

Oncobiologics, Inc.  
Form 10-Q  
June 27, 2016

**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, 2016**

**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 ☐

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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” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☒ (Do not check if a smaller reporting company) Smaller reporting company ☐

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 June 23, 2016 was 22,802,778.

**Oncobiologics, Inc.**

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Table of Contents**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****Oncobiologics, Inc.****Consolidated Balance Sheets****(unaudited)**

	March 31, 2016	September 30, 2015
Assets		
Current assets:		
Cash	\$2,842,194	\$9,070,975
Accounts receivable	504,857	20,000
Stock subscription receivable	-	4,280,149
Related party receivable	43,187	-
Prepaid and other current assets	712,767	1,793,109
Total current assets	4,103,005	15,164,233
Property and equipment, net	17,358,388	17,759,938
Restricted cash	214,773	213,663
Deferred offering costs	2,272,408	960,563
Other assets	882,877	910,224
Total assets	\$24,831,451	\$35,008,621
Liabilities, redeemable preferred stock, common stock, noncontrolling interests and stockholders' equity (deficit)		
Current liabilities:		
Current portion of debt	\$760,013	\$742,646
Current portion of capital lease obligations	907,274	862,849
Current portion of stockholder notes	9,653,401	14,214,196
Accounts payable	14,416,288	11,563,055
Accrued expenses	6,403,971	5,924,648
Income taxes payable	1,854,629	1,754,629
Deferred revenue	1,979,576	1,979,576
Total current liabilities	35,975,152	37,041,599
Long-term debt	2,547,139	2,922,764

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Capital lease obligations	810,122	1,219,373
Stockholder notes	-	2,000,000
Deferred revenue	5,376,157	6,365,945
Stock-based compensation liability	-	12,726,722
Other liabilities	591,128	284,710
Total liabilities	45,299,698	62,561,113

Redeemable preferred stock, common stock and noncontrolling interests:

Redeemable preferred stock, no par value:

Series A—No shares authorized, issued and outstanding at March 31, 2016; 8,000 shares authorized; 3,568 issued and outstanding at September 30, 2015	-	5,072,653
Series B—No shares authorized, issued and outstanding at March 31, 2016; 4,000 shares authorized, issued and outstanding at September 30, 2015;	-	5,118,208
Redeemable common stock—1,739,130 shares issued and outstanding	17,396,626	15,426,673
Redeemable noncontrolling interests	-	1,703,777
Total redeemable preferred stock, common stock and noncontrolling interests	17,396,626	27,321,311

Stockholders' equity (deficit):

Series A preferred stock, par value \$0.01 per share: 10,000,000 shares authorized, 11,819 shares issued and outstanding at March 31, 2016 (liquidation preference of \$11,819,000 at March 31, 2016); No shares authorized, issued and outstanding at September 30, 2015	118	-
Common stock, par value \$0.01 per share; 100,000,000 shares authorized at March 31, 2016; 12,427,164 shares issued and outstanding at March 31, 2016; No shares authorized, issued and outstanding at September 30, 2015	124,272	-
Common stock, no shares authorized issued and outstanding at March 31, 2016; no par value; 100,000,000 shares authorized; 9,436,294 shares issued and outstanding at September 30, 2015	-	39,844,900
Additional paid-in capital	76,481,615	-
Accumulated deficit	(114,470,878)	(94,064,286 )
Total Oncobiologics, Inc. stockholders' equity (deficit)	(37,864,873 )	(54,219,386 )
Non controlling interests	-	(654,417 )
Total stockholders' equity (deficit)	(37,864,873 )	(54,873,803 )
Total liabilities, redeemable preferred stock, common stock, noncontrolling interests and stockholders' equity (deficit)	\$24,831,451	\$35,008,621

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

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

	Three Months Ended March 31,		Six Months Ended March 31,	
	2016	2015	2016	2015
Collaboration revenues	\$ 994,894	\$ 494,894	\$ 1,989,788	\$ 3,429,449
Operating expenses:				
Research and development	4,138,277	10,154,469	16,872,253	15,994,499
General and administrative	(189,438 )	4,342,090	4,484,717	5,579,929
	3,948,839	14,496,559	21,356,970	21,574,428
Loss from operations	(2,953,945 )	(14,001,665 )	(19,367,182 )	(18,144,979 )
Interest expense, net	537,935	705,929	936,910	1,063,509
Loss before income taxes	(3,491,880 )	(14,707,594 )	(20,304,092 )	(19,208,488 )
Income tax expense (benefit)	50,500	(726,218 )	102,500	(319,855 )
Net loss	(3,542,380 )	(13,981,376 )	(20,406,592 )	(18,888,633 )
Accretion of redeemable preferred stock and noncontrolling interests	(1,030,414 )	(1,034,529 )	(1,969,953 )	(2,105,693 )
Deemed dividends upon the repurchase of Series A redeemable preferred stock and redeemable noncontrolling interests	-	(67,633 )	-	(1,298,631 )
Net loss attributable to common stockholders of Oncobiologics, Inc.	\$ (4,572,794 )	\$ (15,083,538 )	\$ (22,376,545 )	\$ (22,292,957 )
Per share information:				
Net loss per share of common stock, basic and diluted	\$ (0.32 )	\$ (1.61 )	\$ (1.64 )	\$ (2.38 )
Weighted average shares outstanding, basic and diluted	14,155,081	9,377,450	13,605,331	9,377,450

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



Table of Contents**Oncobiologics, Inc.****Consolidated Statements of Redeemable Preferred Stock, Common Stock, Noncontrolling Interests  
and Stockholders' Equity (Deficit)****For the Six months ended March 31, 2016****(unaudited)**

<b>Redeemable Preferred Stock, Common Stock and Noncontrolling Interests</b>										<b>Stockholders' Equity</b>
	<b>Preferred Stock</b>				<b>Common Stock</b>		<b>Noncontrolling Interests</b>	<b>Series A Preferred Stock</b>		<b>Common Stock</b>
	<b>Series A</b>		<b>Series B</b>							
	<b>Shares</b>	<b>Amount</b>	<b>Shares</b>	<b>Amount</b>	<b>Shares</b>	<b>Amount</b>	<b>Interests</b>	<b>Shares</b>	<b>Amount</b>	<b>Shares</b>
Balance at October 1, 2015	3,568	\$5,072,653	4,000	\$5,118,208	1,739,130	\$15,426,673	\$1,703,777	-	\$-	9,111
Deconsolidation of Sonnet Biotherapeutics, Inc.	-	-	-	-	-	-	-	-	-	-
Employee tax withholdings related to the vesting of restricted stock	-	-	-	-	-	-	-	-	-	(2,000)
Reincorporation to a Delaware Corporation	(3,568)	(5,072,653)	(4,000)	(5,118,208)	-	-	-	10,193	102	2,000
Issuance of common stock upon the dissolution of Parilis	-	-	-	-	-	-	(1,703,777)	1,626	16	2,000
Sale of common stock, net of issuance costs	-	-	-	-	-	-	-	-	-	5,000
Reclassification of stock-based compensation liability	-	-	-	-	-	-	-	-	-	-
	-	-	-	-	-	-	-	-	-	-

953	-	-	-	-
	-	-	-	-
5,626	\$-	11,819	\$118	1

financial statements.

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

	Six Months Ended March 31,	
	2016	2015
<b>OPERATING ACTIVITIES</b>		
Net loss	\$ (20,406,592 )	\$ (18,888,633 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,192,074	441,071
Non-cash interest expense	6,090	6,105
Stock-based compensation	(1,956,455 )	7,175,780
Loss on disposal of fixed assets	13,647	-
Changes in operating assets and liabilities:		
Accounts receivable	(484,857 )	(1,072,910 )
Prepaid expenses and other current assets	1,080,342	263,667
Other assets	27,347	(100,000 )
Accounts payable	1,878,794	3,344,446
Accrued expenses	156,677	732,247
Income taxes payable	100,000	151,113
Deferred revenue	(989,788 )	1,520,551
Other liabilities	312,227	-
Net cash used in operating activities	(19,070,494 )	(6,426,563 )
<b>INVESTING ACTIVITIES</b>		
Purchase of property and equipment	(317,293 )	(2,020,557 )
Net cash used in investing activities	(317,293 )	(2,020,557 )
<b>FINANCING ACTIVITIES</b>		
Repurchase of Series A redeemable preferred stock	-	(226,001 )
Proceeds from the sale of common stock	16,137,913	-
Proceeds from subscriptions receivable	4,280,149	-
Proceeds from stockholders notes	-	8,380,252
Payments of capital leases obligations	(443,326 )	(254,869 )
Repayment of debt	(364,348 )	(375,754 )
Payment of deferred offering costs	(200,000 )	-
Repayment of stockholder notes	(6,560,795 )	(1,000,000 )
Change in restricted cash	(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	13,159,006	6,523,628

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Net decrease in cash	(6,228,781 )	(1,923,492 )
Cash at beginning of period	9,070,975	2,349,313
Cash at end of period	\$2,842,194	\$425,821
Supplemental disclosure of cash flow information		
Cash paid for interest	\$794,663	\$855,446
Cash paid for taxes	\$2,500	\$2,250
Supplemental schedule of noncash investing activities:		
Purchases of property and equipment in accounts payable and accrued expenses	\$635,341	\$2,769,817
Supplemental schedule of noncash financing activities:		
Accretion of redeemable preferred stock, common stock and noncontrolling interests	\$1,969,953	\$2,105,693
Deemed dividend upon repurchase of Series A redeemable preferred stock in excess of carrying value	\$-	\$1,215,000
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	\$78,500	\$-
Deferred offering costs and common stock issuance costs in accounts payable and accrued expenses	\$(1,111,845 )	\$-

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

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**Oncobiologics, Inc.**

**Notes to Unaudited Interim Consolidated Financial Statements**

**1. Organization and Description of Business**

Oncobiologics, Inc. (“Oncobiologics” or the “Company”) was incorporated in New Jersey on January 5, 2010 and started operations in July 2011. Oncobiologics is a clinical-stage biopharmaceutical company focused on identifying, developing, manufacturing and commercializing complex biosimilar therapeutics in the disease areas of immunology and oncology. The Company has established fully integrated in-house development and manufacturing capabilities that addresses the numerous complex technical and regulatory challenges in developing and commercializing mAb biosimilars. Since inception, the Company has advanced two product candidates into clinical trials: a Phase 3-ready biosimilar to adalimumab (Humira®) and a Phase 3-ready biosimilar to bevacizumab (Avastin®). Additionally, the Company has six preclinical biosimilar product candidates under active development.

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. As a result of the merger, each share of the Company’s previously issued and outstanding common stock converted into and became a share of common stock of the Delaware corporation on a 1-for-1 basis, each share of the Company’s previously issued and outstanding Series A redeemable preferred stock converted into 1,000 shares of common stock and approximately 1.4035 shares of Series A preferred stock of the Delaware corporation, and each share of the Company’s previously issued and outstanding Series B redeemable preferred stock converted into 1,000 shares of common stock and approximately 1.2867 shares of Series A preferred stock of the Delaware corporation. The holders of Series A and B also received an aggregate of 10,193 shares of Series A preferred stock of the Delaware corporation. Additionally, effective upon the reincorporation and in connection with the dissolution of the Company’s business development subsidiary, Parilis Biopharmaceuticals (“Parilis”), the Company issued 226,663 shares of common stock and 1,626 shares of Series A preferred stock to the holders of outstanding Parilis preferred member units in exchange for all such units.

In May 2016, the Company completed the initial public offering (“IPO”) of its securities by offering 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 \$34.4 million in net proceeds, after deducting discounts and commissions of approximately \$2.8 million and estimated offering expenses of approximately \$2.8 million payable by the Company. The interim consolidated financial statements, do not give effect to the IPO and concurrent private placement.

## **2. Liquidity**

The Company has incurred substantial losses and negative cash flows from operations since its inception and has an accumulated deficit of \$114.5 million and \$94.1 million as of March 31, 2016 and September 30, 2015, respectively. In addition, the Company has \$8.9 million and \$14.2 million of indebtedness that is due on demand, as of March 31, 2016 and September 30, 2015, respectively. 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 has substantial indebtedness that includes \$9.7 million in notes payable to stockholders that are payable on demand. There can be no assurance that note holders will not exercise their right to demand repayment.

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**Oncobiologics, Inc.**

**Notes to Unaudited Interim Consolidated Financial Statements**

The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its products currently in development. Although the Company closed the IPO of its securities and the concurrent private placement on May 18, 2016 raising aggregate net proceeds of approximately \$34.4 million, excluding any proceeds it may receive from the exercise of the Series A warrants and Series B warrants, which proceeds are expected to fund the Company's operations through June 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: private placements of equity and/or debt, payments from potential strategic research and development, licensing and/or marketing arrangements with pharmaceutical companies, and public offerings of equity and/or debt securities. There can be no assurance that these future funding efforts will be successful.

**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, 2016 and its results of operations for the three and six months ended March 31, 2016 and 2015 and cash flows for the six months ended March 31, 2016 and 2015. Operating results for the six months ended March 31, 2016 are not necessarily indicative of the results that may be expected for the full year ending September 30, 2016. The unaudited interim condensed 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, 2015 included in the final prospectus dated May 12, 2016 filed with the Securities and Exchange Commission ("SEC").

### ***Recapitalization***

On April 26, 2016, the Company filed a certificate of amendment to amend its certificate of incorporation effecting a 1-for-3.45 reverse split of the Company's common stock. All references in the unaudited interim consolidated financial statements to the number of shares and per-share amounts of common stock have been retroactively restated to reflect the reverse split.

### **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 (benefit) of \$50,500 and \$(726,218) for the three months ended March 31, 2016 and 2015, respectively, and \$102,500 and \$(319,855) for the six months ended March 31, 2016 and 2015, respectively, which is primarily attributable to the foreign withholding taxes in connection with the Company's collaboration and licensing agreements and the sale of New Jersey net operating losses.



Table of Contents**Oncobiologics, Inc.****Notes to Unaudited Interim Consolidated Financial Statements****Net loss per share**

Basic and diluted net loss per common share is determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period. For all periods presented, the outstanding shares of preferred stock have been excluded from the calculation because their effects would be anti-dilutive. Therefore, the weighted-average shares used to calculate both basic and diluted loss per share are the same.

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding as of March 31, 2016 and 2015, as they would be antidilutive:

	March 31,	
	2016	2015
Series A redeemable preferred stock	-	1,059,710
Series B redeemable preferred stock	-	1,159,418
Series A preferred stock	984,899	-
Performance-based stock units	247,887	-
Restricted stock units	1,066,039	-
Unvested shares of restricted common stock	-	32,463
Convertible stockholder note	96,618	96,618

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 will 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 new standard will be effective in the first annual period ending after December 15, 2016. Early application is permitted.

The Company is currently evaluating the potential impact of the adoption of this standard, but the Company believes its adoption will have no impact on its consolidated results of operations, financial position or cash flows.

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.

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**Oncobiologics, Inc.**

**Notes to Unaudited Interim Consolidated Financial Statements**

In March 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 annual periods beginning after December 15, 2019 (i.e., calendar periods beginning on January 1, 2020), 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 adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

**4. Fair Value Measurements**

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

Level 1 — Quoted prices in active markets for identical assets or liabilities.

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

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

techniques.

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

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

	September 30, 2015		
	(Level 1)	(Level 2)	(Level 3)
Liabilities			
Stock-based compensation liability	\$-	\$ -	\$ 12,726,722

The table presented below is a summary of changes in the fair value of the Company's Level 3 valuation for the stock-based compensation liability for the six months ended March 31, 2016:

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

Balance at October 1, 2015	\$12,726,722
Change in fair value	2,391,862
Reclassification to stockholders' equity	(15,118,584)
Balance at March 31, 2016	\$-

As of March 31, 2016, the Company had no assets or liabilities that were measured at fair value.

The Company has issued stock-based performance units ("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. In addition, the PSUs are exercisable upon the earlier of (i) a change in control, (ii) consummation of an IPO, or (iii) a corporate valuation in excess of \$400 million and at the discretion by the Company's Board of Directors. Upon exercise, the PSU holder received a cash payment for the difference between the current per share value of the Company and the base price of the PSU. Given the cash settlement, the PSUs were liability classified and re-measured at each reporting date with changes in fair value recorded within the Company's consolidated statements of operations. In December 2015, the PSUs were modified to provide for settlement in common stock or cash, at the Company's discretion. As a result of this modification, the carrying value of the PSUs was reclassified to stockholders' equity (deficit).

The PSUs contain a market condition as the exercisability of the awards are based on the Company achieving a market value of \$400 million during the relevant performance period. The fair value of the market condition is valued using a Monte Carlo simulation model. The significant assumptions used in preparing the Monte Carlo simulation model include (i) volatility of the Company's common stock, (ii) risk free interest rate, (iii) base price of the PSUs, (iv) fair value of the Company's common stock and enterprise value of the Company, and (v) derived service period.

The fair value of the PSUs of \$22.22 per PSU at September 30, 2015 was derived using the following assumptions:

	September 30, 2015
Risk-free interest rate	1.4%
Derived service period	5 years
Expected volatility	60%
Annual dividend yield	0%

Fair value of common stock \$25.79 per share

Table of Contents**Oncobiologics, Inc.****Notes to Unaudited Interim Consolidated Financial Statements****5. Property and Equipment**

Property and equipment, net, consists of:

	March 31, 2016	September 30, 2015
Laboratory equipment	\$10,840,204	\$ 10,936,364
Leasehold improvements	9,927,614	9,889,521
Computer software and hardware	409,684	402,075
Construction in progress	940,621	175,425
	22,118,123	21,403,385
Less: accumulated depreciation and amortization	(4,759,735 )	(3,643,447 )
	\$ 17,358,388	\$ 17,759,938

Depreciation and amortization expense was \$598,097 and \$218,996 for the three months ended March 31, 2016 and 2015, respectively, and \$1,192,074 and \$441,071 for the six months ended March 31, 2016 and 2015, respectively.

At March 31, 2016 and September 30, 2015, \$3,608,801 and \$3,530,301 represents laboratory equipment under capital leases. The term of the leases are between 11 and 36 months and qualify as capital leases. The leases bear interest between 8.2% and 21.4%. At March 31, 2016 and September 30, 2015, \$673,188 and \$407,210, respectively, of accumulated depreciation related to this leased equipment has been recognized.

**6. Accrued Expenses**

Accrued expenses consists of:

March 31, 2016	September 30, 2015
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Compensation	\$3,137,855	\$ 2,321,508
Research and development	1,679,473	951,759
Interest payable	682,538	806,475
Deferred offering costs	450,648	657,892
Professional fees	280,333	594,572
Director fees	-	414,421
Other accrued expenses	173,124	178,021
	\$6,403,971	\$ 5,924,648

## 7. Redeemable Preferred Stock, Common Stock, Noncontrolling Interests and Stockholders' Equity (Deficit)

### Common stock

During the six months ended March 31, 2016, the Company sold 573,788 shares of its common stock at \$29.05 per share raising \$16,137,913 in net proceeds.



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**Oncobiologics, Inc.**

**Notes to Unaudited Interim Consolidated Financial Statements**

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Subject to preferences that may apply to any outstanding preferred stock, holders of common stock are entitled to receive ratably any dividends that the Company's board of directors may declare out of funds legally available for that purpose on a non-cumulative basis. No dividends had been declared through March 31, 2016.

**Series A preferred stock**

In the event of a liquidation, dissolution or winding up of the Company, either voluntary or involuntary, or in the event of a Deemed Liquidation Event, as defined in the Certificate of Incorporation, holders of Series A preferred stock are entitled to receive, in preference to all other stockholders, an amount equal to the original issue price, as defined in the Certificate of Incorporation, plus any unpaid accrued dividends. If upon the occurrence of such event, the assets and funds thus distributed among the holders of the Series A preferred stock shall be insufficient to pay such holders, then the entire assets and funds of the Company legally available for distribution shall be distributed ratably among the holders of the Series A preferred stock in proportion to the respective amount of such stock owned by each such holder.

The Company may redeem the Series A preferred stock, in whole at any time and from time to time in part, at the option of the Company, for cash, at a redemption price equal to the Original Issuance Price (as defined in the Certificate of Incorporation) plus any unpaid accrued dividends. The holders of the Series A preferred stock have no voting rights outside of matters directly related to the Series A preferred stock. Upon the closing of the Company's IPO, all then outstanding shares of Series A preferred stock will automatically convert into shares of the Company's common stock at a conversion rate equal to the IPO price per share of common stock divided by the liquidation preference of the Series A preferred stock.

In connection with the closing of the Company's IPO, the Series A converted into 1,969,818 shares of common stock.

**Deconsolidation of noncontrolling interests**

Through September 30, 2015, the Company consolidated the operations of Sonnet Biotherapeutics, Inc. (“Sonnet”), which was spun-off to the Company’s stockholders in April 2015, because the Company was the primary funding source to Sonnet through September 2015. Effective October 1, 2015, additional capital was contributed to Sonnet by third-party investors triggering a reconsideration event, which resulted in the Company no longer being considered the primary beneficiary and as a result, the Company has deconsolidated Sonnet. Sonnet issued the Company an \$826,561 promissory note which reflects the funding the Company provided Sonnet through September 30, 2015. The note bears interest at 3.0% and matures September 30, 2016. There were no gains or losses recognized upon deconsolidation since no equity interest was owned by the Company. As of March 31, 2016, the balance of the note is \$33,396 plus accrued interest of \$9,791.

## **8. 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, 2016, performance-based stock units (“PSUs”) representing 247,887 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.

Table of Contents**Oncobiologics, Inc.****Notes to Unaudited Interim Consolidated Financial Statements*****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 1,246,377 shares. As of March 31, 2016, RSUs representing 1,066,039 shares of the Company’s common stock were outstanding under the 2015 Plan and 180,338 shares remained available for grant under the 2015 Plan.

The Company recorded stock-based compensation (income) expense in the following expense categories of its statements of operations for the three and six months ended March 31, 2016 and 2015:

	Three Months ended March 31,		Six Months ended March 31,	
	2016	2015	2016	2015
Research and development	\$ (3,281,214 )	\$ 3,650,718	\$ (1,924,806 )	\$ 3,734,993
General and administrative	(1,165,275 )	3,379,388	(31,649 )	3,440,787
	\$ (4,446,489 )	\$ 7,030,106	\$ (1,956,455 )	\$ 7,175,780

	Three Months ended March 31,		Six Months ended March 31,	
	2016	2015	2016	2015
Equity-classified compensation	\$ (4,446,489 )	\$ 2,231	\$ (4,348,317 )	\$ 4,462
Liability-classified compensation	-	7,027,875	2,391,862	7,171,318
	\$ (4,446,489 )	\$ 7,030,106	\$ (1,956,455 )	\$ 7,175,780

**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 and at the discretion by the Company's board of directors. Upon exercise, the PSU holder receives common stock or cash, at the Company's discretion. See note 4 for discussion of fair value of the PSUs.

The following table summarizes the PSU activity for the six months ended March 31, 2016:

	Number of PSUs	Base Price Per PSU
Balance at October 1, 2015	687,013	\$ 3.45
Forfeitures	(4,346 )	3.45
Exchanged for restricted stock units	(434,780)	3.45
Balance at March 31, 2016	247,887	\$ 6.33

In December 2015, the Company completed a tender-offer to holders of outstanding PSUs to amend the terms of such outstanding awards to increase the base price to an amount equal to the fair market value of a share of the Company's common stock on the date of grant of the PSU, remove the right to be paid dividend equivalents and provide for settlement in shares of the Company's

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

common stock or cash, at the Company's discretion. Upon amending the settlement terms of the PSUs, the Company reclassified the stock-based compensation liability to additional paid-in capital. The PSUs continue to be re-measured at each reporting period until the earlier of (i) an IPO, (ii) change in control, or (iii) action taken by the Board of directors to confirm the vesting criteria has been achieved.

Concurrent with the tender-offer, several PSU holders cancelled an aggregate of 434,780 PSUs in exchange for 391,303 restricted stock units ("RSUs"). The Company accounted for the exchange as a modification, and, as a result, recognized \$98,172 of additional stock-based compensation during the six months ended March 31, 2016 based on the fair value of the RSUs in excess of the fair value of the PSUs exchanged.

As of March 31, 2016, there was \$300,000 of unamortized expense that will be recognized in future periods.

**Restricted stock units**

The following table summarizes the activity related to RSUs granted during the six months ended March 31, 2016:

	Number of RSUs	Grant Date Fair Value
Balance at October 1, 2015	-	\$ -
Granted	674,890	29.05
Forfeitures	(154 )	29.05
Issued in connection with PSU exchange	391,303	29.05
Balance at March 31, 2016	1,066,039	\$ 29.05

As of March 31, 2016, there were 387,868 RSUs that will vest upon the expiration of the 180-day lock up period following the Company's IPO or a change in control. The remaining 678,171 RSUs will vest upon the expiration of the 180-day lock up period following the Company's IPO or change in control and over the following time-based vesting periods:

- 525,999 RSUs with 50% vesting on each of the first and second anniversaries of the recipient's grant date
- 21,738 RSUs with one-third vesting on each of the first, second, and third anniversaries of the recipient's hire date
- 130,434 RSUs with 50% vesting on each of the third and fourth anniversaries of the recipient's hire date

The expiration of the lock-up period following an IPO or a change in control are performance conditions that are 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, 2016, there was \$21,100,000 of unamortized expense.

## 9. Subsequent Events

On May 18, 2016, the Company filed an amended and restated certificate of incorporation (the "Restated Certificate") with the Secretary of State of the State of Delaware in connection with the closing of its IPO. As set forth in the Restated Certificate, the Company's authorized capital stock now consists of 200,000,000 shares of common stock, par value \$0.01 per share, and 10,000,000 shares of preferred stock, par value \$0.01 per share.

On May 18, 2016, upon the closing of the IPO, the Company issued warrants to acquire an aggregate of 1,520,269 shares of its common stock to certain of the investors party to that certain investors' rights agreement dated March 10, 2014, as amended, pursuant to the terms of an amendment to such agreement dated April 26, 2016. The warrants issued to these investors are not exercisable until 180 days after May 12, 2016, and have an initial exercise price of \$0.01 per share, which may increase to \$1.00 per share under certain circumstances, and expire November 18, 2019.

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**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, 2015 and 2014 included in our prospectus dated May 12, 2016, filed with the Securities and Exchange Commission, or SEC, pursuant to Rule 424(b) under the Securities Act of 1933, as amended, or the Securities Act, on May 13, 2016.*

**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 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 prospectus dated May 12, 2016, filed with the SEC pursuant to Rule 424(b) under the Securities Act on May 13, 2016, 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 into clinical trials: ONS-3010, a Phase 3-ready biosimilar to adalimumab (Humira®), and ONS-1045, a Phase 3-ready 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 have also completed a site feasibility study to identify global sites (North and South America, Europe, Australia and New Zealand) in preparation for the commencement of our planned Phase 3 clinical trial in 2016. 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



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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 to commence upon receipt of additional funding. 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, 2016, we have funded substantially all of our operations through the sale and issuance of approximately \$105.5 million of our common stock, preferred stock and debt. Through March 31, 2016, we have also received \$24.0 million pursuant to our collaboration and licensing agreements. Subsequently, on May 18, 2016 we completed the initial public offering, or IPO, of our securities, through the sale of units. Each unit consisted of one share of 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 initial public offering price was \$6.00 per unit. We also completed a private placement of 833,332 shares of common stock, 416,666 Series A warrants and 416,666 Series B warrants for aggregate gross proceeds of approximately \$5.0 million that closed concurrent with the IPO. The units separated in accordance with their terms and ceased trading, and on June 13, 2016, each of the component securities underlying the units (common stock, Series A warrants and Series B warrants) began trading on the NASDAQ Global Market. We raised net proceeds of approximately \$29.8 million from our IPO and an additional \$4.6 million of net proceeds from the concurrent private placement, in each case excluding any proceeds we may receive from the exercise of the Series A and Series B warrants.

As described in their audit report included in the prospectus filed May 13, 2016 with the SEC, 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, 2015 of \$94.1 million and \$14.2 million of indebtedness that is due on demand. While we believe that the proceeds received from our IPO and concurrent private placement will be sufficient to fund our operations through June 2017, we will need to raise substantial additional financing to fund our future operations. We will need to raise substantial additional capital in order to receive approval for and commercialize ONS-3010, commence any Phase 3 clinical trials of ONS-1045 and continue to develop our other pipeline candidates. We plan to finance our future operations with a combination of proceeds from the issuance of equity securities, the issuance of additional debt, potential collaborations and revenues from potential future product sales, if any. There are no assurances that we will be successful in obtaining an adequate level of financing for the development and commercialization of ONS-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.

We do not have any products approved for sale and we have only generated revenue from our collaboration agreements. We have incurred operating losses and negative operating cash flows since inception and there is no assurance that we will ever achieve profitable operations, and if achieved, that profitable operations will be sustained. Our net loss for the six months ended March 31, 2016 was \$20.4 million. We also had net losses of \$47.4 million and \$13.7 million for the years ended September 30, 2015 and 2014, respectively. In addition, development activities, clinical and preclinical testing and commercialization of our product candidates will require significant additional financing.

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**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 cells created lines using the Selexis expression technology, or the Selexis Technology. The original research license had a three-year term, but on October 9, 2014, was extended for an additional three-year term through October 9, 2017. 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, 2016, 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

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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, 2016, 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, 2016, 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 December 2014, we received an option to reacquire all rights to ONS-3010 from Huahai, which would have terminated the joint participation agreement. We had to exercise the option prior to December 23, 2015 and pay Huahai a total of \$28.0 million, consisting of an \$11.0 million initial payment due within seven days of exercise, and four additional installment payments of \$4.25 million payable over the course of the following year. We decided not to make the \$11.0 million initial payment within the time frame required.

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. To maintain its 51% value ownership of ONS-3010 as of March 31, 2016, Huahai is required to make a payment to us of \$9.1 million. Similarly, revenues from commercialization of ONS-3010 in the agreed countries (including major markets such as the United States and the European Union, 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 for the research, development, manufacture, use or sale of ONS-3010 or ONS-1045 in the territory, which includes 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.

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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, 2016 and 2015:

	Three months ended March 31,		Six months ended March 31,	
	2016	2015	2016	2015
IPCA collaboration	\$ 105,433	\$ 105,433	\$ 210,866	\$ 691,511
Liomont collaboration	595,566	95,566	1,191,132	150,148
Huahai collaboration	293,895	293,895	587,790	2,587,790
	\$ 994,894	\$ 494,894	\$ 1,989,788	\$ 3,429,449

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, 2016 and 2015:

	Three months ended March 31,		Six months ended March 31,	
	2016	2015	2016	2015
Milestone payments	\$ 500,000	\$ -	\$ 1,000,000	\$ 2,500,000
Recognition of deferred revenues	494,894	494,894	989,788	929,449
	\$ 994,894	\$ 494,894	\$ 1,989,788	\$ 3,429,449

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. 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 expenses.

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;



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

Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals. We may never succeed in achieving regulatory approval for any of our biosimilar product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some 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 Securities and Exchange Commission, or SEC, requirements, accounting and 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 bank loans, notes with current and former stockholders, equipment loans and capital lease obligations.

### ***Income Taxes***

During the three and six months ended March 31, 2016, we incurred \$0.1 million and \$0.1 million, respectively, of foreign withholding taxes in connection with our collaboration and licensing agreements. During the three and six months ended March 31, 2015, we recorded an income tax benefit of \$0.7 million and \$0.3 million, respectively, due to the sale of New Jersey state net operating losses, or NOLs, partially offset by 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 NOLs) 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, 2015, we had federal and state NOL carryforwards of \$52.9 million and \$36.9 million, respectively that will begin to expire in 2030 and 2032, respectively. As of September 30, 2015, we had federal

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foreign tax credit carryforwards of \$2.6 million available to reduce future tax liabilities, which begin to expire at various dates starting in 2023. As of September 30, 2015, we also had federal and state research and development tax credit carryforwards of \$4.2 million and \$1.7 million, respectively, which begin to expire in 2021.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its NOLs to offset future taxable income. We have not completed a study to assess whether an ownership change has occurred in the past. Our existing NOLs may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change in connection with or after this offering, 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, 2016 and 2015***

	Three months ended March 31,		
	2016	2015	Change
Collaboration revenues	\$ 994,894	\$ 494,894	\$ 500,000
Operating expenses:			
Research and development	4,138,277	10,154,469	(6,016,192 )
General and administrative	(189,438 )	4,342,090	(4,531,528 )
	3,948,839	14,496,559	(10,547,720)
Loss from operations	(2,953,945 )	(14,001,665 )	11,047,720
Interest expense	537,935	705,929	(167,994 )
Loss before income taxes	(3,491,880 )	(14,707,594 )	11,215,714
Income tax expense (benefit)	50,500	(726,218 )	776,718
Net loss	\$ (3,542,380 )	\$ (13,981,376 )	\$ 10,438,996

***Collaboration Revenues***

Our collaboration revenues increased \$0.5 million, to \$1.0 million, for the three months ended March 31, 2016, as compared to \$0.5 million for the three months ended March 31, 2015. The change is attributable to achievement of a milestone resulting in a \$0.5 million payment.

Table of Contents*Research and Development Expenses*

The following table summarizes our research and development expenses by functional area for the three months ended March 31, 2016 and 2015:

	Three months ended March 31,	
	2016	2015
Preclinical and clinical development	\$ 3,548,055	\$ 3,950,096
Compensation and related benefits	3,839,549	2,293,998
Stock-based compensation	(3,281,214 )	3,650,718
Regulatory filings and other	31,887	259,657
Total research and development expenses	\$ 4,138,277	\$ 10,154,469

The following table summarizes our research and development expenses by compound for the three months ended March 31, 2016 and 2015:

	Three months ended March 31,	
	2016	2015
ONS-3010	\$ 2,470,872	\$ 1,802,485
ONS-1045	1,079,783	1,595,790
Other research and development	131,135	811,477
Personnel related and stock-based compensation	456,487	5,944,717
Total research and development expenses	\$ 4,138,277	\$ 10,154,469

Research and development expenses were \$4.1 million for the three months ended March 31, 2016, compared to \$10.2 million for the three months ended March 31, 2015. The primary reason for the decrease was a reduction in stock-based compensation of \$6.9 million upon the re-measurement of our Performance Stock Units, or PSUs, in 2016. Additionally, as compared to our fiscal second quarter of 2015, we saw compensation expense increase by approximately \$1.5 million, direct ONS-3010 clinical and regulatory costs increase by \$0.7 million, direct ONS-1045 clinical and regulatory costs decrease by \$0.5 million and pre-clinical development costs decrease by \$0.7 million, as we increased staff and moved forward in our efforts to launch our Phase 3 clinical program for ONS-3010 later in 2016.

*General and Administrative Expenses*

The following table summarizes our general and administration expenses by type for the three months ended March 31, 2016 and 2015:

	Three months ended March 31,	
	2016	2015
Professional fees	\$ 55,688	\$ 242,678
Compensation and related benefits	603,519	708,424
Stock-based compensation	(1,165,275 )	3,379,388
Fees and other	316,630	11,600
Total general and administration expenses	\$ (189,438 )	\$ 4,342,090

General and administrative expenses were \$(0.2) million for the three months ended March 31, 2016, compared to \$4.3 million for the three months ended March 31, 2015. The decrease was primarily attributable to decreased stock-based compensation expense of \$4.6 million due to the re-measurement of our PSUs.

Table of Contents*Interest Expense*

Interest expense decreased by \$0.2 million to \$0.5 million for the three months ended March 31, 2016 as compared to \$0.7 million for the three months ended March 31, 2015 primarily due to the reductions in outstanding balances under stockholder notes, and other debt obligations over the comparable period.

*Comparison of Six Months Ended March 31, 2016 and 2015*

	Six months ended March 31,		
	2016	2015	Change
Collaboration revenues	\$1,989,788	\$3,429,449	\$(1,439,661)
Operating expenses:			
Research and development	16,872,253	15,994,499	877,754
General and administrative	4,484,717	5,579,929	(1,095,212)
	21,356,970	21,574,428	(217,458 )
Loss from operations	(19,367,182 )	(18,144,979 )	(1,222,203)
Interest expense	936,910	1,063,509	(126,599 )
Loss before income taxes	(20,304,092 )	(19,208,488 )	(1,095,604)
Income tax expense (benefit)	102,500	(319,855 )	422,355
Net loss	\$(20,406,592 )	\$(18,888,633 )	\$(1,517,959)

*Collaboration Revenues*

Our collaboration revenues decreased \$1.4 million, to \$2.0 million, for the six months ended March 31, 2016, as compared to \$3.4 million for the six months ended March 31, 2015. The change is primarily attributable to the \$1.5 million decrease in milestone payments partially offset by a \$60,000 increase in the amortization of deferred revenue.

*Research and Development Expenses*

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The following table summarizes our research and development expenses by functional area for the six months ended March 31, 2016 and 2015:

	Six months ended March 31,	
	2016	2015
Preclinical and clinical development	\$ 10,555,088	\$ 7,474,624
Compensation and related benefits	7,654,906	4,499,087
Stock-based compensation	(1,924,806 )	3,734,993
Regulatory filings and other	587,065	285,795
Total research and development expenses	\$ 16,872,253	\$ 15,994,499



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The following table summarizes our research and development expenses by compound for the six months ended March 31, 2016 and 2015:

	Six months ended March 31,	
	2016	2015
ONS-3010	\$6,679,178	\$3,350,397
ONS-1045	3,820,518	3,314,520
Other research and development	642,457	1,095,502
Personnel related and stock-based compensation	5,730,100	8,234,080
Total research and development expenses	\$16,872,253	\$15,994,499

Research and development expenses were \$16.9 million for the six months ended March 31, 2016, compared to \$16.0 million for the six months ended March 31, 2015. The primary reason for the increase of only \$0.9 million was a reduction in stock-based compensation of \$5.6 million upon the re-measurement of our PSUs in 2016. This offset the other increases, as compared to the first six months of our fiscal 2015, we saw compensation expense increase by approximately \$3.1 million, and direct ONS-3010 clinical and regulatory costs increase by \$3.3 million, as we increased staff and moved forward in our efforts to launch our Phase 3 clinical program for ONS-3010 later in 2016.

*General and Administrative Expenses*

The following table summarizes our general and administration expenses by type for the six months ended March 31, 2016 and 2015:

	Six months ended March 31,	
	2016	2015
Professional fees	\$2,270,714	\$760,709
Compensation and related benefits	1,726,896	1,213,956
Stock-based compensation	(31,529)	3,440,787
Fees and other	518,636	164,477
Total general and administration expenses	\$4,484,717	\$5,579,929

General and administrative expenses were \$4.5 million for the six months ended March 31, 2016, compared to \$5.6 million for the six months ended March 31, 2015. The decrease was primarily attributable to decreased compensation costs of approximately \$2.9 million, which included reduced stock-based compensation expense of \$3.5 million due to the re-measurement of our PSUs. Net of the stock based compensation costs, we saw higher compensation costs of

\$0.6 million plus increased professional and other fees of approximately \$1.9 million all related to additional staff and services to prepare for our IPO in 2016.

*Interest Expense*

Interest expense decreased by \$0.1 million to \$0.9 million for the six months ended March 31, 2016 from \$1.0 million for the six months ended March 31, 2015 primarily due to the reductions in outstanding balances under stockholder notes and other debt obligations over the comparable period.

Table of Contents**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, 2016, we have funded substantially all of our operations through the sale and issuance of \$105.5 million net proceeds of our common stock, and sales of our preferred stock and borrowings under debt facilities. We have also received an aggregate of \$24.0 million pursuant to our collaboration and licensing agreements. As of March 31, 2016, we had an accumulated deficit of \$114.5 million and had a cash balance of \$2.8 million. In addition, we had \$9.7 million of indebtedness that is due on demand. These matters raise substantial doubt about our ability to continue as a going concern. Although we closed the IPO of our securities and the concurrent private placement to an accredited investor in May 2016 raising net proceeds of approximately \$29.8 million from our IPO and \$4.6 million from the concurrent private placement, in each case excluding any proceeds we may receive from the exercise of the Series A and Series B warrants, which we expect will fund our operations through June 2017, our unaudited interim consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. We anticipate incurring additional losses until such time, if ever, that we can generate significant sales of our product candidates currently in development. We will need substantial additional financing to fund our operations and to commercially develop our product candidates. Management is currently evaluating different strategies to obtain the required funding for future operations. These strategies may include, but are not limited to: private placements of equity and/or debt, payments from potential strategic research and development, licensing and/or marketing arrangements with pharmaceutical companies, and public offerings of equity and/or debt securities. There can be no assurance that these future funding efforts will be successful.

Our future operations are highly dependent on a combination of factors, including (i) the timely and successful completion of additional financing discussed above, (ii) our ability to complete revenue-generating partnerships with pharmaceutical companies, (iii) the success of our research and development, (iv) the development of competitive therapies by other biotechnology and pharmaceutical companies, and, ultimately, (v) regulatory approval and market acceptance of our proposed future products.

***Cash Flows***

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

	Six months ended March 31,	
	2016	2015
	(Unaudited)	
Net cash used in operating activities	\$ (19,070,494 )	\$ (6,426,563 )
Net cash used in investing activities	(317,293 )	(2,020,557 )

Net cash provided by financing activities	13,159,006	6,523,628
Net decrease in cash	\$(6,228,781 )	\$(1,923,492 )

*Operating Activities.*

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.

During the six months ended March 31, 2015, we used \$6.4 million of cash in operating activities, primarily resulting from our net loss of \$18.9 million that was offset by \$7.6 million of noncash items and \$4.8 million in net cash provided by changes in our operating assets and liabilities. The change in our operating assets and liabilities were primarily due to increases in deferred revenue related to our collaboration and licensing arrangements and accounts payable and accrued expenses related to our Phase 1 clinical trials

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and the timing of vendor payments. These inflows were partially offset by increases in accounts receivable related to our collaboration and licensing arrangements.

*Investing Activities.*

During the six months ended March 31, 2016 and 2015, we used cash of \$0.3 million and \$2.0 million, respectively, in investing activities for the purchase of property and equipment. The decrease in purchases of property and equipment during the six months ended March 31, 2016 was primarily attributable to the fact that the prior year period reflects the launch of our manufacturing facility, which resulted in significant increases in our laboratory equipment and leasehold improvements for the six months ended March 31, 2015.

*Financing Activities.*

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. See note 7 to our unaudited interim consolidated financial statements for more information regarding Sonnet Biotherapeutics, Inc.

During the six months ended March 31, 2015, net cash provided by financing activities was \$6.5 million, primarily attributable to \$8.4 million upon the issuance of stockholder notes offset by \$1.6 million in debt payments.

**Off-Balance Sheet Arrangements**

We did not have any off-balance sheet arrangements as of March 31, 2016.

**Contractual Obligations and Commitments**

There have been no material changes to our contractual obligations from those described in our prospectus dated May 12, 2016, filed with the SEC pursuant to Rule 424(b) under the Securities Act on May 13, 2016.

### **Critical Accounting Policies and Significant Judgments and Estimates**

The Critical Accounting Policies and Significant Judgments and Estimates included in our prospectus dated May 12, 2016, filed with the SEC pursuant to Rule 424(b) under the Securities Act on May 13, 2016 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**

We are exposed to market risks in the ordinary course of our business. As of March 31, 2016, we had \$2.8 million of cash, and we had approximately \$14.7 million of debt obligations. Our cash is deposited in accounts at three financial institutions, and amounts may exceed federally insured limits. We do not believe we are exposed to significant credit risk due to the financial strength of the depository institutions in which the cash is held. As a result, a change in market interest rates would not have a material impact on our financial position or results of operations.

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**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, 2016.

**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**

The Risk Factors included in our prospectus dated May 12, 2016, filed with the SEC pursuant to Rule 424(b) under the Securities Act on May 13, 2016 have not materially changed.

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

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

In January 2016, we sold an aggregate of 87,287 shares of our common stock to 5 accredited investors for a purchase price of \$29.05 per share or approximately \$2.5 million in the aggregate. Jefferies LLC, Arclight Advisors LLC and Alere Financial Partners (a division of COVA Capital Partners, LLC), each a registered broker-dealer and member of Financial Industry Regulation Authority, Inc., served as placement agents in this offering. The placement agents earned an aggregate of approximately \$0.2 million in commissions with respect to this offering.

In April 2016, we issued 30,421 restricted stock unit awards under our 2015 Equity Incentive Plan.

### **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 an aggregate offering price 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 \$29.8 million, after deducting approximately \$5.2 million of underwriting discounts, commissions and offering expenses. None of these expenses consisted of payments made by us to directors, officers or persons owning 10% or more of our common stock



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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

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**Item 6. Exhibits**

Exhibits

- 3.1 Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-37759), as filed with the SEC on May 19, 2016).
- 3.2 Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-37759), as filed with the SEC on May 19, 2016).
- 10.1 Form of Unit Certificate (incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1/A (File No. 333-209011), as filed with the SEC on May 11, 2016).
- 10.2 Form of Series A warrant Certificate (included in Exhibit 10.4).
- 10.3 Form of Series B warrant Certificate (included in Exhibit 10.4).
- 10.4 Form of Warrant Agreement by and between Oncobiologics, Inc. and American Stock Transfer & Trust Company LLC, as Warrant Agent, dated May 18, 2016.
- 10.5 Securities Purchase Agreement by and between Oncobiologics, Inc. and Sabby Healthcare Master Fund Ltd., dated May 11, 2016 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-37759), as filed with the SEC on May 19, 2016).
- 10.6 Investors' Rights Agreement by and among Oncobiologics, Inc. and certain of its stockholders, dated March 10, 2014, as amended (incorporated herein by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1/A (File No. 333-209011), as filed with the SEC on May 11, 2016).
- 10.7 Form of Warrant to Purchase Common Stock (incorporated herein by reference to Exhibit 10.30 to the Company's Registration Statement on Form S-1/A (File No. 333-209011), as filed with the SEC on May 11, 2016).
- 10.8 2016 Employee Stock Purchase Plan (incorporated herein by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1/A (File No. 333-209011), as filed with the SEC on February 12, 2016).
- 10.9 Employment Agreement between Oncobiologics, Inc. and Pankaj Mohan, Ph.D., dated February 22, 2016 (incorporated herein by reference to Exhibit 10.25 to the Company's Registration Statement on Form S-1/A (File No. 333-209011), as filed with the SEC on April 27, 2016).
- 10.10 Employment Agreement between Oncobiologics, Inc. and Kenneth Bahrt, M.D., dated February 22, 2016 (incorporated herein by reference to Exhibit 10.26 to the Company's Registration Statement on Form S-1/A (File No. 333-209011), as filed with the SEC on April 27, 2016).
- 10.11

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Employment Agreement between Oncobiologics, Inc. and Elizabeth A. Yamashita, dated February 24, 2016 (incorporated herein by reference to Exhibit 10.27 to the Company's Registration Statement on Form S-1/A (File No. 333-209011), as filed with the SEC on April 27, 2016).

10.12 Employment Agreement between Oncobiologics, Inc. and Lawrence A. Kenyon, dated February 18, 2016 (incorporated herein by reference to Exhibit 10.28 to the Company's Registration Statement on Form S-1/A (File No. 333-209011), as filed with the SEC on April 27, 2016).

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\* Certification of Principal Executive Officer and Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

101.INS XBRL Instance Document

101.SCH XBRL Taxonomy Extension Schema Document

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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.

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**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: June 27, 2016 By: /s/ Lawrence A. Kenyon

Lawrence A. Kenyon

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