088
Accumulated deficit	(195,675,782)	(186,215,402)
<b>Total stockholders' equity (deficit)</b>	<b>(33,565,089)</b>	<b>(33,650,975)</b>
<b>Total liabilities, convertible preferred stock and stockholders' equity (deficit)</b>	<b>\$ 27,786,656</b>	<b>\$ 20,733,870</b>

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

**Oncobiologics, Inc.**  
**Consolidated Statements of Operations**  
**(unaudited)**

	<b>Three Months Ended March 31,</b>		<b>Six Months Ended March 31,</b>	
	<b>2018</b>	<b>2017</b>	<b>2018</b>	<b>2017</b>
Collaboration revenues	\$ 771,890	\$ 303,140	\$ 1,543,780	\$ 606,281
Operating expenses:				
Research and development	5,156,386	4,116,856	5,558,788	17,347,243
General and administrative	2,446,505	4,024,276	5,995,757	8,892,271
	<u>7,602,891</u>	<u>8,141,132</u>	<u>11,554,545</u>	<u>26,239,514</u>
Loss from operations	(6,831,001)	(7,837,992)	(10,010,765)	(25,633,233)
Interest expense, net	920,870	1,243,892	1,638,753	1,733,037
Loss on extinguishment of debt	-	-	1,252,353	-
Change in fair value of warrant liability	(211,992)	(1,035,902)	(290,775)	(225,819)
Loss before income taxes	(7,539,879)	(8,045,982)	(12,611,096)	(27,140,451)
Income tax (benefit) expense	-	-	(3,150,716)	4,000
Net loss	(7,539,879)	(8,045,982)	(9,460,380)	(27,144,451)
Recognition of beneficial conversion feature upon issuance of Series A convertible preferred stock	(381,664)	-	(15,736,683)	-
Series A convertible preferred stock dividends and related settlement	(636,695)	-	(1,087,496)	-
Net loss attributable to common stockholders	<u>\$ (8,558,238)</u>	<u>\$ (8,045,982)</u>	<u>\$ (26,284,559)</u>	<u>\$ (27,144,451)</u>
<b>Per share information:</b>				
Net loss per share of common stock, basic	\$ (0.33)	\$ (0.34)	\$ (1.04)	\$ (1.16)
Net loss per share of common stock, diluted	<u>\$ (0.34)</u>	<u>\$ (0.38)</u>	<u>\$ (1.05)</u>	<u>\$ (1.16)</u>
Weighted average shares outstanding, basic	<u>25,733,467</u>	<u>23,723,551</u>	<u>25,364,247</u>	<u>23,457,361</u>
Weighted average shares outstanding, diluted	<u>25,733,467</u>	<u>23,801,223</u>	<u>25,364,247</u>	<u>23,496,197</u>

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

**Oncobiologics, Inc.**  
**Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)**  
**Six Months Ended March 31, 2018**  
**(unaudited)**

	<u>Convertible Preferred Stock</u>		<u>Stockholders' Equity (Deficit)</u>						
	<u>Series A</u>		<u>Series B Convertible Preferred Stock</u>		<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity (Deficit)</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>			
Balance at October 1, 2017	32,628	\$ 2,924,441	-	\$ -	24,933,944	\$ 249,339	\$ 152,315,088	\$ (186,215,402)	\$ (33,650,975)
Issuance of vested restricted stock units	-	-	-	-	806,514	8,066	(8,066)	-	-
Sale of Series A convertible preferred stock and common stock warrants, net of costs	217,372	14,265,861	-	-	-	-	6,382,181	-	6,382,181
Series A convertible preferred stock dividends and settlement	11,045	1,104,480	-	-	-	-	(1,087,496)	-	(1,087,496)
Conversion of senior secured notes into Series B convertible preferred stock	-	-	1,500,000	2,661,972	-	-	-	-	2,661,972
Stock-based compensation expense	-	-	-	-	-	-	1,589,609	-	1,589,609
Net loss	-	-	-	-	-	-	-	(9,460,380)	(9,460,380)
Balance at March 31, 2018	<u>261,045</u>	<u>\$ 18,294,782</u>	<u>1,500,000</u>	<u>\$ 2,661,972</u>	<u>25,740,458</u>	<u>\$ 257,405</u>	<u>\$ 159,191,316</u>	<u>\$ (195,675,782)</u>	<u>\$ (33,565,089)</u>

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

**Oncobiologics, Inc.**  
**Consolidated Statements of Cash Flows**  
**(unaudited)**

	<b>Six Months Ended March 31,</b>	
	<b>2018</b>	<b>2017</b>
<b>OPERATING ACTIVITIES</b>		
Net loss	\$ (9,460,380)	\$ (27,144,451)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,407,888	1,349,930
Loss on extinguishment of debt	1,252,353	-
Non-cash interest expense	970,287	977,693
Stock-based compensation	1,589,609	4,791,443
Change in fair value of warrant liability	(290,775)	(225,819)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(262,503)	2,552,975
Other assets	(56,401)	33,550
Accounts payable	(6,909,512)	6,973,453
Accrued expenses	(2,584,186)	1,193,392
Deferred revenue	(1,543,780)	(606,280)
Other liabilities	(222,627)	151,986
Net cash used in operating activities	<u>(16,110,027)</u>	<u>(9,952,128)</u>
<b>INVESTING ACTIVITIES</b>		
Purchase of property and equipment	(1,350,329)	(191,877)
Net cash used in investing activities	<u>(1,350,329)</u>	<u>(191,877)</u>
<b>FINANCING ACTIVITIES</b>		
Proceeds from the sale of common stock, net of offering costs	-	679,789
Payment of debt issuance costs	-	(40,000)
Proceeds from issuance of Series A convertible preferred stock	21,737,200	-
Proceeds from the sale of senior secured notes and detachable warrants	-	10,000,000
Proceeds from exercise of common stock warrants	-	123,001
Change in restricted cash	-	216,086
Payments of capital leases obligations	(375,081)	(477,299)
Repayment of debt	(62,009)	(2,628,410)
Payment of financing costs	(1,089,158)	-
Net cash provided by financing activities	<u>20,210,952</u>	<u>7,873,167</u>
Net increase (decrease) in cash	2,750,596	(2,270,838)
Cash at beginning of period	3,185,519	2,351,887
Cash at end of period	<u>\$ 5,936,115</u>	<u>\$ 81,049</u>
<b>Supplemental disclosure of cash flow information</b>		
Cash paid for interest	<u>\$ 25,505</u>	<u>\$ 418,496</u>
<b>Supplemental schedule of noncash investing activities:</b>		
Purchases of property and equipment in accounts payable and accrued expenses	<u>\$ 27,870</u>	<u>\$ 79,236</u>
<b>Supplemental schedule of noncash financing activities:</b>		
Issuance of Series B convertible preferred stock upon conversion of senior secured notes, net of unamortized debt discount	<u>\$ 1,409,619</u>	<u>\$ -</u>
Issuance of capital lease obligations in connection with purchase of property and equipment	<u>\$ 3,401,964</u>	<u>\$ 62,230</u>
Series A convertible preferred stock dividends	<u>\$ -</u>	<u>\$ -</u>
Settlement of Series A convertible preferred stock dividends upon issuance of Series A convertible preferred stock	<u>\$ 1,104,480</u>	<u>\$ -</u>
Deferred offering costs and common stock issuance costs in accounts payable and accrued expenses	<u>\$ -</u>	<u>\$ (288,725)</u>

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

**Oncobiologics, Inc.**  
**Notes to Unaudited Interim Consolidated Financial Statements**

**1. Organization and Description of Business**

Oncobiologics, Inc. (“Oncobiologics” or the “Company”) was incorporated in New Jersey on January 5, 2010 and started operations in July 2011. Oncobiologics is a clinical-stage biopharmaceutical company focused on identifying, developing, manufacturing and commercializing complex monoclonal antibody (“mAb”) therapeutics. The Company has established fully integrated in-house development and manufacturing capabilities that addresses the numerous complex technical and regulatory challenges in developing and commercializing mAb therapeutics. Since inception, the Company has advanced two product candidates through Phase 1 clinical trials: ONS-3010, a biosimilar to adalimumab (Humira®) and ONS-1045, a biosimilar to bevacizumab (Avastin®). Additionally, the Company has a pipeline of preclinical product candidates in various stages of development. The Company is based in Cranbury, New Jersey.

**2. Liquidity**

The Company has incurred substantial losses and negative cash flows from operations since its inception and has an accumulated deficit of \$195.7 million as of March 31, 2018. The Company has substantial indebtedness that includes \$13.5 million of senior secured notes due in December 2018 and \$4.6 million in notes payable to stockholders that are payable on demand. There can be no assurance that the holders of the stockholder notes will not exercise their right to demand repayment. These factors raise substantial doubt about the Company’s ability to continue as a going concern. The accompanying unaudited interim consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The unaudited interim consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Management believes that the Company’s existing cash as of March 31, 2018 and the proceeds received and to be received from the May 2018 private placement of common stock and warrants, will be sufficient to fund its operations through December 2018, excluding repayment of debt. See Note 11. 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: private placements of equity and/or debt, payments from potential strategic research and development, licensing and/or marketing arrangements with pharmaceutical companies, providing manufacturing services on a contract basis to other biopharmaceutical companies 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. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Updates (“ASU”) of the Financial Accounting Standards Board (“FASB”).

In the opinion of management, the accompanying unaudited interim consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company’s financial position as of March 31, 2018 and its results of operations for the three and six months ended March 31, 2018 and 2017 and cash flows for the six months ended March 31, 2018. Operating results for the three and six months ended March 31, 2018 are not necessarily indicative of the results that may be expected for the full year ending September 30, 2018. 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, 2017 included in the Company’s Annual Report on Form 10-K, as amended to date, filed with the Securities and Exchange Commission (“SEC”), on December 29, 2017.

**Oncobiologics, Inc.**  
**Notes to Unaudited Interim Consolidated Financial Statements**

**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, 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.

**Income taxes**

In November 2017, the Company received approval from the New Jersey Economic Development Authority's Technology Business Tax Certificate Transfer Program to sell a portion of its unused New Jersey net operating losses ("NOLs"), and research and development ("R&D") tax credits. As a result, the Company received \$3.15 million of cash from the sale of these NOLs and credits in December 2017, which it recognized as an income tax benefit for the six months ended March 31, 2018. The Company recorded income tax expense of \$4,000 for the six months ended March 31, 2017, which is primarily attributable to state and foreign withholding taxes in connection with the Company's collaboration and licensing agreements.

**Net loss per share**

Basic and diluted net loss per common share is determined by dividing net loss applicable to common stockholders by the weighted-average common shares 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. The diluted loss per common share calculation is further affected by an add-back of change in fair value of warrant liability to the numerator under the assumption that the change in fair value of warrant liability would not have been incurred if the warrants had been converted into common stock.

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

	<b>Three months ended March 31,</b>		<b>Six months ended March 31,</b>	
	<b>2018</b>	<b>2017</b>	<b>2018</b>	<b>2017</b>
<b>Basic Earnings Per Share</b>				
Net loss	\$ (8,558,238)	\$ (8,045,982)	\$ (26,284,559)	\$ (27,144,451)
Common stock outstanding (weighted average)	25,733,467	23,723,551	25,364,247	23,457,361
Basic net loss per share	<u>\$ (0.33)</u>	<u>\$ (0.34)</u>	<u>\$ (1.04)</u>	<u>\$ (1.16)</u>
<b>Diluted Earnings Per Share</b>				
Net loss	(8,558,238)	(8,045,982)	(26,284,559)	(27,144,451)
Add change in fair value of warrant liability	(211,992)	(1,035,902)	(290,775)	(225,819)
Diluted net loss	(8,770,230)	(9,081,884)	(26,575,334)	(27,370,270)
Common stock outstanding (weighted average)	25,733,467	23,723,551	25,364,247	23,457,361
Add shares from dilutive warrants	-	77,672	-	38,836
Common stock equivalents	25,733,467	23,801,223	25,364,247	23,496,197
Diluted net loss per share	<u>\$ (0.34)</u>	<u>\$ (0.38)</u>	<u>\$ (1.05)</u>	<u>\$ (1.16)</u>



**Oncobiologics, Inc.**  
**Notes to Unaudited Interim Consolidated Financial Statements**

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding as of March 31, 2018 and 2017, as they would be antidilutive:

	<b>As of March 31,</b>	
	<b>2018</b>	<b>2017</b>
Series A convertible preferred stock	39,465,772	-
Series B convertible preferred stock	2,112,676	-
Performance-based stock units	163,934	241,573
Restricted stock units	97,773	1,200,529
Common stock warrants	28,116,505	7,786,573

**Correction of immaterial error related to prior periods**

During fiscal 2017, the Company identified an error related to its accounting and classification for the 82,000 square feet of office and laboratory space in Cranbury, New Jersey that was entered into during August 2015. Due to the Company's involvement in the construction required to complete the leased facility, the Company concluded that the lease should have been accounted for as a direct financing arrangement, whereby the Company records, the fair value of the asset in property and equipment, net on the consolidated balance sheets. A corresponding liability is also recorded and amortized over the lease term through monthly rental payments using the effective interest method.

For the three and six months ended March 31, 2017, rent expense was overstated by \$0.1 million and \$0.2 million, respectively, and interest expense was understated by \$0.1 million and \$0.2 million, respectively. This was primarily attributable to the reclassification of rental payments into interest expense payments in connection with a financing arrangement rather than an operating lease arrangement, as previously presented.

The Company reviewed the impact of this error on the prior periods in accordance with SEC *Staff Accounting Bulletin No. 99, "Materiality,"* and determined that the error was not material to the prior periods. However, the Company has corrected the unaudited interim consolidated statement of operations for the three months ended March 31, 2017 by decreasing research and development expenses and general and administrative expenses by \$82,000 and \$21,000, respectively, and by increasing interest expense by \$0.1 million. The Company corrected the unaudited interim consolidated statement of operations for the six months ended March 31, 2017 by decreasing research and development expenses and general and administrative expenses by \$0.2 million and \$42,000, respectively, and by increasing interest expense by \$0.2 million.

**Recently issued and adopted accounting pronouncements**

In May 2017, the FASB, issued ASU, No. 2017-09, *Compensation — Stock Compensation (Topic 718): Scope of Modification Accounting*. This new ASU is intended to provide clarity and reduce both the diversity in practice of and cost and complexity of applying the guidance in Topic 718, *Compensation — Stock Compensation*, to a change to the terms or conditions of a share-based payment award. This ASU provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. This ASU is effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted. This ASU is not expected to have a material impact on the Company's consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*, (Topic 842). This new ASU represents a wholesale change to lease accounting and introduces a lease model that brings most leases on the balance sheet. It also eliminates the required use of bright-line tests in current U.S. GAAP for determining lease classification. This ASU is effective for annual periods beginning after December 15, 2018 (i.e., calendar periods beginning on January 1, 2019), and interim periods thereafter. Earlier application is permitted for all entities. The Company is currently evaluating the impact of ASU 2016-02 on its consolidated financial statements.

**Oncobiologics, Inc.**  
**Notes to Unaudited Interim Consolidated Financial Statements**

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers*. This guidance requires an entity to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This guidance also requires an entity to disclose sufficient information to enable users of financial statements to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. Qualitative and quantitative information is required about:

- *Contracts with customers* — including revenue and impairments recognized, disaggregation of revenue and information about contract balances and performance obligations (including the transaction price allocated to the remaining performance obligations).
- *Significant judgments and changes in judgments* — determining the timing of satisfaction of performance obligations (over time or at a point in time), and determining the transaction price and amounts allocated to performance obligations.
- *Certain assets* — assets recognized from the costs to obtain or fulfill a contract.

In July 2015, the FASB delayed the effective date of this guidance. As a result, this guidance will be effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. Earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. The Company is currently evaluating the impact that this guidance will have on its consolidated results of operations, financial position and cash flows.

**4. Fair Value Measurements**

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

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

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

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

	March 31, 2018		
	(Level 1)	(Level 2)	(Level 3)
<b>Liabilities</b>			
Warrant liability	\$ -	\$ -	\$ 1,984,179
	September 30, 2017		
	(Level 1)	(Level 2)	(Level 3)
<b>Liabilities</b>			
Warrant liability	\$ -	\$ -	\$ 2,274,954

**Oncobiologics, Inc.**  
**Notes to Unaudited Interim Consolidated Financial Statements**

The table presented below is a summary of changes in the fair value of the Company's Level 3 valuation for the warrant liability for the six months ended March 31, 2018:

Balance at October 1, 2017	\$ 2,274,954
Change in fair value	(290,775)
Balance at March 31, 2018	<u>\$ 1,984,179</u>

The warrants issued in connection with the senior secured notes are classified as liabilities on the accompanying consolidated balance sheet as such 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:

	<b>March 31,</b>
	<b>2018</b>
Risk-free interest rate	2.48%
Remaining contractual life of warrant	3.89 years
Expected volatility	114%
Annual dividend yield	0%
Fair value of common stock	\$0.89 per share

**5. Property and Equipment, Net**

Property and equipment, net, consists of:

	<b>March 31,</b>	<b>September 30,</b>
	<b>2018</b>	<b>2017</b>
Laboratory equipment	\$ 13,846,649	\$ 11,574,474
Leasehold improvements	10,032,640	10,032,640
Computer software and hardware	483,807	472,054
Land and building	3,000,000	-
Construction in progress	2,866,581	2,654,675
	<u>30,229,677</u>	<u>24,733,843</u>
Less: accumulated depreciation and amortization	<u>(10,052,830)</u>	<u>(8,644,941)</u>
	<u>\$ 20,176,847</u>	<u>\$ 16,088,902</u>

Depreciation and amortization expense was \$706,264 and \$680,149 for the three months ended March 31, 2018 and 2017 respectively, and \$1,407,888 and \$1,349,930 for the six months ended March 31, 2018 and 2017, respectively.

At March 31, 2018, \$6,965,545 represents laboratory equipment under capital leases and the Company's corporate office that is classified as a capital lease. At September 30, 2017, \$3,692,913 represents laboratory equipment under capital leases. The term of the equipment leases are between 22 and 36 months and qualify as capital leases. The Company's corporate office lease matures in February 2028. The equipment leases bear interest between 5.0% and 19.4% and the effective interest rate on the corporate office lease is 43.9%. At March 31, 2018 and September 30, 2017, \$1,259,136 and \$1,061,901, respectively, of accumulated amortization related to capital leases.

**Oncobiologics, Inc.**  
**Notes to Unaudited Interim Consolidated Financial Statements**

**6. Accrued Expenses**

Accrued expenses consists of:

	<b>March 31, 2018</b>	<b>September 30, 2017</b>
Compensation	\$ 3,301,826	\$ 3,688,592
Research and development	125,208	1,637,657
Interest payable	1,498,560	1,047,122
Professional fees	53,786	521,973
Director fees	58,903	376,695
Other accrued expenses	-	65,430
	<u>\$ 5,038,283</u>	<u>\$ 7,337,469</u>

**7. Senior Secured Notes**

	<b>March 31, 2018</b>
Senior secured notes	\$ 13,500,000
Unamortized debt discount	(992,632)
	<u>\$ 12,507,368</u>

In September 2017, the Company entered into a purchase and exchange agreement (the “Exchange Agreement”) with two existing investors and holders of its senior secured notes (the “Noteholders”), pursuant to which the Noteholders exchanged \$1.5 million aggregate principal amount of senior secured notes for 1,500,000 shares of Series B convertible preferred stock (“Series B Convertible”) and \$41,507 of accrued interest on such exchanged senior secured notes in October 2017. The Company recognized a loss on extinguishment of \$1,252,353 in connection with the exchange and represents the excess fair value of the Series B convertible preferred stock issued over the net carrying amount of the debt and accrued interest.

Interest expense on the senior secured notes for the three months ended March 31, 2018 and 2017 was \$484,746 and \$958,037, respectively, and \$989,331 and \$1,047,929 for the six months ended March 31, 2018 and 2017, respectively.

**8. Commitments**

During the three months ended March 31, 2018, the Company entered into an amendment to its lease for its corporate offices in Cranbury, New Jersey. Pursuant to the amended terms, the Company is occupying 100% of the corporate facility and has extended the lease term through February 2028 with two five year renewal options. As a result of this amendment, the lease is now classified as a capital lease. The Company initially recorded the lease obligation and corresponding building asset based on its estimated fair value of approximately \$3,000,000. The building is being depreciated over the lease term. Future lease payments will be allocated to interest expense and a paydown of the lease obligation.

Future minimum payments under the amended lease at March 31, 2018 are as follows:

	<b>March 31, 2018</b>
Within one year	\$ 1,491,022
Two years	1,395,842
Three years	1,411,752
Four years	1,486,125
Five years	1,512,586
Thereafter	8,071,794
Total rental payments	\$ 15,369,121
Less: amount representing interest	(12,162,295)
Present value of payments	<u>\$ 3,206,826</u>

**Oncobiologics, Inc.**  
**Notes to Unaudited Interim Consolidated Financial Statements**

**9. Convertible Preferred Stock and Stockholders' Equity (Deficit)**

**Common stock**

During the six months ended March 31, 2018, the Company issued 806,514 shares of common stock upon the vesting of RSUs.

**Convertible preferred stock**

In September 2017, the Company entered into a purchase agreement (the "Purchase Agreement") with GMS Tenshi Holdings Pte. Limited, a Singapore private limited company ("GMS Tenshi"), pursuant to which GMS Tenshi agreed to purchase, in a private placement (the "Private Placement"), \$25.0 million of the Company's newly-created voting Series A Convertible Preferred Stock (the "Series A Convertible"), and warrants (the "GMS Tenshi Warrants" and together with the Series A Convertible, the "Securities") to acquire 16,750,000 shares of common stock. On September 11, 2017, the Company completed the initial sale of 32,628 shares of Series A Convertible to GMS Tenshi for \$3,262,800 in cash. In October 2017, the Company completed the sale of the remaining 217,372 shares of Series A Convertible and the GMS Tenshi Warrants to GMS Tenshi in the Private Placement, for \$21,737,200 in cash.

The Series A Convertible is initially convertible into 37,795,948 shares of the Company's common stock, representing an effective conversion rate of \$0.66 per share, which represents a discount to the market value of the Company's common stock as of September 7, 2017 and October 31, 2017 (on which dates, the closing price of the Company's common stock was \$0.90 and \$1.26 per share, respectively). In connection with the second closing of the Series A Convertible in October 2017, the Company issued the GMS Tenshi Warrants, which have a term of 8-years and an initial exercise price of \$0.90 per share. The proceeds from the second closing of the Series A Convertible were allocated among the Series A Convertible and the GMS Tenshi Warrants based on their relative fair values. As a result of the discount to the market value and the allocation of a portion of the proceeds to the GMS Tenshi Warrants, the Company recognized a beneficial conversion charge of \$15,355,019, which represents the in-the-money value of the conversion rate as of the date of sale.

The Series A Convertible accrue 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 Convertible, although the initial dividends payable on the shares of Series A Convertible issued in September 2017, while accruing from issuance, was payable in December 2017. The Series A Convertible will also be 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 is subject to appropriate adjustment in the event of a stock split, stock dividend, combination, reclassification or other recapitalization affecting the common stock. During the six months ended March 31, 2018, the Company issued an additional 11,045 shares of Series A Convertible to settle the related dividends that are due on a quarterly basis. The Company recognized a beneficial conversion charge of \$381,664 during the three months ended March 31, 2018, which represents the in-the-money value of the conversion rate as of the date of issuance.

Concurrent with completing the sale of Series A Convertible in October 2017, the Noteholders exchanged \$1,500,000 in aggregate principal borrowings and \$41,507 in accrued interest for 1,500,000 shares of Series B Convertible. The exchange was accounted for as an extinguishment of debt. See Note 7.

The Series B Convertible are non-voting, do not accrue dividends nor do the shares of Series B Convertible have any specific rights or preferences, and have a stated value of \$1.00 per share and are convertible into 2,112,676 shares of common stock. The Series B Convertible are not convertible into common stock if the holder thereof would beneficially own more than 9.99% of the common stock, or, if during the first six-month period following the closing of the exchange, 7.50%, but automatically converts into common stock in part from time to time if the holder beneficially owns below a certain beneficial ownership threshold of the common stock.

**Oncobiologics, Inc.**  
**Notes to Unaudited Interim Consolidated Financial Statements**

**Common stock warrants**

As of March 31, 2018, the Company had the following warrants outstanding to acquire shares of its common stock:

	<u>Outstanding</u>	<u>Exercise price per share</u>	<u>Expiration date</u>
Series A warrants	3,333,333	\$ 6.60	February 18, 2019
Series B warrants	3,333,333	\$ 8.50	May 18, 2018
Common stock warrants issued with initial public offering	817,838	\$ 0.01	November 11, 2019
Common stock warrants issued with senior secured notes	3,882,001	\$ 3.00	December 22, 2021
Common stock warrants issued with Series A Convertible	16,750,000	\$ 0.90	October 31, 2025
	<u>28,116,505</u>		

**10. 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 851,926. As of March 31, 2018, PSUs representing 163,934 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 maximum number of shares of common stock that may be issued under the 2015 Plan is 2,638,101 shares. As of March 31, 2018, 1,697,339 shares remained available for grant under the 2015 Plan.

The Company recorded stock-based compensation (income) expense in the following expense categories of its statements of operations for the three and six months ended March 31, 2018 and 2017:

	<u>Three months ended March 31,</u>		<u>Six months ended March 31,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Research and development	\$ (403,034)	\$ 431,706	\$ (84,793)	\$ 817,815
General and administrative	102,823	1,895,685	1,674,402	3,973,628
	<u>\$ (300,211)</u>	<u>\$ 2,327,391</u>	<u>\$ 1,589,609</u>	<u>\$ 4,791,443</u>

**Stock options**

During the six months ended March 31, 2018, the Company granted a total of 205,000 stock options to its board of directors and employees of which 20,000 options granted will vest 50% on the third anniversary of the commencement date and the remaining 50% on the fourth anniversary of the commencement date, 60,000 options granted will vest on the first anniversary of the grant date and 125,000 options granted will vest ratably over three years.

**Oncobiologics, Inc.**  
**Notes to Unaudited Interim Consolidated Financial Statements**

As of March 31, 2018, 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, 2017	-	\$ -	
Granted	205,000	1.23	
Expired/forfeited/cancelled	(15,000)	1.32	
Balance at March 31, 2018	190,000	\$ 1.22	9.7
Vested and exercisable	-		
Vested and expected to vest at March 31, 2018	190,000	1.22	9.7

The weighted average grant date fair value of the options awarded to employees for the six months ended March 31, 2018 was \$0.73 per share. 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.

As of March 31, 2018, the aggregate intrinsic value of the unvested options was \$0.

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:

	March 31, 2018
Risk-free interest rate	2.25%
Expected life	5.93 years
Expected volatility	64%
Expected dividend yield	-

As of March 31, 2018, there was \$112,015 of unrecognized compensation expense that is expected to be recognized over a weighted-average period of 2.42 years.

**Performance-based stock units**

The Company has issued PSUs, which generally have a ten year life from the date of grant and vest 50% after the third anniversary from issuance and the remaining 50% on the fourth anniversary. The PSUs are exercisable upon the earlier of (i) a change in control, (ii) consummation of an initial public offering, or (iii) a corporate valuation in excess of \$400 million. Upon exercise, the PSU holder receives common stock or cash at the Company's discretion.

The following table summarizes the activity related to PSUs during the six months ended March 31, 2018:

	Number of PSUs	Weighted Average Base Price Per Unit
Balance at October 1, 2017	175,530	\$ 6.30
Forfeitures	(11,596)	6.21
Balance at March 31, 2018	163,934	\$ 6.30

As of March 31, 2018, there was \$46,066 of unamortized expense that will be recognized over a weighted-average period of 0.69 years.

**Oncobiologics, Inc.**  
**Notes to Unaudited Interim Consolidated Financial Statements**

**Restricted stock units**

The RSUs generally vest over a period of two to four years from the date of grant. The following table summarizes the activity related to RSUs during the six months ended March 31, 2018:

	<b>Number of RSUs</b>	<b>Weighted Average Grant Date Fair Value</b>
Balance at October 1, 2017	939,879	\$ 18.78
Granted	20,000	1.16
Vested and settled	(806,514)	17.51
Forfeitures	(55,592)	16.62
Balance at March 31, 2018	<u>97,773</u>	<u>\$ 22.84</u>

As of March 31, 2018, there was \$880,559 of unamortized expense that will be recognized over a weighted-average period of 1.40 years.

**11. Subsequent Events**

On May 11, 2018, the Company entered into a purchase agreement (the "May 2018 Purchase Agreement") with GMS Tenshi pursuant to which the Company agreed to sell to GMS Tenshi, and GMS Tenshi agreed to purchase, in a private placement, \$15.0 million of the Company's common stock and warrants to acquire that number of shares of common stock having an aggregate exercise price of approximately \$20.0 million, to close in two tranches. On May 14, 2018, the Company closed the sale of the first tranche of the common stock and warrants for aggregate cash proceeds of \$7.5 million, issuing to GMS Tenshi an aggregate of 6,377,383 shares of its common stock and warrants to acquire up to 10,256,410 additional shares of its common stock at an exercise price of \$0.975 per share, which warrants have a term of eight years from their issuance date. Under the May 2018 Purchase Agreement, the Company and GMS Tenshi will close the sale of the remaining \$7.5 million of common stock and warrants beginning on June 11, 2018 but no later than September 21, 2018, although, if necessary, GMS Tenshi agreed to acquire that portion of the second tranche of common stock and warrants no later than June 11, 2018 if necessary for the Company to achieve compliance with the minimum market value of listed securities requirement of the Nasdaq Capital Market.

In connection with the May 2018 Purchase Agreement, the Company and GMS Tenshi amended the Investor Rights Agreement dated September 11, 2017, in order to provide GMS Tenshi certain registration and other rights with respect to the shares of common stock to be acquired pursuant to the May 2018 Purchase Agreement and the shares of common stock that may be issuable upon exercise of the warrants acquired pursuant to the May 2018 Purchase Agreement.



## 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, 2017 and 2016 included in our Annual Report on Form 10-K for the year ended September 30, 2017, filed with the Securities and Exchange Commission, or SEC, on December 29, 2017, as amended to date.*

### 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. 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, 2017, filed with the SEC on December 29, 2017, as amended to date, and elsewhere in this report. 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 clinical-stage biopharmaceutical company focused on identifying, developing, manufacturing and commercializing complex, technically challenging and commercially attractive monoclonal antibody, or mAb, therapeutics. A mAb is a type of protein that is produced by a single clone of cells or cell line and made to bind to a specific substance in the body. Our strategy is to cost-effectively develop these innovative and/or biosimilar product candidates on an accelerated timeline, which is fundamental to our success and we believe positions us to be a leading biotechnology company. We have leveraged our team’s biopharmaceutical expertise to establish fully integrated in-house development and manufacturing capabilities, which we refer to as our BioSymphony Platform. We believe this platform addresses the numerous complex technical and regulatory challenges in developing and commercializing mAb therapeutics and was designed to provide significant pricing flexibility to meet the need for clinically important yet affordable drugs. We have advanced two of our product candidates through Phase 1 clinical trials and into preparations for Phase 3 clinical trials: ONS-3010, a biosimilar to adalimumab (Humira®), and ONS-1045, a biosimilar to bevacizumab (Avastin®). We plan to advance ONS-3010 and ONS-1045 into Phase 3 clinical trials upon entering into a license or co-development agreement with a partner. Additionally, we are developing ONS-5010 as an innovative mAb therapeutic that is expected to enter the clinic in 2018. We continue to develop other earlier stage therapeutic candidates that we intend to take through the pre-clinical stage with the goal of entering into clinical trials upon securing a development partner for major markets such as the United States and the EU.

We have made a strategic decision to maximize the value of our BioSymphony Platform to assist development stage biopharmaceutical and biotechnology companies with the development and manufacturing of their product candidates for clinical trials on a contract basis. We believe that this strategy to leverage the BioSymphony Platform and its capabilities will generate funding for our in-house development programs while we continue to develop our pipeline by providing a flexible and cost-effective alternative to the larger contract manufacturing organizations currently serving this market.

Through March 31, 2018, we have funded substantially all of our operations through the sale and issuance of \$180.3 million in net proceeds of our equity and debt securities. We have also received \$29.0 million pursuant to our collaboration and licensing agreements. In September 2017, we closed on the initial sale of 32,628 shares of our newly-created Series A Convertible Preferred Stock, or the Series A Convertible, to GMS Tenshi Holdings Pte. Limited, or GMS Tenshi, for \$3.3 million of cash, and entered into an investor rights agreement in connection therewith. In October 2017, following receipt of necessary stockholder approval, we issued an additional 217,372 shares of our Series A Convertible and warrants to acquire 16,750,000 shares of our common stock to GMS Tenshi for \$21.7 million of cash. Concurrent with such second closing, we also exchanged an aggregate \$1.5 million of outstanding senior secured notes into 1,500,000 shares of our newly-created Series B Convertible Preferred Stock, or the Series B Convertible.

Additionally, as part of the GMS Tenshi transaction, in September 2017, we entered into a joint development and licensing agreement for ONS-3010 and ONS-1045 in all emerging market territories not previously licensed to other development partners.

On May 11, 2018, we entered into a purchase agreement with GMS Tenshi pursuant to which we agreed to sell to GMS Tenshi, and GMS Tenshi agreed to purchase, in a private placement, \$15.0 million of our common stock and warrants to acquire that number of shares of common stock having an aggregate exercise price of approximately \$20.0 million, to close in two tranches. On May 14, 2018, we closed the sale of the first tranche of the common stock and warrants for aggregate cash proceeds of \$7.5 million, issuing to GMS Tenshi an aggregate of 6,377,383 shares of our common stock and warrants to acquire up to 10,256,410 additional shares of our common stock at an exercise price of \$0.975 per share, which warrants have a term of eight years from their issuance date. Under the purchase agreement, we and GMS Tenshi will close the sale of the remaining \$7.5 million of common stock and warrants beginning on June 11, 2018 but no later than September 21, 2018, although, if necessary, GMS Tenshi agreed to acquire that portion of the second tranche of common stock and warrants no later than June 11, 2018 if necessary for us to achieve compliance with the minimum market value of listed securities requirement of the Nasdaq Capital Market. In connection with the entry into the purchase agreement, we and GMS Tenshi amended the Investor Rights Agreement dated September 11, 2017, in order to provide GMS Tenshi certain registration and other rights with respect to the shares of common stock to be acquired pursuant to the purchase agreement and the shares of common stock that may be issuable upon exercise of the warrants acquired pursuant to the purchase agreement.

We have incurred recurring losses and negative cash flows from operations since inception and have an accumulated deficit at March 31, 2018 of \$195.7 million, \$13.5 million of senior secured notes due in December 2018 and \$4.6 million of indebtedness that is due on demand. We will need to raise substantial additional capital to fund our planned future operations, commence clinical trials, receive approval for and commercialize ONS-5010, ONS-3010 and ONS-1045 and continue to develop our other pipeline candidates. We plan to finance our future operations with a combination of proceeds from providing contract development and manufacturing services on a fee for service basis, 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, ONS-3010, ONS-1045 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 interim unaudited consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

Our current cash resources of \$5.9 million as of March 31, 2018 and the \$15.0 million in proceeds received and to be received from our May 2018 private placement of common stock and warrants to GMS Tenshi, are expected to fund our operations through December 2018, excluding repayment of debt. To provide additional working capital, we continue to engage in active discussions with global and regional pharmaceutical companies for licensing and/or co-development rights to our late- and early-stage pipeline product candidates. 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 scale back our plans and place certain activities on hold.

We do not have any products approved for sale and we have only generated revenue from our collaboration agreements. We have incurred operating losses and negative operating cash flows since inception and there is no assurance that we will ever achieve profitable operations, and if achieved, that profitable operations will be sustained. Our net loss for the six months ended March 31, 2018 was \$9.5 million. Our net loss for the six months ended March 31, 2017 was \$27.1 million. In addition, development activities, clinical and preclinical testing and commercialization of our product candidates will require significant additional financing.

### **Collaboration and License Agreements**

From time to time, we enter into collaboration and license agreements for the research and development, manufacture and/or commercialization of our products and/or product candidates. These agreements generally provide for non-refundable upfront license fees, development and commercial performance milestone payments, cost sharing, royalty payments and/or profit sharing.

#### ***Selexis SA***

In October 2011, we entered into a research license agreement with Selexis SA, or Selexis, pursuant to which we acquired a non-exclusive license to conduct research internally or in collaboration with third parties to develop recombinant proteins from mammalian cells created lines using the Selexis expression technology, or the Selexis Technology. The original research license had a three-year term, but on October 9, 2014, was extended for an additional three-year term through October 9, 2017, and then extended for one more year through October 9, 2018. We may sublicense our rights with Selexis' prior written consent but are prohibited from making commercial use of the Selexis Technology or the resultant recombinant proteins comprising our product candidates in humans, or from filing an investigational new drug, absent a commercial license agreement with Selexis covering the particular product candidate developed under the research license. In connection with the entry into the research license, we paid Selexis an initial fee and agreed to make additional annual maintenance payments of the same amount for each of the three years that the research license agreement term was extended.

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 and ONS-1050 biosimilar 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.

***IPCA Laboratories Limited —Humira (ONS-3010), Avastin (ONS-1045) and Herceptin (ONS-1050)***

In August 2013, we entered into a strategic license agreement with IPCA Laboratories Limited, or IPCA, under which we granted IPCA and its affiliates a license for the research, development, manufacture, use or sale of ONS-3010 and, by amendment in May 2014, ONS-1045. The license is exclusive with respect to India, Sri Lanka and Myanmar, and non-exclusive with respect to Nepal and Bhutan. Under the terms of the August 2013 agreement, we received an upfront payment from IPCA, and are eligible to earn additional regulatory milestone payments for each of ONS-3010 and ONS-1045. In addition, we are eligible to receive royalties at a low teens percentage rate of annual net sales of products by IPCA and its affiliates in the agreed territory.

In January 2014, we entered into an agreement with IPCA to assist IPCA in establishing its research, development and manufacturing capabilities for mAbs and biologics, including, in part, through collaborative development, manufacture and commercialization of ONS-1050 (our Herceptin biosimilar), in the agreed territory (as specified below). The agreed territory for ONS-1050 includes the Republics of India, Sri Lanka, Myanmar, Nepal and Bhutan, while the agreed territory for any product candidates developed independent of our involvement is global without geographical restriction. We also agreed to assist IPCA with its research and development program. Under the terms of the January 2014 agreement, we are eligible to receive development payments and commercialization fees. In addition, we are eligible to receive royalties from IPCA at a mid-single digit rate on annual net sales of ONS-1050 commercialized by IPCA and its affiliates in the agreed territory.

As of March 31, 2018, we have received an aggregate of \$5.0 million of payments from IPCA under our various agreements.

***Liomont — Humira (ONS-3010) and Avastin (ONS-1045)***

In June 2014, we entered into a strategic license agreement with Laboratories Liomont, S.A. de C.V., or Liomont, under which we granted Liomont and its affiliates an exclusive, sublicenseable license in Mexico for the research, development, manufacture, use or sale of the ONS-3010 and ONS-1045 biosimilar product candidates in Mexico. Under the terms of the agreement, we received an upfront payment from Liomont, and we are eligible to earn milestone payments for each of ONS-3010 and ONS-1045. In addition, we are eligible to receive tiered royalties at upper single-digit to low teens percentage rates of annual net sales of products by Liomont and its affiliates in Mexico. As of March 31, 2018, we have received an aggregate of \$3.0 million of upfront and milestone payments from Liomont.

***Huahai — Humira (ONS-3010) and Avastin (ONS-1045)***

In May 2013, we entered into a series of agreements with Zhejiang Huahai Pharmaceutical Co., Ltd., or Huahai, to form an alliance for the purpose of developing and obtaining regulatory approval for, and commercial launch and marketing of licensed products in an agreed territory, as described below. The agreements include a strategic alliance agreement, which sets out the governance framework for the relationship, along with a joint participation agreement regarding joint development and commercialization of ONS-3010, and a co-development and license agreement for each of ONS-3010 and ONS-1045. As of March 31, 2018, we have received an aggregate of \$16.0 million of upfront and milestone payments from Huahai.

As contemplated by the strategic alliance agreement, we entered into a joint participation agreement with Huahai where we agreed to co-fund the development and share the value ownership interest of ONS-3010 in the United States, Canada, European Union, Japan, Australia and New Zealand. Under the agreement as amended, we are responsible for completing a defined “Phase-3 Ready Package” at our expense, for which the portion of the funds received from Huahai to date under this joint participation agreement was used.

In the event Huahai funds its proportionate share of development costs incurred after completion of the “Phase-3 Ready Packages,” Huahai would be entitled to retain its 51% value ownership, with us entitled to retain our 49% value ownership, of ONS-3010 in the agreed territories. Similarly, revenues from commercialization of ONS-3010 in the agreed countries (including major markets such as the United States and the European Union, or EU, among others), would also be shared based on such proportional ownership interests. In the event that Huahai does not fund its proportionate share of such development costs, the joint participation agreement provides for a proportionate adjustment to our respective value ownership interests based on our respective investments in such development costs, which would increase our value ownership interest in ONS-3010. Under the joint participation agreement, we could also be required to form a joint venture to further develop and commercialize ONS-3010 with Huahai in the agreed countries, if so requested by Huahai.

In conjunction with the strategic alliance agreement, we also entered into a co-development and license agreement with Huahai, under which we granted Huahai and its affiliates an exclusive license, in the territory (as specified below) for the research, development, manufacture, use or sale of ONS-3010 or ONS-1045 in China, including, the People’s Republic of China, Hong Kong, Macau and Taiwan. We will each bear our respective costs under the development plans. Huahai agreed to carry out all clinical, manufacturing and regulatory requirements necessary for approval of the products in the agreed territory. Under the terms of the agreement, we received an upfront payment from Huahai for ONS-3010, and have received regulatory milestone payments for each of ONS-3010 and ONS-1045.

## GMS Tenshi — Humira (ONS-3010) and Avastin (ONS-1045)

On September 7, 2017, in connection with the entry into the GMS Tenshi purchase agreement for the Series A Convertible and warrants, we also entered into a joint development and license agreement providing for the license of rights to ONS-3010 and ONS-1045 in emerging markets, excluding China, India and Mexico, which superseded and replaced a previous strategic licensing agreement dated July 25, 2017. As of March 31, 2018, we have received an aggregate of \$5.0 million of payments from GMS Tenshi under our joint development and license agreement.

### Components of our Results of Operations

#### Collaboration Revenue

To date, we have derived revenue only from activities pursuant to our collaboration and licensing agreements. We have not generated any revenue from commercial product sales. Until we begin generating revenue from our contract development and manufacturing services, we expect all of our revenue, if any, will be generated from our collaboration and licensing agreements. If any of our biosimilar 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.

The following table sets forth a summary of revenue recognized from our collaboration and licensing agreements for the three and six months ended March 31, 2018 and 2017, all of which was from the recognition of deferred revenues under such agreements:

	Three months ended March 31,		Six months ended March 31,	
	2018	2017	2018	2017
IPCA Collaboration	\$ 65,268	\$ 65,268	\$ 130,536	\$ 130,536
Liomont Collaboration	59,160	59,160	118,321	118,320
Huahai Collaboration	178,712	178,712	357,423	357,425
GMS Tenshi Collaboration	468,750	-	937,500	-
	<u>\$ 771,890</u>	<u>\$ 303,140</u>	<u>\$ 1,543,780</u>	<u>\$ 606,281</u>

Each of our collaboration and licensing agreements is considered to be a multiple-element arrangement for accounting purposes. We determined that there are two deliverables; specifically, the license to our biosimilar product candidate and the related research and development services that we are obligated to provide. We concluded that these deliverables should be accounted for as a single unit of accounting. We determined that the upfront license payments received should be deferred and recognized as revenue on a straight-line basis through the estimated period of completion of our obligations under the agreement. During the three months ended December 31, 2016, we revised our estimate of the period of completion from December 2019 to December 2021.

#### 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;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial materials and commercial materials, including manufacturing validation batches;
- outsourced professional scientific development services;
- employee-related expenses, which include salaries, benefits and stock-based compensation;
- payments made under a third-party assignment agreement, under which we acquired intellectual property;
- expenses relating to regulatory activities, including filing fees paid to regulatory agencies;
- laboratory materials and supplies used to support our research activities; and
- allocated expenses, utilities and other facility-related costs.

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

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

Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals. We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the U.S. Food and Drug Administration, or FDA, or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment 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 and duration of later-stage clinical trials. We expect our research and development expenses to increase significantly over the next several years as we increase personnel costs, including stock-based compensation, conduct clinical trials and prepare regulatory filings for our product candidates.

#### ***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 as a result of increased payroll, expanded infrastructure and an increase in accounting, consulting, legal and tax-related services associated with maintaining compliance with stock exchange listing and SEC requirements, investor relations costs, and director and officer insurance premiums associated with being a public company. We also anticipate that our general and administrative expenses will increase in support of our clinical trials as we expand and progress our development programs. Additionally, if and when we believe a regulatory approval of a product candidate appears likely, 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, former bank loans, notes with current and former stockholders, equipment loans and capital lease and other finance obligations.

#### ***Loss on Extinguishment of Debt***

Loss on extinguishment of debt is attributable to the exchange of \$1.5 million of principal borrowings under our senior secured notes for shares of Series B Convertible. The loss represents the excess fair value of the Series B Convertible that was issued over the carrying value of the senior secured notes and accrued interest.

### **Change in Fair Value of Warrant Liability**

Warrants to purchase our common stock that have been issued in conjunction with our senior secured notes 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 as other (income) expense.

### **Income Taxes**

In November 2017, we received approval from the New Jersey Economic Development Authority's Technology Business Tax Certificate Transfer Program to sell a portion of our unused New Jersey net operating losses, or NOLs, and research and development, or R&D, tax credits. As a result, we received \$3.15 million of cash from the sale of these NOLs and credits in December 2017. Since inception, we have not recorded any U.S. federal or state income tax benefits (excluding the sale of New Jersey state NOLs and research credits) for the net losses we have incurred in each year or on our earned R&D tax credits, due to our uncertainty of realizing a benefit from those items. As of September 30, 2017, we had federal and state NOL carryforwards of \$131.5 million and \$69.6 million, respectively that will begin to expire in 2030 and 2036, respectively. As of September 30, 2017, we had federal foreign tax credit carryforwards of \$2.9 million available to reduce future tax liabilities, which begin to expire starting in 2023. As of September 30, 2017, we also had federal research and development tax credit carryforwards of \$0.8 million, which begin to expire in 2031.

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 in connection with or after our initial public offering, or IPO, our ability to utilize NOLs could be further limited by Section 382 of the Code. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Code. Our NOLs are also subject to international regulations, which could restrict our ability to utilize our NOLs. Furthermore, our ability to utilize NOLs of companies that we may acquire in the future may be subject to limitations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

### **Results of Operations**

#### **Comparison of Three Months Ended March 31, 2018 and 2017**

	<b>Three months ended March 31,</b>		<b>Change</b>
	<b>2018</b>	<b>2017</b>	
Collaboration revenues.	\$ 771,890	\$ 303,140	\$ 468,750
Operating expenses:			
Research and development	5,156,386	4,116,856	1,039,530
General and administrative	2,446,505	4,024,276	(1,577,771)
	<u>7,602,891</u>	<u>8,141,132</u>	<u>(538,241)</u>
Loss from operations	(6,831,001)	(7,837,992)	1,006,991
Interest expense, net	920,870	1,243,892	(323,022)
Change in fair value of warrant liability	(211,992)	(1,035,902)	823,910
Net loss	<u>\$ (7,539,879)</u>	<u>\$ (8,045,982)</u>	<u>\$ 506,103</u>

### Collaboration Revenues

Collaboration revenues increased \$0.5 million, to \$0.8 million, for the three months ended March 31, 2018, as compared to \$0.3 million for the three months ended March 31, 2017. The change is due to the amortization of the upfront payments received in August and September 2017 under our collaboration arrangement with GMS Tenshi.

### Research and Development Expenses

The following table summarizes our research and development expenses by functional area for the three months ended March 31, 2018 and 2017:

	Three months ended March 31,	
	2018	2017
Preclinical and clinical development	\$ 2,074,684	\$ 188,754
Compensation and related benefits	1,676,419	2,449,646
Stock-based compensation	(403,034)	431,706
Other research and development	1,808,317	1,046,750
Total research and development expenses	<u>\$ 5,156,386</u>	<u>\$ 4,116,856</u>

The following table summarizes our research and development expenses by compound for the three months ended March 31, 2018 and 2017:

	Three months ended March 31,	
	2018	2017
ONS-3010	\$ 53,351	\$ -
ONS-1045	60,429	86,610
ONS-5010	1,953,850	-
Early-stage compounds	7,054	102,144
Personnel related and stock-based compensation	1,273,385	2,881,352
Other research and development	1,808,317	1,046,750
Total research and development expenses	<u>\$ 5,156,386</u>	<u>\$ 4,116,856</u>

Research and development expenses for the three months ended March 31, 2018 increased by \$1.0 million compared to the three months ended March 31, 2017. The increase in research and development expenses is primarily related to an increase of \$1.9 million resulting from development costs incurred for the ONS-5010 program as we prepare to initiate clinical trials later in 2018. In addition, we also had an increase of \$0.8 million in other research and development costs related to the restart of our manufacturing plant in fiscal 2018, as well as increases in rent and business insurance premiums. These increases were offset by decreased personnel related costs of \$1.6 million for the three months ended March 31, 2018. The decrease in personnel related costs was due to a combination of lower salaries and benefits from reduced employee headcount in March 2018 related to attrition in late 2017 and lower stock-based compensation due to the related forfeitures of equity awards by departing employees and the completion of the vesting period of most pre-IPO equity grants in the prior quarter of fiscal 2018.

### General and Administrative Expenses

The following table summarizes our general and administrative expenses by type for the three months ended March 31, 2018 and 2017:

	Three months ended March 31,	
	2018	2017
Professional fees	\$ 699,503	\$ 1,022,618
Compensation and related benefits	708,618	744,170
Stock-based compensation	102,823	1,895,685
Facilities, fees and other related costs	935,561	361,803
Total general and administrative expenses	<u>\$ 2,446,505</u>	<u>\$ 4,024,276</u>

General and administrative expenses for the three months ended March 31, 2018 decreased by \$1.6 million compared to the three months ended March 31, 2017. The reduction was primarily driven by a reduction in stock-based compensation expense of \$1.8 million related to the completion of the vesting period of most pre-IPO equity grants in the prior quarter of fiscal 2018. Professional fees, including legal fees, also declined by \$0.3 million as part of our ongoing cost reduction efforts. These decreases were offset by a \$0.6 million increase in facilities, fees and other related costs due to increases in rent and business insurance premiums.

#### *Interest Expense*

Interest expense decreased by \$0.3 million for the three months ended March 31, 2018 as compared to the three months ended March 31, 2017, primarily due to the conversion of a portion of our senior secured notes in October 2017.

#### *Change in Fair Value of Warrant Liability*

During the three months ended March 31, 2018, we recorded income of \$0.2 million related to the decrease in the fair value of our common stock warrant liability as a result of a decrease in the price of our common stock during the period. For the three months ended March 31, 2017, we recorded income of \$1.0 million.

#### ***Comparison of Six Months Ended March 31, 2018 and 2017***

	<b>Six months ended March 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>Change</b>
Collaboration revenues	\$ 1,543,780	\$ 606,281	\$ 937,499
Operating expenses:			
Research and development	5,558,788	17,347,243	(11,788,455)
General and administrative	5,995,757	8,892,271	(2,896,514)
	<u>11,554,545</u>	<u>26,239,514</u>	<u>(14,684,969)</u>
Loss from operations	(10,010,765)	(25,633,233)	15,622,468
Interest expense, net	1,638,753	1,733,037	(94,284)
Loss on extinguishment of debt	1,252,353	-	(1,252,353)
Change in fair value of warrant liability	(290,775)	(225,819)	(64,956)
Loss before income taxes	(12,611,096)	(27,140,451)	14,529,355
Income tax (benefit) expense	(3,150,716)	4,000	(3,154,716)
Net loss	<u>\$ (9,460,380)</u>	<u>\$ (27,144,451)</u>	<u>\$ 17,684,071</u>

#### *Collaboration Revenues*

Collaboration revenues increased \$0.9 million, to \$1.5 million, for the six months ended March 31, 2018, as compared to \$0.6 million for the three months ended March 31, 2017. The change is due to the amortization of the upfront payments received in August and September 2017 under our collaboration arrangement with GMS Tenshi.



## Research and Development Expenses

The following table summarizes our research and development expenses by functional area for the six months ended March 31, 2018 and 2017:

	<b>Six months ended March 31,</b>	
	<b>2018</b>	<b>2017</b>
Preclinical and clinical development	\$ 3,001,755	\$ 9,133,645
Settlement of clinical development contract	(3,228,613)	-
Compensation and related benefits	3,102,821	4,919,255
Stock-based compensation	(84,793)	817,815
Other research and development	2,767,618	2,476,528
Total research and development expenses	<u>\$ 5,558,788</u>	<u>\$ 17,347,243</u>

The following table summarizes our research and development expenses by compound for the six months ended March 31, 2018 and 2017:

	<b>Six months ended March 31,</b>	
	<b>2018</b>	<b>2017</b>
ONS-3010	\$ 551,188	\$ 5,590,558
ONS-1045	341,332	2,841,635
ONS-5010	1,953,850	-
Early-stage compounds	155,385	701,452
Settlement of clinical development contract	(3,228,613)	-
Personnel related and stock-based compensation	3,018,028	5,737,070
Other research and development	2,767,618	2,476,528
Total research and development expenses	<u>\$ 5,558,788</u>	<u>\$ 17,347,243</u>

Research and development expenses for the six months ended March 31, 2018 decreased by \$11.8 million compared to the six months ended March 31, 2017 due to reductions in pre-clinical and clinical development spending, a related contract settlement and lower personnel related costs. The reduction of \$6.1 million in pre-clinical and clinical research and development expenses is directly related to our decision to postpone the initiation of our planned Phase 3 clinical trials for ONS-3010 and ONS-1045 until we secure additional development partners. This resulted in a \$7.5 million decrease in costs related to these two programs, which was partially offset by almost \$2.0 million in development costs incurred related to our new ONS-5010 program as we prepare for clinical trials in 2018. During the six months ended March 31, 2018, we also terminated an agreement related to ONS-3010 and ONS-1045 and were able to favorably settle amounts previously owed under the contract resulting in a reduction to our accrued research and development expenses of \$3.2 million. Additionally, we experienced a reduction of \$2.7 million in personnel related costs for the six months ended March 31, 2018 due to a combination of lower salaries and benefits from reduced employee headcount in the current period as a result of attrition in late 2017 and lower stock-based compensation due to the related forfeitures of equity awards by departing employees and the completion of the vesting period of most pre-IPO equity grants in the prior quarter of fiscal 2018.

## General and Administrative Expenses

The following table summarizes our general and administrative expenses by type for the six months ended March 31, 2018 and 2017:

	<b>Six Months Ended March 31,</b>	
	<b>2018</b>	<b>2017</b>
Professional fees	\$ 1,427,523	\$ 2,199,797
Compensation and related benefits	1,304,864	1,466,304
Stock-based compensation	1,674,402	3,973,628
Facilities, fees and other related costs	1,588,968	1,252,542
Total general and administrative expenses	<u>\$ 5,995,757</u>	<u>\$ 8,892,271</u>

General and administrative expenses for the six months ended March 31, 2018 decreased by \$2.9 million compared to the six months ended March 31, 2017. The reduction was primarily a result of a decrease in stock-based compensation expenses of \$2.3 million related to the completion of the vesting period of most pre-IPO equity grants in the prior quarter of fiscal 2018. In addition, professional fees, including legal fees, declined by \$0.8 million as part of our ongoing cost reduction efforts.

## Interest Expense

Interest expense decreased by \$0.1 million for the six months ended March 31, 2018 as compared to the six months ended March 31, 2017.

## Change in Fair Value of Warrant Liability

During the six months ended March 31, 2018, we recorded income of \$0.3 million related to the decrease in the fair value of our common stock warrant liability as a result of a decrease in the price of our common stock during the period. For the six months ended March 31, 2017 we recorded income of \$0.2 million.

## Liquidity and Capital Resources

We have not generated any revenue from product sales. Since inception, we have incurred net losses and negative cash flows from our operations. Through March 31, 2018, we have funded substantially all of our operations through the sale and issuance of \$180.3 million net proceeds of our equity securities, debt securities and borrowings under debt facilities. We have also received an aggregate of \$29.0 million pursuant to our collaboration and licensing agreements. In September 2017, we closed on the initial sale of 32,628 shares of Series A Convertible to GMS Tenshi for \$3.3 million of cash, and entered into an investor rights agreement and joint development and licensing agreement. In October 2017, following receipt of stockholder approval, we issued an additional 217,372 shares of our Series A Convertible and warrants to acquire an aggregate of 16,750,000 shares of our common stock to GMS Tenshi for \$21.7 million of cash. We also converted \$1.5 million aggregate principal amount of our senior secured notes into 1,500,000 shares of our Series B Convertible. In November 2017, we received approval from the New Jersey Economic Development Authority's Technology Business Tax Certificate Transfer Program to sell a portion of our unused New Jersey net operating losses, or NOLs, and research and development tax credits. As a result, we received \$3.15 million of cash from the sale of these NOLs and credits in December 2017. We will require additional capital to fund our operations past December 2018. Alternatively, we will be required to scale back our plans and place certain activities on hold.

As of March 31, 2018, we had an accumulated deficit of \$195.7 million and a cash balance of \$5.9 million. In addition, we have \$13.5 million of senior secured notes due in December 2018 and \$4.6 million of indebtedness that is due on demand. These matters raise substantial doubt about our ability to continue as a going concern. Our 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. We anticipate incurring additional losses until such time, if ever, that we can generate significant sales of our product candidates currently in development or from receiving fees for contract development and manufacturing services that we plan to provide for other biopharmaceutical companies. 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: providing contract development and manufacturing services on a fee for service basis, private placements of equity and/or debt, payments from potential strategic research and development, licensing and/or marketing arrangements with pharmaceutical companies, and public offerings of equity and/or debt securities. Additionally, we continue to engage in active discussions with global and regional pharmaceutical companies for licensing and/or co-development rights to our late- and early-stage pipeline candidates. 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.

### Cash Flows

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

	<b>Six months ended March 31,</b>	
	<b>2018</b>	<b>2017</b>
Net cash used in operating activities	\$ (16,110,027)	\$ (9,952,128)
Net cash used in investing activities	(1,350,329)	(191,877)
Net cash provided by financing activities	20,210,952	7,873,167
Net increase (decrease) in cash	<u>\$ 2,750,596</u>	<u>\$ (2,270,838)</u>

#### Operating Activities.

During the six months ended March 31, 2018, we used \$16.1 million of cash in operating activities resulting from our net loss of \$9.5 million and the change in our operating assets and liabilities of \$11.6 million. This use of cash was partially offset by \$4.9 million of noncash items such as non-cash interest expense, stock-based compensation, change in fair value of warrant liability, loss on extinguishment of debt and depreciation and amortization expense. The change in our operating assets and liabilities was primarily due to payments of our outstanding accounts payable and accrued expenses from September 30, 2017 as well as the prepayment of certain research and development expenses and the amortization of our deferred revenues from collaborations.

During the six months ended March 31, 2017, we used \$10.0 million of cash in operating activities, primarily resulting from our net loss of \$27.1 million and the net cash provided from changes in our operating assets and liabilities of \$10.3 million. These uses of cash in our operating activities were offset by \$6.9 million of noncash items such as non-cash interest expense, stock-based compensation, change in fair value of warrant liability and depreciation and amortization expense. The change in our operating assets and liabilities was primarily due to increases in accounts payable related to the timing of vendor payments for research and development and in deferred revenues due to ratable recognition of upfront payments received under our collaboration arrangements. These outflows were offset by decreases in our prepaid expenses and other current assets, and increases in accrued expenses, and other liabilities that relate to the timing of vendor payments and the recognition of research and development expenses.

#### Investing Activities.

During the six months ended March 31, 2018 and 2017, we used cash of \$1.4 million and \$0.2 million, respectively, in investing activities for the purchase of property and equipment.

#### Financing Activities.

During the six months ended March 31, 2018, net cash provided by financing activities was \$20.2 million, primarily attributable to \$20.6 million in net proceeds from our second closing of our Series A Convertible in October 2017. We also had \$0.4 million in debt payments.

During the six months ended March 31, 2017, net cash provided by financing activities was \$7.9 million, primarily attributable to \$10.0 million in aggregate proceeds from our senior secured notes and warrants in December 2016 and January 2017 and \$0.8 million from the sale of common stock and exercise of warrants, net of expenses, these inflows were offset by \$3.1 million in debt payments, primarily \$2.4 million to repay senior bank loans in December 2016.

**Off-Balance Sheet Arrangements**

We did not have any off-balance sheet arrangements as of March 31, 2018.

**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, 2017, filed with the SEC on December 29, 2017, as amended to date, 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. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our management, with the participation of our chief executive officer and our 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 our 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 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting during our second fiscal quarter ended March 31, 2018.

## **Part II. Other Information**

### **Item 1. Legal Proceedings**

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

### **Item 1A. Risk Factors**

Not applicable.

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

#### **Unregistered Sales of Equity Securities**

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 INDEX**

<b>Exhibit Number</b>	<b>Description</b>
<a href="#"><u>10.1</u></a>	<a href="#"><u>Sixth Amendment to Lease Agreement by and between Oncobiologics, Inc. and Cedar Brook 7 Corporate Center L.P., dated as of February 1, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on February 7, 2018).</u></a>
<a href="#"><u>10.2</u></a>	<a href="#"><u>Amendment #2 to Warrant Agreement dated May 18, 2016 by and between the Registrant and American Stock Transfer &amp; Trust Company LLC, as Warrant Agent, dated February 9, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on February 9, 2018)</u></a>
<a href="#"><u>31.1</u></a>	<a href="#"><u>Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u></a>
<a href="#"><u>31.2</u></a>	<a href="#"><u>Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u></a>
<a href="#"><u>32.1*</u></a>	<a href="#"><u>Certifications of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u></a>
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

*\* These certifications are being furnished solely to accompany this Quarterly Report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are 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.

**ONCOBIOLOGICS, INC.**

Date: May 15, 2018

By: /s/ Lawrence A. Kenyon

Lawrence A. Kenyon

Chief Financial Officer and Secretary, (Principal Accounting and Financial Officer)

## CERTIFICATIONS

I, Pankaj Mohan, certify that:

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

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

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

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

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our 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 our 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 our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

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

Date: May 15, 2018

By: /s/ Pankaj Mohan  
Pankaj Mohan, Ph.D.  
Chief Executive Officer  
(Principal Executive Officer)

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## CERTIFICATIONS

I, Lawrence A. Kenyon, certify that:

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

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

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

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

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our 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 our 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 our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

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

Date: May 15, 2018

By: /s/ Lawrence A. Kenyon  
Lawrence A. Kenyon  
Chief Financial Officer  
(Principal Financial Officer)

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**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 Oncobiologics, Inc. (the "Company") for the period ended March 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 15, 2018

By /s/ Pankaj Mohan  
Pankaj Mohan, Ph.D.  
Chief Executive Officer

Date: May 15, 2018

By /s/ Lawrence A. Kenyon  
Lawrence A. Kenyon  
Chief Financial Officer

*"This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Oncobiologics, 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."*

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