

**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, 2017
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 or a smaller reporting 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. (Check one):

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 11, 2017 was 24,453,013.

Oncobiologics, Inc.
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PART I. FINANCIAL INFORMATION**Item 1. Financial Statements**

Oncobiologics, Inc.
Consolidated Balance Sheets
(unaudited)

	March 31, 2017	September 30, 2016
Assets		
Current assets:		
Cash	\$ 81,049	\$ 2,351,887
Prepaid and other current assets	773,632	3,326,607
Total current assets	854,681	5,678,494
Property and equipment, net	15,786,378	16,958,553
Restricted cash	-	216,086
Other assets	819,251	852,801
Total assets	<u>\$ 17,460,310</u>	<u>\$ 23,705,934</u>
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Senior secured notes	\$ 6,611,141	\$ -
Current portion of debt	74,749	586,454
Current portion of capital lease obligations	840,105	977,248
Current portion of stockholder notes	4,612,500	4,612,500
Accounts payable	12,153,079	5,071,520
Accrued expenses	7,419,601	6,121,942
Income taxes payable	1,854,629	1,854,629
Deferred revenue	1,212,561	1,212,561
Total current liabilities	<u>34,778,365</u>	<u>20,436,854</u>
Long-term debt	178,322	2,233,803
Capital lease obligations	42,811	320,737
Warrant liability	3,855,052	-
Deferred revenue	4,547,104	5,153,384
Other liabilities	912,467	761,334
Total liabilities	<u>44,314,121</u>	<u>28,906,112</u>
Stockholders' equity (deficit):		
Series A preferred stock, par value \$0.01 per share; 10,000,000 shares authorized, no shares issued and outstanding	-	-
Common stock, par value \$0.01 per share; 200,000,000 shares authorized; 24,099,951 and 22,802,778 shares issued and outstanding at March 31, 2017 and September 30, 2016, respectively	241,000	228,028
Additional paid-in capital	147,442,335	141,965,342
Accumulated deficit	(174,537,146)	(147,393,548)
Total stockholders' deficit	<u>(26,853,811)</u>	<u>(5,200,178)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 17,460,310</u>	<u>\$ 23,705,934</u>

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

Oncobiologics, Inc.
Consolidated Statements of Operations
(unaudited)

	<u>Three Months Ended March 31,</u>		<u>Six Months Ended March 31,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Collaboration revenues	\$ 303,141	\$ 994,894	\$ 606,281	\$ 1,989,788
Operating expenses:				
Research and development	4,198,775	4,138,277	17,511,081	16,872,253
General and administrative	4,045,141	(189,438)	8,934,001	4,484,717
	<u>8,243,916</u>	<u>3,948,839</u>	<u>26,445,082</u>	<u>21,356,970</u>
Loss from operations	(7,940,775)	(2,953,945)	(25,838,801)	(19,367,182)
Interest expense, net	1,139,903	537,935	1,526,616	936,910
Change in fair value of warrant liability	(1,035,902)	-	(225,819)	-
Loss before income taxes	(8,044,776)	(3,491,880)	(27,139,598)	(20,304,092)
Income tax expense	-	50,500	4,000	102,500
Net loss	(8,044,776)	(3,542,380)	(27,143,598)	(20,406,592)
Accretion of redeemable preferred stock and noncontrolling interests	-	(1,030,414)	-	(1,969,953)
Net loss attributable to common stockholders	<u>\$ (8,044,776)</u>	<u>\$ (4,572,794)</u>	<u>\$ (27,143,598)</u>	<u>\$ (22,376,545)</u>
Per share information:				
Net loss per share of common stock, basic	\$ (0.34)	\$ (0.32)	\$ (1.16)	\$ (1.64)
Net loss per share of common stock, diluted	\$ (0.38)	\$ (0.32)	\$ (1.16)	\$ (1.64)
Weighted average shares outstanding, basic	<u>23,723,551</u>	<u>14,155,081</u>	<u>23,457,361</u>	<u>13,605,331</u>
Weighted average shares outstanding, diluted	<u>23,801,223</u>	<u>14,155,081</u>	<u>23,496,197</u>	<u>13,605,331</u>

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

Oncobiologics, Inc.
Consolidated Statement of Stockholders' Equity (Deficit)
Six Months Ended March 31, 2017
(unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance at October 1, 2016	22,802,778	\$ 228,028	\$ 141,965,342	\$ (147,393,548)	\$ (5,200,178)
Proceeds from exercise of common stock warrants	440,027	4,400	118,601	-	123,001
Issuance of vested restricted stock units	483,913	4,840	(4,840)	-	-
Issuance of common stock in connection with equity facility	115,416	1,154	(1,154)	-	-
Sale of common stock, net of issuance costs	257,817	2,578	572,943	-	575,521
Stock-based compensation expense	-	-	4,791,443	-	4,791,443
Net loss	-	-	-	(27,143,598)	(27,143,598)
Balance at March 31, 2017	<u>24,099,951</u>	<u>\$ 241,000</u>	<u>\$ 147,442,335</u>	<u>\$ (174,537,146)</u>	<u>\$ (26,853,811)</u>

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

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

	Six Months Ended March 31,	
	2017	2016
OPERATING ACTIVITIES		
Net loss	\$ (27,143,598)	\$ (20,406,592)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,349,930	1,192,074
Non-cash interest expense	977,693	6,090
Stock-based compensation	4,791,443	(1,956,455)
Change in fair value of warrant liability	(225,819)	-
Loss on disposal of fixed assets	-	13,647
Changes in operating assets and liabilities:		
Accounts receivable	-	(484,857)
Prepaid expenses and other current assets	2,552,975	1,080,342
Other assets	33,550	27,347
Accounts payable	6,973,453	1,878,794
Accrued expenses	1,193,392	156,677
Income taxes payable	-	100,000
Deferred revenue	(606,280)	(989,788)
Other liabilities	151,133	312,227
Net cash used in operating activities	<u>(9,952,128)</u>	<u>(19,070,494)</u>
INVESTING ACTIVITIES		
Purchase of property and equipment	(191,877)	(317,293)
Net cash used in investing activities	<u>(191,877)</u>	<u>(317,293)</u>
FINANCING ACTIVITIES		
Proceeds from the sale of common stock, net of offering costs	679,789	16,137,913
Payment of debt issuance costs	(40,000)	-
Proceeds from subscriptions receivable	-	4,280,149
Proceeds from exercise of common stock warrants	123,001	-
Proceeds from the sale of senior secured notes and detachable warrants	10,000,000	-
Payments of capital leases obligations	(477,299)	(443,326)
Repayment of debt	(2,628,410)	(364,348)
Payment of deferred offering costs	-	(200,000)
Repayment of stockholder notes	-	(6,560,795)
Change in restricted cash	216,086	(1,110)
Proceeds from related party receivable	-	783,374
Deconsolidation of Sonnet Biotherapeutics, Inc.	-	(401,091)
Payment of employee tax withholdings related to the vesting of restricted stock	-	(71,760)
Net cash provided by financing activities	<u>7,873,167</u>	<u>13,159,006</u>
Net decrease in cash	(2,270,838)	(6,228,781)
Cash at beginning of period	2,351,887	9,070,975
Cash at end of period	<u>\$ 81,049</u>	<u>\$ 2,842,194</u>
Supplemental disclosure of cash flow information		
Cash paid for interest	\$ 418,496	\$ 794,663
Cash paid for income taxes	\$ -	\$ 2,500
Supplemental schedule of noncash investing activities:		
Purchases of property and equipment in accounts payable and accrued expenses	\$ 79,236	\$ 635,341
Supplemental schedule of noncash financing activities:		
Accretion of redeemable common stock	\$ -	\$ 1,969,953
Issuance of common and Series A preferred stock to redeemable preferred stockholders and noncontrolling interests upon reincorporation	\$ -	\$ (11,894,638)
Reclassification of equity classified stock-based compensation	\$ -	\$ (15,118,584)
Issuance of capital lease obligations in connection with purchase of property and equipment	\$ 62,230	\$ 78,500
Offering costs and common stock issuance costs in accounts payable and accrued expenses	\$ (288,725)	\$ (1,111,845)

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. In October 2015, the Company reincorporated in Delaware through the merger with and into Oncobiologics, Inc., a newly formed Delaware corporation, with the Delaware corporation surviving the merger. Oncobiologics is a clinical-stage biopharmaceutical company focused on identifying, developing, manufacturing and commercializing complex biosimilar therapeutics in the disease areas of immunology and oncology. The Company has established fully integrated in-house development and manufacturing capabilities that address the numerous complex technical and regulatory challenges in developing and commercializing mAb biosimilars. Since inception, the Company has advanced two product candidates into clinical trials: a biosimilar to adalimumab (Humira®) and a biosimilar to bevacizumab (Avastin®), both of which are being prepared to move into Phase 3 clinical trials. Additionally, the Company has six preclinical biosimilar product candidates under active development.

In May 2016, the Company completed the initial public offering (“IPO”) of its securities by offering 5,833,334 units. Each unit consisted of one share of the Company’s common stock, one-half of a Series A warrant and one-half of a Series B warrant. Each whole Series A warrant entitles the holder to purchase one share of common stock at an initial exercise price of \$6.60, subject to adjustment. Each whole Series B warrant entitles the holder to purchase one share of common stock at an initial exercise price of \$8.50, subject to adjustment. The IPO price was \$6.00 per unit. In addition, the Company also completed a concurrent private placement of an additional 833,332 shares of its common stock, 416,666 Series A warrants and 416,666 Series B warrants, for gross proceeds of approximately \$5.0 million. On May 13, 2016, the units began trading on the NASDAQ Global Market. The units separated in accordance with their terms and ceased trading, and on June 13, 2016, the component securities (common stock, Series A warrants and Series B warrants) began trading on the NASDAQ Global Market. As a result of the IPO and the concurrent private placement, the Company received approximately \$33.8 million in net proceeds, after deducting discounts and commissions of approximately \$2.9 million and offering expenses of approximately \$3.3 million payable by the Company.

2. Liquidity

The Company has incurred substantial losses and negative cash flows from operations since its inception and has an accumulated deficit of \$174.5 million as of March 31, 2017. The Company has substantial indebtedness that includes \$10.0 million of senior secured notes due in December 2017 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.

The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its products currently in development. Management believes that the Company’s existing cash of \$0.1 million as of March 31, 2017 and the \$3.5 million of cash proceeds in April 2017 from the issuance of additional senior secured notes and warrants will be sufficient to fund its operations through May 2017. Substantial additional financing will be needed by the Company to fund its operations and to commercially develop its product candidates. Management is currently evaluating different strategies to obtain the required funding for future operations. These strategies may include, but are not limited to: payments from current and potential new strategic research and development, licensing and/or marketing arrangements with pharmaceutical companies, private placements of equity and/or debt, public offerings of equity and/or debt securities, generating revenue by using the capabilities of its BioSymphony platform to provide development and manufacturing services for a fee to other pharmaceutical companies developing mAbs, the potential disposition of some of its assets, and exploring additional cost reduction opportunities.

Oncobiologics, Inc.
Notes to Unaudited Interim Consolidated Financial Statements

There can be no assurance that these future funding efforts will be successful, and if not successful, the Company may be required to explore all other alternatives.

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, 2017 and its results of operations for the three and six months ended March 31, 2017 and 2016 and cash flows for the six months ended March 31, 2017 and 2016. Operating results for the six months ended March 31, 2017 are not necessarily indicative of the results that may be expected for the full year ending September 30, 2017. 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, 2016 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, 2016.

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

The Company recorded income tax expense of \$0 and \$50,500 for the three months ended March 31, 2017 and 2016, respectively, and \$4,000 and \$102,500 for the six months ended March 31, 2017 and 2016, respectively, which is primarily attributable to state and foreign withholding taxes in connection with the Company's collaboration and licensing agreements.

Oncobiologics, Inc.
Notes to Unaudited Interim Consolidated Financial Statements

Net loss per share

Basic net loss per common share is determined by dividing net loss applicable to common shareholders 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 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:

	Three months ended March 31,		Six months ended March 31,	
	2017	2016	2017	2016
Basic Earnings Per Share				
Net loss	\$ (8,044,776)	\$ (4,572,794)	\$ (27,143,598)	\$ (22,376,545)
Common stock outstanding (weighted average)	23,723,551	14,155,081	23,457,361	13,605,331
Basic net loss per share	<u>\$ (0.34)</u>	<u>\$ (0.32)</u>	<u>\$ (1.16)</u>	<u>\$ (1.64)</u>
Diluted Earnings Per Share				
Net loss	(8,044,776)	(4,572,794)	(27,143,598)	(22,376,545)
Add change in fair value of warrant liability	(1,035,902)	-	(225,819)	-
Diluted net loss	<u>(9,080,678)</u>	<u>(4,572,794)</u>	<u>(27,369,417)</u>	<u>(22,376,545)</u>
Common stock outstanding (weighted average)	23,723,551	14,155,081	23,457,361	13,605,331
Add shares from dilutive warrants	77,672	-	38,836	-
Common stock equivalents	<u>23,801,223</u>	<u>14,155,081</u>	<u>23,496,197</u>	<u>13,605,331</u>
Diluted net loss per share	<u>\$ (0.38)</u>	<u>\$ (0.32)</u>	<u>\$ (1.16)</u>	<u>\$ (1.64)</u>

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding as of March 31, 2017 and 2016, as they would be antidilutive:

	March 31,	
	2017	2016
Series A preferred stock	-	984,899
Performance-based stock units	241,573	247,887
Restricted stock units	1,200,529	1,066,039
Convertible stockholder note	-	96,618
Common stock warrants	7,786,573	-

Amounts in the table above reflect the common stock equivalents of the noted instruments.

Recently issued and adopted accounting pronouncements

In August 2014, the FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. The amendments in this update explicitly require a company's management to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. The Company adopted this new standard effective in the quarter ended December 31, 2016.

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.

Oncobiologics, Inc.
Notes to Unaudited Interim Consolidated Financial Statements

In February 2016, the FASB issued ASU 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 fiscal years 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.

In March 2016, the FASB issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which is intended to simplify the accounting and reporting for employee share-based payment transactions. The pronouncement is effective for interim and annual periods beginning after December 31, 2016 with early adoption permitted. The Company adopted this ASU in the quarter ended March 31, 2017. The guidance did not have a material impact on the Company's consolidated financial statements upon adoption.

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, 2017		
	(Level 1)	(Level 2)	(Level 3)
Liabilities			
Warrant liability	\$ -	\$ -	\$ 3,855,052

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, 2017:

Balance at October 1, 2016	\$	-
Issuance of warrants		4,080,871
Change in fair value		(225,819)
Balance at March 31, 2017	\$	<u>3,855,052</u>

The warrants issued in connection with the senior secured notes are classified as liabilities on the accompanying consolidated balance sheet as the warrants include cash settlement features at the option of the holders under certain circumstances. The warrant liability is revalued each reporting period with the change in fair value recorded in the accompanying consolidated statements of operations until the warrants are exercised or expire. The fair value of the warrant liability is estimated using the Black-Scholes option pricing model using the following assumptions:

	March 31,
	2017
Risk-free interest rate	1.93%
Remaining contractual life of warrant	4.78 years
Expected volatility	84%
Annual dividend yield	0%
Fair value of common stock	\$2.68 per share

5. Property and Equipment

Property and equipment, net, consists of:

	March 31,	September 30,
	2017	2016
Laboratory equipment	\$ 11,574,475	\$ 11,452,858
Leasehold improvements	10,032,640	10,031,739
Computer software and hardware	471,152	421,206
Construction in progress	1,010,882	1,014,690
	<u>23,089,149</u>	<u>22,920,493</u>
Less: accumulated depreciation and amortization	(7,302,771)	(5,961,940)
	<u>\$ 15,786,378</u>	<u>\$ 16,958,553</u>

Depreciation and amortization expense was \$680,149 and \$598,097 for the three months ended March 31, 2017 and 2016, respectively, and \$1,349,930 and \$1,192,074 for the six months ended March 31, 2017 and 2016, respectively.

At March 31, 2017 and September 30, 2016, \$3,692,913 and \$3,630,683, respectively, represents laboratory equipment under capital leases. The term of the leases are between 22 and 36 months and qualify as capital leases. The leases bear interest between 5.0% and 19.4%. At March 31, 2017 and September 30, 2016, \$894,890 and \$732,002, respectively, of accumulated amortization related to this leased equipment has been recognized.

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6. Accrued Expenses

Accrued expenses consists of:

	March 31, 2017	September 30, 2016
Compensation	\$ 4,445,041	\$ 3,884,386
Research and development	1,717,383	1,343,910
Interest payable	540,106	234,754
Deferred offering costs	-	26,028
Professional fees	397,871	486,705
Director fees	219,375	73,125
Other accrued expenses	99,825	73,034
	<u>\$ 7,419,601</u>	<u>\$ 6,121,942</u>

7. Senior Secured Notes

	March 31, 2017
Senior secured notes	\$ 10,000,000
Unamortized debt discount	(3,388,859)
	<u>\$ 6,611,141</u>

In October, November and December 2016, the Company issued \$1.85 million aggregate principal amount of unsecured bridge notes to accredited investors. These unsecured notes bore interest at a rate of 15% per year and had a one-year maturity date from the date of issuance. These unsecured notes were exchanged for senior secured promissory notes in December 2016 as described below.

On December 22, 2016, the Company entered into a Note and Warrant Purchase Agreement (the "NWPA") with accredited investors providing for the issuance and sale of up to \$10.0 million of senior secured promissory notes (the "Notes"), which bear interest at a rate of 5% per year and mature December 22, 2017 and warrants (the "Warrants") to acquire an aggregate 2.3 million shares of the Company's common stock at an exercise price of \$3.00 per share, which have a five-year term. The Company closed the initial sale and purchase of the Notes and Warrants on December 22, 2016, issuing \$8.35 million aggregate principal amount of Notes and Warrants to acquire up to 1,920,500 shares of the Company's common stock in exchange for \$6.5 million and an aggregate of \$1.85 million of existing unsecured bridge notes issued by the Company in October, November and December 2016. The proceeds were first allocated to the warrant liability based on their initial fair value of \$3.3 million with an offsetting amount recorded as a debt discount. In addition, the Company incurred \$40,000 of debt issuance costs that have been recorded as a debt discount. The debt discount is being amortized into interest expense over the term of the Notes.

The Company used \$2.4 million of the proceeds from the sale of the Notes to pay off its remaining senior secured bank loans, and will use the remainder for working capital purposes. In January 2017, the Company issued the remaining Notes and Warrants for \$1.65 million. The proceeds were first allocated to the warrant liability based on their initial fair value of \$0.8 million with an offsetting amount recorded as a debt discount.

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Under the NWPA, the Company agreed to customary negative covenants restricting its ability to repay indebtedness to officers, pay dividends to stockholders, repay or incur other indebtedness other than as permitted, grant or suffer to exist a security interest in any of the Company's assets, other than as permitted, or enter into any transactions with affiliates. In addition to the negative covenants in the NWPA, the Notes include customary events of default. In connection with the closing of the initial sale of the Notes and Warrants, the Company entered into a Security Agreement and an Intellectual Property Security Agreement, each dated December 22, 2016, granting the holders of the Notes a security interest in all of its assets.

Interest expense on the Notes for the three and six months ended March 31, 2017 was \$958,037 and \$1,047,929, respectively.

On April 13, 2017, the Company entered into the First Amendment to the NWPA (the "Amendment") with the required holders of its Notes named therein, to amend certain terms of the NWPA. The primary purpose of the Amendment was to increase the amount of Notes that may be issued pursuant to the NWPA from \$10.0 million to \$15.0 million, permit the issuance of additional Warrants to acquire an aggregate 1,665,000 shares of its common stock, as well as increase the amount of time for the Company to issue additional Notes and Warrants in additional closings under the NWPA without approval of the holders of the Notes from 90 days to 180 days.

In connection with the Amendment, on April 13, 2017, the Company issued an additional \$3.5 million of Notes and Warrants to acquire an aggregate 1,165,500 shares of its common stock in exchange for \$3.5 million. Under the NWPA as amended by the Amendment, the Company may now issue up to \$1.5 million of additional Notes and Warrants to acquire up to an additional 499,500 shares of its common stock in additional closings over 180 days from the original date of the NWPA without approval of the holders of the Notes.

8. Stockholders' Equity (Deficit)

Lincoln Park Capital, LLC transaction

On March 8, 2017, the Company entered into a Purchase Agreement and a Registration Rights Agreement with an accredited investor, Lincoln Park Capital, LLC ("Lincoln Park"), providing for the purchase of the Company's common stock over the 30-month term of the Purchase Agreement. Under the terms and subject to the conditions of the Purchase Agreement, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to \$15.4 million of shares of the Company's common stock.

As contemplated by the Purchase Agreement, and so long as the closing price of the Company's common stock exceeds \$1.50 per share, then the Company may direct Lincoln Park, at its sole discretion to purchase up to 30,000 shares of its common stock on any business day. The price per share for such purchases will be equal to

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the lower of: (i) the lowest sale price on the applicable purchase date and (ii) the arithmetic average of the three (3) lowest closing sale prices for the Company's common stock during the ten (10) consecutive business days ending on the business day immediately preceding such purchase date (in each case, to be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction that occurs on or after the date of the purchase agreement). The maximum amount of shares subject to any single regular purchase increases as the Company's share price increases, subject to a maximum of \$1.0 million.

In addition to regular purchases, the Company may also direct Lincoln Park to purchase other amounts as accelerated purchases or as additional purchases if the closing sale price of the common stock exceeds certain threshold prices as set forth in the purchase agreement. In all instances, the Company may not sell shares of its common stock to Lincoln Park under the purchase agreement if it would result in Lincoln Park beneficially owning more than 4.99% of its common stock. There are no trading volume requirements or restrictions under the purchase agreement nor any upper limits on the price per share that Lincoln Park must pay for shares of common stock.

The Purchase Agreement and the Registration Rights Agreement contain customary representations, warranties, agreements and conditions to completing future sale transactions, indemnification rights and obligations of the parties. The Company has the right to terminate the purchase agreement at any time, at no cost or penalty. During any "event of default" under the Purchase Agreement, all of which are outside of Lincoln Park's control, Lincoln Park does not have the right to terminate the Purchase Agreement; however, the Company may not initiate any regular or other purchase of shares by Lincoln Park, until such event of default is cured. In addition, in the event of bankruptcy proceedings by or against the Company, the Purchase Agreement will automatically terminate.

During the three months ended March 31, 2017, the Company sold 257,817 shares of common stock to Lincoln Park for \$693,061 and incurred \$117,540 of issuance costs. In addition, the Company issued 115,416 shares of common stock to Lincoln Park as commitment shares pursuant to the Purchase Agreement. The Company may issue up to an additional 110,995 commitment shares to Lincoln Park in connection with additional purchases.

In April and May 2017, Lincoln Park purchased an additional 300,000 shares of the Company's common stock for \$659,790 of proceeds.

Common stock warrants

As of March 31, 2017, 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, 2018
Series B warrants	3,333,333	\$ 8.50	May 18, 2018
Common stock warrants issued with IPO	1,119,907	\$ 0.01	November 11, 2019
Common stock warrants issued with senior secured notes	2,260,334	\$ 3.00	December 22, 2021
	<u>10,046,907</u>		

During the six months ended March 31, 2017, warrants to purchase 400,361 and 39,666 shares with exercise prices of \$0.01 and \$3.00 per share, respectively, were exercised.

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9. 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, restricted stock units ("RSUs"), performance-based awards, 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 1,159,420. As of March 31, 2017, performance-based stock unit awards ("PSUs") representing 241,573 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, no future awards under the 2011 Plan will be granted.

2015 Equity Incentive Plan

In December 2015, the Company adopted the 2015 Equity Incentive Plan (the "2015 Plan"). The 2015 Plan provides for the grant of stock options, stock appreciation rights, restricted stock awards, restricted stock unit 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, 2017, RSUs representing 1,200,529 shares of the Company's common stock were outstanding under the 2015 Plan and 953,659 shares remained available for grant under the 2015 Plan.

The Company recorded stock-based compensation expense in the following expense categories of its statements of operations for the three and six months ended March 31, 2017 and 2016:

	<u>Three months ended March 31,</u>		<u>Six months ended March 31,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Research and development	\$ 431,706	\$ (3,281,214)	\$ 817,815	\$ (1,924,806)
General and administrative	1,895,685	(1,165,275)	3,973,628	(31,649)
	<u>\$ 2,327,391</u>	<u>\$ (4,446,489)</u>	<u>4,791,443</u>	<u>(1,956,455)</u>
	<u>Three months ended March 31,</u>		<u>Six months ended March 31,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Equity-classified compensation	\$ 2,327,391	\$ (4,446,489)	4,791,443	(4,348,317)
Liability-classified compensation	-	-	-	2,391,862
	<u>\$ 2,327,391</u>	<u>\$ (4,446,489)</u>	<u>4,791,443</u>	<u>(1,956,455)</u>

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.

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The following table summarizes the PSU activity for the six months ended March 31, 2017:

	Number of PSUs	Base Price Per PSU
Balance at October 1, 2016	247,309	\$ 6.33
Forfeitures	(5,736)	7.68
Balance at March 31, 2017	<u>241,573</u>	<u>\$ 6.29</u>

As of March 31, 2017, there was \$420,252 of unamortized expense that will be recognized over a weighted-average period of 1.25 years.

Restricted stock units

The following table summarizes the activity related to RSUs during the six months ended March 31, 2017:

	Number of RSUs	Weighted Average Grant Date Fair Value
Balance at October 1, 2016	1,094,351	\$ 28.61
Granted	615,000	2.11
Vested and settled	(483,913)	29.05
Forfeitures	(24,909)	2.65
Balance at March 31, 2017	<u>1,200,529</u>	<u>\$ 15.40</u>

The Company has granted RSUs that generally vest over a period of two to four years from the date of grant. In addition, vesting of the RSUs was also dependent upon the closing of the Company's IPO, which is a performance condition that is outside the Company's control. Therefore, the Company did not recognize any stock-based compensation until the consummation of the IPO in May 2016. As of March 31, 2017, there was \$9,094,284 of unamortized expense that will be recognized over a weighted-average period of 1.24 years.

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, 2016 and 2015 included in our Annual Report on Form 10-K for the year ended September 30, 2016, filed with the Securities and Exchange Commission, or SEC, on December 29, 2016, 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 such 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, 2016, filed with the SEC on December 29, 2016, 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 biosimilar therapeutics. Our current focus is on technically challenging and commercially attractive monoclonal antibodies, or mAbs, in the disease areas of immunology and oncology. 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 biosimilars on an accelerated timeline, which is fundamental to our success and we believe positions us to be a leading biosimilar 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 biosimilars and was designed to provide significant pricing flexibility. We have identified eight biosimilar product candidates for further development and have advanced two of these 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[®]).

- **ONS-3010** We have successfully completed a randomized, double-blind, single-dose and single-center Phase 1 clinical trial comparing ONS-3010 to Humira in three treatment arms. In this trial, ONS-3010 met its primary and secondary endpoints, demonstrating a similar pharmacokinetic (meaning how the body affects the molecule), or PK, profile, as well as an immunogenicity profile equivalent to both U.S.- and E.U.-Humira across all three treatment arms. In addition, ONS-3010 demonstrated a rate of injection site reactions lower than that of Humira. We have received regulatory feedback and agreement on our Phase 3 clinical trial design in the sensitive plaque psoriasis patient population from the U.S. Food and Drug Administration, or FDA, the European Medical Agency, or EMA, and national agencies such as the Medicines and Healthcare Products Regulatory Agency, or MHRA, and the Swedish regulatory authority. We plan to initiate our Phase 3 program in 500+ plaque psoriasis patients in 2018 upon the receipt of further partnership funding. The ONS-3010 Phase 3 program has been reviewed by the FDA and is designed to support both biosimilarity and interchangeability to Humira. Humira is currently approved in the United States for multiple indications. We initially intend to seek approval of ONS-3010 for the treatment of plaque psoriasis, and will seek to expand such approval to the

same indications as Humira as appropriate. We have informed the regulatory authorities of our intent to seek extrapolation to all approved Humira indications, and have also reviewed our Phase 3 interchangeability study design with the FDA.

· **ONS-1045** We have completed a randomized, double-blind, single-dose and single-center Phase 1 clinical trial. In this trial, ONS-1045 met its primary and secondary endpoints demonstrating a similar PK profile, as well as an immunogenicity profile equivalent to both U.S.- and EU-Avastin. We are preparing ONS-1045 for a global Phase 3 clinical trial treating 700+ non-squamous non-small cell lung cancer patients to commence in mid-2018 upon receipt of funding from a development partner. Avastin is currently approved in the United States for multiple indications. We initially intend to seek approval of ONS-1045 for the treatment of non-squamous non-small cell lung cancer, and will seek to expand such approval to the same indications as Avastin when appropriate. We have informed the regulatory authorities of our intent to seek extrapolation to all approved Avastin indications, and have also discussed our study design with the FDA.

Through March 31, 2017, we have funded substantially all of our operations through the sale and issuance of our common stock, preferred stock and senior secured notes and warrants, generating approximately \$150.3 million net proceeds. In April 2017, we issued additional senior secured notes and warrants and received \$3.5 million in cash proceeds.

As described in their audit report included in our annual report on Form 10-K for the year ended September 30, 2016 filed on December 29, 2016 with the SEC, as amended to date, our auditors have included an explanatory paragraph that states that we have incurred recurring losses and negative cash flows from operations since inception and have an accumulated deficit at September 30, 2016 of \$147.4 million 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 Phase 3 clinical trials, receive approval for and commercialize 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 current and potential future collaborations, the issuance of equity securities, the issuance of additional debt, revenues from potential future product sales, if any, and other strategic alternatives. There are no assurances that we will be successful in obtaining an adequate level of financing for the development and commercialization of ONS-3010, ONS-1045 or any other current or future biosimilar product candidates. If we are unable to secure adequate additional funding, our business, operating results, financial condition and cash flows may be materially and adversely affected. These matters raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

Our current cash resources as of March 31, 2017 and the proceeds from our April 2017 note and warrant issuance are expected to fund our operations through May 2017. 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 and other opportunities. While we are actively pursuing these transactions and intend to conclude one or more of them in the near-term, there can be no assurance that these future funding efforts will be successful. If we are not successful in raising additional capital or entering into one or more licensing and/or co-development rights agreements or other opportunities, we will be required to further scale back our plans and place certain activities on hold as we explore other alternatives.

We do not have any products approved for sale and we have only generated limited 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, 2017 was \$27.1 million. We also had net losses of \$53.3 million and \$47.4 million for the years ended September 30, 2016 and 2015, respectively. 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 biosimilar products and/or biosimilar 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 cell lines created 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. 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 biosimilars in humans, or from filing an investigational new drug, absent a commercial license agreement with Selexis covering the particular biosimilar 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, 2017, 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, 2017, 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, 2017, 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.

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. For the foreseeable future, we expect all of our revenue, if any, will be generated from our collaboration and licensing agreements. If any of our 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, 2017 and 2016:

	<u>Three months ended March 31,</u>		<u>Six months ended March 31,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
IPCA Collaboration	\$ 65,268	\$ 105,433	\$ 130,536	\$ 210,866
Liomont Collaboration	59,160	595,566	118,320	1,191,132
Huahai Collaboration	178,713	293,895	357,425	587,790
	<u>\$ 303,141</u>	<u>\$ 994,894</u>	<u>\$ 606,281</u>	<u>\$ 1,989,788</u>

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The following table summarizes the milestone payments and recognition of deferred revenues from our collaboration and licensing agreements during the three and six months ended March 31, 2017 and 2016:

	<u>Three months ended March 31,</u>		<u>Six months ended March 31,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Milestone payments	\$ -	\$ 500,000	\$ -	\$ 1,000,000
Recognition of deferred revenues	303,141	494,894	606,281	989,788
	<u>\$ 303,141</u>	<u>\$ 994,894</u>	<u>\$ 606,281</u>	<u>\$ 1,989,788</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. We recognize revenues from the achievement of milestones if the milestone event is substantive and achievability of the milestone was not reasonably assured at the inception of the agreement.

Research and Development Expenses

Research and development expense consists of expenses incurred in connection with the discovery and development of our biosimilar 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 biosimilar 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 biosimilar 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.

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Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals. We may never succeed in achieving regulatory approval for any of our biosimilar product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some biosimilar product candidates or focus on others. A change in the outcome of any of these variables with respect to the development of a biosimilar product candidate could mean a significant change in the costs and timing associated with the development of that biosimilar 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. Biosimilar product commercialization will take several years and millions of dollars in development costs.

Research and development activities are central to our business model. Biosimilar 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 biosimilar 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 biosimilar 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 biosimilar 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 obligations.

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

During the three and six months ended March 31, 2017, we incurred \$0 and \$4,000, respectively, of state withholding taxes in connection with our collaboration and licensing agreements. During the three and six months ended March 31, 2016, we incurred \$0.1 million in both periods for state and foreign withholding taxes in connection with our collaboration and licensing agreements.

Since inception, we have not recorded any U.S. federal or state income tax benefits (excluding the sale of New Jersey state net operating losses, or NOLs and research credits) for the net losses we have incurred in each year or on our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. As of September 30, 2016, we had federal and state NOL carryforwards of \$99.8 million and \$37.0 million, respectively, which will begin to expire in 2030 and 2036, respectively. As of September 30, 2016, we had federal foreign tax credit carryforwards of \$2.3 million available to reduce future tax liabilities, which begin to expire starting in 2023. As of September 30, 2016, we also had federal research and development tax credit carryforwards of \$0.8 million that begin to expire in 2032.

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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 our May 2016 initial public offering, or IPO, and 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, 2017 and 2016

	<u>Three months ended March 31,</u>		
	<u>2017</u>	<u>2016</u>	<u>Change</u>
Collaboration revenues	\$ 303,141	\$ 994,894	\$ (691,753)
Operating expenses:			
Research and development	4,198,775	4,138,277	60,498
General and administrative	4,045,141	(189,438)	4,234,579
	<u>8,243,916</u>	<u>3,948,839</u>	<u>4,295,077</u>
Loss from operations	(7,940,775)	(2,953,945)	(4,986,830)
Interest expense	1,139,903	537,935	601,968
Change in fair value of warrant liability	(1,035,902)	-	(1,035,902)
Loss before income taxes	(8,044,776)	(3,491,880)	(4,552,896)
Income tax expense	-	50,500	(50,500)
Net loss	<u>\$ (8,044,776)</u>	<u>\$ (3,542,380)</u>	<u>\$ (4,502,396)</u>

Collaboration Revenues

Collaboration revenues decreased \$0.7 million, to \$0.3 million, for the three months ended March 31, 2017, as compared to \$1.0 million for the three months ended March 31, 2016. The change is due to a \$0.5 million reduction in milestone payments and \$0.2 million reduction in the amortization of deferred revenue as compared to the prior year period as a result of the increase in the expected performance period.

Research and Development Expenses

The following table summarizes our research and development expenses by functional area for the three months ended March 31, 2017 and 2016:

	<u>Three months ended March 31,</u>		
	<u>2017</u>	<u>2016</u>	
Preclinical and clinical development	\$ 188,754	\$ 3,548,055	
Compensation and related benefits	2,453,634	2,690,836	
Stock-based compensation	427,718	(3,281,214)	
Other research and development	1,128,669	1,180,600	
Total research and development expenses	<u>\$ 4,198,775</u>	<u>\$ 4,138,277</u>	

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The following table summarizes our research and development expenses by compound for the three months ended March 31, 2017 and 2016:

	Three months ended March 31,	
	2017	2016
ONS-3010	\$ —	\$ 2,470,872
ONS-1045	86,610	1,079,783
Early-stage compounds	102,144	99,248
Personnel related and stock-based compensation	2,881,352	(692,226)
Other research and development	1,128,669	1,180,600
Total research and development expenses	<u>\$ 4,198,775</u>	<u>\$ 4,138,277</u>

Research and development expenses for the three months ended March 31, 2017 increased by \$0.1 million compared to the three months ended March 31, 2016. The increase in research and development expenses resulted from a \$3.6 million increase in stock-based compensation, due to the fact that we had a negative expense in the prior year period as a result of remeasurement of outstanding performance stock unit awards, or PSUs, as of March 31, 2016. This increase was partially offset by a \$3.5 million decrease in ONS-3010 and ONS-1045 clinical costs as we postponed the bulk of our Phase 3 clinical trial efforts until we secure funding from potential partners to advance the programs.

General and Administrative Expenses

The following table summarizes our general and administrative expenses by type for the three months ended March 31, 2017 and 2016:

	Three months ended March 31,	
	2017	2016
Professional fees	\$ 1,215,843	\$ 55,688
Compensation and related benefits	746,283	539,103
Stock-based compensation	1,895,685	(1,165,275)
Facilities, fees and other related costs	187,330	381,046
Total general and administration expenses	<u>\$ 4,045,141</u>	<u>\$ (189,438)</u>

General and administrative expenses for the three months ended March 31, 2017 increased by \$4.2 million compared to the three months ended March 31, 2016, primarily due to an increase in stock-based compensation, \$3.1 million of which primarily resulted from the March 31, 2016 remeasurement of outstanding PSUs, which resulted in negative expense in the prior year period, and an increase in public company related professional fees of \$1.2 million not incurred prior to our May 2016 IPO.

Interest Expense

Interest expense increased by \$0.6 million for the three months ended March 31, 2017 as compared to the three months ended March 31, 2016 primarily due to the amortization of debt discount and accrued interest on the senior secured notes issued in December 2016 and January 2017.

Change in Fair Value of Warrant Liability

During the three months ended March 31, 2017, we recorded income of \$1.0 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. There was no warrant liability or related charges during the three months ended March 31, 2016.

Comparison of Six Months Ended March 31, 2017 and 2016

	Six months ended March 31,		Change
	2017	2016	
Collaboration revenues	\$ 606,281	\$ 1,989,788	\$ (1,383,507)
Operating expenses:			
Research and development	17,511,081	16,872,253	638,838
General and administrative	8,934,001	4,484,717	4,449,284
	<u>26,445,082</u>	<u>21,356,970</u>	<u>5,088,112</u>
Loss from operations	(25,838,801)	(19,367,182)	(6,471,619)
Interest expense	1,526,616	936,910	589,706
Change in fair value of warrant liability	(225,819)	-	(225,819)
Loss before income taxes	(27,139,598)	(20,304,092)	(6,835,506)
Income tax expense	4,000	102,500	(98,500)
Net loss	<u>\$ (27,143,598)</u>	<u>\$ (20,406,592)</u>	<u>\$ (6,737,006)</u>

Collaboration Revenues

Collaboration revenues decreased \$1.4 million, to \$0.6 million, for the six months ended March 31, 2017, as compared to \$2.0 million for the six months ended March 31, 2016. The change is due to a \$1.0 million reduction in milestone payments and \$0.4 million reduction in the amortization of deferred revenue as compared to the prior year as a result of the increase in the expected performance period.

Research and Development Expenses

The following table summarizes our research and development expenses by functional area for the six months ended March 31, 2017 and 2016:

	Six months ended March 31,	
	2017	2016
Preclinical and clinical development	\$ 9,133,645	\$ 10,555,088
Compensation and related benefits	4,923,243	5,110,676
Stock-based compensation	813,827	(1,924,806)
Other research and development	2,640,366	3,131,295
Total research and development expenses	<u>\$ 17,511,081</u>	<u>\$ 16,872,253</u>

The following table summarizes our research and development expenses by compound for the six months ended March 31, 2017 and 2016:

	Six months ended March 31,	
	2017	2016
ONS-3010	\$ 5,590,558	\$ 6,679,178
ONS-1045	2,841,635	3,820,518
Early-stage compounds	701,452	55,392
Personnel related and stock-based compensation	5,737,070	3,185,870
Other research and development	2,640,366	3,131,295
Total research and development expenses	<u>\$ 17,511,081</u>	<u>\$ 16,872,253</u>

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Research and development expenses for the six months ended March 31, 2017 increased by \$0.6 million compared to the six months ended March 31, 2016. This increase in research and development expenses resulted from an increase of \$2.7 million in stock-based compensation primarily due to the fact that the prior year period reflects a \$5.6 million decrease in stock-based compensation as a result of remeasurement of PSUs that occurred as of March 31, 2016. This increase was partially offset by a \$2.1 million decrease in ONS-3010 and ONS-1045 clinical costs as we postponed the bulk of our Phase 3 clinical trial efforts until we secure funding from potential partners to advance the programs.

General and Administrative Expenses

The following table summarizes our general and administrative expenses by type for the six months ended March 31, 2017 and 2016:

	<u>Six months ended March 31,</u>	
	<u>2017</u>	<u>2016</u>
Professional fees	\$ 2,199,797	\$ 2,270,714
Compensation and related benefits	1,466,076	1,398,143
Stock-based compensation	3,973,628	(31,529)
Facilities, fees and other related costs	1,294,500	847,389
Total general and administration expenses	<u>\$ 8,934,001</u>	<u>\$ 4,484,717</u>

General and administrative expenses for the six months ended March 31, 2017 increased by \$4.4 million compared to the six months ended March 31, 2016, primarily due to an increase in stock-based compensation of \$4.0 million, which is primarily due to the fact that the prior year period stock compensation expense reflects a \$3.5 million reduction due to remeasurement of PSUs as of March 31, 2016. A portion of the increase is also due to a \$0.4 million increase in facilities, fees and other related costs, primarily due to receipt of a refund from one of our vendors in the period ended March 31, 2016.

Interest Expense

Interest expense increased by \$0.6 million for the six months ended March 31, 2017 as compared to the six months ended March 31, 2016 primarily due to the amortization of debt discount and accrued interest on the senior secured notes issued in December 2016 and January 2017.

Change in Fair Value of Warrant Liability

During the six months ended March 31, 2017, 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 the decrease in the price of our common stock during the period. There was no warrant liability or related charges during the six months ended March 31, 2016.

Liquidity and Capital Resources

We have not generated any revenue from biosimilar product sales. Since inception, we have incurred net losses and negative cash flows from our operations. Through March 31, 2017, we have funded substantially all of our operations through the sale and issuance of equity and debt securities and borrowings under debt facilities, raising aggregate net proceeds of \$150.3 million. We have also received an aggregate of \$24.0 million pursuant to our collaboration and licensing agreements. In addition, in April 2017 we issued \$3.5 million of additional senior secured promissory notes and warrants to acquire 1,165,500 shares of our common stock in exchange for \$3.5 million. We will require additional capital to fund our operations past May 2017. Alternatively, we will be required to further scale back our plans and place certain activities on hold.

As of March 31, 2017, we had an accumulated deficit of \$174.5 million and a cash balance of \$0.1 million. In addition, we had \$10.0 million of senior secured notes due in December 2017 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

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statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. We anticipate incurring additional losses until such time, if ever, that we can generate significant sales of our product candidates currently in development. We will need substantial additional financing to fund our operations and to commercially develop our product candidates. Management is currently evaluating various strategic opportunities to obtain the required funding for future operations. These strategies include, but are not limited to: payments from current and potential new strategic research and development, licensing and/or marketing arrangements with pharmaceutical companies, private placements of equity and/or debt, public offerings of equity and/or debt securities, generating revenue by using the capabilities of our BioSymphony platform to provide development and manufacturing services for a fee to other pharmaceutical companies developing mAbs, the potential disposition of some of our assets, and exploring additional cost reduction opportunities. 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. While we are actively pursuing these transactions and intend to conclude one or more of them in the near-term, there can be no assurance that these future funding efforts will be successful, and if not successful, we may be required to explore all other alternatives.

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:

	Six months ended March 31,	
	2017	2016
Net cash used in operating activities	\$ (9,952,128)	\$ (19,070,494)
Net cash used in investing activities	(191,877)	(317,293)
Net cash provided by financing activities	7,873,167	13,159,006
Net decrease in cash	<u>\$ (2,270,838)</u>	<u>\$ (6,228,781)</u>

Operating Activities.

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.

During the six months ended March 31, 2016, we used \$19.1 million of cash in operating activities, primarily resulting from our net loss of \$20.4 million that included \$0.7 million of noncash items and offset by \$2.1 million in net cash provided by changes in our operating assets and liabilities. The noncash items were primarily comprised of depreciation and amortization of our fixed assets, stock-based compensation, and the re-measurement of our PSU awards. The change in our operating assets and liabilities was primarily due to decreases in prepaid expenses and other current assets and deferred revenue; increases in accounts payable and accrued expenses related to our planned Phase 3 clinical trials and the timing of vendor payments. These inflows were partially offset primarily from an increase in accounts receivable from our collaboration and licensing agreements.

Investing Activities.

During the six months ended March 31, 2017 and 2016, we used cash of \$0.2 million and \$0.3 million, respectively, in investing activities for the purchase of property and equipment.

Financing Activities.

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.

During the six months ended March 31, 2016, net cash provided by financing activities was \$13.2 million, primarily attributable to \$16.1 million in net proceeds from the sale of our common stock and \$4.3 million in proceeds from the collection of subscriptions receivable. We also received \$0.8 million from Sonnet Biotherapeutics, Inc. in connection with their note receivable. These inflows were offset by \$7.4 million in debt payments, \$0.4 million upon the deconsolidation of Sonnet Biotherapeutics, Inc. and \$0.2 million in deferred IPO costs payments.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of March 31, 2017.

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 dated September 30, 2016, filed with the SEC on December 29, 2016, 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, 2017.

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.

Use of Proceeds

On May 12, 2016, the Registration Statement on Form S-1 (File No. 333-204091) for our initial public offering of units was declared effective by the SEC, pursuant to which we sold an aggregate 5.8 million units at a public offering price of \$6.00 per unit for aggregate gross proceeds of \$35.0 million. Jefferies LLC and Barclays Capital Inc. acted as joint book-running managers for the offering, and Cantor Fitzgerald & Co. acted as the lead manager. We received net proceeds from the IPO of approximately \$29.2 million, after deducting approximately \$5.8 million of underwriting discounts, commissions and offering expenses paid by us. None of these expenses consisted of payments made by us to directors, officers or persons owning 10% or more of our common stock or to their associates, or to our affiliates. There has been no material change in the planned use of proceeds from our initial public offering as described in our prospectus dated May 12, 2016 filed with the SEC on May 13, 2016 pursuant to Rule 424(b)(4).

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**

Exhibit Number	Description
10.1	Registration Rights Agreement by and between Oncobiologics, Inc. and the Investors named therein dated February 3, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on February 3, 2017)
10.2	Amendment to the Warrant Agreement dated May 18, 2016 by and between Oncobiologics, Inc. and American Stock Transfer & Trust Company LLC, as Warrant Agent, dated February 6, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on February 6, 2017)
10.3	Purchase Agreement dated March 8, 2017 by and between Oncobiologics, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on March 9, 2017)
10.4	Registration Rights Agreement dated March 8, 2017 by and between Oncobiologics, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K filed with the SEC on March 9, 2017)
10.5	First Amendment to Note and Warrant Purchase Agreement dated April 13, 2017 by and between Oncobiologics, Inc. and the Purchasers named therein (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on April 17, 2017)
31.1	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	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.
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, 2017

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(s) 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)) 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) 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

(c) 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, 2017

By: /s/ Pankaj Mohan

Pankaj Mohan, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

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(s) 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)) 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) 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

(c) 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, 2017

By: /s/ Lawrence A. Kenyon

Lawrence A. Kenyon
Chief Financial Officer
(Principal Financial Officer)

**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, 2017, 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, 2017

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

Date: May 15, 2017

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."
