

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

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended June 30, 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

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>

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 August 11, 2016 was 22,802,778.

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

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

	June 30, 2016	September 30, 2015
<b>Assets</b>		
Current assets:		
Cash	\$ 13,555,375	\$ 9,070,975
Accounts receivable	3,670	20,000
Stock subscription receivable	-	4,280,149
Related party receivable	43,350	-
Prepaid and other current assets	1,259,348	1,793,109
Total current assets	14,861,743	15,164,233
Property and equipment, net	17,054,098	17,759,938
Restricted cash	215,520	213,663
Deferred offering costs	-	960,563
Other assets	860,964	910,224
Total assets	\$ 32,992,325	\$ 35,008,621
<b>Liabilities, redeemable preferred stock, common stock, noncontrolling interests and stockholders' equity (deficit)</b>		
Current liabilities:		
Current portion of debt	\$ 752,449	\$ 742,646
Current portion of capital lease obligations	936,783	862,849
Current portion of stockholder notes	4,612,500	14,214,196
Accounts payable	4,534,396	11,563,055
Accrued expenses	8,266,564	5,924,648
Income taxes payable	1,854,629	1,754,629
Deferred revenue	1,979,576	1,979,576
Total current liabilities	22,936,897	37,041,599
Long-term debt	2,370,267	2,922,764
Capital lease obligations	564,536	1,219,373
Stockholder notes	-	2,000,000
Deferred revenue	4,881,263	6,365,945
Stock-based compensation liability	-	12,726,722
Other liabilities	676,231	284,710
Total liabilities	31,429,194	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 June 30, 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 June 30, 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 at September 30, 2015	-	15,426,673
Redeemable noncontrolling interests	-	1,703,777
Total redeemable preferred stock, common stock and noncontrolling interests	-	27,321,311
Stockholders' equity (deficit):		
Series A preferred stock, par value \$0.01 per share: 10,000,000 shares authorized, no shares issued and outstanding	-	-
Common stock, par value \$0.01 per share; 200,000,000 shares authorized at June 30, 2016; 22,802,778 shares issued and outstanding at June 30, 2016; No shares authorized, issued and outstanding at September 30, 2015	228,028	-
Common stock, no shares authorized issued and outstanding at June 30, 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	138,133,413	-
Accumulated deficit	(136,798,310)	(94,064,286)
Total Oncobiologics, Inc. stockholders' equity (deficit)	1,563,131	(54,219,386)
Non controlling interests	-	(654,417)
Total stockholders' equity (deficit)	1,563,131	(54,873,803)
Total liabilities, redeemable preferred stock, common stock, noncontrolling interests and stockholders' equity (deficit)	\$ 32,992,325	\$ 35,008,621

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



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

	<u>Three Months Ended June 30,</u>		<u>Nine Months Ended June 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Collaboration revenues	\$ 494,894	\$ 1,294,894	\$ 2,484,682	\$ 4,724,343
Operating expenses:				
Research and development	12,017,724	9,681,019	28,889,977	25,675,518
General and administrative	10,504,663	2,659,616	14,989,380	8,239,545
	<u>22,522,387</u>	<u>12,340,635</u>	<u>43,879,357</u>	<u>33,915,063</u>
Loss from operations	(22,027,493)	(11,045,741)	(41,394,675)	(29,190,720)
Interest expense, net	299,439	554,831	1,236,349	1,618,340
Loss before income taxes	(22,326,932)	(11,600,572)	(42,631,024)	(30,809,060)
Income tax expense (benefit)	500	120,000	103,000	(199,855)
Net loss	(22,327,432)	(11,720,572)	(42,734,024)	(30,609,205)
Less: Net loss attributable to noncontrolling interests	-	(380,435)	-	(380,435)
Net loss attributable to Oncobiologics, Inc.	(22,327,432)	(11,340,137)	(42,734,024)	(30,228,770)
Accretion of redeemable preferred stock and noncontrolling interests	(493,207)	(1,091,590)	(2,463,160)	(3,197,283)
Deemed dividend upon issuance of warrants to common stockholders	(7,373,820)	-	(7,373,820)	-
Deemed dividends upon the repurchase of Series A redeemable preferred stock and redeemable noncontrolling interests	-	-	-	(1,298,631)
Net loss attributable to common stockholders of Oncobiologics, Inc.	<u>\$ (30,194,459)</u>	<u>\$ (12,431,727)</u>	<u>\$ (52,571,004)</u>	<u>\$ (34,724,684)</u>
Per share information:				
Net loss per share of common stock, basic and diluted	<u>\$ (1.60)</u>	<u>\$ (1.30)</u>	<u>\$ (3.43)</u>	<u>\$ (3.67)</u>
Weighted average shares outstanding, basic and diluted	<u>18,816,708</u>	<u>9,588,022</u>	<u>15,336,117</u>	<u>9,449,575</u>

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

**Oncobiologics, Inc.**  
**Consolidated Statements of Redeemable Preferred Stock, Common Stock, Noncontrolling Interests**  
**and Stockholders' Equity (Deficit)**  
**For the Nine Months Ended June 30, 2016**  
**(unaudited)**

	Redeemable Preferred Stock, Common Stock and Noncontrolling Interests							Stockholders' Equity (Deficit)							
	Preferred Stock				Common Stock	Noncontrolling Interests	Series A Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Noncontrolling Interests	Total Stockholders' Equity (Deficit)	
	Series A	Series B	Series A	Series B			Shares	Amount	Shares	Amount					
Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Interests	Equity (Deficit)		
Balance at October 1, 2015	3,568	\$ 5,072,653	4,000	\$ 5,118,208	1,739,130	\$ 15,426,673	\$ 1,703,777	-	\$ -	9,436,294	\$ 39,844,900	\$ -	\$ (94,064,286)	\$ (654,417)	\$ (54,873,803)
Deconsolidation of Sonnet Biotherapeutics, Inc.	-	-	-	-	-	-	-	-	-	-	-	-	-	654,417	654,417
Employee tax withholdings related to the vesting of restricted stock	-	-	-	-	-	-	-	-	-	-	-	-	-	-	(71,760)
Reincorporation to a Delaware Corporation	(3,568)	(5,072,653)	(4,000)	(5,118,208)	-	-	-	10,193	102	2,193,601	(39,656,869)	49,847,628	-	-	10,190,861
Issuance of common stock upon the dissolution of Parilis	-	-	-	-	-	-	(1,703,777)	1,626	16	226,663	2,267	1,701,494	-	-	1,703,777
Sale of common stock, net of issuance costs	-	-	-	-	-	-	-	-	-	573,388	5,734	16,132,179	-	-	16,137,913
Reclassification of stock-based compensation liability	-	-	-	-	-	-	-	-	-	-	-	15,118,584	-	-	15,118,584
Accretion of redeemable common stock	-	-	-	-	-	2,463,160	-	-	-	-	-	(2,463,160)	-	-	(2,463,160)
Sale of common stock units upon consummation of initial public offering and concurrent private placement, net of issuance costs	-	-	-	-	-	-	-	-	-	6,666,666	66,667	33,717,538	-	-	33,784,205
Reclassification of redeemable common stock upon consummation of the initial public offering	-	-	-	-	(1,739,130)	(17,889,833)	-	-	-	1,739,130	17,391	17,872,442	-	-	17,889,833
Conversion of Series A preferred stock in connection with the initial public offering	-	-	-	-	-	-	-	(11,819)	(118)	1,969,818	19,698	(19,580)	-	-	-
Stock-based compensation expense	-	-	-	-	-	-	-	-	-	-	-	6,226,288	-	-	6,226,288
Net loss	-	-	-	-	-	-	-	-	-	-	-	(42,734,024)	-	-	(42,734,024)
Balance at June 30, 2016	-	\$ -	-	\$ -	-	\$ -	\$ -	-	\$ -	22,802,778	\$ 228,028	\$ 138,133,413	\$ (136,798,310)	\$ -	\$ 1,563,131

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

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

	<b>Nine Months Ended June 30,</b>	
	<b>2016</b>	<b>2015</b>
<b>OPERATING ACTIVITIES</b>		
Net loss	\$ (42,734,024)	\$ (30,609,205)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,790,690	862,230
Non-cash interest expense	8,594	9,196
Stock-based compensation	8,618,150	9,206,563
Loss on disposal of fixed assets	13,647	-
Changes in operating assets and liabilities:		
Accounts receivable	16,330	(72,910)
Prepaid expenses and other current assets	533,761	(896,824)
Other assets	49,260	(100,000)
Accounts payable	(5,708,893)	2,479,447
Accrued expenses	3,287,479	1,455,139
Income taxes payable	100,000	180,473
Deferred revenue	(1,484,682)	1,025,657
Other liabilities	397,330	(2,323)
Net cash used in operating activities	<u>(35,112,358)</u>	<u>(16,462,557)</u>
<b>INVESTING ACTIVITIES</b>		
Purchase of property and equipment	(769,769)	(5,509,812)
Net cash used in investing activities	<u>(769,769)</u>	<u>(5,509,812)</u>
<b>FINANCING ACTIVITIES</b>		
Repurchase of Series A redeemable preferred stock	-	(226,001)
Proceeds from the sale of common stock, net of offering costs	16,137,913	18,000,000
Proceeds from sale of common stock units in connection with initial public offering and private placement	37,074,996	-
Payment of offering costs and common stock issuance costs	(4,622,647)	-
Proceeds from subscriptions receivable	4,280,149	-
Proceeds from stockholders notes	-	10,880,252
Payments of capital leases obligations	(659,403)	(467,590)
Repayment of debt	(551,288)	(548,732)
Repayment of stockholder notes	(11,601,696)	(2,632,658)
Change in restricted cash	(1,857)	(1,649)
Proceeds from related party receivable	783,211	-
Deconsolidation of Sonnet Biotherapeutics, Inc.	(401,091)	-
Payment of employee tax withholdings related to the vesting of restricted stock	(71,760)	-
Net cash provided by financing activities	<u>40,366,527</u>	<u>25,003,622</u>
Net increase in cash	4,484,400	3,031,253
Cash at beginning of period	9,070,975	2,349,313
Cash at end of period	<u>\$ 13,555,375</u>	<u>\$ 5,380,566</u>
<b>Supplemental disclosure of cash flow information</b>		
Cash paid for interest	\$ 1,500,675	\$ 1,036,292
Cash paid for income taxes	<u>\$ 3,000</u>	<u>\$ 2,250</u>
<b>Supplemental schedule of noncash investing activities:</b>		
Purchases of property and equipment in accounts payable and accrued expenses	<u>\$ 477,191</u>	<u>\$ 1,164,506</u>
<b>Supplemental schedule of noncash financing activities:</b>		
Accretion of redeemable preferred stock, common stock and noncontrolling interests	<u>\$ 2,463,160</u>	<u>\$ 3,197,283</u>
Deemed dividend upon repurchase of Series A redeemable preferred stock in excess of carrying value	<u>\$ -</u>	<u>\$ 1,215,000</u>
Issuance of subscription receivable upon sale of common stock	<u>\$ -</u>	<u>\$ 1,300,000</u>
Issuance of common and Series A preferred stock to redeemable preferred stockholders and noncontrolling interests upon reincorporation	<u>\$ 11,894,638</u>	<u>\$ -</u>
Reclassification of equity classified stock-based compensation	<u>\$ 15,118,584</u>	<u>\$ -</u>
Issuance of capital lease obligations in connection with purchase of property and equipment	<u>\$ 78,500</u>	<u>\$ -</u>
Deferred offering costs and common stock issuance costs in accounts payable and accrued expenses	<u>\$ 18,145</u>	<u>\$ 1,260,000</u>

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

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

**1. Organization and Description of Business**

Oncobiologics, Inc. (“Oncobiologics” or the “Company”) was incorporated in New Jersey on January 5, 2010 and started operations in July 2011. Oncobiologics is a clinical-stage biopharmaceutical company focused on identifying, developing, manufacturing and commercializing complex 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 5,833,334 units. Each unit consisted of one share of the Company’s common stock, one-half of a Series A warrant and one-half of a Series B warrant. Each whole Series A warrant entitles the holder to purchase one share of common stock at an initial exercise price of \$6.60, subject to adjustment. Each whole Series B warrant entitles the holder to purchase one share of common stock at an initial exercise price of \$8.50, subject to adjustment. The IPO price was \$6.00 per unit. In addition, the Company also completed a concurrent private placement of an additional 833,332 shares of its common stock, 416,666 Series A warrants and 416,666 Series B warrants, for gross proceeds of approximately \$5.0 million. On May 13, 2016, the units began trading on the NASDAQ Global Market. The units separated in accordance with their terms and ceased trading, and on June 13, 2016, the component securities (common stock, Series A warrants and Series B warrants) began trading on the NASDAQ Global Market. As a result of the IPO and the concurrent private placement, the Company received approximately \$33.8 million in net proceeds, after deducting discounts and commissions of approximately \$2.9 million and offering expenses of approximately \$3.3 million payable by the Company.

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.

**2. Liquidity**

The Company has incurred substantial losses and negative cash flows from operations since its inception and has an accumulated deficit of \$136.8 million and \$94.1 million as of June 30, 2016 and September 30, 2015, respectively. In addition, the Company has \$4.6 million and \$14.2 million of indebtedness that is due on demand, as of June 30, 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.

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

The Company has substantial indebtedness that includes \$4.6 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.

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 \$33.8 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 December 2016, 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 June 30, 2016 and its results of operations for the three and nine months ended June 30, 2016 and 2015 and cash flows for the nine months ended June 30, 2016 and 2015. Operating results for the nine months ended June 30, 2016 are not necessarily indicative of the results that may be expected for the full year ending September 30, 2016. The unaudited interim consolidated financial statements, presented herein, do not contain the required disclosures under GAAP for annual consolidated financial statements. The accompanying unaudited interim consolidated financial statements should be read in conjunction with the annual audited consolidated financial statements and related notes as of and for the year ended September 30, 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.

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

**Income taxes**

The Company recorded income tax expense (benefit) of \$500 and \$120,000 for the three months ended June 30, 2016 and 2015, respectively, and \$103,000 and \$(199,855) for the nine months ended June 30, 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.

**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 June 30, 2016 and 2015, as they would be antidilutive:

	<u>June 30,</u>	
	<u>2016</u>	<u>2015</u>
Series A redeemable preferred stock	-	1,034,203
Series B redeemable preferred stock	-	1,159,418
Performance-based stock units	247,598	-
Restricted stock units	1,096,171	-
Unvested shares of restricted common stock	-	20,869
Convertible stockholder note	-	96,618
Common stock warrants	8,186,935	-

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

**Oncobiologics, Inc.**  
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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.

In February 2016, the FASB issued ASU 2016-02, *Leases*, (Topic 842). This new ASU represents a wholesale change to lease accounting and introduces a lease model that brings most leases on the balance sheet. It also eliminates the required use of bright-line tests in current U.S. GAAP for determining lease classification. This ASU is effective for annual periods beginning after December 15, 2018 (i.e., calendar periods beginning on January 1, 2019), and interim periods thereafter. Earlier application is permitted for all entities. The Company is currently evaluating the impact of ASU 2016-02 on its consolidated financial statements.

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)
<b>Liabilities</b>			
Stock-based compensation liability	\$ -	\$ -	\$ 12,726,722

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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 nine months ended June 30, 2016:

Balance at October 1, 2015	\$ 12,726,722
Change in fair value	2,391,862
Reclassification to stockholders' equity (deficit)	(15,118,584)
Balance at June 30, 2016	<u>\$ -</u>

As of June 30, 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:

	<b>September 30, 2015</b>
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

**5. Property and Equipment**

Property and equipment, net, consists of:

	<b>June 30, 2016</b>	<b>September 30, 2015</b>
Laboratory equipment	\$ 10,881,344	\$ 10,936,364
Leasehold improvements	9,927,614	9,889,521
Computer software and hardware	421,206	402,075
Construction in progress	1,182,284	175,425
	<u>22,412,448</u>	<u>21,403,385</u>
Less: accumulated depreciation and amortization	(5,358,350)	(3,643,447)
	<u>\$ 17,054,098</u>	<u>\$ 17,759,938</u>

Depreciation and amortization expense was \$598,615 and \$421,162 for the three months ended June 30, 2016 and 2015, respectively, and \$1,790,690 and \$862,230 for the nine months ended June 30, 2016 and 2015, respectively.

At June 30, 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 June 30, 2016 and September 30, 2015, \$805,974 and \$407,210, respectively, of accumulated depreciation related to this leased equipment has been recognized.

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**6. Accrued Expenses**

Accrued expenses consists of:

	June 30, 2016	September 30, 2015
Compensation	\$ 3,819,984	\$ 2,321,508
Research and development	3,871,303	951,759
Interest payable	206,417	806,475
Deferred offering costs	-	657,892
Professional fees	254,997	594,572
Director fees	-	414,421
Other accrued expenses	113,863	178,021
	<u>\$ 8,266,564</u>	<u>\$ 5,924,648</u>

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

From October 2015 through January 2016, the Company sold 573,788 shares of its common stock at \$29.05 per share raising \$16,137,913 in net proceeds. In May 2016, upon consummation of its IPO and private placement, the Company sold 5,833,334 units at \$6.00 per unit and 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, at the same price (See Note 1), raising \$33,802,350 in aggregate net proceeds. Each unit consisted of one share of the Company's common stock and warrants described below.

Concurrent with the closing of the IPO, 1,739,130 shares of redeemable common stock were reclassified to common stock upon the lapse of a contractual redemption right.

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 June 30, 2016.

**Series A Warrants and Series B Warrants**

Each unit offered in connection with the Company's IPO consisted of one share of the Company's common stock, one-half of a Series A warrant to purchase one share of the Company's common stock and one-half of a Series B warrant to purchase one share of the Company's common stock. The Company also issued Series A warrants and Series B warrants in the concurrent private placement (see Note 1). Each whole Series A warrant and Series B warrant has an exercise price of \$6.60 per share and \$8.50 per share, respectively, and are exercisable until February 18, 2017 and May 18, 2018, respectively. Neither the Series A warrant holders nor Series B warrant holders has the rights or privileges of holders of common stock or any voting rights until they exercise their warrants and receive common stock.

The exercise price and number of shares issuable upon exercise of the Series A and Series B warrants may be adjusted upon the occurrence of certain events, including but not limited to any stock split, stock dividend, extraordinary dividend, recapitalization, reorganization, merger or consolidation.

Immediately following the consummation of the IPO and concurrent private placement, there were 3,333,333 Series A warrants and 3,333,333 Series B warrants outstanding.

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**Common Stock Warrants**

In May 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. The estimated fair value of the warrants issued to these investors was \$7,373,820 and is reflected as a deemed dividend in the statements of operations for purposes of computing basic and diluted loss per share.

**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 June 30, 2016, the balance of the note is \$33,396 plus accrued interest of \$9,954.

**Series A preferred stock**

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

**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 June 30, 2016, PSUs representing 247,598 shares of the Company's common stock were outstanding under the 2011 Plan. In light of the December 2015 adoption of the 2015 Equity Incentive Plan, no future awards under the 2011 Plan will be granted.

***2015 Equity Incentive Plan***

In December 2015, the Company adopted the 2015 Equity Incentive Plan (the "2015 Plan"). The 2015 Plan provides for the grant of stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards and other forms of equity compensation to Company employees, directors and consultants. The maximum number of shares of common stock that may be issued under the 2015 Plan is 1,246,377 shares. As of June 30, 2016, RSUs representing 1,096,171 shares of the Company's common stock were outstanding under the 2015 Plan and 150,206 shares remained available for grant under the 2015 Plan.

The Company recorded stock-based compensation expense in the following expense categories of its statements of operations for the three and nine months ended June 30, 2016 and 2015:

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	<u>Three Months ended June 30,</u>		<u>Nine Months ended June 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Research and development	\$ 3,771,214	\$ 1,059,684	\$ 1,846,408	\$ 4,794,677
General and administrative	6,803,391	971,099	6,771,742	4,411,886
	<u>\$ 10,574,605</u>	<u>\$ 2,030,783</u>	<u>\$ 8,618,150</u>	<u>\$ 9,206,563</u>
	<u>Three Months ended June 30,</u>		<u>Nine Months ended June 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Equity-classified compensation	\$ 10,574,605	\$ 2,231	\$ 6,226,288	\$ 6,694
Liability-classified compensation	-	2,028,552	2,391,862	9,199,869
	<u>\$ 10,574,605</u>	<u>\$ 2,030,783</u>	<u>\$ 8,618,150</u>	<u>\$ 9,206,563</u>

**Performance-based stock units**

The Company has issued PSUs, which generally have a 10-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 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 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 nine months ended June 30, 2016:

	<u>Number of PSUs</u>	<u>Base Price Per PSU</u>
Balance at October 1, 2015	687,013	\$ 3.45
Forfeitures	(4,635)	4.68
Exchanged for restricted stock units	(434,780)	3.45
Balance at June 30, 2016	<u>247,598</u>	<u>\$ 6.33</u>

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 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.

Concurrent with the tender-offer, several PSU holders cancelled an aggregate of 434,780 PSUs in exchange for 391,303 RSUs. The Company accounted for the exchange as a modification, and, as a result, recognized \$98,172 of additional stock-based compensation during the nine months ended June 30, 2016 based on the fair value of the RSUs in excess of the fair value of the PSUs exchanged.

The PSU represents an award that is exercisable based upon the achievement of either a performance condition or a market condition. As a result, the Company measures and records compensation cost taking into consideration both conditions: (1) an award that becomes exercisable upon the Company achieving a market value of \$400 million and at the discretion by the Company's Board of Directors and (2) an award that is exercisable upon the earlier of a change in control or consummation of an IPO. Through December 2015, the fair value of both the performance and market conditions were remeasured prior to the PSUs being reclassified into equity. However, given the discretionary action required to be taken by the Company's Board of Directors, the fair value of the market condition continued to be remeasured each reporting period as compensation cost was recognized. Because a change of control or an IPO is not deemed probable until such event occurs, no compensation cost related

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to the performance condition was recognized prior to the consummation of the Company's IPO. Upon the consummation of the IPO in May 2016, the Company recorded compensation expense for the three and nine months ended June 30, 2016 based upon the fair value of the performance condition of the PSUs which was established in December 2015 when the PSUs became equity classified.

The fair value of the PSUs of \$25.74 per PSU at December 31, 2015 was derived using the following assumptions:

	December 31, 2015
Risk-free interest rate	1.0%
Derived service period	2.3 years
Expected volatility	57.6%
Annual dividend yield	0%
Fair value of common stock	\$29.05 per share

As of June 30, 2016, there was \$901,451 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 nine months ended June 30, 2016:

	Number of RSUs	Weighted Average Grant Date Fair Value
Balance at October 1, 2015	-	\$ -
Granted	705,311	29.05
Forfeitures	(443)	17.93
Issued in connection with PSU exchange	391,303	29.05
Balance at June 30, 2016	<u>1,096,171</u>	<u>\$ 28.58</u>

As of June 30, 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 708,303 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
- 160,566 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 June 30, 2016, there was \$13,447,517 of unamortized expense that will be recognized in future periods.

## 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 Exchange Act of 1934, as amended. Forward-looking statements are identified by words such as “believe,” “may,” “could,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “seek,” “plan,” “expect,” “should,” “would,” “potentially” or the negative of these terms or similar expressions in this report. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other “forward-looking” information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to certain risks and uncertainties that could cause such a difference include, but are not limited to, those discussed under the caption “Risk Factors” in our 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 both U.S. and EU-sourced 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. In addition, ONS-3010 demonstrated a rate of injection site reactions lower than that of the Humira arms. 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 Medical Products Agency. 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 conduct a Phase 3 study of ONS-3010 for the treatment of plaque psoriasis, and will seek approval for such indication, along with all other Humira-approved indications that are not protected by exclusivity at the time of the biologics license application, or BLA, filing. We have informed the regulatory authorities of our intent to seek extrapolation, 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 have received regulatory feedback and agreement on our Phase 3 clinical trial design in the non-squamous non-small cell cancer patient population from the FDA, EMA, and national agencies, MHRA and the Danish Medicines Agency. 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 several indications. We initially intend to conduct a Phase 3 study of ONS-1045 for the treatment of non-squamous non-small cell lung cancer, and will seek approval for such indication, along with all other Avastin-approved indications that are not protected by exclusivity at the time of the BLA filing. We have informed the FDA and EMA of our intent to seek extrapolation, and have also discussed our study design.

Through June 30, 2016, we have funded substantially all of our operations through the sale and issuance of approximately \$142.6 million of our common stock, preferred stock and debt. Through June 30, 2016, we have also received \$24.0 million pursuant to our collaboration and licensing agreements. 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 \$29.2 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 12, 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. We will need to raise substantial additional capital in order to fund our planned future operations, 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.

Our current cash resources are expected to fund our operations through December 2016. To provide additional working capital, we have engaged an advisor to help us secure a debt facility and are currently in active discussions with potential lenders. Additionally, we continue to engage in active discussions with global and regional pharmaceutical companies for licensing and/or co-development rights to our late- and early-stage pipeline product candidates. While we expect to finalize one or more of these transactions prior to the end of 2016, there is no guarantee that we will be able to do so. If we are not successful in raising additional capital or entering into one or more licensing and/or co-development rights agreements, we will be required to scale back our plans and place certain activities on hold.

We do not have any products approved for sale and we have only generated revenue from our collaboration agreements. We have incurred operating losses and negative operating cash flows since inception and there is no assurance that we will ever achieve profitable operations, and if achieved, that profitable operations will be sustained. Our net loss for the nine months ended June 30, 2016 was \$42.7 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.

## **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 June 30, 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 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 June 30, 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 June 30, 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 did not 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 June 30, 2016, Huahai is required to make a payment to us of \$11.8 million. Similarly, revenues from commercialization of ONS-3010 in the agreed countries (including major markets such as the United States and the European Union (“EU”), among others), would also be shared based on such proportional ownership interests. In the event that Huahai does not fund its proportionate share of such development costs, the joint participation agreement provides for a proportionate adjustment to our respective value ownership interests based on our respective investments in such development costs, which would increase our value ownership interest in ONS-3010. Under the joint participation agreement, we could also be required to form a joint venture to further develop and commercialize ONS-3010 with Huahai in the agreed countries, if so requested by Huahai.

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

**Components of Our Results of Operations**

***Collaboration Revenue***

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

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The following table sets forth a summary of revenue recognized from our collaboration and licensing agreements for the three and nine months ended June 30, 2016 and 2015:

	<u>Three months ended June 30,</u>		<u>Nine months ended June 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
IPCA Collaboration	\$ 105,433	\$ 905,433	\$ 316,299	\$ 1,596,944
Liomont Collaboration	95,566	95,566	1,286,698	245,714
Huahai Collaboration	293,895	293,895	881,685	2,881,685
	<u>\$ 494,894</u>	<u>\$ 1,294,894</u>	<u>\$ 2,484,682</u>	<u>\$ 4,724,343</u>

The following table summarizes the milestone payments and recognition of deferred revenues from our collaboration and licensing agreements during the three and nine months ended June 30, 2016 and 2015:

	<u>Three months ended June 30,</u>		<u>Nine months ended June 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Milestone payments	\$ -	\$ 800,000	\$ 1,000,000	\$ 3,300,000
Recognition of deferred revenues	494,894	494,894	1,484,682	1,424,343
	<u>\$ 494,894</u>	<u>\$ 1,294,894</u>	<u>\$ 2,484,682</u>	<u>\$ 4,724,343</u>

Each of our collaboration and licensing agreements is considered to be a multiple-element arrangement for accounting purposes. We determined that there are two deliverables; specifically, the license to our biosimilar product candidate and the related research and development services that we are obligated to provide. We concluded that these deliverables should be accounted for as a single unit of accounting. We determined that the upfront license payments received should be deferred and recognized as revenue on a straight-line basis through the estimated period of completion of our obligations under the agreement. We recognize revenues from the achievement of milestones if the milestone event is substantive and achievability of the milestone was not reasonably assured at the inception of the agreement.

### **Research and Development Expenses**

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

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

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

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

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

Research and development activities are central to our business model. Biosimilar product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase significantly over the next several years as we increase personnel costs, including stock-based compensation, conduct clinical trials and prepare regulatory filings for our biosimilar product candidates.

### ***General and Administrative Expenses***

General and administrative expenses consist principally of salaries and related costs for personnel in executive, administrative, finance and legal functions, including stock-based compensation, travel expenses and recruiting expenses. Other general and administrative expenses include facility related costs, patent filing and prosecution costs and professional fees for business development, legal, auditing and tax services and insurance costs.

We anticipate that our general and administrative expenses will increase as a result of increased payroll, expanded infrastructure and an increase in accounting, consulting, legal and tax-related services associated with maintaining compliance with stock exchange listing and SEC requirements, investor relations costs, and director and officer insurance premiums associated with being a public company. We also anticipate that our general and administrative expenses will increase in support of our clinical trials as we expand and progress our development programs. Additionally, if and when we believe a regulatory approval of a biosimilar product candidate appears likely, we anticipate an increase in payroll and expense as a result of our preparation for commercial operations, particularly as it relates to the sales and marketing of our biosimilar product.

### ***Interest Expense***

Interest expense consists of cash paid and non-cash interest expense related to our bank loans, notes with current and former stockholders, equipment loans and capital lease obligations.

### ***Income Taxes***

During the nine months ended June 30, 2016, we incurred \$0.1 million of foreign withholding taxes in connection with our collaboration and licensing agreements. During the three and nine months ended June 30, 2015, we recorded an income tax expense (benefit) of \$0.1 million and \$(0.2) 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.

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

### Results of Operations

#### Comparison of Three Months Ended June 30, 2016 and 2015

	Three Months Ended June 30,		Change
	2016	2015	
Collaboration revenues	\$ 494,894	\$ 1,294,894	\$ (800,000)
Operating expenses:			
Research and development	12,017,724	9,681,019	2,336,705
General and administrative	10,504,663	2,659,616	7,845,047
	<u>22,522,387</u>	<u>12,340,635</u>	<u>10,181,752</u>
Loss from operations	(22,027,493)	(11,045,741)	(10,981,752)
Interest expense	299,439	554,831	(255,392)
Loss before income taxes	<u>(22,326,932)</u>	<u>(11,600,572)</u>	<u>(10,726,360)</u>
Income tax expense	500	120,000	(119,500)
Net loss	<u>\$ (22,327,432)</u>	<u>\$ (11,720,572)</u>	<u>\$ (10,606,860)</u>

#### Collaboration Revenues

Collaboration revenues decreased \$0.8 million, to \$0.5 million, for the three months ended June 30, 2016, as compared to \$1.3 million for the three months ended June 30, 2015. The change is due to a \$0.8 million reduction in milestone payments as compared to the prior year period.

#### Research and Development Expenses

The following table summarizes our research and development expenses by functional area for the three months ended June 30, 2016 and 2015:

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	Three months ended June 30,	
	2016	2015
Preclinical and clinical development	\$ 3,893,492	\$ 4,209,752
Compensation and related benefits	2,409,772	1,670,368
Stock-based compensation	3,771,214	1,059,684
Other research and development	1,943,246	2,741,215
Total research and development expenses	<u>\$ 12,017,724</u>	<u>\$ 9,681,019</u>

The following table summarizes our research and development expenses by compound for the three months ended June 30, 2016 and 2015:

	Three months ended June 30,	
	2016	2015
ONS-3010	\$ 2,722,280	\$ 1,802,485
ONS-1045	812,798	1,595,790
Early-stage compounds	358,414	811,477
Personnel related and stock-based compensation	6,180,986	2,730,052
Other research and development	1,943,246	2,741,215
Total research and development expenses	<u>\$ 12,017,724</u>	<u>\$ 9,681,019</u>

Research and development expenses for the three months ended June 30, 2016 increased by \$2.3 million compared to the three months ended June 30, 2015, primarily due to an increase in stock-based compensation of \$2.7 million as a result of meeting the exercisability condition of our outstanding PSUs, and vesting criteria of our RSUs, upon the completion of our IPO on May 12, 2016. Excluding stock-based compensation expense, and despite an increase of \$0.9 million for preparing our lead biosimilar product candidate ONS-3010 for planned Phase 3 clinical trials later in 2016, overall research and development expenses were relatively flat as we controlled spending in advance of the completion of our IPO.

#### *General and Administrative Expenses*

The following table summarizes our general and administrative expenses by type for the three months ended June 30, 2016 and 2015:

	Three months ended June 30,	
	2016	2015
Professional fees	\$ 905,395	\$ 444,518
Compensation and related benefits	2,036,226	727,528
Stock-based compensation	6,803,391	971,099
Facilities, fees and other related costs	759,651	516,471
Total general and administration expenses	<u>\$ 10,504,663</u>	<u>\$ 2,659,616</u>

General and administrative expenses for the three months ended June 30, 2016 increased by \$7.8 million compared to the three months ended June 30, 2015, primarily due to an increase in stock-based compensation expense, and increased compensation and related benefits, both of which increased primarily due to completion of our IPO. Stock-based compensation expense increased by \$5.8 million as a result of meeting the exercisability and vesting conditions of our outstanding PSUs and RSUs, respectively, upon the completion of our IPO. In addition, we had a one-time performance bonus payable as a result of completion of our IPO, which contributed to the increase in compensation and related benefits.

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### *Interest Expense*

Interest expense decreased by \$0.3 million to \$0.3 million for the three months ended June 30, 2016 as compared to \$0.6 million for the three months ended June 30, 2015, primarily due to reductions in outstanding balances under stockholder notes and other debt obligations over the comparable period.

### *Comparison of Nine Months Ended June 30, 2016 and 2015*

	<u>Nine Months Ended June 30,</u>		<u>Change</u>
	<u>2016</u>	<u>2015</u>	
Collaboration revenues	\$ 2,484,682	\$ 4,724,343	\$ (2,239,661)
Operating expenses:			
Research and development	28,889,977	25,675,518	3,214,459
General and administrative	14,989,380	8,239,545	6,749,835
	<u>43,879,357</u>	<u>33,915,063</u>	<u>9,964,294</u>
Loss from operations	(41,394,675)	(29,190,720)	(12,203,955)
Interest expense	1,236,349	1,618,340	(381,991)
Loss before income taxes	(42,631,024)	(30,809,060)	(11,821,964)
Income tax expense (benefit)	103,000	(199,855)	302,855
Net loss	<u>\$ (42,734,024)</u>	<u>\$ (30,609,205)</u>	<u>\$ (12,124,819)</u>

### *Collaboration Revenues*

Collaboration revenues decreased \$2.2 million, to \$2.5 million, for the nine months ended June 30, 2016, as compared to \$4.7 million for the nine months ended June 30, 2015. The change is the result of a \$2.3 million decrease in milestone payments.

### *Research and Development Expenses*

The following table summarizes our research and development expenses by functional area for the nine months ended June 30, 2016 and 2015:

	<u>Nine months ended June 30,</u>	
	<u>2016</u>	<u>2015</u>
Preclinical and clinical development	\$ 15,035,645	\$ 13,757,087
Compensation and related benefits	6,857,474	4,690,508
Stock-based compensation	1,846,408	4,794,677
Other research and development	5,150,450	2,433,246
Total research and development expenses	<u>\$ 28,889,977</u>	<u>\$ 25,675,518</u>

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The following table summarizes our research and development expenses by compound for the nine months ended June 30, 2016 and 2015:

	Nine months ended June 30,	
	2016	2015
ONS-3010	\$ 9,401,458	\$ 4,943,851
ONS-1045	4,633,316	7,279,978
Early-stage compounds	1,000,871	1,533,258
Personnel related and stock-based compensation	8,703,882	9,485,185
Other research and development	5,150,450	2,433,246
Total research and development expenses	<u>\$ 28,889,977</u>	<u>\$ 25,675,518</u>

Research and development expenses increased by \$3.2 million for the nine months ended June 30, 2016 compared to the nine months ended June 30, 2015. The increase was primarily related to a \$4.5 million increase in expenses for our lead biosimilar product candidate, ONS-3010, as we continued to prepare for initiating our Phase 3 clinical program later in 2016. These increased costs were partially offset by lower development costs for ONS-1045 and our other development programs as we controlled spending in advance of our May 2016 IPO.

### *General and Administrative Expenses*

The following table summarizes our general and administrative expenses by type for the nine months ended June 30, 2016 and 2015:

	Nine months ended June 30,	
	2016	2015
Professional fees	\$ 3,176,109	\$ 1,208,901
Compensation and related benefits	3,402,167	1,449,262
Stock-based compensation	6,771,742	4,411,886
Facilities, fees and other related costs	1,639,362	1,169,496
Total general and administration expenses	<u>\$ 14,989,380</u>	<u>\$ 8,239,545</u>

General and administrative expenses increased \$6.7 million for the nine months ended June 30, 2016, compared to the nine months ended June 30, 2015, primarily due to an increase in stock-based compensation expense, and increased professional fees and compensation and related benefits, all of which increased primarily due to completion of our IPO. Stock-based compensation expense increased by \$2.4 million as a result of meeting the exercisability and vesting conditions of our PSUs and RSUs upon the completion of our IPO, Compensation and related benefits for the nine months ended June 30, 2016 reflects a one-time performance bonus payable as a result of completion of our IPO.

### *Interest Expense*

Interest expense decreased by \$0.4 million to \$1.2 million for the nine months ended June 30, 2016 as compared to \$1.6 million for the nine months ended June 30, 2015, primarily due to reductions in outstanding balances under stockholder notes and other debt obligations over the comparable period.

### **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 June 30, 2016, we have funded substantially all of our operations through the sale and issuance of \$142.6 million net proceeds of our equity securities and borrowings under debt facilities. We have also received an aggregate of \$24.0 million pursuant to our collaboration and licensing agreements. In May 2016 we closed the IPO and concurrent private placement raising aggregate net proceeds of approximately \$33.8 million, excluding any proceeds we may receive from the exercise of the warrants. We will require additional capital to fund our operations past December 2016. Alternatively, we will be required to scale back our plans and place certain activities on hold.

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As of June 30, 2016, we had an accumulated deficit of \$136.8 million and had a cash balance of \$13.6 million. In addition, we had \$4.6 million of indebtedness that is due on demand. These matters raise substantial doubt about our ability to continue as a going concern. Our unaudited interim consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. We anticipate incurring additional losses until such time, if ever, that we can generate significant sales of our product candidates currently in development. 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. We have engaged an advisor to help us secure a debt facility and are currently in active discussions with potential lenders. Additionally, we continue to engage in active discussions with global and regional pharmaceutical companies for licensing and/or co-development rights to our late- and early-stage pipeline candidates. While we expect to finalize one or more of these transactions prior to the end of 2016, there can be no assurance that these future funding efforts will be successful.

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

### **Cash Flows**

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

	<b>Nine months ended June 30,</b>	
	<b>2016</b>	<b>2015</b>
	<b>(Unaudited)</b>	
Net cash used in operating activities	\$ (35,112,358)	\$ (16,462,557)
Net cash used in investing activities	(769,769)	(5,509,812)
Net cash provided by financing activities	40,366,527	25,003,622
Net increase in cash	<u>\$ 4,484,400</u>	<u>\$ 3,031,253</u>

#### *Operating Activities.*

During the nine months ended June 30, 2016, we used \$35.1 million of cash in operating activities, primarily resulting from our net loss of \$42.7 and the net cash used from changes in our operating assets and liabilities of \$2.8 million. These uses of cash in our operating activities were offset by \$10.4 million of noncash items such as stock-based compensation and depreciation and amortization expense. The change in our operating assets and liabilities was primarily due to decreases in accounts payable related to the timing of vendor payments for research and development and professional services in connection with preparations for our IPO in May 2016 and decreases in deferred revenues due to ratable recognition of upfront payments received under our collaboration arrangements. These outflows were offset by decreases in our prepaid expenses and other current assets, and increases in accrued expenses and other liabilities that relate to the timing of vendor payments and the recognition of research and development expenses.

During the nine months ended June 30, 2015, we used \$16.5 million of cash in operating activities, primarily resulting from our net loss of \$30.6 million that was offset by \$10.1 million of noncash items and \$4.1 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 and the timing of vendor payments. These inflows were partially offset by increases in prepaid expenses and other current assets.

#### *Investing Activities.*

During the nine months ended June 30, 2016 and 2015, we used cash of \$0.8 million and \$5.5 million, respectively, in investing activities for the purchase of property and equipment. The decrease in purchases of property and equipment during the nine months ended June 30, 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 nine months ended June 30, 2015.

*Financing Activities.*

During the nine months ended June 30, 2016, net cash provided by financing activities was \$40.4 million, primarily attributable to \$33.8 in aggregate net proceeds from our IPO and concurrent private placement in May 2016, \$14.8 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 \$12.8 million in debt payments and \$0.4 million upon the deconsolidation of Sonnet Biotherapeutics, Inc. See Note 7 to our unaudited interim consolidated financial statements for more information regarding Sonnet Biotherapeutics, Inc.

During the nine months ended June 30, 2015, net cash provided by financing activities was \$25.0 million, primarily attributable to \$18.0 million in net proceeds from the sale of our common stock and \$10.9 million upon the issuance of stockholder notes, offset by \$3.6 million in debt payments.

**Off-Balance Sheet Arrangements**

We did not have any off-balance sheet arrangements as of June 30, 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 June 30, 2016, we had \$13.6 million of cash, and we had \$9.2 million of debt obligations. Our cash is deposited in accounts at four 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.

**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 third fiscal quarter ended June 30, 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**

Not applicable

#### **Use of Proceeds**

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

### **Item 3. Defaults Upon Senior Securities**

Not applicable.

### **Item 4. Mine Safety Disclosures**

Not applicable.

### **Item 5. Other Information**

None

**Item 6. Exhibits**

**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 (incorporated herein by reference to Exhibit A to Exhibit 4.4 to the Company's Registration Statement on Form S-1/A (File No. 333-209011), as filed with the SEC on May 11, 2016).
10.3	Form of Series B warrant Certificate (incorporated herein by reference to Exhibit B to Exhibit 4.4 to the Company's Registration Statement on Form S-1/A (File No. 333-209011), as filed with the SEC on May 11, 2016).
10.4	Form of Warrant Agreement between Oncobiologics, Inc. and American Stock Transfer & Trust Company LLC, as Warrant Agent, dated May 18, 2016 (incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on June 27, 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, 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).
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
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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

**SIGNATURES**

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

**ONCOBIOLOGICS, INC.**

Date: August 15, 2016

By: /s/ Lawrence A. Kenyon

\_\_\_\_\_  
Lawrence A. Kenyon

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

## CERTIFICATIONS

I, Pankaj Mohan, certify that:

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

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

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

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

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

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

Date: August 15, 2016

By: /s/ Pankaj Mohan

Pankaj Mohan, Ph.D.

Chief Executive Officer

(Principal Executive Officer)

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## CERTIFICATIONS

I, Lawrence A. Kenyon, certify that:

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

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

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

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

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

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

Date: August 15, 2016

By: /s/ Lawrence A. Kenyon

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

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**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Oncobiologics, Inc. (the "Company") for the period ended June 30, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

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

Date: August 15, 2016

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

Date: August 15, 2016

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

*"This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Oncobiologics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing."*

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