

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2015

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 number: 001-35005

**ASSEMBLY BIOSCIENCES, INC.**

(Exact name of Registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**20-8729264**  
(I.R.S. Employer Identification No.)

**99 Hudson Street, 5<sup>th</sup> Floor**  
**New York, New York**  
(Address of principal executive offices)

**10013**  
(zip code)

(646) 706-5208

(Registrant's telephone number, including area code)

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

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

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

Large Accelerated Filer  Accelerated Filer   
Non-accelerated Filer  (Do not check if smaller reporting company) Smaller Reporting Company

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

As of November 5, 2015, there were 17,225,662 shares of registrant's common stock outstanding.

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## Index

Page  
Number

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### **PART I: FINANCIAL INFORMATION**

|   |    |
|---|----|
| <a href="#">Item 1. Condensed Consolidated Financial Statements (unaudited)</a>                               | 1  |
| <a href="#">Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</a> | 12 |
| <a href="#">Item 3. Quantitative and Qualitative Disclosures about Market Risk</a>                            | 15 |
| <a href="#">Item 4. Controls and Procedures</a>   | 15 |

### **PART II: OTHER INFORMATION**

|   |    |
|---|----|
| <a href="#">Item 1. Legal Proceedings</a>   | 15 |
| <a href="#">Item 1A. Risk Factors</a>   | 16 |
| <a href="#">Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</a> | 16 |
| <a href="#">Item 3. Defaults Upon Senior Securities</a>                             | 16 |
| <a href="#">Item 4. Mine Safety Disclosures</a>                                     | 16 |
| <a href="#">Item 5. Other Information</a>   | 16 |
| <a href="#">Item 6. Exhibits</a>  | 16 |

### **SIGNATURES**

17

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**PART I - FINANCIAL INFORMATION****Item 1. Condensed Consolidated Financial Statements (unaudited).****ASSEMBLY BIOSCIENCES, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS**

|  | <u>September 30,</u><br><u>2015</u> | <u>December 31,</u><br><u>2014</u> |
|--|-------------------------------------|------------------------------------|
|  | (Unaudited)                         |                                    |
| <b>ASSETS</b>  |                                     |                                    |
| Current assets   |                                     |                                    |
| Cash and cash equivalents  | \$ 36,401,487                       | \$ 29,091,113                      |
| Marketable securities  | 29,396,382                          | -                                  |
| Other current assets   | 705,295                             | 125,284                            |
| Total current assets   | <u>66,503,164</u>                   | <u>29,216,397</u>                  |
| Long-term assets   |                                     |                                    |
| Marketable securities  | 31,186,107                          | -                                  |
| Property, plant and equipment, net   | 156,483                             | 156,441                            |
| Security deposits  | 170,126                             | 115,005                            |
| Intangible assets  | 29,000,000                          | 29,000,000                         |
| Goodwill   | 12,638,136                          | 12,737,350                         |
| Total long-term assets   | <u>73,150,852</u>                   | <u>42,008,796</u>                  |
| <b>Total assets</b>  | <b><u>\$ 139,654,016</u></b>        | <b><u>\$ 71,225,193</u></b>        |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>  |                                     |                                    |
| Current liabilities  |                                     |                                    |
| Accounts payable   | \$ 1,464,339                        | \$ 907,601                         |
| Accrued expenses   | 1,187,230                           | 146,420                            |
| Total current liabilities  | <u>2,651,569</u>                    | <u>1,054,021</u>                   |
| Long-term liabilities  |                                     |                                    |
| Deferred tax liabilities   | 11,600,000                          | 11,600,000                         |
| Total long-term liabilities  | <u>11,600,000</u>                   | <u>11,600,000</u>                  |
| <b>Total liabilities</b>   | <b><u>14,251,569</u></b>            | <b><u>12,654,021</u></b>           |
| <b>Commitments and contingencies</b>   |                                     |                                    |
| <b>Stockholders' equity</b>  |                                     |                                    |
| Preferred stock, \$0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding   | -                                   | -                                  |
| Common stock, \$0.001 par value; 50,000,000 shares authorized; 17,225,662 and 10,672,059 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively | 17,226                              | 10,672                             |
| Additional paid-in capital   | 281,990,728                         | 194,072,572                        |
| Accumulated other comprehensive loss   | (387,878)                           | -                                  |
| Accumulated deficit  | (156,217,629)                       | (135,512,072)                      |
| Total stockholders' equity   | <u>125,402,447</u>                  | <u>58,571,172</u>                  |
| <b>Total liabilities and stockholders' equity</b>  | <b><u>\$ 139,654,016</u></b>        | <b><u>\$ 71,225,193</u></b>        |

*See Notes to Condensed Consolidated Financial Statements.*

ASSEMBLY BIOSCIENCES, INC.

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS  
(UNAUDITED)**

|   | <b>Three Months Ended September 30,</b> |                               | <b>Nine Months Ended September 30,</b> |                               |
|---|---|-------------------------------|--|-------------------------------|
|   | <b>2015</b>                             | <b>2014</b>                   | <b>2015</b>                            | <b>2014</b>                   |
| <b>Operating expenses:</b>                                    |   |                               |  |                               |
| Research and development                                      | \$ 4,630,148                            | \$ 3,671,983                  | \$ 13,132,336                          | \$ 7,741,317                  |
| General and administrative                                    | 2,492,078                               | 7,383,457                     | 8,347,013                              | 9,930,418                     |
| Total operating expenses                                      | <u>7,122,226</u>                        | <u>11,055,440</u>             | <u>21,479,349</u>                      | <u>17,671,735</u>             |
| <b>Loss from operations</b>                                   | <b><u>(7,122,226)</u></b>               | <b><u>(11,055,440)</u></b>    | <b><u>(21,479,349)</u></b>             | <b><u>(17,671,735)</u></b>    |
| <b>Other income</b>   |   |                               |  |                               |
| Interest and other income                                     | 502,684                                 | 35,182                        | 772,183                                | 112,287                       |
| Realized gain from marketable securities                      | 1,609                                   | -                             | 1,609                                  | -                             |
| Total other income  | <u>504,293</u>                          | <u>35,182</u>                 | <u>773,792</u>                         | <u>112,287</u>                |
| <b>Net loss</b>   | <b><u>\$ (6,617,933)</u></b>            | <b><u>\$ (11,020,258)</u></b> | <b><u>\$ (20,705,557)</u></b>          | <b><u>\$ (17,559,448)</u></b> |
| Unrealized loss on marketable securities                      | (253,659)                               | -                             | (387,878)                              | -                             |
| <b>Comprehensive loss</b>                                     | <b><u>\$ (6,871,592)</u></b>            | <b><u>\$ (11,020,258)</u></b> | <b><u>\$ (21,093,435)</u></b>          | <b><u>\$ (17,559,448)</u></b> |
| Net loss per share, basic and diluted                         | <u>\$ (0.38)</u>                        | <u>\$ (1.33)</u>              | <u>\$ (1.36)</u>                       | <u>\$ (3.02)</u>              |
| Weighted average common shares outstanding, basic and diluted | <u>17,205,863</u>                       | <u>8,277,355</u>              | <u>15,189,395</u>                      | <u>5,814,316</u>              |

*See Notes to Condensed Consolidated Financial Statements.*

ASSEMBLY BIOSCIENCES, INC.

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(UNAUDITED)

|   | <b>Nine Months Ended September 30,</b> |                             |
|---|--|-----------------------------|
|   | <b>2015</b>                            | <b>2014</b>                 |
| <b>Cash flows from operating activities</b>   |  |                             |
| Net loss  | \$ (20,705,557)                        | \$ (17,559,448)             |
| Adjustments to reconcile net loss to net cash used in operating activities:                       |  |                             |
| Depreciation and amortization   | 47,949                                 | 3,894                       |
| Stock-based compensation  | 6,355,453                              | 8,002,033                   |
| Realized gain from marketable securities  | (1,609)                                | -                           |
| Issuance of warrants for services   | -                                      | 679,447                     |
| Changes in operating assets and liabilities:  |  |                             |
| Other current assets  | (580,011)                              | (43,360)                    |
| Accounts payable  | 556,738                                | (2,481,612)                 |
| Accrued expenses  | 1,140,024                              | 18,464                      |
| Security deposits   | (55,121)                               | -                           |
| Net cash used in operating activities   | <u>(13,242,134)</u>                    | <u>(11,380,582)</u>         |
| <b>Cash flows from investing activities</b>   |  |                             |
| Purchase of fixed assets  | (47,991)                               | (20,526)                    |
| Cash acquired in business combination   | -                                      | 509,363                     |
| Purchases of marketable securities  | (63,668,536)                           | -                           |
| Redemption of marketable securities   | 2,699,778                              | -                           |
| Net cash (used in) provided by investing activities   | <u>(61,016,749)</u>                    | <u>488,837</u>              |
| <b>Cash flows from financing activities</b>   |  |                             |
| Proceeds from common stock sold, net of underwriters' discounts and cost                          | 81,014,989                             | 1,763,104                   |
| Proceeds from exercise of stock options   | 554,268                                | -                           |
| Net cash provided by financing activities   | <u>81,569,257</u>                      | <u>1,763,104</u>            |
| Net increase (decrease) in cash   | 7,310,374                              | (9,128,641)                 |
| Cash and cash equivalents at beginning of period  | 29,091,113                             | 27,061,268                  |
| <b>Cash and cash equivalents at end of period</b>   | <b><u>\$ 36,401,487</u></b>            | <b><u>\$ 17,932,627</u></b> |
| <b>Supplemental disclosure of cash flow information:</b>  |  |                             |
| Cashless exercise of warrants   | \$ 88                                  | \$ -                        |
| Change in unrealized loss on marketable securities available-for-sale                             | (387,878)                              | -                           |
| Conversion of preferred stock to common stock   | -                                      | 440                         |
| <b>Supplemental disclosure of non-cash activities:</b>  |  |                             |
| Assembly business combination   |  |                             |
| Other current assets  | \$ -                                   | \$ (23,540)                 |
| Equipment, net  | -                                      | (10,350)                    |
| Intangible assets   | -                                      | (29,000,000)                |
| Goodwill  | -                                      | (12,638,136)                |
| Security deposits   | -                                      | (16,606)                    |
| Accounts payable and accrued expenses   | -                                      | 774,899                     |
| Share exchange - business combination   | -                                      | 29,064,148                  |
| Fair value of vested options and restricted stock units - in connection with business combination | -                                      | 758,948                     |
| Deferred tax liability  | -                                      | 11,600,000                  |
| Cash acquired in business combination   | <u>\$ -</u>                            | <u>\$ 509,363</u>           |

*See Notes to Condensed Consolidated Financial Statements.*

**ASSEMBLY BIOSCIENCES, INC.**

**CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY  
(UNAUDITED)**

|  | <u>Common Stock</u> |                  | <u>Additional<br/>Paid-in Capital</u> | <u>Accumulated Other<br/>Comprehensive Loss</u> | <u>Accumulated<br/>Deficit</u> | <u>Total Stockholders'<br/>Equity</u> |
|--|---------------------|------------------|---------------------------------------|---|--------------------------------|---------------------------------------|
|  | <u>Shares</u>       | <u>Amount</u>    |                                       |   |                                |                                       |
| <b>Balance as of December 31, 2014</b>                                   | <b>10,672,059</b>   | <b>\$ 10,672</b> | <b>\$ 194,072,572</b>                 | <b>\$ -</b>                                     | <b>\$ (135,512,072)</b>        | <b>\$ 58,571,172</b>                  |
| Proceeds from common stock sold, net of underwriters' discounts and cost | 6,388,888           | 6,389            | 81,008,600                            | -   | -                              | 81,014,989                            |
| Exercise of stock options  | 76,422              | 77               | 554,191                               | -   | -                              | 554,268                               |
| Cashless exercise of warrants  | 88,293              | 88               | (88)                                  | -   | -                              | -                                     |
| Stock-based compensation   | -                   | -                | 6,355,453                             | -   | -                              | 6,355,453                             |
| Change in unrealized loss on marketable securities                       | -                   | -                | -                                     | (387,878)                                       | -                              | (387,878)                             |
| Net loss   | -                   | -                | -                                     | -   | (20,705,557)                   | (20,705,557)                          |
| <b>Balance as of September 30, 2015</b>                                  | <b>17,225,662</b>   | <b>\$ 17,226</b> | <b>\$ 281,990,728</b>                 | <b>\$ (387,878)</b>                             | <b>\$ (156,217,629)</b>        | <b>\$ 125,402,447</b>                 |

*See Notes to Condensed Consolidated Financial Statements.*

## Note 1 - Business

### Overview

Assembly Biosciences, Inc. (“Assembly” or the “Company”) is a biopharmaceutical company committed to developing novel oral therapies for the cure of intractable infectious diseases, focusing on the hepatitis B virus (HBV) and C. difficile-associated diarrhea (CDAD). The Company’s HBV-Cure research team is working on discovering and developing multiple core protein allosteric modifiers (CpAMs) with the potential to modulate the HBV core protein - a polyfunctional essential viral protein - at multiple complementary points in the viral lifecycle. The goal is to eradicate the infection with an orally-administered regimen. The Company’s CDAD program is based on the premise that an oral capsule containing specific bacteria grown in monoculture and manufactured under pharmaceutical-like GMP conditions might be effective in providing the therapeutic benefits of fecal microbiota transplant (FMT) therapy in a form that is economically viable and scalable for use.

### 2014 Highlights

Assembly Biosciences was formed on July 11, 2014 by the merger of private company Assembly Pharmaceuticals, Inc. and Nasdaq-listed Ventrus Biosciences, Inc. (the “Merger”). The Merger resulted in a shift in strategic focus, the addition of a new lead drug development program and changes in personnel. In connection with the Merger, the Company’s Board of Directors and stockholders approved a 1-for-5 reverse stock split of the Company’s common stock. The reverse stock split became effective on July 11, 2014. All share and per share amounts in the consolidated financial statements and notes thereto have been retroactively adjusted for all periods presented to give effect to this reverse stock split, including reclassifying an amount equal to the reduction in par value of common stock to additional paid-in capital. In connection with the Merger, the shares of common stock issued and outstanding of Assembly Pharmaceuticals, were converted into an aggregate of 4,008,848 shares of the Company’s common stock. Also pursuant to the terms of the Merger, the outstanding options to purchase shares of Assembly Pharmaceuticals’ common stock were assumed by the Company and became exercisable for an aggregate of 621,651 shares of the Company’s common stock.

The Company accounted for the acquisition of Assembly Pharmaceuticals, Inc. as a business combination under Accounting Standards Codification (“ASC”) 805 with Ventrus Biosciences, Inc. as the accounting acquirer. The Company determined Ventrus Biosciences, Inc. was the accounting acquirer in accordance with ASC 805-10-25-5 as Ventrus Biosciences, Inc. gained control of Assembly Pharmaceuticals, Inc. upon completion of the Merger. To make this determination, the Company considered factors as indicated in ASC 805-10-55, including which entity issued equity interests to effect the combination, board of director composition, shareholder ownership, voting control, restrictions on shareholder voting rights, anticipated management positions and the relative size of the two companies.

On October 6, 2014, the Company sold to various institutional investors an aggregate of 1,959,000 shares of common stock in a registered direct offering. The purchase price paid by the investors was \$8.04 per share and an aggregate of \$15.0 million in net proceeds were received.

### 2015 Highlights

On March 19, 2015, the Company sold to various investors an aggregate of 5,555,555 shares of common stock in a public offering. The purchase price paid by the investors was \$13.50 per share and an aggregate of \$70.4 million (net of underwriters’ discount and equity issuance costs) were received.

On April 6, 2015, the underwriters exercised in full their option to purchase an additional 833,333 shares of common stock at the public offering price of \$13.50 per share, less underwriting discounts and commissions and offering expenses. Proceeds from the sale of shares on the exercise of the underwriters’ option (net of underwriting discounts and commissions) were approximately \$10.6 million.

The Company has not derived any revenue from product sales to date as it currently has no products. Once a product has been developed, it will need to be approved for sale by the FDA or any foreign regulatory agency. Since inception, the Company’s operations have been financed primarily through the sale of equity securities, the proceeds from the exercise of warrants and stock options and issuance of debt. The Company has incurred losses from operations and negative cash flows since inception and expects to continue to incur substantial losses for the next several years as it continues its product development efforts. Management believes the Company currently has sufficient funds to meet its operating requirements for at least the next twelve months. If the Company cannot generate significant cash from its operations, it intends to obtain any additional funding it requires through strategic relationships, public or private equity or debt financings, or other arrangements and it cannot assure such funding will be available on reasonable terms, if at all.

## **Note 2 - Summary of Significant Accounting Policies**

### **Basis of Presentation**

The accompanying condensed consolidated interim financial statements include the accounts of the Company and its subsidiary. All intercompany balances and transactions have been eliminated.

The accompanying condensed consolidated financial statements as of September 30, 2015 and for the three and nine months ended September 30, 2015 and 2014 have been prepared in accordance with the accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and pursuant to the instructions to Form 10-Q and Article 8 of Regulation S-X of the Securities and Exchange Commission ("SEC") and on the same basis as the Company prepares its annual audited consolidated financial statements. The condensed consolidated balance sheet as of September 30, 2015, condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2015 and 2014, the condensed consolidated statements of cash flows for the nine months ended September 30, 2015 and 2014, and condensed consolidated statement of changes in stockholders' equity for the nine months ended September 30, 2015 are unaudited, but include all adjustments, consisting only of normal recurring adjustments, which the Company considers necessary for a fair presentation of the financial position, operating results and cash flows for the periods presented. The results for the three and nine months ended September 30, 2015 are not necessarily indicative of results to be expected for the year ending December 31, 2015 or for any future interim period. The consolidated balance sheet at December 31, 2014 has been derived from audited financial statements; however, it does not include all of the information and notes required by U.S. GAAP for complete financial statements. The accompanying condensed financial statements should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2014, and notes thereto included in the Company's 2014 Annual Report on Form 10-K, as amended, filed on March 16, 2015.

### **Use of Estimates**

The preparation of financial statements in conformity with U.S. 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 revenue and expenses during the reporting period. Actual results could differ from those estimates.

Significant estimates inherent in the preparation of the accompanying financial statements include recoverability and useful lives (indefinite or finite) of intangible assets, assessment of impairment of goodwill, the valuation allowance related to the Company's deferred tax assets, and the fair value of stock options and warrants granted to employees, consultants, directors, investors, licensors, placement agents and underwriters.

The Company's estimates could be affected by external conditions, including those unique to the Company and general economic conditions. It is reasonably possible that these external factors could have an effect on the Company's estimates and could cause actual results to differ from those estimates and assumptions.

### **Reclassification**

Certain reclassifications have been made to prior year amounts to conform to the current year presentation. The Company reclassified certain non-cash activities in the condensed consolidated statements of cash flows to conform to the Assembly Pharmaceutical's final purchase price allocation.

### **Marketable Securities**

The Company has designated marketable securities as of September 30, 2015 as available-for-sale securities and measures these securities at their respective fair values. Marketable securities are classified as short-term or long-term based on the maturity date and their availability to meet current operating requirements. Marketable securities that mature in one year or less are classified as short-term available-for-sale securities and are reported as a component of current assets. Marketable securities that are not considered available for use in current operations are classified as long-term available-for-sale securities and are reported as a component of long-term assets.

Securities that are classified as available-for-sale are measured at fair value with temporary unrealized gains and losses reported in other comprehensive income (loss), and as a component of stockholders' equity until their disposition. The Company reviews all available-for-sale securities at each period end to determine if they remain available-for-sale based on then current intent and ability to sell the security if it is required to do so.

Marketable securities are subject to a periodic impairment review. The Company may recognize an impairment charge when a decline in the fair value of investments below the cost basis is determined to be other-than-temporary.



## Recent Accounting Pronouncements

In the first quarter of 2015, the Company adopted Accounting Standard Update (“ASU”) 2014-08, *Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity* issued by the FASB. ASU 2014-08 changes the definition of a discontinued operation to include only those disposals of components of an entity that represent a strategic shift that has (or will have) a major effect on an entity's operations and financial results (e.g., a disposal of a major geographical area, a major line of business, a major equity method investment or other major parts of an entity). The Company's adoption of ASU 2014-08 did not have a material impact on the Company's condensed consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers*, an updated standard on revenue recognition. ASU 2014-09 provides enhancements to the quality and consistency of how revenue is reported by companies while also improving comparability in the financial statements of companies reporting using International Financial Reporting Standards or GAAP. The main purpose of the new standard is for companies to recognize revenue to depict the transfer of goods or services to customers in amounts that reflect the consideration to which a company expects to be entitled in exchange for those goods or services. The new standard also will result in enhanced disclosures about revenue, provide guidance for transactions that were not previously addressed comprehensively and improve guidance for multiple-element arrangements. In July 2015, the FASB voted to approve a one-year deferral of the effective date of ASU 2014-09, which will be effective for the Company in the first quarter of fiscal year 2018 and may be applied on a full retrospective or modified retrospective approach. This ASU will have no impact on the Company until it begins to generate revenue.

In June 2014, the FASB issued ASU 2014-12, *Compensation-Stock Compensation (Topic 718)*. The ASU clarifies how entities should treat performance targets that can be achieved after the requisite service period of a share-based payment award. The accounting standard is effective for interim and annual periods beginning after December 15, 2015. This ASU will have no impact on the Company until it begins to grant performance awards.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. The guidance, which is effective for annual reporting periods ending after December 15, 2016, with early adoption permitted, extends the responsibility for performing the going-concern assessment to management and contains guidance on how to perform a going-concern assessment and when going-concern disclosures would be required under GAAP. The Company is currently evaluating the impact of this ASU on its condensed consolidated financial statements.

### Note 3 - Assembly Pharmaceuticals, Inc. Transaction

As described in Note 1, on July 11, 2014, the Company completed the Merger, whereby Assembly Pharmaceuticals, Inc. became the Company's wholly-owned subsidiary. Pursuant to the terms of the Merger, the shares of Assembly Pharmaceuticals were converted into an aggregate of 4,008,848 shares of the Company's common stock. Also pursuant to the terms of the Merger, the outstanding options to purchase shares of Assembly Pharmaceuticals were assumed by the Company and an aggregate of 621,651 shares of the Company's common stock were reserved for issuance thereunder.

The allocation of the purchase price is shown below:

|                                     |                      |
|-------------------------------------|----------------------|
| Cash and cash equivalents           | \$ 509,363           |
| Other current assets                | 23,540               |
| Property, plant and equipment, net  | 10,350               |
| In-process research and development | 29,000,000           |
| Goodwill                            | 12,638,136           |
| Security deposits                   | 16,606               |
| <b>Total assets</b>                 | <b>42,197,995</b>    |
| Accrued expenses                    | 774,899              |
| Deferred tax liabilities            | 11,600,000           |
| <b>Total liabilities</b>            | <b>12,374,899</b>    |
| <b>Net assets acquired</b>          | <b>\$ 29,823,096</b> |

The transaction was accounted for using the acquisition method. Accordingly, goodwill has been measured as the excess of the total consideration over the amounts assigned to the identifiable assets acquired and liabilities assumed including the related deferred tax liability. Goodwill is not deductible for tax purposes.

On the acquisition date, the fair value of net assets acquired was \$29,823,096. The fair value of stock issued to the Assembly Pharmaceuticals' shareholders as part of the consideration of \$29,064,148 was based on reference to quoted market values of the Company's common stock as of the date of acquisition. The options assumed in the Merger were valued at \$758,948. As of June 30, 2015, the Company finalized its purchase price allocation. The Company adjusted certain accrued expenses, resulting in a decrease of goodwill and accrued expenses of approximately \$99,000 in the second quarter of 2015.

#### Note 4 - Marketable Securities

Marketable securities consists of the following as of September 30, 2015:

|   | September 30, 2015   |                       |                      |
|---|----------------------|-----------------------|----------------------|
|   | Amortized Cost       | Gross Unrealized Loss | Fair Value           |
| <b>Short-term available-for-sale securities</b> |                      |                       |                      |
| Corporate bonds                                 | \$ 29,582,978        | \$ (186,596)          | \$ 29,396,382        |
|   | <u>29,582,978</u>    | <u>(186,596)</u>      | <u>29,396,382</u>    |
| <b>Long-term available-for-sale securities</b>  |                      |                       |                      |
| Government and agency obligations               | 1,225,000            | -                     | 1,225,000            |
| Corporate bonds                                 | 30,162,389           | (201,282)             | 29,961,107           |
|   | <u>31,387,389</u>    | <u>(201,282)</u>      | <u>31,186,107</u>    |
| <b>Total</b>                                    | <b>\$ 60,970,367</b> | <b>\$ (387,878)</b>   | <b>\$ 60,582,489</b> |

The contractual term to maturity of short-term marketable securities held by the Company as of September 30, 2015 is less than one year. The contractual term to maturity of long-term marketable securities held by the Company as of September 30, 2015 is from 1 to 2 years.

The fair value of marketable securities was classified into fair value measurement categories as follows:

|  |                      |
|--|----------------------|
| Quoted prices in active markets for identical assets (Level 1)           | \$ -                 |
| Quoted prices for similar assets observable in the marketplace (Level 2) | 60,582,489           |
| Significant unobservable inputs (Level 3)                                | -                    |
| Total  | <u>\$ 60,582,489</u> |

The fair values of marketable securities are determined using quoted market prices from daily exchange traded markets based on the closing price as of September 30, 2015 and are classified as Level 2.

#### Note 5 - Goodwill and Intangible Assets

##### Goodwill

Goodwill is not amortized for financial reporting purposes but is tested for impairment on an annual basis or when indications of impairment exist. No goodwill impairment losses have been recognized. Goodwill is not deductible for income tax purposes since the tax basis is \$0. The Company will perform its annual impairment test of the carrying value of the Company's goodwill in the fourth quarter of 2015.

The net book value of goodwill decreased by \$99,214 from December 31, 2014 to September 30, 2015, as a result of the adjustment to purchase price accounting within the measurement period.

##### Intangible Assets

The intangible assets acquired are recorded as indefinite-lived assets and are not amortized for financial reporting purposes until product commercialization but are tested for impairment on an annual basis or when indications of impairment exist. Intangible assets are not deductible for income tax purposes since the tax basis is \$0. The Company will perform its annual impairment test of the carrying value of the Company's intangible assets in the fourth quarter of 2015.

There was no change in intangible assets from December 31, 2014 to September 30, 2015.

#### Note 6 - Property, Plant and Equipment, Net

Property, plant and equipment, consists of the following:

|   | <u>Useful life (Years)</u> | <u>September 30, 2015</u> | <u>December 31, 2014</u> |
|---|----------------------------|---------------------------|--------------------------|
| Computer hardware and software                  | 3                          | \$ 86,792                 | \$ 75,196                |
| Lab equipment                                   | 3 to 5                     | 166,772                   | 130,377                  |
| Office equipment                                | 3 to 5                     | 1,109                     | 1,109                    |
| Total property, plant and equipment             |                            | <u>254,673</u>            | <u>206,682</u>           |
| Less: Accumulated depreciation and amortization |                            | <u>(98,190)</u>           | <u>(50,241)</u>          |
| Property, plant and equipment, net              |                            | <u>\$ 156,483</u>         | <u>\$ 156,441</u>        |

Depreciation expense for the three months ended September 30, 2015 and 2014 was \$17,552 and \$1,602, respectively, and was recorded in both research and development expense and general and administrative expense in the condensed consolidated statements of operations and comprehensive loss.

Depreciation expense for the nine months ended September 30, 2015 and 2014 was \$47,949 and \$3,894, respectively, and was recorded in both research and development expense and general and administrative expense in condensed consolidated statements of operations and comprehensive loss.

#### Note 7 - Accrued Expenses

Accrued expenses consists of the following:

|   | <u>September 30, 2015</u> | <u>December 31, 2014</u> |
|---|---------------------------|--------------------------|
| Accrued expenses:                       |                           |                          |
| Salaries, bonuses and employee benefits | \$ 886,211                | \$ -                     |
| Severance accrued for former CEO        | 234,908                   | -                        |
| Other                                   | 66,111                    | 146,420                  |
| Total accrued expenses                  | <u>\$ 1,187,230</u>       | <u>\$ 146,420</u>        |

#### Note 8 - Stockholders' Equity

##### Equity Financing

On March 19, 2015, the Company sold to various investors an aggregate of 5,555,555 shares of common stock in a public offering. The purchase price paid by the investors was \$13.50 per share and an aggregate of \$70.4 million in net proceeds were received, after deducting underwriting discounts and commissions and estimated offering expenses. In addition, the Company granted the underwriters a 30-day option to purchase up to an additional 833,333 shares of common stock.

On April 6, 2015, the underwriters exercised in full their option to purchase an additional 833,333 shares of common stock at the public offering price of \$13.50 per share, less underwriting discounts and commissions and offering expenses. The closing of the option exercise resulted in net proceeds of approximately \$10.6 million. Exercise of the underwriters' option increased the net proceeds (net of underwriting discounts and commissions) of the public offering, from \$70.4 million to \$81.0 million.

##### Options

The Company has two equity incentive plans available for the granting of equity awards. In July 2010, the stockholders approved the 2010 Equity Incentive Plan, under which, as of September 30, 2015, there were outstanding options for an aggregate of 143,667 shares of common stock and an aggregate of 611,792 shares available for grant. In July 2014, the stockholders approved the 2014 Stock Incentive Plan (the "2014 Plan"), under which, as of September 30, 2015, there were options for an aggregate of 2,479,666 shares of common stock outstanding and 8,245 shares available for grant.

On February 10, 2015, the Company's former Chief Executive Officer, Dr. Russell Ellison, transitioned to service as a consultant. The Company accelerated 266,667 of his options on March 3, 2015 in accordance with the original terms of his employment agreement. The corresponding charge related to these options was also accelerated in the first quarter of 2015. The exercise period for Dr. Ellison's vested options were also extended until the end of their term, or July 9, 2024 in accordance with the original terms of his employment agreement. The remainder of 266,666 unvested options were forfeited in accordance with the original terms of his employment agreement.

A summary of the Company's option activity and related information for the nine-month period ended September 30, 2015 is as follows:

|                                      | Number of Shares | Weighted Average Exercise Price | Total Intrinsic Value |
|--------------------------------------|------------------|---------------------------------|-----------------------|
| Outstanding as of December 31, 2014  | 3,237,851        | \$ 6.26                         | \$ 5,187,924          |
| Granted                              | 377,500          | 14.69                           | -                     |
| Exercised                            | (76,422)         | 7.25                            | 91,942                |
| Forfeited                            | (293,945)        | 7.26                            | -                     |
| Outstanding as of September 30, 2015 | 3,244,984        | \$ 7.13                         | \$ 9,824,224          |
| Options vested and exercisable       | 2,023,713        | \$ 6.32                         | \$ 6,638,359          |

The fair value of the options granted for the nine-month periods ended September 30, 2015 and 2014, were based on the following assumptions:

|                                 | Nine Months Ended September 30, |                   |
|---------------------------------|---------------------------------|-------------------|
|                                 | 2015                            | 2014              |
| Exercise price                  | \$ 9.42 - \$16.55               | \$ 2.22 - \$15.75 |
| Expected stock price volatility | 89.18% - 95.55%                 | 97.3% - 105.0%    |
| Risk-free rate of interest      | 1.49% - 2.08%                   | 1.66% - 2.57%     |
| Term (years)                    | 5.13 - 6.97                     | 4.9 - 10.0        |

Estimated future stock-based compensation expense relating to unvested stock options is as follows:

|                         | Future Stock Option Compensation Expense |
|-------------------------|--|
| Three months ended 2015 | \$ 1,295,040                             |
| 2016                    | 2,767,874                                |
| 2017                    | 695,674                                  |
| 2018                    | 231,236                                  |
| 2019                    | 46,968                                   |
| Total                   | \$ 5,036,792                             |

The weighted average remaining contractual life of options outstanding at September 30, 2015 is approximately 8.9 years.

Stock-based compensation expense for the three and nine months ended September 30, 2015 and 2014 are as follows:

|  | Three Months Ended September 30, |              | Nine Months Ended September 30, |              |
|--|----------------------------------|--------------|---------------------------------|--------------|
|  | 2015                             | 2014         | 2015                            | 2014         |
| Research and development               | \$ 148,963                       | \$ 1,926,473 | \$ 2,624,265                    | \$ 2,000,449 |
| General and administrative             | 1,000,466                        | 5,508,048    | 3,731,188                       | 6,001,584    |
| Total stock-based compensation expense | \$ 1,149,429                     | \$ 7,434,521 | \$ 6,355,453                    | \$ 8,002,033 |

## Warrants

On April 17, 2015, the Company issued an aggregate of 88,293 shares of common stock from the cashless exercise of 120,265 warrants. The Company did not receive any proceeds from this cashless exercise.

During the nine months ended September 30, 2015, 94,147 warrants to purchase common stock expired.

The following is a summary of warrant activity for the nine months ended September 30, 2015:

|                                      | <b>Warrants</b> | <b>Weighted Average<br/>Exercise Price</b> |
|--------------------------------------|-----------------|--|
| Outstanding as of December 31, 2014  | 270,761         | \$ 24.34                                   |
| Expired                              | (94,147)        | -  |
| Exercised                            | (120,265)       | -  |
| Outstanding as of September 30, 2015 | <u>56,349</u>   | <u>\$ 35.49</u>                            |

The weighted average remaining contractual life of outstanding warrants at September 30, 2015 is approximately 1.6 years.

### Loss per Common Share

Basic net loss per common share excludes dilution and is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per common share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the entity unless inclusion of such shares would be anti-dilutive. Since the Company has only incurred losses, basic and diluted net loss per share is the same. Securities that could potentially dilute earnings per share in the future that were not included in the computation of diluted loss per share for the nine months ended September 30, 2015 and 2014 are as follows:

|                                   | <b>Nine Months Ended September 30,</b> |                         |
|-----------------------------------|--|-------------------------|
|                                   | <b>2015</b>                            | <b>2014</b>             |
| Warrants to purchase common stock | 56,349                                 | 271,501                 |
| Options to purchase common stock  | 3,244,984                              | 3,199,651               |
| <b>Total</b>                      | <b><u>3,301,333</u></b>                | <b><u>3,471,152</u></b> |

### Note 9 - Commitments

#### *Real Property Leases*

The Company leases office space in New York, NY under an agreement with a monthly lease payment of \$10,130 that expires in August 2016. The Company also subleases approximately 6,286 square feet (subject to increase up to an aggregate of approximately 10,794 square feet) of office and laboratory space in San Francisco, CA under a sublease agreement that expires in December 2017, for monthly payments ranging from \$44,316 to \$82,142 based on the total square footage of the subleased premises. Additionally, the Company leases approximately 4,534 square feet of office space in Carmel, IN under a lease agreement that expires in June 2021, for monthly payments ranging from \$5,042 to \$9,257.

#### *Equipment Lease*

Pursuant to a Master Lease agreement dated November 25, 2014, the Company is leasing certain laboratory equipment. The equipment lease expense for the three months and nine months ended September 30, 2015 amounted to \$70,414 and \$171,225, respectively.

#### *Employment Agreements*

The Company has employment agreements with its Chief Executive Officer and Chief Financial Officer/Chief Operating Officer which provide for an aggregate annual salary of approximately \$780,500 in 2015.

### Note 10 - Legal Proceedings

The Company is not a party to any legal proceedings and is not aware of any claims or actions pending or threatened against it. In the future, the Company might from time to time become involved in litigation relating to claims arising from ordinary course of business.

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

*The interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2014, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K, as amended, for the year ended December 31, 2014 filed on March 16, 2015. In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements are subject to risks and uncertainties, including those set forth under "Part I. Item 1. Business - Risk Factors" in our Annual Report on Form 10-K, as amended, for the year ended December 31, 2014, and elsewhere in this report, that could cause actual results to differ materially from historical results or anticipated results.*

### Overview

We are a biopharmaceutical company committed to developing novel oral therapies for the cure of intractable infectious diseases, focusing on direct-acting anti-virals for the hepatitis B virus (HBV) and microbiome-based therapeutics for *C. difficile*-associated diarrhea (CDAD). On July 11, 2014, Assembly Biosciences was formed through the merger of private company Assembly Pharmaceuticals, Inc. and Nasdaq-listed Ventrus Biosciences, Inc. (the "Merger"). The Merger resulted in a shift in strategic focus, the addition of a new lead drug development program for the company, and changes in personnel.

Assembly's antiviral program aims to achieve a clinical cure for chronic hepatitis B virus infection (HBV), which affects hundreds of millions of people worldwide. We are developing a series of novel agents that modulate HBV core protein, which is associated with functions that are essential for HBV survival and persistence. These core protein allosteric modulators, or CpAMs, have the potential to eliminate HBV by modulating core protein at multiple complementary points in the viral lifecycle.

Our microbiome program is initially focused on developing curative treatments for resistant *C. difficile* infections (CDI) using our proprietary Gemice1™ technology for targeted delivery to specific regions of the gastrointestinal, or GI tract. Gemice1's novel coating and encapsulation technology enables oral delivery of a wide range of biologic and small molecule agents, and it is easy and cost-effective to scale-up and manufacture. We are currently developing this unique platform to deliver beneficial bacteria in novel "synthetic" formats to cure resistant CDI.

We currently have administrative offices in New York City and research facilities in San Francisco. Research activities for the HBV program are also being conducted at Indiana University at Bloomington, under the direction of Adam Zlotnick, PhD, Assembly co-founder and head of our HBV Scientific Advisory Board.

Since our inception, we have had no revenue from product sales, and have funded our operations principally through debt financings prior to our initial public offering in 2010 and through equity financings since then. Our operations to date have been primarily limited to organizing and staffing our company, licensing our product candidates, developing clinical trials for our product candidates, establishing manufacturing for our product candidates, maintaining and improving our patent portfolio and raising capital. We have generated significant losses to date, and we expect to continue to generate losses as we develop our product candidates. As of September 30, 2015, we had an accumulated deficit of \$156,217,629 and accumulated other comprehensive loss of \$387,878. Because we do not generate revenue from any of our product candidates, our losses will continue as we seek regulatory approval and commercialization of our product candidates. As a result, our operating losses are likely to be substantial over the next several years as we continue the development of our product candidates and thereafter if none is approved or successfully launched. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

We believe that our existing cash will be sufficient to fund our projected operating requirements for at least the next twelve months.

Our operations are subject to other certain risks and uncertainties, including but not limited to: uncertainty of product candidate development; uncertainty of regulatory approval; unpredictability of the size of the markets for, and market acceptance of, any of our products; our anticipated capital expenditures, our estimates regarding our capital requirements; our ability to retain and hire necessary employees and to staff our operations appropriately; and the possible impairment of, or inability to obtain, intellectual property rights and the costs of obtaining such rights from third parties. Any significant delays in the development or marketing of products could have material adverse effect on our business and financial results.

## Recent Events

### *Management Changes*

In February 2015, Derek Small was named Chief Executive Officer, in addition to his position as President; current director William Ringo was named non-executive Chairman of our Board of Directors; and David J. Barrett was named Chief Operating Officer, in addition to his role as Chief Financial Officer. As had been agreed during the Merger establishing Assembly Biosciences last year, Mr. Small succeeded Russell H. Ellison, MD, as CEO. In addition, Mr. Ringo succeeded Dr. Ellison as Chairman. Dr. Ellison continues to serve the Company as a Senior Advisor and head of Assembly's microbiome development program as the Company approaches several key milestones. The succession constitutes a "termination without cause" under Dr. Ellison's employment agreement. As a result, Dr. Ellison was entitled to 12 months of salary, immediate vesting of one third of his outstanding options and an extension of the exercise period to the option expiration date of July 10, 2024, and reimbursement of COBRA premiums for 12 months or until he is eligible for insurance benefits from another employer, whichever is earlier.

### *Equity Financing*

On March 19, 2015, we sold to various investors an aggregate of 5,555,555 shares of common stock in a public offering. The purchase price paid by the investors was \$13.50 per share and an aggregate of \$70.4 million in net proceeds (net of underwriting discounts and commissions) were received. In addition, we granted the underwriters a 30-day option to purchase up to an additional 833,333 shares of common stock.

On April 6, 2015, the underwriters exercised in full their option to purchase an additional 833,333 shares of our common stock at the public offering price of \$13.50 per share, less underwriting discounts and commissions and offering expenses. The closing of the option exercise resulted in net proceeds to us of \$10.6 million. Exercise of the underwriters' option increased the net proceeds to us of the public offering, after any underwriting discounts and commissions and estimated offering expenses, from \$70.4 million to \$81.0 million.

## Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect our reported amounts of assets, liabilities, revenues, and expenses.

On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We based our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the reported amounts of revenues and expenses that are not readily apparent from other sources. Actual results may differ from these estimates.

Our critical accounting policies and significant estimates are detailed in our Annual Report on Form 10-K for the year ended December 31, 2014. Our critical accounting policies and significant estimates have not changed from those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014.

### *Off-Balance Sheet Arrangements*

Since our inception, we have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities, or variable interest entities.

## Results of Operations

### *Comparison of the Three Months Ended September 30, 2015 and 2014*

#### *Research and Development Expense*

Research and development expense, excluding stock-based compensation expense, was \$4,481,185 for the three months ended September 30, 2015, an increase of \$2,735,675 or 157%, from \$1,745,510 for the same period in 2014. The reason for the increase was primarily due to an increase of \$1,493,272 in research expenses for our HBV program, which started in July 2014, and an increase of 1,652,850 in research expenses for our Microbiome program, offset by a decrease of approximately \$410,447 due to termination of the VEN 307 study in the second quarter of 2014.

Stock-based compensation was \$148,963 for the three months ended September 30, 2015, a decrease of \$1,777,510 or 92%, from \$1,926,473 for the same period in 2014.

#### *General and Administrative Expense*

General and administrative expense consists primarily of salaries, consulting fees and other related costs, professional fees for legal services and accounting services, insurance and travel expenses, as well as the stock based compensation expense associated with equity awards to our employees, consultants, and directors.

General and administrative expense, excluding stock-based compensation expense, was \$1,491,612 for the three months ended September 30, 2015, a decrease of \$383,797 or 20% from \$1,875,409 for the three months ended September 30, 2014. The reason for the decrease was primarily due to a decrease in consulting expenses.

Stock-based compensation expense was \$1,000,466 for the three months ended September 30, 2015, a decrease of \$4,507,582 or 82%, from \$5,508,048 for the same period in 2014.

### ***Comparison of the Nine Months Ended September 30, 2015 and 2014***

#### *Research and Development Expense*

Research and development expense, excluding stock-based compensation expense, was \$10,508,071 for the nine months ended September 30, 2015, an increase of \$4,767,203 or 83%, from \$5,740,868 for the same period in 2014. The increase was primarily due to an increase of \$5,863,298 in research expenses for our HBV which was started in July 2014, an increase of approximately \$2,830,079 for Microbiome study and offset by a decrease of approximately \$3,926,174 due to termination of the VEN 307 study in the second quarter of 2014.

Stock-based compensation was \$2,624,265 for the nine months ended September 30, 2015, an increase of \$623,816 or 31%, from \$2,000,449 for the same period in 2014.

#### *General and Administrative Expense*

General and administrative expense consists primarily of salaries, consulting fees and other related costs, professional fees for legal services and accounting services, insurance and travel expenses, as well as the stock based compensation expense associated with equity awards to our employees, consultants, and directors.

General and administrative expense, excluding stock-based compensation expense, was \$4,615,825 for the nine months ended September 30, 2015, an increase of \$686,991 or 17% from \$3,928,834 for the nine months ended September 30, 2014. The reason for the increase was primarily due to an increase in employees' benefits and bonus and an increase in consulting, legal and accounting expenses.

Stock-based compensation expense was \$3,731,188 for the nine months ended September 30, 2015, a decrease of \$2,270,396 or 38%, from \$6,001,584 for the same period in 2014.

### **Liquidity and Capital Resources**

#### Sources of Liquidity

As a result of our significant research and development expenditures and the lack of any FDA-approved products to generate product sales revenue, we have not been profitable and have generated operating losses since we were incorporated in October 2005. We have funded our operations through September 30, 2015 principally with convertible debt and equity financing.

On March 19, 2015, we sold to various investors an aggregate of 5,555,555 shares of common stock in a public offering. The purchase price paid by the investors was \$13.50 per share and an aggregate of \$70.4 million in net proceeds were received. In addition, we had granted the underwriters a 30-day option to purchase up to an additional 833,333 shares of common stock.

On April 6, 2015, the underwriters exercised in full their option to purchase an additional 833,333 shares of our common stock at the public offering price of \$13.50 per share, less underwriting discounts and commissions and offering expenses. The closing of the option exercise resulted in net proceeds (net of underwriters' discount) to us of \$10.6 million.

Net cash used in operating activities was \$13,242,134 for the nine months ended September 30, 2015. The use of cash in operating activities was primarily due to the loss (expenses) occurred during the nine months ended September 30, 2015 of \$20,705,557, offset by stock-based compensation expenses of \$6,355,453 and increase in accounts payable and accrued expenses of \$1,696,762.

Net cash used in investing activities was \$61,016,749 mostly due to the purchase of marketable securities during the nine months ended September 30, 2015.

Net cash provided by financing activities was \$81,569,257 for the nine months ended September 30, 2015. On March 19, 2015, we received net proceeds of approximately \$70.5 million in an underwritten equity offering. On April 6, 2015, we received additional net proceeds of \$10.6 million from the exercise of underwriters' option to purchase additional shares. On April 20, 2015, we paid \$0.1 million in accrued offering costs.



## Funding Requirements

We expect to incur losses for at least the next several years as we develop our product pipeline. We expect to incur increasing research and development expenses as we begin preclinical and clinical activities on both platform technologies. We expect that our general and administrative expenses will also increase as we add infrastructure related to the Merger with Assembly Pharmaceuticals. Our future capital requirements will depend on a number of factors, including the timing and outcome of preclinical activities, clinical trials and regulatory approvals, the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims and other intellectual property rights, the acquisition of licenses to new products or compounds, the status of competitive products, and the availability of financing.

Based on our cash position at September 30, 2015 and our analysis of our future development costs, we believe that our existing cash and cash equivalents will be sufficient to enable us to fund our operating expenses and capital expenditure requirements for at least twelve months. We have based these estimates on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect, which would cause us to require additional capital earlier. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated preclinical and clinical activities. We will need to raise additional funds to continue and finalize the development of our product candidates.

We may need to finance our future cash needs through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements, or a bank credit facility or other financing vehicle if one or more of our assumptions prove to be incorrect or if we choose to expand our product development efforts more rapidly than we presently anticipate, and we may decide to raise additional funds even before we need them if the conditions for raising capital are favorable. We do not currently have any commitments for future external funding. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations.

Additional financing might not be available on acceptable terms, if at all. If we need additional capital and adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our planned commercialization efforts, or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently.

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

There have been no material changes to our quantitative and qualitative disclosures about market risk as compared to the quantitative and qualitative disclosures about market risk described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014.

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

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

We maintain a system of disclosure controls and procedures, as defined in Exchange Act Rules 13a-15(e) and 15d-15(e), which is designed to provide reasonable assurance that information, which is required to be disclosed in our reports filed pursuant to the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), is accumulated and communicated to management in a timely manner. At the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15(b). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective at the reasonable assurance level.

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

There were no changes in our internal control over financial reporting in the third quarter of 2015 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II - OTHER INFORMATION**

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

We are not a party to any material legal proceedings and we are not aware of any claims or actions pending or threatened against us. In the future, we might from time to time become involved in litigation relating to claims arising from our ordinary course of business.

**Item 1A. Risk Factors.**

There have been no changes that constitute a material change from the risk factors previously disclosed in our 2014 Annual Report on Form 10-K filed on March 12, 2015, and amended on March 16, 2015.

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

None.

**Item 3. Defaults upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

Not applicable.

**Item 6. Exhibits**

| <b>Exhibit Number</b> | <b>Description of Document</b>  | <b>Filed Herewith</b> |
|-----------------------|---|-----------------------|
| 31.1                  | Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | X                     |
| 31.2                  | Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | X                     |
| 32.1                  | Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | X                     |
| 32.2                  | Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | X                     |
| 101                   | Financials in XBRL format.  | X                     |

**SIGNATURES**

In accordance with the requirements of the Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**Assembly Biosciences, Inc.**

Date: November 9, 2015

By: /s/ Derek Small  
Derek Small  
President and Chief Executive Officer

Date: November 9, 2015

By: /s/ David J. Barrett  
David J. Barrett  
Chief Financial Officer and Chief Operating Officer

## CERTIFICATION

I, Derek Small, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Assembly Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2015

By: /s/ Derek Small  
Derek Small  
President and Chief Executive Officer

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## CERTIFICATION

I, David J. Barrett, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Assembly Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2015

By: /s/ David J. Barrett  
David J. Barrett  
Chief Financial Officer and Chief Operating Officer

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

In connection with the Quarterly Report on Form 10-Q of Assembly Biosciences, Inc. (the "Company") for the period ended September 30, 2015 as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, Derek Small, Chief Executive Officer, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

/s/ Derek Small  
Derek Small  
President and Chief Executive Officer

November 9, 2015

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

In connection with the Quarterly Report on Form 10-Q of Assembly Biosciences, Inc. (the "Company") for the period ended September 30, 2015 as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, David J. Barrett, Chief Financial Officer, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

/s/ David J. Barrett

David J. Barrett

Chief Financial Officer and Chief Operating Officer

November 9, 2015

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