

Oncobiologics, Inc.  
Form 10-Q  
August 14, 2018

**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  
X ACT OF 1934**

**For the quarterly period ended June 30, 2018**

**or**

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

**For the transition period from                      to**

**COMMISSION FILE NO. 001-37759**

**ONCOBIOLOGICS, INC.**

**(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)**

|  |  |
|--|--|
| <b>DELAWARE</b><br><b>(STATE OR OTHER JURISDICTION OF</b>                      | <b>38-3982704</b><br><b>(I.R.S. EMPLOYER</b> |
| <b>INCORPORATION OR ORGANIZATION)</b>  | <b>IDENTIFICATION NO.)</b>                   |
| <b>7 CLARKE DRIVE</b>  | <b>08512</b>                                 |
| <b>CRANBURY, NEW JERSEY</b><br><b>(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES)</b> | <b>(ZIP CODE)</b>                            |

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer," "smaller reporting company and emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The number of shares of the registrant's common stock, \$0.01 par value, outstanding as of August 10, 2018 was 72,198,468.

**Oncobiologics, Inc.**

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SIGNATURES

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

|   | June 30,<br>2018 | September 30,<br>2017 |
|---|------------------|-----------------------|
| Assets  |                  |                       |
| Current assets:   |                  |                       |
| Cash  | \$ 11,796,668    | \$ 3,185,519          |
| Prepaid and other current assets  | 1,335,654        | 719,087               |
| Total current assets  | 13,132,322       | 3,904,606             |
| Property and equipment, net   | 20,284,405       | 16,088,902            |
| Other assets  | 669,315          | 740,362               |
| Total assets  | \$ 34,086,042    | \$ 20,733,870         |
| Liabilities, convertible preferred stock and stockholders' equity (deficit) |                  |                       |
| Current liabilities:  |                  |                       |
| Senior secured notes  | \$ 12,839,092    | \$ -                  |
| Current portion of long-term debt   | 86,735           | 52,600                |
| Current portion of capital lease obligations                                | 694,878          | 341,120               |
| Stockholder notes   | 4,612,500        | 4,612,500             |
| Accounts payable  | 3,351,211        | 10,954,358            |
| Accrued expenses  | 6,119,446        | 7,337,469             |
| Income taxes payable  | 2,352,129        | 2,352,129             |
| Deferred revenue  | 2,207,353        | 3,087,561             |
| Total current liabilities   | 32,263,344       | 28,737,737            |
| Senior secured notes  | -                | 13,231,700            |
| Long-term debt  | 111,541          | 151,110               |
| Capital lease obligations   | 3,507,211        | 28,067                |
| Warrant liability   | 2,048,838        | 2,274,954             |
| Deferred revenue  | 3,061,402        | 4,466,865             |
| Other liabilities   | 2,358,339        | 2,569,971             |
| Total liabilities   | 43,350,675       | 51,460,404            |
| Commitments (Note 8)  |                  |                       |
|   | 3,934,967        | 2,924,441             |

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Series A convertible preferred stock, par value \$0.01 per share: 1,000,000 shares authorized, 52,209 and 32,628 shares issued and outstanding at June 30, 2018 and September 30, 2017, respectively

Stockholders' equity (deficit):

Preferred stock, par value \$0.01 per share: 7,500,000 shares authorized, no shares issued and outstanding at June 30, 2018 and September 30, 2017, respectively

- -

Series B convertible preferred stock, par value \$0.01 per share: 1,500,000 shares authorized, no shares issued and outstanding at June 30, 2018 and September 30, 2017, respectively

- -

Common stock, par value \$0.01 per share; 200,000,000 shares authorized; 72,198,468 and 24,933,944 shares issued and outstanding at June 30, 2018 and September 30, 2017, respectively

721,985 249,339

Additional paid-in capital

190,186,119 152,315,088

Accumulated deficit

(204,107,704) (186,215,402)

Total stockholders' equity (deficit)

(13,199,600 ) (33,650,975 )

Total liabilities, convertible preferred stock and stockholders' equity (deficit)

\$34,086,042 \$20,733,870

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

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

|  | Three Months Ended June 30, |                 | Nine Months Ended June 30, |                  |
|--|-----------------------------|-----------------|----------------------------|------------------|
|  | 2018                        | 2017            | 2018                       | 2017             |
| Collaboration revenues   | \$ 771,890                  | \$ 303,140      | \$ 2,315,670               | \$ 909,421       |
| Operating expenses:  |                             |                 |                            |                  |
| Research and development   | 5,795,993                   | 4,157,696       | 11,354,781                 | 21,504,939       |
| General and administrative   | 2,195,789                   | 3,481,854       | 8,191,546                  | 12,374,125       |
|  | 7,991,782                   | 7,639,550       | 19,546,327                 | 33,879,064       |
| Loss from operations   | (7,219,892 )                | (7,336,410 )    | (17,230,657 )              | (32,969,643 )    |
| Interest expense, net  | 1,147,371                   | 1,745,544       | 2,786,124                  | 3,478,581        |
| Loss on extinguishment of debt   | -                           | -               | 1,252,353                  | -                |
| Change in fair value of warrant liability  | 64,659                      | (3,750,578 )    | (226,116 )                 | (3,976,397 )     |
| Loss before income taxes   | (8,431,922 )                | (5,331,376 )    | (21,043,018 )              | (32,471,827 )    |
| Income tax (benefit) expense   | -                           | -               | (3,150,716 )               | 4,000            |
| Net loss   | (8,431,922 )                | (5,331,376 )    | (17,892,302 )              | (32,475,827 )    |
| Recognition of beneficial conversion feature upon issuance of Series A convertible preferred stock | -                           | -               | (15,736,683 )              | -                |
| Series A convertible preferred stock dividends and related settlement                              | (652,612 )                  | -               | (1,740,108 )               | -                |
| Net loss attributable to common stockholders   | \$ (9,084,534 )             | \$ (5,331,376 ) | \$ (35,369,093 )           | \$ (32,475,827 ) |
| Per share information:   |                             |                 |                            |                  |
| Net loss per share of common stock, basic  | \$ (0.26 )                  | \$ (0.22 )      | \$ (1.24 )                 | \$ (1.37 )       |
| Net loss per share of common stock, diluted  | \$ (0.26 )                  | \$ (0.22 )      | \$ (1.24 )                 | \$ (1.53 )       |
| Weighted average shares outstanding, basic   | 34,540,056                  | 24,442,056      | 28,422,852                 | 23,788,046       |
| Weighted average shares outstanding, diluted   | 34,540,056                  | 24,442,056      | 28,422,852                 | 23,813,910       |

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



**Oncobiologics, Inc.****Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)****Nine Months Ended June 30, 2018****(unaudited)**

|  | <b>Convertible Preferred Stock</b> |               | <b>Stockholders' Equity (Deficit)</b>       |               |                     |               |                                   |                            |
|--|------------------------------------|---------------|---|---------------|---------------------|---------------|-----------------------------------|----------------------------|
|  | <b>Series A</b>                    |               | <b>Series B Convertible Preferred Stock</b> |               | <b>Common Stock</b> |               | <b>Additional Paid-in Capital</b> | <b>Accumulated Deficit</b> |
|  | <b>Shares</b>                      | <b>Amount</b> | <b>Shares</b>                               | <b>Amount</b> | <b>Shares</b>       | <b>Amount</b> | <b>Capital</b>                    | <b>Deficit</b>             |
| Balance at October 1, 2017   | 32,628                             | \$2,924,441   | -   | \$-           | 24,933,944          | \$249,339     | \$152,315,088                     | \$(186,215,400)            |
| Proceeds from exercise of common stock warrants                                      | -                                  | -             | -   | -             | 3,460               | 35            | (35)                              | -                          |
| Issuance of vested restricted stock units  | -                                  | -             | -   | -             | 821,006             | 8,210         | (8,210)                           | -                          |
| Private placement sale of common stock and common stock warrants, net of costs       | -                                  | -             | -   | -             | 12,754,766          | 127,548       | 14,728,540                        | -                          |
| Sale of Series A convertible preferred stock and common stock warrants, net of costs | 217,372                            | 14,265,861    | -   | -             | -                   | -             | 6,382,181                         | -                          |
| Series A convertible preferred stock dividends and                                   | 11,045                             | 1,104,481     | -   | -             | -                   | -             | (1,740,108)                       | -                          |

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|  |           |              |             |             |            |           |               |                 |
|--|-----------|--------------|-------------|-------------|------------|-----------|---------------|-----------------|
| settlement   |           |              |             |             |            |           |               |                 |
| Conversion of Series A convertible preferred stock into common stock         | (208,836) | (14,359,816) | -           | -           | 31,572,617 | 315,726   | 14,044,090    | -               |
| Conversion of senior secured notes into Series B convertible preferred stock | -         | -            | 1,500,000   | 2,661,972   | -          | -         | -             | -               |
| Conversion of Series B convertible preferred stock into common stock         | -         | -            | (1,500,000) | (2,661,972) | 2,112,675  | 21,127    | 2,640,845     | -               |
| Stock-based compensation expense   | -         | -            | -           | -           | -          | -         | 1,823,728     | -               |
| Net loss   | -         | -            | -           | -           | -          | -         | -             | (17,892,302)    |
| Balance at June 30, 2018   | 52,209    | \$3,934,967  | -           | \$-         | 72,198,468 | \$721,985 | \$190,186,119 | \$(204,107,700) |

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

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

|   | Nine Months Ended June 30, |                 |
|---|----------------------------|-----------------|
|   | 2018                       | 2017            |
| <b>OPERATING ACTIVITIES</b>   |                            |                 |
| Net loss  | \$(17,892,302 )            | \$(32,475,827 ) |
| Adjustments to reconcile net loss to net cash used in operating activities: |                            |                 |
| Depreciation and amortization   | 2,229,947                  | 2,022,028       |
| Loss on extinguishment of debt  | 1,252,353                  | -               |
| Non-cash interest expense   | 1,200,504                  | 2,310,096       |
| Stock-based compensation  | 1,823,728                  | 6,912,547       |
| Change in fair value of warrant liability                                   | (226,116 )                 | (3,976,397 )    |
| Changes in operating assets and liabilities:                                |                            |                 |
| Prepaid expenses and other current assets                                   | (606,067 )                 | 2,278,590       |
| Other assets  | (33,612 )                  | 51,604          |
| Accounts payable  | (8,002,074 )               | 6,661,571       |
| Accrued expenses  | (2,101,223 )               | 1,396,417       |
| Deferred revenue  | (2,285,671 )               | (909,421 )      |
| Other liabilities   | (4,806 )                   | 143,884         |
| Net cash used in operating activities                                       | (24,645,339 )              | (15,584,908 )   |
| <b>INVESTING ACTIVITIES</b>   |                            |                 |
| Purchase of property and equipment  | (1,518,349 )               | (268,106 )      |
| Net cash used in investing activities                                       | (1,518,349 )               | (268,106 )      |
| <b>FINANCING ACTIVITIES</b>   |                            |                 |
| Proceeds from the sale of common stock, net of offering costs               | 14,856,088                 | 1,607,396       |
| Payment of debt issuance costs  | -                          | (40,000 )       |
| Proceeds from issuance of Series A convertible preferred stock              | 21,737,200                 | -               |
| Proceeds from the sale of senior secured notes and detachable warrants      | -                          | 15,000,000      |
| Proceeds from exercise of common stock warrants                             | -                          | 253,289         |
| Change in restricted cash   | -                          | 216,086         |
| Payments of capital leases obligations                                      | (634,866 )                 | (730,024 )      |
| Repayment of debt   | (94,427 )                  | (2,665,722 )    |
| Payment of financing costs  | (1,089,158 )               | -               |
| Net cash provided by financing activities                                   | 34,774,837                 | 13,641,025      |
| Net increase (decrease) in cash   | 8,611,149                  | (2,211,989 )    |
| Cash at beginning of period   | 3,185,519                  | 2,351,887       |
| Cash at end of period   | \$ 11,796,668              | \$ 139,898      |

Supplemental disclosure of cash flow information

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|  |             |           |
|--|-------------|-----------|
| Cash paid for interest   | \$81,005    | \$556,299 |
| Supplemental schedule of noncash investing activities:   |             |           |
| Purchases of property and equipment in accounts payable and accrued expenses   | \$463,007   | \$23,698  |
| Supplemental schedule of noncash financing activities:   |             |           |
| Issuance of Series B convertible preferred stock upon conversion of senior secured notes, net of unamortized debt discount | \$1,409,619 | \$-       |
| Issuance of capital lease obligations in connection with purchase of property and equipment                                | \$4,260,942 | \$62,230  |
| Series A convertible preferred stock dividends   | \$652,612   | \$-       |
| Settlement of Series A convertible preferred stock dividends upon issuance of Series A convertible preferred stock         | \$1,104,481 | \$-       |
| Deferred offering costs and common stock issuance costs in accounts payable and accrued expenses                           | \$-         | \$292,367 |

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

**Oncobiologics, Inc.**

**Notes to Unaudited Interim Consolidated Financial Statements**

**1. Organization and Description of Business**

Oncobiologics, Inc. (“Oncobiologics” or the “Company”) was incorporated in New Jersey on January 5, 2010 and started operations in July 2011. Oncobiologics is a clinical-stage biopharmaceutical company focused on identifying, developing, manufacturing and commercializing complex monoclonal antibody (“mAb”) therapeutics. The Company has established fully integrated in-house development and manufacturing capabilities that addresses the numerous complex technical and regulatory challenges in developing and commercializing mAb therapeutics. The Company is based in Cranbury, New Jersey.

**2. Liquidity**

The Company has incurred substantial losses and negative cash flows from operations since its inception and has an accumulated deficit of \$204.1 million as of June 30, 2018. The Company has substantial indebtedness that includes \$13.5 million of senior secured notes due in December 2018 and \$4.6 million in notes payable to stockholders that are payable on demand. There can be no assurance that the holders of the stockholder notes will not exercise their right to demand repayment. These factors raise substantial doubt about the Company’s ability to continue as a going concern. The accompanying unaudited interim consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The unaudited interim consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Management believes that the Company’s existing cash as of June 30, 2018 will be sufficient to fund its operations into November 2018, excluding repayment of debt. Substantial additional financing will be needed by the Company to fund its operations in the future and to commercially develop its product candidates. Management is currently evaluating different strategies to obtain the required funding for future operations. These strategies may include, but are not limited to: private placements of equity and/or debt, payments from potential strategic research and development partners, licensing and/or marketing arrangements with pharmaceutical companies, providing manufacturing services on a contract basis to other biopharmaceutical companies and public or private offerings of equity and/or debt securities. There can be no assurance that these future funding efforts will be successful.

The Company’s future operations are highly dependent on a combination of factors, including (i) the timely and successful completion of additional financing discussed above; (ii) the Company’s ability to complete

revenue-generating partnerships with pharmaceutical companies; (iii) the success of its research and development; (iv) the development of competitive therapies by other biotechnology and pharmaceutical companies, and, ultimately, (v) regulatory approval and market acceptance of the Company's proposed future products.

### **3. Basis of Presentation and Summary of Significant Accounting Policies**

#### **Basis of presentation**

The accompanying unaudited interim consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("GAAP") for interim financial information. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

In the opinion of management, the accompanying unaudited interim consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company's financial position as of June 30, 2018 and its results of operations for the three and nine months ended June 30, 2018 and 2017 and cash flows for the nine months ended June 30, 2018 and 2017. Operating results for the three and nine months ended June 30, 2018 are not necessarily indicative of the results that may be expected for the full year ending September 30, 2018. The unaudited interim consolidated financial statements, presented herein, do not contain the required disclosures under GAAP for annual consolidated financial statements. The accompanying unaudited interim consolidated financial statements should be read in conjunction with the annual audited consolidated financial statements and related notes as of and for the year ended September 30, 2017 included in the Company's Annual Report on Form 10-K, as amended to date, filed with the Securities and Exchange Commission ("SEC"), on December 29, 2017.

**Oncobiologics, Inc.**

**Notes to Unaudited Interim Consolidated Financial Statements**

**Use of estimates**

The preparation of the unaudited interim consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Due to the uncertainty of factors surrounding the estimates or judgments used in the preparation of the unaudited interim consolidated financial statements, actual results may materially vary from these estimates. Estimates and assumptions are periodically reviewed and the effects of revisions are reflected in the unaudited interim consolidated financial statements in the period they are determined to be necessary.

**Income taxes**

In November 2017, the Company received approval from the New Jersey Economic Development Authority's Technology Business Tax Certificate Transfer Program to sell a portion of its unused New Jersey net operating losses ("NOLs"), and research and development ("R&D") tax credits. As a result, the Company received \$3.15 million of cash from the sale of these NOLs and credits in December 2017, which it recognized as an income tax benefit for the nine months ended June 30, 2018. The Company recorded income tax expense of \$4,000 for the nine months ended June 30, 2017, which is primarily attributable to state and foreign withholding taxes in connection with the Company's collaboration and licensing agreements.

**Net loss per share**

Basic and diluted net loss per common share is determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period.

For purposes of calculating diluted loss per common share, the denominator includes both the weighted average common shares outstanding and the number of common stock equivalents if the inclusion of such common stock equivalents would be dilutive. Dilutive common stock equivalents potentially include warrants, stock options and

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non-vested restricted stock unit (“RSU”) awards using the treasury stock method. The diluted loss per common share calculation is further affected by an add-back of change in fair value of warrant liability to the numerator under the assumption that the change in fair value of warrant liability would not have been incurred if the warrants had been converted into common stock.

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

|   | Three Months Ended June 30, |                 | Nine Months Ended June 30, |                  |
|---|-----------------------------|-----------------|----------------------------|------------------|
|   | 2018                        | 2017            | 2018                       | 2017             |
| <b>Basic Earnings Per Share</b>               |                             |                 |                            |                  |
| Net loss                                      | \$ (9,084,534 )             | \$ (5,331,376 ) | \$ (35,369,093 )           | \$ (32,475,827 ) |
| Common stock outstanding (weighted average)   | 34,540,056                  | 24,442,056      | 28,422,852                 | 23,788,046       |
| Basic net loss per share                      | \$ (0.26 )                  | \$ (0.22 )      | \$ (1.24 )                 | \$ (1.37 )       |
| <b>Diluted Earnings Per Share</b>             |                             |                 |                            |                  |
| Net loss                                      | (9,084,534 )                | (5,331,376 )    | (35,369,093 )              | (32,475,827 )    |
| Add change in fair value of warrant liability | -                           | -               | -                          | (3,976,397 )     |
| Diluted net loss                              | (9,084,534 )                | (5,331,376 )    | (35,369,093 )              | (36,452,224 )    |
| Common stock outstanding (weighted average)   | 34,540,056                  | 24,442,056      | 28,422,852                 | 23,788,046       |
| Add shares from dilutive warrants             | -                           | -               | -                          | 25,864           |
| Common stock equivalents                      | 34,540,056                  | 24,442,056      | 28,422,852                 | 23,813,910       |
| Diluted net loss per share                    | \$ (0.26 )                  | \$ (0.22 )      | \$ (1.24 )                 | \$ (1.53 )       |



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

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding as of June 30, 2018 and 2017, as they would be antidilutive:

|                                      | As of June 30, |           |
|--------------------------------------|----------------|-----------|
|                                      | 2018           | 2017      |
| Series A convertible preferred stock | 7,893,155      | -         |
| Performance-based stock units        | 150,951        | 214,413   |
| Restricted stock units               | 83,281         | 1,068,260 |
| Common stock warrants                | 45,292,494     | 7,760,988 |
| Stock options                        | 1,062,075      | -         |

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

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

For the three and nine months ended June 30, 2017, rent expense was overstated by \$0.1 million and \$0.3 million, respectively, and interest expense was understated by \$0.1 million and \$0.3 million, respectively. This was primarily attributable to the reclassification of rental payments into interest expense payments in connection with a financing arrangement rather than an operating lease arrangement, as previously presented.

The Company reviewed the impact of this error on the prior periods in accordance with SEC *Staff Accounting Bulletin No. 99, "Materiality,"* and determined that the error was not material to the prior periods. However, the Company has corrected the unaudited interim consolidated statement of operations for the three months ended June 30, 2017 by decreasing research and development expenses and general and administrative expenses by \$82,000 and \$21,000, respectively, and by increasing interest expense by \$0.1 million. The Company corrected the unaudited interim consolidated statement of operations for the nine months ended June 30, 2017 by decreasing research and development expenses and general and administrative expenses by \$0.2 million and \$63,000, respectively, and by

increasing interest expense by \$0.3 million.

### **Recently issued and adopted accounting pronouncements**

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* (“Topic 718”), which simplifies the accounting for nonemployee share-based payment transactions. The amendments specify that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor’s own operations by issuing share-based payment awards. The standard will be effective for fiscal years beginning after December 15, 2018, although early adoption is permitted (but no sooner than the adoption of Topic 606). The Company does not expect that the adoption of this ASU will have a significant impact on its consolidated financial statements.

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

**Oncobiologics, Inc.**

**Notes to Unaudited Interim Consolidated Financial Statements**

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

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

*Contracts with customers* — including revenue and impairments recognized, disaggregation of revenue and information about contract balances and performance obligations (including the transaction price allocated to the remaining performance obligations).

*Significant judgments and changes in judgments* — determining the timing of satisfaction of performance obligations (over time or at a point in time), and determining the transaction price and amounts allocated to performance obligations.

*Certain assets* — assets recognized from the costs to obtain or fulfill a contract.

In July 2015, the FASB delayed the effective date of this guidance. As a result, this guidance will be effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. Earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. This ASU 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.

**Oncobiologics, Inc.**

**Notes to Unaudited Interim Consolidated Financial Statements**

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

|                   | June 30, 2018 |           |              |
|-------------------|---------------|-----------|--------------|
|                   | (Level 1)     | (Level 2) | (Level 3)    |
| Liabilities       |               |           |              |
| Warrant liability | \$ -          | \$ -      | \$ 2,048,838 |

|                   | September 30, 2017 |           |              |
|-------------------|--------------------|-----------|--------------|
|                   | (Level 1)          | (Level 2) | (Level 3)    |
| Liabilities       |                    |           |              |
| Warrant liability | \$ -               | \$ -      | \$ 2,274,954 |

The table presented below is a summary of changes in the fair value of the Company's Level 3 valuation for the warrant liability for the nine months ended June 30, 2018:

|                            |              |
|----------------------------|--------------|
| Balance at October 1, 2017 | \$ 2,274,954 |
| Change in fair value       | (226,116 )   |
| Balance at June 30, 2018   | \$ 2,048,838 |

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

|                                       | June 30,<br>2018 |
|---------------------------------------|------------------|
| Risk-free interest rate               | 2.68%            |
| Remaining contractual life of warrant | 3.64 years       |
| Expected volatility                   | 128%             |
| Annual dividend yield                 | 0%               |
| Fair value of common stock            | \$0.85 per share |

**5. Property and Equipment, Net**

Property and equipment, net, consists of:

|   | June 30,<br>2018 | September 30,<br>2017 |
|---|------------------|-----------------------|
| Laboratory equipment                            | \$ 14,172,847    | \$ 11,574,474         |
| Leasehold improvements                          | 10,071,574       | 10,032,640            |
| Computer software and hardware                  | 483,807          | 472,054               |
| Land and building                               | 3,000,000        | -                     |
| Construction in progress                        | 3,431,065        | 2,654,675             |
|   | 31,159,293       | 24,733,843            |
| Less: accumulated depreciation and amortization | (10,874,888)     | (8,644,941 )          |
|   | \$ 20,284,405    | \$ 16,088,902         |

Depreciation and amortization expense was \$822,059 and \$672,098 for the three months ended June 30, 2018 and 2017 respectively, and \$2,229,947 and \$2,022,028 for the nine months ended June 30, 2018 and 2017, respectively.

At June 30, 2018, \$7,953,856 represents laboratory equipment under capital leases and the Company's corporate office that is classified as a capital lease. At September 30, 2017, \$3,692,913 represents laboratory equipment under capital leases. The term of the equipment leases are between 22 and 36 months and qualify as capital leases. The Company's corporate office lease matures in February 2028. The equipment leases bear interest between 5.0% and 19.4% and the effective interest rate on the corporate office lease is 43.9%. At June 30, 2018 and September 30, 2017, \$1,462,554 and \$1,061,901, respectively, of accumulated amortization related to capital leases.

**Oncobiologics, Inc.****Notes to Unaudited Interim Consolidated Financial Statements****6. Accrued Expenses**

Accrued expenses consists of:

|                                   | June 30,<br>2018   | September 30,<br>2017 |
|-----------------------------------|--------------------|-----------------------|
| Compensation                      | \$2,367,295        | \$ 3,688,592          |
| Severance and related costs       | 766,046            | -                     |
| Dividends on Series A Convertible | 652,613            | -                     |
| Research and development          | 208,130            | 1,637,657             |
| Interest payable                  | 1,745,907          | 1,047,122             |
| Professional fees                 | 331,576            | 521,973               |
| Director fees                     | 45,632             | 376,695               |
| Other accrued expenses            | 2,247              | 65,430                |
|                                   | <b>\$6,119,446</b> | <b>\$ 7,337,469</b>   |

**7. Senior Secured Notes**

|                           | June 30,<br>2018    |
|---------------------------|---------------------|
| Senior secured notes      | \$13,500,000        |
| Unamortized debt discount | (660,908 )          |
|                           | <b>\$12,839,092</b> |

In September 2017, the Company entered into a purchase and exchange agreement (the “Exchange Agreement”) with two existing investors and holders of its senior secured notes (the “Noteholders”), pursuant to which the Noteholders exchanged \$1.5 million aggregate principal amount of senior secured notes for 1,500,000 shares of Series B convertible preferred stock (“Series B Convertible”) and \$41,507 of accrued interest on such exchanged senior secured notes in October 2017. The Company recognized a loss on extinguishment of \$1,252,353 in connection with the exchange and represents the excess fair value of the Series B Convertible issued over the net carrying amount of the debt and accrued interest. The 1,500,000 shares of Series B Convertible were converted into an aggregate of 2,112,675 shares of common stock in the three months ended June 30, 2018 and there are no longer any shares of Series B

Convertible issued and outstanding.

Interest expense on the senior secured notes for the three months ended June 30, 2018 and 2017 was \$500,012 and \$1,500,500, respectively, and \$1,486,737 and \$2,548,428 for the nine months ended June 30, 2018 and 2017, respectively.

## **8. Commitments**

During the nine months ended June 30, 2018, the Company entered into an amendment to its lease for its corporate offices in Cranbury, New Jersey. Pursuant to the amended terms, the Company is occupying 100% of the corporate facility and has extended the lease term through February 2028 with two five year renewal options. As a result of this amendment, the lease is now classified as a capital lease. The Company initially recorded the lease obligation and corresponding building asset based on its estimated fair value of approximately \$3,000,000. The building is being depreciated over the lease term. Future lease payments will be allocated to interest expense and a pay-down of the lease obligation.



**Oncobiologics, Inc.**

**Notes to Unaudited Interim Consolidated Financial Statements**

Future minimum payments under the amended lease at June 30, 2018 are as follows:

|                                     | June 30,<br>2018 |
|-------------------------------------|------------------|
| Within one year                     | \$1,379,876      |
| Two years                           | 1,397,616        |
| Three years                         | 1,418,820        |
| Four years                          | 1,506,204        |
| Five years                          | 1,531,732        |
| Thereafter                          | 7,676,097        |
| Total rental payments               | 14,910,345       |
| Less: Amounts representing interest | (11,692,316)     |
| Present value of payments           | \$3,218,029      |

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

**Common stock**

In May 2018, the Company entered into a purchase agreement with GMS Tenshi Holdings Pte. Limited, a Singapore private limited company and the Company's controlling stockholder and strategic partner ("GMS Tenshi"), pursuant to which GMS Tenshi purchased, in a private placement, 12,754,766 shares of common stock and common stock warrants to purchase 20,512,820 shares of common stock for cash proceeds of \$15.0 million. The transaction closed in two tranches in May and June 2018. The warrants have an exercise price of \$0.975 per share and a term of eight years from their issuance date.

During the nine months ended June 30, 2018, the Company issued 821,006 shares of common stock upon the vesting of RSUs.

**Convertible preferred stock**

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

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

**Oncobiologics, Inc.**

**Notes to Unaudited Interim Consolidated Financial Statements**

The Series A Convertible accrues dividends at a rate of 10% per annum, compounded quarterly, payable quarterly at the Company's option in cash or in kind in additional shares of Series A Convertible, although the initial dividends payable on the shares of Series A Convertible issued in September 2017, while accruing from issuance, was payable in December 2017. The Series A Convertible was also entitled to dividends on an as-if-converted basis in the same form as any dividends actually paid on shares of common stock or other securities. The initial conversion rate was subject to appropriate adjustment in the event of a stock split, stock dividend, combination, reclassification or other recapitalization affecting the common stock. During the nine months ended June 30, 2018, the Company issued an additional 11,045 shares of Series A Convertible to settle the related dividends that were due on a quarterly basis. The Company recognized a beneficial conversion charge of \$381,664 during the nine months ended June 30, 2018, which represents the in-the-money value of the conversion rate as of the date of issuance.

In June 2018, GMS Tenshi converted 208,836 shares of Series A Convertible into 31,572,617 shares of common stock.

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

The Series B Convertible were non-voting, did not accrue dividends nor did the shares of Series B Convertible have any specific rights or preferences, and had a stated value of \$1.00 per share and were convertible into 2,112,675 shares of common stock. During May and June 2018, the Noteholders converted all 1,500,000 shares of Series B Convertible into 2,112,675 shares of common stock. Accordingly, there are no longer any shares of Series B Convertible issued and outstanding.

**Common stock warrants**

As of June 30, 2018, the Company had the following warrants outstanding to acquire shares of its common stock:

| Outstanding | Exercise | Expiration |
|-------------|----------|------------|
|-------------|----------|------------|

|   |            | <b>Price Per</b> | <b>Date</b>       |
|---|------------|------------------|-------------------|
|   |            | <b>Share</b>     |                   |
| Series A warrants   | 3,333,333  | \$ 6.60          | February 18, 2019 |
| Common stock warrants issued with initial public offering | 814,340    | \$ 0.01          | November 11, 2019 |
| Common stock warrants issued with senior secured notes    | 3,882,001  | \$ 3.00          | December 22, 2021 |
| Common stock warrants issued with Series A Convertible    | 16,750,000 | \$ 0.90          | October 31, 2025  |
| Common stock warrants issued in May 2018                  | 10,256,410 | \$ 0.975         | May 10, 2026      |
| Common stock warrants issued in June 2018                 | 10,256,410 | \$ 0.975         | June 8, 2026      |
|   | 45,292,494 |                  |                   |

## 10. Stock-Based Compensation

### 2011 Equity Incentive Plan

The Company's 2011 Equity Compensation Plan (the "2011 Plan") provided for the Company to sell or issue restricted common stock, RSUs, performance-based awards ("PSUs"), cash-based awards or to grant stock options for the purchase of common stock to officers, employees, consultants and directors of the Company. The 2011 Plan was administered by the board of directors or, at the discretion of the board of directors, by a committee of the board. The number of shares of common stock reserved for issuance under the 2011 Plan is 851,926. As of June 30, 2018, PSUs representing 150,951 shares of the Company's common stock were outstanding under the 2011 Plan. In light of the December 2015 adoption of the 2015 Equity Incentive Plan, (the "2015 Plan") no future awards under the 2011 Plan will be granted.

### 2015 Equity Incentive Plan

In December 2015, the Company adopted the 2015 Plan. The 2015 Plan provides for the grant of stock options, stock appreciation rights, restricted stock awards, RSU awards, performance stock awards and other forms of equity compensation to Company employees, directors and consultants. The maximum number of shares of common stock that may be issued under the 2015 Plan is 2,638,101 shares. As of June 30, 2018, 839,756 shares remained available for grant under the 2015 Plan.

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

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, 2018 and 2017:

|                            | Three Months Ended June 30, |              | Nine Months Ended June 30, |              |
|----------------------------|-----------------------------|--------------|----------------------------|--------------|
|                            | 2018                        | 2017         | 2018                       | 2017         |
| Research and development   | \$ 86,872                   | \$ 205,104   | \$ 2,079                   | \$ 1,022,919 |
| General and administrative | 147,247                     | 1,916,000    | 1,821,649                  | 5,889,628    |
|                            | \$ 234,119                  | \$ 2,121,104 | \$ 1,823,728               | \$ 6,912,547 |

**Stock options**

During the nine months ended June 30, 2018, the Company granted a total of 1,077,075 stock options to its board of directors and employees of which 20,000 options granted will vest 50% on the third anniversary of the commencement date and the remaining 50% on the fourth anniversary of the commencement date, 60,000 options granted will vest on the first anniversary of the grant date and 997,075 options granted will vest annually over three years.

As of June 30, 2018, options to purchase common stock of the Company outstanding under the 2015 Plan were as follows:

|                             | Number of<br>Shares | Weighted<br>Average<br>Exercise Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Term (Years) |
|-----------------------------|---------------------|---------------------------------------|---|
| Balance at October 1, 2017  | -                   | \$ -                                  |   |
| Granted                     | 1,077,075           | 0.96                                  |   |
| Expired/forfeited/cancelled | (15,000 )           | 1.32                                  |   |
| Balance at June 30, 2018    | 1,062,075           | 0.96                                  | 9.9   |
| Vested and exercisable      | -                   |                                       |   |

Vested and expected to vest at June 30, 2018      1,062,075      \$    0.96                      9.9

The weighted average grant date fair value of the options awarded to employees for the nine months ended June 30, 2018 was \$0.52 per share. The aggregate intrinsic value represents the total amount by which the fair value of the common stock subject to options exceeds the exercise price of the related options.

As of June 30, 2018, the aggregate intrinsic value of the unvested options was \$0.

The fair value of the options was estimated on the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions:

|                         |  |
|-------------------------|--|
|                         | Nine Months<br>Ended<br>June 30,<br>2018 |
| Risk-free interest rate | 2.72%                                    |
| Expected life           | 5.99 years                               |
| Expected volatility     | 61%                                      |
| Expected dividend yield | -  |

As of June 30, 2018, there was \$503,538 of unrecognized compensation expense that is expected to be recognized over a weighted-average period of 2.84 years.

**Oncobiologics, Inc.****Notes to Unaudited Interim Consolidated Financial Statements****Performance-based stock units**

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

The following table summarizes the activity related to PSUs during the nine months ended June 30, 2018:

|                            | Number<br>of<br>PSUs | Weighted<br>Average<br>Base Price<br>Per Unit |
|----------------------------|----------------------|---|
| Balance at October 1, 2017 | 175,530              | \$ 6.27                                       |
| Forfeitures                | (24,579 )            | 6.21  |
| Balance at June 30, 2018   | 150,951              | \$ 6.31                                       |

As of June 30, 2018, there was \$26,908 of unamortized expense that will be recognized over a weighted-average period of 0.52 years.

**Restricted stock units**

The RSUs generally vest over a period of two to four years from the date of grant. The following table summarizes the activity related to RSUs during the nine months ended June 30, 2018:

| Number<br>of | Weighted<br>Average<br>Grant Date |
|--------------|-----------------------------------|
|--------------|-----------------------------------|

|                            | RSUs      | Fair Value |
|----------------------------|-----------|------------|
| Balance at October 1, 2017 | 939,879   | \$ 18.78   |
| Granted                    | 20,000    | 1.16       |
| Vested and settled         | (821,006) | 17.95      |
| Forfeitures                | (55,592 ) | 16.62      |
| Balance at June 30, 2018   | 83,281    | \$ 21.76   |

As of June 30, 2018, there was \$714,046 of unamortized expense that will be recognized over a weighted-average period of 1.17 years.

## 11. Related-Party Transactions

During the three months ended June 30, 2018, the Company negotiated a contract with Sonnet Biotherapeutics, Inc. (“Sonnet”) to provide contract development and manufacturing (“CDMO”) services. The maximum contract value is estimated to be approximately \$5.1 million, if all milestones are met. Additionally, in order to provide services to Sonnet and other potential CDMO customers, in November 2017, the Company acquired laboratory and office equipment from Sonnet with a value of \$115,000 and during the nine months ended June 30, 2018, assumed leases of \$201,000 for equipment necessary for the planned expansion of the Company’s development and manufacturing facilities. Such leases were personally guaranteed by Pankaj Mohan, Ph.D., the Company’s former Chairman and Chief Executive Officer (“CEO”), and current Class III director.

Dr. Mohan and Mr. Donald Griffith, Class II Director, are members of the board of directors of Sonnet, with Dr. Mohan serving as Executive Chairman of Sonnet. In addition, Dr. Mohan is a significant stockholder of Sonnet and Mr. Griffith is the President, Chief Executive Officer and Chief Financial Officer, of Sonnet.



**Oncobiologics, Inc.**

**Notes to Unaudited Interim Consolidated Financial Statements**

**12. Subsequent Events**

In July 2018, the Company entered into an exchange agreement with GMS Tenshi, pursuant to which the Company exchanged 58,735 shares of Series A Convertible held by GMS Tenshi for 58,735 shares of its newly created series of voting convertible preferred stock, voting Series A-1 Convertible Preferred Stock (the “Series A-1 Preferred”). Accordingly, all of the issued Series A Convertible have been retired and cancelled and may not be reissued as shares of such series in accordance with their terms.

A total of 200,000 shares of Series A-1 Preferred have been authorized for issuance. The shares of Series A-1 Preferred have a stated value of \$100.00 per share, are initially convertible into 8,879,780 shares of common stock and rank senior to all junior securities.

The Series A-1 Preferred has the same conversion and dividend features as the Series A Convertible, but reflect an increased redemption premium and increased liquidation preference that provides GMS Tenshi with similar redemption premium and liquidation preference as before the June 20, 2018 conversion of 208,836 shares of Series A Convertible by GMS Tenshi. The Series A-1 Preferred accrue dividends at a rate of 10% per annum, compounded quarterly, payable quarterly at the Company’s option in cash or in kind in additional shares of Series A-1 Preferred.

## **Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*You should read this section in conjunction with our unaudited interim consolidated financial statements and related notes included in Part I. Item 1 of this report and our audited consolidated financial statements and related notes thereto and management's discussion and analysis of financial condition and results of operations for the years ended September 30, 2017 and 2016 included in our Annual Report on Form 10-K for the year ended September 30, 2017, filed with the Securities and Exchange Commission, or SEC, on December 29, 2017, as amended to date.*

### **Forward-Looking Statements**

*This discussion contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are identified by words such as "believe," "may," "could," "will," "estimate," "continue," "anticipate," "intend," "seek," "plan," "would," "potentially" or the negative of these terms or similar expressions in this report. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to certain risks and uncertainties that could cause a difference include, but are not limited to, those discussed under the caption "Risk Factors" in our Annual Report on Form 10-K for the year ended September 30, 2017, filed with the SEC on December 29, 2017, as amended to date, and elsewhere in this report. Forward-looking statements are based on our management's current beliefs and assumptions and based on information currently available to our management. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments.*

### **Overview**

We are a clinical-stage biopharmaceutical company focused on identifying, developing, manufacturing and commercializing complex, technically challenging and commercially attractive monoclonal antibody, or mAb, therapeutics. A mAb is a type of protein that is produced by a single clone of cells or cell line and made to bind to a specific substance in the body. We have leveraged our team's biopharmaceutical expertise to establish fully integrated in-house development and manufacturing capabilities, which we refer to as our BioSymphony Platform. We believe this platform addresses the numerous complex technical and regulatory challenges in developing and commercializing mAb therapeutics and was designed to provide significant pricing flexibility. Our strategy is to use the BioSymphony Platform to develop mAb product candidates that expand access to important therapeutic options for patients. Our ability to pursue product candidates using either the innovative or biosimilar product pathway is fundamental to our success and we believe positions us to be a leading biotechnology company.

Our lead product candidate, ONS-5010, is an innovative mAb therapeutic that is expected to enter clinical trials in 2018. Additionally, we have advanced two other product candidates through Phase 1 clinical trials and into preparations for Phase 3 clinical trials: ONS-3010, a biosimilar to adalimumab (Humira®), and ONS-1045, a biosimilar to bevacizumab (Avastin®). We plan to advance ONS-3010 and ONS-1045 into Phase 3 clinical trials upon entering into a license or co-development agreement with a partner. We continue to develop other earlier stage therapeutic candidates that we intend to take through the pre-clinical stage with the goal of entering into clinical trials upon securing a development partner for major markets such as the United States and the European Union, or EU.

We have made a strategic decision to maximize the value of our BioSymphony Platform by beginning to assist development stage biopharmaceutical and biotechnology companies with the development and manufacturing of their product candidates for clinical trials on a contract basis. We believe that this strategy to leverage the BioSymphony Platform and its capabilities will generate funding for our in-house development programs while we continue to develop our pipeline by providing a flexible and cost-effective alternative to the larger contract manufacturing organizations currently serving this market. Planned improvements to our manufacturing and development facilities required to support the ongoing development and commercialization of our ONS-5010 program will provide the necessary foundation to support this new business upon completion in 2019.

Through June 30, 2018, we have funded substantially all of our operations with \$195.3 million in proceeds from the sale and issuance of our equity and debt securities. We have also received \$29.0 million pursuant to our collaboration and licensing agreements. In September 2017, we closed on the initial sale of 32,628 shares of our newly-created Series A Convertible Preferred Stock, or the Series A Convertible, to GMS Tenshi Holdings Pte. Limited, or GMS Tenshi, our controlling stockholder and strategic partner, for \$3.3 million of cash, and entered into an investor rights agreement in connection therewith. In October 2017, following receipt of necessary stockholder approval, we issued an additional 217,372 shares of our Series A Convertible and warrants to acquire 16,750,000 shares of our common stock to GMS Tenshi for \$21.7 million of cash. Concurrent with such second closing, we also exchanged an aggregate \$1.5 million of outstanding senior secured notes into 1,500,000 shares of our newly-created Series B Convertible Preferred Stock, or the Series B Convertible. During May and June 2018, all 1,500,000 shares of Series B Convertible converted into 2,112,675 shares of common stock in accordance with their terms and there are no shares of Series B Convertible outstanding.

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

On May 11, 2018, we entered into a purchase agreement with GMS Tenshi pursuant to which we agreed to sell to GMS Tenshi, and GMS Tenshi agreed to purchase, in a private placement, \$15.0 million of our common stock and warrants to acquire that number of shares of common stock having an aggregate exercise price of approximately \$20.0 million, to close in two tranches. On May 14, 2018, we closed the sale of the first tranche of the common stock and warrants for aggregate cash proceeds of \$7.5 million, issuing to GMS Tenshi an aggregate of 6,377,383 shares of our common stock and warrants to acquire up to 10,256,410 additional shares of our common stock at an exercise price of \$0.975 per share, which warrants have a term of eight years from their issuance date. On June 8, 2018, we closed the sale of the second tranche of the common stock and warrants for aggregate cash proceeds of \$7.5 million, issuing to GMS Tenshi an aggregate of 6,377,383 shares of our common stock and warrants to acquire up to 10,256,410 additional shares of our common stock at an exercise price of \$0.975 per share, which warrants have a term of eight years from their issuance date. In connection with the entry into the purchase agreement, we and GMS Tenshi amended the Investor Rights Agreement dated September 11, 2017, in order to provide GMS Tenshi certain registration and other rights with respect to the shares of common stock to be acquired pursuant to the purchase agreement and the shares of common stock that may be issuable upon exercise of the warrants acquired pursuant to the purchase agreement.

On June 20, 2018, GMS Tenshi converted 208,836 shares of Series A Convertible into 31,572,617 shares of common stock. In connection therewith, we agreed in principle to exchange GMS Tenshi's remaining shares of Series A Convertible (along with accrued but unpaid dividends) into a newly created class of preferred stock that was intended to have the same conversion and dividend features as the Series A Convertible, but reflect an increased redemption premium and increased liquidation preference that provides GMS Tenshi with similar redemption premium and liquidation preference as before the June 20, 2018 conversion into common stock. Accordingly, on July 18, 2018, we entered into an exchange agreement with GMS Tenshi pursuant to which we exchanged an aggregate of 58,735 shares of Series A Convertible then held by GMS Tenshi for 58,735 shares of our newly created series of voting convertible

preferred stock, voting Series A-1 Convertible Preferred Stock, par value \$0.01 per share, or the Series A-1 Preferred. Accordingly, all of the issued Series A Convertible have been retired and cancelled and may not be reissued as shares of such series in accordance with their terms.

The Series A-1 Preferred has the same conversion and dividend features as the Series A Convertible (10% per annum, compounded quarterly, payable quarterly at our option in cash or in kind in additional shares of Series A-1 Preferred), but reflects an increased redemption premium (110% to 550%) and increased liquidation preference (120% to 600%) that provides GMS Tenshi with similar redemption premium and liquidation preference for its aggregate Series A Convertible holdings before the conversion.

We have incurred recurring losses and negative cash flows from operations since inception and have an accumulated deficit at June 30, 2018 of \$204.1 million, \$13.5 million of senior secured notes due in December 2018 and \$4.6 million of indebtedness that is due on demand. We will need to raise substantial additional capital to fund our planned future operations, commence clinical trials, receive approval for and commercialize ONS-5010, ONS-3010 and ONS-1045 and continue to develop our other pipeline candidates. We plan to finance our future operations with a combination of proceeds from providing contract development and manufacturing services on a fee for service basis, the issuance of equity securities, the issuance of additional debt, potential collaborations and revenues from potential future product sales, if any. There are no assurances that we will be successful in obtaining an adequate level of financing for the development and commercialization of ONS-5010, ONS-3010, ONS-1045 or any other current or future product candidates. If we are unable to secure adequate additional funding, our business, operating results, financial condition and cash flows may be materially and adversely affected. These matters raise substantial doubt about our ability to continue as a going concern. Our interim unaudited consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

Our current cash resources of \$11.8 million as of June 30, 2018 are expected to fund our operations into November 2018, excluding repayment of debt. To provide additional working capital, we continue to engage in active discussions with global and regional pharmaceutical companies for licensing and/or co-development rights to our late- and early-stage pipeline product candidates. If we are not successful in raising additional capital or entering into one or more licensing and/or co-development rights agreements, we may be required to, among other things, make reductions in our workforce, discontinue our development programs, liquidate all or a portion of our assets, and/or seek protection under the provisions of the U.S. Bankruptcy Code.

We do not have any products approved for sale and we have only generated revenue from our 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, 2018 was \$17.9 million. Our net loss for the nine months ended June 30, 2017 was \$32.5 million. In addition, development activities, clinical and preclinical testing and commercialization of our product candidates will require significant additional financing.

### **Collaboration and License Agreements**

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

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

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

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

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

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

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

As of June 30, 2018, we have received an aggregate of \$5.0 million of payments from IPCA under our various agreements.

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

In June 2014, we entered into a strategic license agreement with Laboratories Liomont, S.A. de C.V., or Liomont, under which we granted Liomont and its affiliates an exclusive, sublicenseable license in Mexico for the research, development, manufacture, use or sale of the ONS-3010 and ONS-1045 biosimilar product candidates in Mexico. Under the terms of the agreement, we received an upfront payment from Liomont, and we are eligible to earn milestone payments for each of ONS-3010 and ONS-1045. In addition, we are eligible to receive tiered royalties at upper single-digit to low teens percentage rates of annual net sales of products by Liomont and its affiliates in Mexico. As of June 30, 2018, we have received an aggregate of \$3.0 million of upfront and milestone payments from Liomont.

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

In May 2013, we entered into a series of agreements with Zhejiang Huahai Pharmaceutical Co., Ltd., or Huahai, to form an alliance for the purpose of developing and obtaining regulatory approval for, and commercial launch and marketing of licensed products in an agreed territory, as described below. The agreements include a strategic alliance agreement, which sets out the governance framework for the relationship, along with a joint participation agreement regarding joint development and commercialization of ONS-3010, and a co-development and license agreement for each of ONS-3010 and ONS-1045. As of June 30, 2018, we have received an aggregate of \$16.0 million of upfront and milestone payments from Huahai.

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

In the event Huahai funds its proportionate share of development costs incurred after completion of the “Phase-3 Ready Packages,” Huahai would be entitled to retain its 51% value ownership, with us entitled to retain our 49% value ownership, of ONS-3010 in the agreed territories. Similarly, revenues from commercialization of ONS-3010 in the agreed countries (including major markets such as the United States and the European Union, among others), would also be shared based on such proportional ownership interests. In the event that Huahai does not fund its proportionate share of such development costs, the joint participation agreement provides for a proportionate adjustment to our



respective value ownership interests based on our respective investments in such development costs, which would increase our value ownership interest in ONS-3010. Under the joint participation agreement, we could also be required to form a joint venture to further develop and commercialize ONS-3010 with Huahai in the agreed countries, if so requested by Huahai. In conjunction with the strategic alliance agreement, we also entered into a co-development and license agreement with Huahai, under which we granted Huahai and its affiliates an exclusive license, in the territory (as specified below) for the research, development, manufacture, use or sale of ONS-3010 or ONS-1045 in China, including, the People's Republic of China, Hong Kong, Macau and Taiwan. We will each bear our respective costs under the development plans. Huahai agreed to carry out all clinical, manufacturing and regulatory requirements necessary for approval of the products in the agreed territory. Under the terms of the agreement, we received an upfront payment from Huahai for ONS-3010, and have received regulatory milestone payments for each of ONS-3010 and ONS-1045.

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

On September 7, 2017, in connection with the entry into the GMS Tenshi purchase agreement for the Series A Convertible and warrants, we also entered into a joint development and license agreement providing for the license of rights to ONS-3010 and ONS-1045 in emerging markets, excluding China, India and Mexico, which superseded and replaced a previous strategic licensing agreement dated July 25, 2017. As of June 30, 2018, we have received an aggregate of \$5.0 million of payments from GMS Tenshi under our joint development and license agreement.

**Components of our Results of Operations**

***Collaboration Revenue***

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

The following table sets forth a summary of revenue recognized from our collaboration and licensing agreements for the three and nine months ended June 30, 2018 and 2017, all of which was from the recognition of deferred revenues under such agreements:

|                          | Three months ended June 30, |            | Nine months ended June 30, |            |
|--------------------------|-----------------------------|------------|----------------------------|------------|
|                          | 2018                        | 2017       | 2018                       | 2017       |
| IPCA Collaboration       | \$ 65,268                   | \$ 65,268  | \$ 195,804                 | \$ 195,804 |
| Liomont Collaboration    | 59,160                      | 59,160     | 177,482                    | 177,481    |
| Huahai Collaboration     | 178,712                     | 178,712    | 536,134                    | 536,136    |
| GMS Tenshi Collaboration | 468,750                     | -          | 1,406,250                  | -          |
|                          | \$ 771,890                  | \$ 303,140 | \$ 2,315,670               | \$ 909,421 |

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.

### ***Research and Development Expenses***

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

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

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the

development of, or when, if ever, material net cash inflows may commence from any of our other product candidates. This uncertainty is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of many factors, including:

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

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

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

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

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

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

### ***Interest Expense***

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

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

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

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

Warrants to purchase our common stock that have been issued in conjunction with our senior secured notes are classified as liabilities and recorded at fair value. The warrants are subject to re-measurement at each balance sheet date and we recognize any change in fair value in our statements of operations as other (income) expense.

### ***Income Taxes***

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

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its NOLs to offset future taxable income. We have not completed a study to assess whether an ownership change has occurred in the past. Our existing NOLs may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change in connection with or after our initial public offering, or IPO, our ability to utilize NOLs could be further limited by Section 382 of the Code. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Code. Our NOLs are also subject to international regulations, which could restrict our ability to utilize our NOLs. Furthermore, our ability to utilize NOLs of companies that we may acquire in the future may be subject to limitations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

**Results of Operations*****Comparison of Three Months Ended June 30, 2018 and 2017***

|   | Three months ended June 30, |                 | Change         |
|---|-----------------------------|-----------------|----------------|
|   | 2018                        | 2017            |                |
| Collaboration revenues                    | \$ 771,890                  | \$ 303,140      | \$468,750      |
| Operating expenses:                       |                             |                 |                |
| Research and development                  | 5,795,993                   | 4,157,696       | 1,638,297      |
| General and administrative                | 2,195,789                   | 3,481,854       | (1,286,065)    |
|   | 7,991,782                   | 7,639,550       | 352,232        |
| Loss from operations                      | (7,219,892 )                | (7,336,410 )    | 116,518        |
| Interest expense, net                     | 1,147,371                   | 1,745,544       | (598,173 )     |
| Change in fair value of warrant liability | 64,659                      | (3,750,578 )    | 3,815,237      |
| Net loss                                  | \$ (8,431,922 )             | \$ (5,331,376 ) | \$ (3,100,546) |

***Collaboration Revenues***

Collaboration revenues increased \$0.5 million, to \$0.8 million, for the three months ended June 30, 2018, as compared to \$0.3 million for the three months ended June 30, 2017. The change is due to the amortization of the upfront payments received in August and September 2017 under our collaboration arrangement with GMS Tenshi.

***Research and Development Expenses***

The following table summarizes our research and development expenses by functional area for the three months ended June 30, 2018 and 2017:

|  | Three months ended June 30,    |
|--|--------------------------------|
|  | 2018                      2017 |

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|   |              |              |
|---|--------------|--------------|
| Preclinical and clinical development    | \$ 1,813,631 | \$ 432,910   |
| Compensation and related benefits       | 1,760,865    | 1,883,234    |
| Stock-based compensation                | 86,872       | 205,104      |
| Other research and development          | 2,134,625    | 1,636,448    |
| Total research and development expenses | \$ 5,795,993 | \$ 4,157,696 |

The following table summarizes our research and development expenses by compound for the three months ended June 30, 2018 and 2017:

|  | Three months ended June 30, |              |
|--|-----------------------------|--------------|
|  | 2018                        | 2017         |
| ONS-3010                                       | \$ 53,351                   | \$ 150,978   |
| ONS-1045                                       | 60,429                      | 198,726      |
| ONS-5010                                       | 1,692,797                   | -            |
| Early-stage compounds                          | 7,054                       | 83,206       |
| Personnel related and stock-based compensation | 1,847,737                   | 2,088,338    |
| Other research and development                 | 2,134,625                   | 1,636,448    |
| Total research and development expenses        | \$ 5,795,993                | \$ 4,157,696 |

Research and development expenses for the three months ended June 30, 2018 increased by \$1.6 million compared to the three months ended June 30, 2017. The increase in research and development expenses is primarily related to an increase of \$1.7 million resulting from development costs incurred for the ONS-5010 program as we prepare to initiate clinical trials in 2018.

### *General and Administrative Expenses*

The following table summarizes our general and administrative expenses by type for the three months ended June 30, 2018 and 2017:

|   | Three months ended June 30, |              |
|---|-----------------------------|--------------|
|   | 2018                        | 2017         |
| Professional fees                         | \$ 785,549                  | \$ 489,280   |
| Compensation and related benefits         | 677,733                     | 573,029      |
| Stock-based compensation                  | 147,247                     | 1,916,000    |
| Facilities, fees and other related costs  | 585,260                     | 503,545      |
| Total general and administrative expenses | \$ 2,195,789                | \$ 3,481,854 |

General and administrative expenses for the three months ended June 30, 2018 decreased by \$1.3 million compared to the three months ended June 30, 2017. The reduction was primarily driven by a reduction in stock-based compensation expense of \$1.8 million related to the completion of the vesting period of most pre-IPO equity grants in the first quarter of our fiscal 2018.

### *Interest Expense*

Interest expense decreased by \$0.6 million for the three months ended June 30, 2018 as compared to the three months ended June 30, 2017, primarily due to the conversion of a portion of our senior secured notes in October 2017.

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



During the three months ended June 30, 2018, we recorded expense of \$0.1 million related to the increase in the fair value of our common stock warrant liability. For the three months ended June 30, 2017, we recorded income of \$3.8 million resulting from a decrease in the fair value of our common stock warrant liability from a decline in the price of our common stock.

***Comparison of Nine Months Ended June 30, 2018 and 2017***

|   | Nine months ended June 30, |                |              |
|---|----------------------------|----------------|--------------|
|   | 2018                       | 2017           | Change       |
| Collaboration revenues                    | \$2,315,670                | \$909,421      | \$1,406,249  |
| Operating expenses:                       |                            |                |              |
| Research and development                  | 11,354,781                 | 21,504,939     | (10,150,158) |
| General and administrative                | 8,191,546                  | 12,374,125     | (4,182,579 ) |
|   | 19,546,327                 | 33,879,064     | (14,332,737) |
| Loss from operations                      | (17,230,657)               | (32,969,643)   | 15,738,986   |
| Interest expense, net                     | 2,786,124                  | 3,478,581      | (692,457 )   |
| Loss on extinguishment of debt            | 1,252,353                  | -              | 1,252,353    |
| Change in fair value of warrant liability | (226,116 )                 | (3,976,397 )   | 3,750,281    |
| Loss before income taxes                  | (21,043,018)               | (32,471,827)   | 11,428,809   |
| Income tax (benefit) expense              | (3,150,716 )               | 4,000          | (3,154,716 ) |
| Net loss                                  | \$(17,892,302)             | \$(32,475,827) | \$14,583,525 |

*Collaboration Revenues*

Collaboration revenues increased \$1.4 million, to \$2.3 million, for the nine months ended June 30, 2018, as compared to \$0.9 million for the nine months ended June 30, 2017. The change is due to the amortization of the upfront payments received in August and September 2017 under our collaboration arrangement with GMS Tenshi.

*Research and Development Expenses*

The following table summarizes our research and development expenses by functional area for the nine months ended June 30, 2018 and 2017:

|   | Nine months ended June 30, |               |
|---|----------------------------|---------------|
|   | 2018                       | 2017          |
| Preclinical and clinical development        | \$4,815,386                | \$9,566,555   |
| Settlement of clinical development contract | (3,228,613 )               | -             |
| Compensation and related benefits           | 4,863,686                  | 6,802,489     |
| Stock-based compensation                    | 2,079                      | 1,022,919     |
| Other research and development              | 4,902,243                  | 4,112,976     |
| Total research and development expenses     | \$ 11,354,781              | \$ 21,504,939 |

The following table summarizes our research and development expenses by compound for the nine months ended June 30, 2018 and 2017:

|  | Nine months ended June 30, |               |
|--|----------------------------|---------------|
|  | 2018                       | 2017          |
| ONS-3010                                       | \$573,518                  | \$ 5,741,536  |
| ONS-1045                                       | 348,596                    | 3,040,361     |
| ONS-5010                                       | 3,730,327                  | -             |
| Early-stage compounds                          | 162,945                    | 784,658       |
| Settlement of clinical development contract    | (3,228,613 )               | -             |
| Personnel related and stock-based compensation | 4,865,765                  | 7,825,408     |
| Other research and development                 | 4,902,243                  | 4,112,976     |
| Total research and development expenses        | \$ 11,354,781              | \$ 21,504,939 |

Research and development expenses for the nine months ended June 30, 2018 decreased by \$10.2 million compared to the nine months ended June 30, 2017 due to reductions in pre-clinical and clinical development spending, a related contract settlement and lower personnel related costs. Overall pre-clinical and clinical research and development expenses decreased by \$4.8 million due primarily to our decision to postpone the initiation of our planned Phase 3 clinical trials for ONS-3010 and ONS-1045 until we secure additional development partners. This resulted in a \$7.9 million decrease in costs related to these two programs, which was partially offset by \$3.7 million in development costs incurred related to our ONS-5010 program as we prepare for clinical trials in 2018. During the nine months ended June 30, 2018, we also terminated an agreement related to ONS-3010 and ONS-1045 and were able to favorably settle amounts previously owed under the contract resulting in a reduction to our accrued research and development expenses of \$3.2 million. Additionally, we experienced a reduction of \$3.0 million in personnel related costs for the nine months ended June 30, 2018 due to a combination of lower salaries and benefits from reduced employee headcount in the current period as a result of attrition in late 2017 and lower stock-based compensation due to the related forfeitures of equity awards by departing employees and the completion of the vesting period of most pre-IPO equity grants earlier in fiscal 2018.

*General and Administrative Expenses*

The following table summarizes our general and administrative expenses by type for the nine months ended June 30, 2018 and 2017:

|   | Nine months ended June 30, |               |
|---|----------------------------|---------------|
|   | 2018                       | 2017          |
| Professional fees                         | \$ 2,213,073               | \$ 2,689,077  |
| Compensation and related benefits         | 1,982,597                  | 2,039,105     |
| Stock-based compensation                  | 1,821,649                  | 5,889,628     |
| Facilities, fees and other related costs  | 2,174,227                  | 1,756,315     |
| Total general and administrative expenses | \$ 8,191,546               | \$ 12,374,125 |

General and administrative expenses for the nine months ended June 30, 2018 decreased by \$4.2 million compared to the nine months ended June 30, 2017. The reduction was primarily a result of a decrease in stock-based compensation expenses of \$4.1 million related to the completion of the vesting period of most pre-IPO equity grants earlier in fiscal 2018.

*Interest Expense*

Interest expense decreased by \$0.7 million for the nine months ended June 30, 2018 as compared to the nine months ended June 30, 2017, primarily due to the conversion of a portion of our senior secured notes in October 2017.

*Change in Fair Value of Warrant Liability*

During the nine months ended June 30, 2018, we recorded income of \$0.2 million related to the decrease in the fair value of our common stock warrant liability. For the nine months ended June 30, 2017 we recorded income of \$4.0 million as a result of a decrease in the price of our common stock during the period.

**Liquidity and Capital Resources**

We have not generated any revenue from product sales. Since inception, we have incurred net losses and negative cash flows from our operations. Through June 30, 2018, we have funded substantially all of our operations through \$195.3 million of net proceeds from the sale and issuance of our equity securities, debt securities and borrowings under debt facilities. We have also received an aggregate of \$29.0 million pursuant to our collaboration and licensing agreements. In the quarter ended June 30, 2018, we sold an aggregate of 12,754,766 shares of our common stock and warrants to acquire an aggregate of 20,512,820 shares of our common stock to GMS Tenshi for aggregate cash proceeds of \$15.0 million. The warrants have an exercise price of \$0.975 per share and a term of eight years from their issuance date.

In September 2017, we closed on the initial sale of 32,628 shares of Series A Convertible to GMS Tenshi for \$3.3 million of cash, and entered into an investor rights agreement and joint development and licensing agreement. In October 2017, following receipt of stockholder approval, we issued an additional 217,372 shares of our Series A Convertible and warrants to acquire an aggregate of 16,750,000 shares of our common stock to GMS Tenshi for \$21.7 million of cash. All of the issues Series A Convertible was exchanged for Series A-1 Preferred in July 2018. We also converted \$1.5 million aggregate principal amount of our senior secured notes into 1,500,000 shares of our Series B Convertible, all of which shares converted into an aggregate of 2,112,675 shares of our common stock in the quarter ended June 30, 2018. In November 2017, we received approval from the New Jersey Economic Development Authority's Technology Business Tax Certificate Transfer Program to sell a portion of our unused New Jersey net operating losses, or NOLs, and research and development tax credits. As a result, we received \$3.15 million of cash from the sale of these NOLs and credits in December 2017. We will require additional capital to fund our operations past November 2018. Alternatively, we will be required to, among other things, make reductions in our workforce, discontinue our development programs, liquidate all or a portion of our assets, and/or seek protection under the provisions of the U.S. Bankruptcy Code.

As of June 30, 2018, we had an accumulated deficit of \$204.1 million and a cash balance of \$11.8 million. In addition, we have \$13.5 million of senior secured notes due in December 2018 and \$4.6 million of indebtedness that is due on demand. These matters raise substantial doubt about our ability to continue as a going concern. Our unaudited interim consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. We anticipate incurring additional losses until such time, if ever, that we can generate significant sales of our product candidates currently in development or from receiving fees for contract development and manufacturing services that we plan to provide for other biopharmaceutical companies. We will need substantial additional financing to fund our operations and to commercially develop our product candidates. Management is currently evaluating various strategic opportunities to obtain the required funding for future operations. These strategies may include, but are not limited to: providing contract development and manufacturing services on a fee for service basis, private placements of equity and/or debt, payments from potential strategic research and development partners, licensing and/or marketing arrangements with pharmaceutical companies, and public offerings of equity and/or debt securities. Additionally, we continue to engage in active discussions with global and regional pharmaceutical companies for licensing and/or co-development rights to our late- and early-stage pipeline candidates. There can be no assurance that these future funding efforts will be successful.

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

### *Cash Flows*

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

|   | Nine months ended June 30, |                |
|---|----------------------------|----------------|
|   | 2018                       | 2017           |
| Net cash used in operating activities     | \$(24,645,339)             | \$(15,584,908) |
| Net cash used in investing activities     | (1,518,349 )               | (268,106 )     |
| Net cash provided by financing activities | 34,774,837                 | 13,641,025     |
| Net increase (decrease) in cash           | \$8,611,149                | \$(2,211,989 ) |

### *Operating Activities.*

During the nine months ended June 30, 2018, we used \$24.6 million of cash in operating activities resulting from our net loss of \$17.9 million and the change in our operating assets and liabilities of \$13.0 million. This use of cash was partially offset by \$6.3 million of non-cash items such as non-cash interest expense, stock-based compensation, change in fair value of warrant liability, loss on extinguishment of debt and depreciation and amortization expense. The change in our operating assets and liabilities was primarily due to payments of our outstanding accounts payable and accrued expenses from September 30, 2017 as well as the prepayment of certain research and development expenses and the amortization of our deferred revenues from collaborations.

During the nine months ended June 30, 2017, we used \$15.6 million of cash in operating activities, primarily resulting from our net loss of \$32.5 million. This use of cash was partially offset by the net cash provided from changes in our operating assets and liabilities of \$9.6 million and \$7.3 million of noncash items such as non-cash interest expense, stock-based compensation, change in fair value of warrant liability and depreciation and amortization expense. The change in our operating assets and liabilities was primarily due to increases in accounts payable and accrued expenses, and a decrease in prepaid expenses related to the timing of vendor payments for research and development. These inflows were partially offset by a decrease in deferred revenues due to ratable recognition of upfront payments received under our collaboration arrangements.

*Investing Activities.*

During the nine months ended June 30, 2018 and 2017, we used cash of \$1.5 million and \$0.3 million, respectively, in investing activities for the purchase of property and equipment.

*Financing Activities.*

During the nine months ended June 30, 2018, net cash provided by financing activities was \$34.8 million, primarily attributable to \$20.6 million in net proceeds from our second closing of our Series A Convertible in October 2017 and \$14.9 million in net proceeds from the sale of common stock and warrants to GMS Tenshi in May and June 2018. We also had \$0.7 million in debt payments.

During the nine months ended June 30, 2017, net cash provided by financing activities was \$13.6 million, primarily attributable to \$15.0 million in proceeds from our senior secured notes and warrants and \$1.9 million from the sale of common stock and exercise of warrants, net of offering costs. These inflows were offset by \$3.4 million in debt payments, \$2.4 million of which was used to repay senior bank loans in December 2016.

### **Off-Balance Sheet Arrangements**

We did not have any off-balance sheet arrangements as of June 30, 2018.

### **Contractual Obligations and Commitments**

Not applicable.

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

The Critical Accounting Policies and Significant Judgments and Estimates included in our Form 10-K for the fiscal year ended September 30, 2017, filed with the SEC on December 29, 2017, as amended to date, have not materially changed.

### **JOBS Act Accounting Election**

The JOBS Act, permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected to “opt out” of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

Not applicable.



## **Item 4. Controls and Procedures**

### **Evaluation of Disclosure Controls and Procedures**

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective, at the reasonable assurance level, as of the end of the period covered by this report.

### **Changes in Internal Control over Financial Reporting**

There have been no changes in our internal control over financial reporting 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, 2018.

## **Part II. Other Information**

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

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

**Item 1A. Risk Factors**

Not applicable.

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

Not applicable.

**Item 3. Defaults Upon Senior Securities**

Not applicable.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

**EXHIBIT INDEX**

| <b>Exhibit<br/>Number</b> | <b>Description</b>  |
|---------------------------|---|
| <u>3.1</u>                | <u>Certificate of Designation of Series A-1 Convertible Preferred Stock of Oncobiologics, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed with the SEC on July 19, 2018).</u>   |
| <u>10.1</u>               | <u>Purchase Agreement by and between Oncobiologics, Inc. and GMS Tenshi Holdings Pte. Limited, dated as of May 11, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on May 15, 2018).</u>                        |
| <u>10.2</u>               | <u>Form of Warrant to Purchase Common Stock issued to GMS Tenshi (incorporated by reference to Exhibit 4.1 to the Registrant's current report on Form 8-K filed with the SEC on May 15, 2018).</u>  |
| <u>10.3</u>               | <u>Amendment to Investor Rights Agreement by and between Oncobiologics, Inc. and GMS Tenshi Holdings Pte. Limited, dated May 11, 2018 (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K filed with the SEC on May 15, 2018).</u>          |
| <u>10.4</u>               | <u>Term Sheet, Convertible Preferred Equity Investment in Oncobiologics, Inc. by and between Oncobiologics, Inc. and GMS Tenshi Holdings Pte. Limited, dated June 20, 2018.</u>   |
| <u>10.5</u>               | <u>Separation Agreement and Release by and between Oncobiologics, Inc. and Pankaj Mohan, Ph.D., dated July 2, 2018.</u>   |
| <u>10.6</u>               | <u>Consulting Agreement by and between Oncobiologics, Inc. and Pankaj Mohan, Ph.D., dated July 2, 2018.</u>   |
| <u>10.7</u>               | <u>Exchange Agreement by and between Oncobiologics, Inc. and GMS Tenshi Holdings Pte. Limited, dated July 18, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on July 19, 2018).</u>                            |
| <u>10.8</u>               | <u>Second Amendment to Investor Rights Agreement by and between Oncobiologics, Inc. and GMS Tenshi Holdings Pte. Limited, dated July 18, 2018 (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K filed with the SEC on July 19, 2018).</u> |
| <u>31.1</u>               | <u>Certification of Principal Executive and Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>  |
| <u>32.1*</u>              | <u>Certification of Principal Executive and Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>   |
| 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  |

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

*any general incorporation language in such filing.*

## **SIGNATURES**

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

### **ONCOBIOLOGICS, INC.**

Date: August 14, 2018 By: /s/ Lawrence A. Kenyon  
Lawrence A. Kenyon  
Chief Executive Officer and Chief Financial Officer  
(Principal Executive, Accounting, and Financial Officer)