

Sevion Therapeutics, Inc.  
Form 10-Q  
November 14, 2014

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 10-Q**

(Mark One)

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

**For the quarterly period ended September 30, 2014**

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. 001-31326

**SEVION THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**84-1368850**

(IRS Employer Identification No.)

**721 Route 202/206, Suite 130**

**Bridgewater, NJ 08807**

(Address of principal executive offices)

**(908) 864-4444**

(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 definitions of "accelerated filer", "large accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐

Non-accelerated filer ☐ Smaller reporting company ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes: ☐ No: ☒

13,866,627 shares of the issuer's common stock, par value \$0.01 per share, were outstanding as of October 31, 2014.

SEVION THERAPEUTICS, INC. AND SUBSIDIARIES

TABLE OF CONTENTS

|  | Page |
|--|------|
| <u>PART I. FINANCIAL INFORMATION</u>   |      |
| Item 1. <u>Financial Statements (Unaudited)</u>  | 1    |
| <u>CONDENSED CONSOLIDATED BALANCE SHEETS</u><br><u>as of September 30, 2014 and June 30, 2014</u>  | 2    |
| <u>CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS</u><br><u>For the Three Months Ended September 30, 2014 and 2013</u> | 3    |
| <u>CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY</u><br><u>For the Three Months Ended September 30, 2014</u>                        | 4    |
| <u>CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS</u><br><u>For the Three Months Ended September 30, 2014 and 2013</u>                        | 5    |
| <u>NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS</u>  | 6    |
| Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>   | 11   |
| <u>Overview</u>  | 11   |
| <u>Liquidity and Capital Resources</u>   | 16   |
| <u>Changes to Critical Accounting Policies and Estimates</u>   | 16   |
| <u>Results of Operations</u>   | 17   |
| <u>Off-Balance Sheet Arrangements</u>  | 19   |
| Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>  | 20   |
| Item 4. <u>Controls and Procedures</u>   | 20   |
| <u>PART II. OTHER INFORMATION</u>  |      |
| Item 1. <u>Legal Proceedings</u>   | 21   |
| Item 1A. <u>Risk Factors</u>   | 21   |

Edgar Filing: Sevion Therapeutics, Inc. - Form 10-Q

|         |  |    |
|---------|--|----|
| Item 2. | <u>Unregistered Sales of Equity Securities and Use of Proceeds</u> | 37 |
| Item 3. | <u>Defaults Upon Senior Securities</u>                             | 37 |
| Item 4. | <u>Mine Safety Disclosures</u>                                     | 37 |
| Item 5. | <u>Other Information</u>   | 37 |
| Item 6. | <u>Exhibits</u>  | 37 |
|         | <u>SIGNATURES</u>  | 38 |

**PART I. FINANCIAL INFORMATION.**

**Item 1. Financial Statements (Unaudited).**

Certain information and footnote disclosures required under United States generally accepted accounting principles have been condensed or omitted from the following consolidated financial statements pursuant to the rules and regulations of the Securities and Exchange Commission. However, Sevion Therapeutics, Inc., a Delaware corporation, and its wholly owned subsidiaries, Senesco, Inc., a New Jersey corporation and Fabrus, Inc., a Delaware corporation (collectively, “Sevion” or the “Company”), believe that the disclosures are adequate to assure that the information presented is not misleading in any material respect.

The results of operations for the interim periods presented herein are not necessarily indicative of the results to be expected for the entire fiscal year.

**SEVION THERAPEUTICS, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED BALANCE SHEETS****(unaudited)**

|   | September 30,<br>2014 | June 30,<br>2014     |
|---|-----------------------|----------------------|
| <b><u>ASSETS</u></b>  |                       |                      |
| <b>CURRENT ASSETS:</b>  |                       |                      |
| Cash and cash equivalents   | \$ 3,837,139          | \$ 6,111,340         |
| Accounts receivable   | 43,133                | 43,133               |
| Prepaid research supplies and expenses  | 163,147               | 1,069,925            |
| Total Current Assets  | 4,043,419             | 7,224,398            |
| Equipment, furniture and fixtures, net  | 262,633               | 223,475              |
| Patent costs, net   | 123,531               | 2,178,867            |
| Acquired research and development   | 9,800,000             | 9,800,000            |
| Goodwill  | 13,902,917            | 13,902,917           |
| Security deposit  | 5,171                 | 5,171                |
| <b>TOTAL ASSETS</b>   | <b>\$ 28,137,671</b>  | <b>\$ 33,334,828</b> |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>                                       |                       |                      |
| <b>CURRENT LIABILITIES:</b>   |                       |                      |
| Accounts payable  | \$ 613,020            | \$ 901,180           |
| Accrued expenses  | 1,074,168             | 923,991              |
| Total Current Liabilities   | 1,687,188             | 1,825,171            |
| Deferred tax liability  | 3,920,000             | 3,920,000            |
| Other liabilities   | 99,728                | 99,728               |
| <b>TOTAL LIABILITIES</b>  | <b>5,706,916</b>      | <b>5,844,899</b>     |
| <b>COMMITMENTS</b>  |                       |                      |
| <b>STOCKHOLDERS' EQUITY:</b>  |                       |                      |
| Convertible preferred stock, \$0.01 par value, authorized 5,000,000 shares        |                       |                      |
| Series A 10,297 shares issued and 580 and 580 shares outstanding, respectively    | 6                     | 6                    |
| (liquidation preference of \$609,000 and \$594,500 at September 30, 2014 and June |                       |                      |

Edgar Filing: Sevion Therapeutics, Inc. - Form 10-Q

30, 2014, respectively)

Common stock, \$0.01 par value, authorized 500,000,000 shares, issued and outstanding 13,846,361 and 13,846,361, respectively

Capital in excess of par

Accumulated deficit

|               |               |
|---------------|---------------|
| 138,463       | 138,463       |
| 115,770,859   | 115,631,726   |
| (93,478,573 ) | (88,280,266 ) |

Total Stockholders' Equity

|            |            |
|------------|------------|
| 22,430,755 | 27,489,929 |
|------------|------------|

TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY

|               |              |
|---------------|--------------|
| \$ 28,137,671 | \$33,334,828 |
|---------------|--------------|

See Notes to Condensed Consolidated Financial Statements

**SEVION THERAPEUTICS, INC. AND SUBSIDIARIES**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

**(unaudited)**

|  | Three Months Ended September 30, |                 |
|--|----------------------------------|-----------------|
|  | 2014                             | 2013            |
| Licensing Revenue  | \$ -                             | \$ 100,000      |
| Operating expenses:  |                                  |                 |
| General and administrative   | 774,600                          | 856,631         |
| Research and development   | 2,120,156                        | 810,937         |
| Write-off of patents   | 2,290,836                        | 185,161         |
| Total operating expenses   | 5,185,592                        | 1,852,729       |
| Loss from operations   | (5,185,592 )                     | (1,752,729 )    |
| Interest expense - net   | 1,785                            | (31,604 )       |
| Net loss   | (5,183,807 )                     | (1,784,333 )    |
| Preferred dividends  | (14,500 )                        | (21,623 )       |
| Loss applicable to common shares                                       | (5,198,307 )                     | (1,805,956 )    |
| Other comprehensive loss   | -                                | -               |
| Comprehensive loss   | \$ (5,198,307 )                  | \$ (1,805,956 ) |
| Basic and diluted net loss per common share                            | \$ (0.38 )                       | \$ (0.78 )      |
| Basic and diluted weighted-average number of common shares outstanding | 13,846,361                       | 2,307,926       |

See Notes to Condensed Consolidated Financial Statements

**SEVION THERAPEUTICS, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY****FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2014****(unaudited)**

|  | Preferred Stock |        | Common Stock |            | Capital in Excess of Par Value | Accumulated Deficit | Stockholders' Equity |
|--|-----------------|--------|--------------|------------|--------------------------------|---------------------|----------------------|
|  | Shares          | Amount | Shares       | Amount     |                                |                     |                      |
| Balance at June 30, 2014                           | 580             | \$ 6   | 13,846,361   | \$ 138,463 | \$ 115,631,726                 | \$(88,280,266)      | \$ 27,489,929        |
| Stock-based compensation                           | -               | -      | -            | -          | 139,133                        | -                   | 139,133              |
| Dividends accrued and unpaid at September 30, 2014 | -               | -      | -            | -          | -                              | (14,500 )           | (14,500 )            |
| Net loss   | -               | -      | -            | -          | -                              | (5,183,807 )        | (5,183,807 )         |
| Balance at September 30, 2014                      | 580             | \$ 6   | 13,846,361   | \$ 138,463 | \$ 115,770,859                 | \$(93,478,573)      | \$ 22,430,755        |

See Notes to Condensed Consolidated Financial Statements

**SEVION THERAPEUTICS, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(unaudited)**

|   | Three Months Ended September<br>30, |                 |
|---|-------------------------------------|-----------------|
|   | 2014                                | 2013            |
| Cash flows from operating activities:   |                                     |                 |
| Net loss  | \$ (5,183,807 )                     | \$ (1,784,333 ) |
| Adjustments to reconcile net loss to net cash used in operating activities:                   |                                     |                 |
| Stock-based compensation expense  | 139,133                             | 124,466         |
| Depreciation and amortization   | 60,146                              | 74,793          |
| Write-off of intangibles  | 2,290,836                           | 185,161         |
| Write-off of prepaid research supplies  | 669,750                             | -               |
| (Increase) decrease in operating assets:  |                                     |                 |
| Prepaid expenses and other current assets   | 237,028                             | 352,705         |
| Increase (decrease) in operating liabilities:   |                                     |                 |
| Accounts payable  | (288,160 )                          | 366,504         |
| Accrued expenses  | 135,677                             | 10,239          |
| Net cash used in operating activities   | (1,939,397 )                        | (670,465 )      |
| Cash flows from investing activities:   |                                     |                 |
| Capitalized Patent costs  | (260,477 )                          | (142,943 )      |
| Purchase of equipment, furniture and fixtures   | (74,327 )                           | -               |
| Net cash used in investing activities   | (334,804 )                          | (142,943 )      |
| Cash flows from financing activities:   |                                     |                 |
| Proceeds from issuance of common stock and warrants, net and exercise of warrants and options | -                                   | 290             |
| Net cash provided by financing activities   | -                                   | 290             |
| Net (decrease) increase in cash and cash equivalents  | (2,274,201 )                        | (813,118 )      |
| Cash and cash equivalents at beginning of period  | 6,111,340                           | 1,602,294       |
| Cash and cash equivalents at end of period  | \$ 3,837,139                        | \$ 789,176      |
| Supplemental disclosure of non-cash transactions:   |                                     |                 |
| Conversion of preferred stock into common stock   | \$ -                                | \$ 73,331       |
| Issuance of common stock for dividend payments on preferred stock                             | \$ -                                | \$ 12,623       |
| Dividends accrued on preferred stock  | \$ 14,500                           | \$ 9,000        |
| Supplemental disclosure of cash flow information:   |                                     |                 |
| Cash paid for interest  | \$ 543                              | \$ 32,197       |

See Notes to Condensed Consolidated Financial Statements



SEVION THERAPUETICS, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

**Note 1 - Basis of Presentation:**

The financial statements included herein have been prepared by Sevion Therapeutics, Inc. (the “Company”), without audit, pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements prepared in accordance with United States generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the fiscal year ended June 30, 2014.

On September 29, 2014, the Company changed its name from Senesco Technologies, Inc. to Sevion Therapeutics, Inc.

In the opinion of the Company’s management, the accompanying unaudited condensed consolidated financial statements contain all adjustments, consisting solely of those which are of a normal recurring nature, necessary to present fairly its financial position as of September 30, 2014 and the results of its operations for the three months ended September 30, 2014 and cash flows for the three months ended September 30, 2014.

Certain prior year amounts have been reclassified from general and administrative expenses to research and development expenses for consistency with the current period presentation. These reclassifications had no effect on the reported results of operations or cash flows from operations in the Consolidated Condensed Statement of Cash Flows, and had no effect on the previously reported Consolidated Condensed Statement of Operations for any period.

Interim results are not necessarily indicative of results for the full fiscal year.

**Note 2 – Liquidity:**

As shown in the accompanying condensed consolidated financial statements, the Company has a history of losses with an accumulated deficit of \$93,478,573 and has generated minimal revenues by licensing its technology for certain crops to companies willing to share in its development costs. In addition, the Company's technology may not be ready for commercialization for several years. The Company expects to continue to incur losses for the next several years because it anticipates that its expenditures on research and development and administrative activities will significantly exceed its revenues during that period. The Company cannot predict when, if ever, it will become profitable.

As of September 30, 2014, the Company had cash and cash equivalents in the amount of \$3,837,139, which consisted of checking accounts and money market funds. The Company estimates that its cash and cash equivalents as of September 30, 2014 will cover its expenses through at least March 31, 2015.

On October 22, 2014, the Company's board of directors decided to suspend all development of the Company's Factor 5A technology based on the Company's limited capital resources and the totality of the safety and efficacy data resulting from our Phase 1b/2a clinical trial. Depending on the Company's future capital resources, possible options for the program are to (i) reformulate the drug to alleviate some of the adverse events observed in the clinical trial and to enhance the efficacy, (ii) partner or sell the program or (iii) discontinue development. The Company's board of directors continues to evaluate the alternatives.

The Company will need additional capital to operate and expand its research program and plans to raise additional capital possibly through the exercise of outstanding warrants, placement of debt instruments, equity instruments or any combination thereof. However, the Company may not be able to obtain adequate funds for its operations when needed or on acceptable terms. If the Company is unable to raise additional funds, it will need to do one or more of the following:

- delay, scale-back or eliminate some or all of its research and product development programs;
- license third parties to develop and commercialize products or technologies that it would otherwise seek to develop and commercialize itself;
- seek strategic alliances or business combinations;
- attempt to sell the Company;
- cease operations; or
- declare bankruptcy.

### Note 3 – Patent Costs:

The Company conducts research and development activities, the cost of which is expensed as incurred, in order to generate patents that can be licensed to third parties in exchange for license fees and royalties. Because the patents are the basis of the Company's future revenue, the patent costs are capitalized. The capitalized patent costs represent the outside legal fees incurred by the Company to submit and undertake all necessary efforts to have such patent applications issued as patents. The Company incurred \$260,477 and \$142,943 of such costs for the three months ended September 30, 2014 and 2013, respectively.

The length of time that it takes for an initial patent application to be approved is generally between four to six years. However, due to the unique nature of each patent application, the actual length of time may vary. If a patent application is denied, the associated cost of that application would be written off. Additionally, should a patent application become impaired during the application process, the Company would write down or write off the associated cost of that patent application.

Issued patents are being amortized over a period of 17 years from inception, the expected economic life of the patent. During the three months ended September 30, 2014 and 2013, the Company recorded amortization expense in the amount of \$24,977 and \$74,270, respectively.

The Company assesses the impairment in value of intangible assets whenever events or circumstances indicate that their carrying value may not be recoverable. Factors the Company considers important which could trigger an impairment review include the following:

- significant negative industry trends;
- significant underutilization of the assets;
- significant changes in how the Company uses the assets or its plans for their use; and
- changes in technology and the appearance of competing technology.

If a triggering event occurs and the Company's review determines that the future undiscounted cash flows related to the asset group will not be sufficient to recover their carrying value, the Company will reduce the carrying values of these assets down to its estimate of fair value and continue amortizing them over their remaining useful lives.

In October 2014, the Company decided to continue to develop our intellectual property only with respect to the human health therapeutic targets and would be reviewing such patents on a patent by patent basis to determine which specific ones to continue to develop. Also, in October 2014, the Company decided to suspend all development of the Factor 5A technology based on the Company's limited capital resources and the totality of the safety and efficacy data resulting from our Phase 1b/2a clinical trial. As the Company is unable to determine if or when the development will be resumed, the Company was unable to determine what the future undiscounted cash flows from these patents could be. Therefore, as of September 30, 2014, the Company determined that carrying value of its patents and patent applications related to Factor 5A were impaired. Accordingly, the Company recorded an impairment of the full carrying value of its patents related to Factor 5A in the amount of \$2,290,836.

Additionally, during the quarter ended September 30, 2014, the Company concluded its Phase 1b /2a clinical trial but did not use all of the material purchased for the clinical trial. As the Company has put the clinical program for this product candidate on hold, the Company wrote-off the cost of the remaining material in the amount of \$669,750 at September 30, 2014.

Note 4 - Loss Per Share:

Basic loss per share is computed by dividing net loss available to common shareholders by the weighted average number of the Company's Common Stock assumed to be outstanding during the period of computation. Diluted earnings per share is computed similar to basic earnings per share except that the denominator is increased to include the number of additional shares of Common Stock that would have been outstanding if the potential shares of Common Stock had been issued and if the additional shares of Common Stock were dilutive.

For all periods presented, basic and diluted loss per share are the same, as any additional Common Stock equivalents would be anti-dilutive. Potentially dilutive shares of Common Stock have been excluded from the calculation of the weighted average number of dilutive shares of Common Stock as follows:

|  | September 30, |         |
|--|---------------|---------|
|  | 2014          | 2013    |
| Common Stock to be issued upon conversion of convertible preferred stock | 290,000       | 193,333 |
| Outstanding warrants   | 7,237,774     | 282,866 |
| Outstanding options  | 970,392       | 277,240 |
| Total potentially dilutive shares of Common Stock                        | 8,498,166     | 753,439 |

Note 5 – Stock-Based Compensation:

The terms and vesting schedules for share-based awards vary by type of grant and the employment status of the grantee. Generally, the awards vest based upon time-based conditions or achievement of specified goals and milestones.

On September 13, 2013, the Company issued 46,780 options that are subject to vesting first based upon specified goals and milestones and then based upon time-based conditions. On the issuance date, such options had an aggregate Black-Scholes value of \$201,154. In September, 2014, the Company and the Company's compensation committee reviewed the specified goals and milestones on an employee by employee basis. Based upon the review, the Company

and the Company's compensation committee determined that, on average, the employees achieved 81% of the target goals. As a result, the Company is recognizing 81% of the aggregate fair value of the options ratably over the time-based vesting period and the remaining 19% of those options were forfeited.

Also, during the three months ended September 30, 2013, the Company issued an additional 26,500 options that are subject to time-based conditions only. On the issuance date, such options had an aggregate Black-Scholes value of \$108,650.

The Company did not issue any options during the three month period ended September 30, 2014.

The fair value of each stock option granted or vesting has been determined using the Black-Scholes model. The material factors incorporated in the Black-Scholes model in estimating the value of the options include the following:

|                             | Three Months Ended September 30, |            |
|-----------------------------|----------------------------------|------------|
|                             | 2014                             | 2013       |
| Risk-free interest rate (1) | -                                | 1.6 - 2.0% |
| Expected volatility(2)      | -                                | 99%        |
| Dividend yield              | -                                | None       |
| Expected life (3)           | -                                | 5.5 - 10.0 |

- (1) Represents the interest rate on a U.S. Treasury security with a maturity date corresponding to that of the option term.
- (2) Estimated volatility was determined based upon the historical volatility of the Company's Common Stock. Expected life for time based stock options was estimated using the "simplified" method, as allowed under the (3) provisions of the Securities and Exchange Commission Staff Accounting Bulletin No. 110. Expected life for performance based stock options was the actual term of the option.

The economic values of the options will depend on the future price of the Company's Common Stock, which cannot be forecast with reasonable accuracy.

Stock option activity under the Company's 2008 Plan and 1998 Plan for the three months ended September 30, 2014 is summarized as follows:

|   | Aggregate | Weighted       | Exercise Price           |
|---|-----------|----------------|--------------------------|
|   | Number    | Average        | Range                    |
|   |           | Exercise Price |                          |
| Outstanding, June 30, 2014                | 979,304   | 9.49           | \$2.65 – \$345.00        |
| Granted                                   | -         | -              | -                        |
| Exercised                                 | -         | -              | -                        |
| Cancelled                                 | (8,912 )  | 5.40           | 5.40                     |
| Expired                                   | -         | -              | -                        |
| Outstanding, September 30, 2014           | 970,392   | \$ 9.52        | <u>\$2.65 - \$345.00</u> |
| Options exercisable at September 30, 2014 | 458,304   | \$ 16.73       |                          |

Edgar Filing: Sevion Therapeutics, Inc. - Form 10-Q

As of September 30, 2014, the aggregate intrinsic value of stock options outstanding was \$0, with a weighted-average remaining term of 8.8 years. The aggregate intrinsic value of stock options exercisable at that same date was \$0, with a weighted-average remaining term of 8.0 years. As of September 30, 2014, the Company has 265,582 shares available for future stock option grants.

Stock-based compensation expense for the three months ended September 30, 2014 and September 30, 2013 amounted to \$139,133 and \$124,466, respectively.

As of September 30, 2014, total stock-based compensation expense not yet recognized related to stock option grants amounted to approximately \$1,137,000, which will be recognized over the next 45 months.

**Note 6 – Income Taxes:**

No provision for income taxes has been made for the three months ended September 30, 2014 and 2013 given the Company's losses in 2014 and 2013 and available net operating loss carryforwards. A benefit has not been recorded as the realization of the net operating losses is not assured and the timing in which the Company can utilize its net operating loss carryforwards in any year or in total may be limited by provisions of the Internal Revenue Code regarding changes in ownership of corporations.

The deferred tax liability in the amount of \$ 3,920,000 was recorded in connection with the related goodwill from the Company's acquisition of Fabrus, Inc. in May 2014.

**Note 7 - Fair Value Measurements:**

The following tables provide the assets and liabilities carried at fair value measured on a recurring basis as of September 30, 2014 and June 30, 2014:

|                           | Carrying<br>Value | Fair Value Measurement at September 30, 2014 |         |         |
|---------------------------|-------------------|--|---------|---------|
|                           |                   | Level 1                                      | Level 2 | Level 3 |
| Assets:                   |                   |  |         |         |
| Cash and cash equivalents | \$3,837,139       | \$ 3,837,139                                 | \$ -    | \$ -    |

|                           | Carrying<br>Value | Fair Value Measurement at June 30, 2014 |         |         |
|---------------------------|-------------------|---|---------|---------|
|                           |                   | Level 1                                 | Level 2 | Level 3 |
| Assets:                   |                   |   |         |         |
| Cash and cash equivalents | \$6,111,340       | \$ 6,111,340                            | \$ -    | \$ -    |

**Note 8 – Recent Accounting Pronouncements**

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

In August 2014, the FASB issued Accounting Standard Update (“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. Under the new guidance, management will be required to assess an entity’s ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. The provisions of this ASU are effective for annual periods beginning after December 15, 2016, and for annual and interim periods thereafter. We are currently evaluating the potential impact that this ASU may have on our financial statements or disclosures.

In June 2014, the FASB issued ASU No. 2014-12, “Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period.” This ASU requires a reporting entity to treat a performance target that affects vesting and that could be achieved after the requisite service period as a performance condition, and apply existing guidance under the Stock Compensation Topic of the ASC as it relates to awards with performance conditions that affect vesting to account for such awards. The provisions of this ASU are effective for interim and annual periods beginning after December 15, 2015. We are currently evaluating the potential impact that this ASU may have on our financial position and results of operations.

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

The following discussion and analysis should be read in conjunction with our condensed consolidated financial statements and the related notes thereto included in this Quarterly Report on Form 10-Q. The discussion and analysis may contain forward-looking statements that are based upon current expectations and entail various risks and uncertainties. Our actual results and the timing of events could differ materially from those anticipated in the forward-looking statements as a result of various factors, including those set forth under "Risk Factors" and elsewhere in this report.

### **Overview**

#### *Our Business*

On September 29, 2014, we changed our name from Senesco Technologies, Inc. to Sevion Therapeutics, Inc.

The primary business of Sevion Therapeutics, Inc., a Delaware corporation incorporated in 1999, and its wholly-owned subsidiaries, Senesco, Inc., a New Jersey corporation incorporated in 1998, and Fabrus, Inc., a Delaware corporation incorporated in 2011, collectively referred to as "Sevion," "we," "us" or "our," is to discover, develop and acquire innovative product candidates for the treatment of cancer and immunological diseases by utilizing our patented and patent-pending technology related to antibody genes, antibody discovery technology, modified cow antibodies, and antibody drug candidates, and certain genes, primarily eukaryotic translation initiation Factor 5A, or Factor 5A..

### **Antibody Technology**

*Antibody Genes* - We believe our antibody platforms have broad applicability to human health by allowing the discovery of unique monoclonal antibodies against difficult membrane targets in several therapeutic areas. Our antibody therapeutic candidates target the Kv1.3 ion channel, which is important in the pathogenesis of several autoimmune and inflammatory disorders. Other antibodies in our pipeline target important cell surface molecules involved in cancer progression.

*Antibody Discovery Technology* - Traditional antibody drug discovery methods, such as phage/yeast display or immunization, rely on competitive selection from a pool of antibodies to identify a lead therapeutic candidate. In these methods, a mixture of antibodies compete for binding to a purified target, and the antibody molecules that bind the strongest to the target, referred to as high affinity, are ultimately discovered. While these approaches have led to many successful antibody therapeutics, there are at least two drawbacks. First, the drug targets have been limited to only those proteins which can be easily purified. Many important target classes, including multispinning membrane proteins, cannot be easily purified in functional form. Secondly, when discovery is driven by selection based on competitive binding and affinity, the result is a significant limitation in the number of functional lead antibodies. However, the highest affinity antibody isn't always the best therapeutic because lower affinity molecules may have unique activities or lower toxicities than the highest affinity binder. Thus, modulating a pathway more subtly to treat disease is often preferable to affecting it in a binary fashion through competition related to high-affinity binding. We believe the technology to identify (i) antibodies against unpurified targets, particularly multispinning membrane proteins like G Protein Coupled Receptors, or GPCR's, and ion channels, and (ii) a range of antibodies with different affinities and activities will enable us to discover new antibody drug leads compared to existing technologies.

We have developed the world's first "spatially addressed" antibody library with an expansive combinatorial collection of recombinant antibodies in which each well contains a single species of antibody of known concentration, composition and sequence. Our spatially addressed library allows us to evaluate the therapeutic potential of each antibody individually in a non-competitive way and allows direct discovery on the cell surface. This approach is more analogous to traditional small molecule drug discovery and allows us to screen antibodies for functional drug activity as opposed to simple binding properties. This next generation discovery system unlocks epitopes, targets, and functions that are only identifiable in the context of a living cell.

*Modified Cow Antibodies* - Despite the enormous diversity of the antibody repertoire, human antibodies all have a similar geometry, shape and binding mode. Our scientists have discovered and humanized a novel class of therapeutic antibodies derived from cows that have a highly unusual structure for binding targets. This unique ultralong Complementary Determining Region 3, or CDR3, structural domain found in cow antibodies is comprised of a knob on a stalk that protrudes far from the antibody surface, creating the potential for entirely new types of therapeutic functionality. Using both our humanized spatially addressed antibody library and direct engineering of the knob, we are exploring the ability of utilizing the knob and stalk structure to functionally interact with important therapeutic targets, including GPCRs, ion channels and other multispansing membrane therapeutic targets on the cell surface. Our lead antibody, SVN001, was derived from these efforts.

*Antibody Drug Candidates* – We have created functional antibodies that modulate GPCRs and ion channels, two classes of targets that have proven difficult to address using conventional antibody discovery approaches.

## **SVN001**

SVN001 is an ion channel blocking antibody that is potentially the first therapeutic antibody against this target class. SVN001 targets an ion channel, Kv1.3, that has been implicated in a number of different autoimmune disorders including rheumatoid arthritis, psoriasis and multiple sclerosis. By targeting a unique subset of immune cells, SVN001 is not believed to be broadly immunosuppressive, therefore potentially improving the safety profile compared to typical immunosuppressants.

## **SVN002**

SVN002 is a unique antibody against an oncology target that holds the potential to significantly impact highly metastatic tumors that are resistant to the class of drugs that target vascular endothelial growth factor, or VEGF. The target is highly expressed in clear cell renal carcinoma, where it is associated with poor prognosis.

*Factor 5A*

On October 22, 2014, our board of directors decided to suspend all development of the Factor 5A technology based on our limited capital resources and the totality of the safety and efficacy data resulting from our Phase 1b/2a clinical trial. Depending on our future capital resources, possible options for the program are to (i) reformulate the drug to alleviate some of the adverse events observed in the clinical trial and to enhance the efficacy, (ii) partner or sell the program or (iii) discontinue development. Our board continues to evaluate these alternatives.

It is believed that our Factor 5A gene regulatory technology could have broad applicability in the human therapeutic field, by either inducing or inhibiting programmed cell death, also known as apoptosis, which is the natural process the human body goes through in order to eliminate redundant or defective cells.

We may enter into a collaboration with a biotechnology or pharmaceutical company to support the further development of SNS01-T now that we have completed our Phases 1b/2a clinical trial in multiple myeloma, MCL and DLBCL. We cannot assure you that we will be able to enter into such a collaboration or that one will be available on terms satisfactory to us.

*SNS01-T for B-cell cancers*

We have been developing a therapeutic candidate, SNS01-T, for the potential treatment of B-cell cancers such as multiple myeloma and non-Hodgkin B-cell lymphomas. SNS01-T utilizes our Factor 5A technology and comprises two active components: a DNA plasmid, or pDNA, expressing human eIF5A containing a lysine to arginine substitution at amino acid position 50, or eIF5A<sub>K50R</sub>, and a small inhibitory RNA, or siRNA. These two components are combined in a fixed ratio with a polymer, polyethyleneimine, or PEI, which enables self-assembly of the DNA and RNA into nanoparticles with demonstrated enhanced delivery to tissues and protection from degradation in the blood stream. Under the control of a B-cell selective promoter, SNS01-T's DNA plasmid up-regulates the apoptotic pathways within cancer cells by preferentially expressing the stable arginine form of the Factor 5A death message in target cells. The siRNA, by silencing the eIF5A gene, reduces expression of the hypusine form of Factor 5A that supports cell survival and proliferation. The silencing of the eIF5A gene by an eIF5A siRNA also down-regulates anti-apoptotic proteins, such as NFkB, ICAM and pro-inflammatory cytokines, which protect malignant cells from apoptosis and promote cell growth in multiple myeloma. The PEI, a cationic polymer, promotes auto-assembly of a nanoparticle with the other two components for intravenous delivery and protects the combination from degradation in the bloodstream until the nanoparticle is taken up by the tumor cell, where the siRNA and DNA plasmid are released.

We have been granted orphan drug status for SNS01-T by the United States Food and Drug Administration, or FDA, for the potential treatment of multiple myeloma, mantle cell lymphoma, or MCL, and diffuse large B-cell lymphoma,

or DLBCL, and we have now completed a Phase 1b/2a clinical study to assess the effects of SNS01-T in patients with these indications. The clinical study was an open-label, multiple-dose, dose-escalation study, which is evaluating the safety and tolerability of SNS01-T when administered by intravenous infusion in patients with relapsed or refractory multiple myeloma and non-Hodgkin B-cell lymphoma. The study design called for four cohorts of three to six patients each. Patients in each cohort received twice-weekly dosing for six weeks followed by up to a four-week safety data review period before escalating to a higher dose level in the next cohort.

While the primary objective of this study was to evaluate safety and tolerability, the effect of SNS01-T on tumor response and time to relapse or progression was also assessed using multiple well-established metrics including measurement of monoclonal protein in multiple myeloma and CT/PET imaging in MCL and DLBCL.

The study was performed at Mayo Clinic in Rochester, MN, the University of Arkansas for Medical Sciences in Little Rock, AR, the Mary Babb Randolph Cancer Center in Morgantown, WV, the John Theurer Cancer Center at Hackensack University Medical Center in Hackensack, NJ, the Seattle Cancer Care Alliance in Seattle, WA, the Pretoria East Hospital, in Pretoria, South Africa and the Groote Schuur Hospital in Cape Town, South Africa.

In August 2014, the safety portion of the study established a maximum tolerated dose following the reporting of a second dose limiting toxicity, or DLT, in the fourth and highest dosing cohort (0.375 mg/kg). The first DLT observed was a Grade 4 infusion reaction that occurred in a patient who had not received the designated pre-medications. The second DLT, an uncomplicated Grade 4 neutropenia, occurred after eight doses in a lymphoma patient. A total of eight patients were enrolled into cohort 4. With the completion of the high dose cohort, the trial has completed recruitment. All patients that were enrolled were able to continue treatment at the recommended cohort 3 dose level of 0.2 mg/kg. All patients in the study have now completed their treatment.

### *Research Program*

We are advancing SVN001 through preclinical development where it has demonstrated potent activity as well as advancing SVN002 through preclinical development.

Our gene-regulation therapeutic research program, which consisted of pre-clinical *in-vitro* and *in-vivo* experiments designed to assess the role and mode of action of Factor 5A in human diseases and a Phase 1b/2a clinical trial, was performed by third party researchers, at our direction. We have completed dosing patients in the Phase 1b/2a clinical trial and we are completing the remaining protocol. However, based on our limited capital resources and the totality of the safety and efficacy data resulting from the Phase 1b/2a clinical trial, we are suspending all development of the Factor 5A technology at this time.

On September 1, 1998, we entered into, and have extended through August 31, 2015, a research and development agreement with the University of Waterloo and Dr. John Thompson, our scientific founder, as the principal inventor. The Research and Development Agreement provides that the University of Waterloo will perform research and development under our direction, and we will pay for the cost of this work and make certain payments to the University of Waterloo. In return for payments made under the Research and Development Agreement, we have all rights to the intellectual property derived from the research. In accordance with the terms of the research and development agreement, on November 5, 2014, we provided the University of Waterloo that the agreement would be

terminated on December 31, 2014.

In order to pursue the above research initiatives, as well as other research initiatives that may arise, we will use our cash reserves as of September 30, 2014. However, it will be necessary for us to raise a significant amount of additional working capital in the future. If we are unable to raise the necessary funds, we may be required to significantly curtail the future development of some or all of our research initiatives and we will be unable to pursue other possible research initiatives.

We may further expand our research and development program beyond the initiatives listed above to include other diseases and research centers.

### *Intellectual Property*

As previously disclosed, our board of directors has decided to suspend all development of the agricultural applications of our intellectual property and to continue to develop our intellectual property only with respect to the human health therapeutic targets.

Currently, we have thirty-one (31) issued patents from the United States Patent and Trademark Office, or PTO, and eighty-one (81) issued patents from foreign countries. Of our one hundred and twelve (112) domestic and foreign issued patents, seventy (70) are for the use of our technology in agricultural applications and forty-two (42) relate to human therapeutics applications.

In addition to our one hundred and twelve (112) patents, we have a wide variety of patent applications, including divisional applications and continuations-in-part, in process with the PTO and internationally. Additionally, we have entered into royalty bearing license agreements whereby we license certain worldwide patent rights. Under the licenses we may receive milestone payments upon our achievement of certain milestones and royalty payments based on net sales of a product containing technology covered by the patent rights.

We also in-license certain intellectual property related to our antibody platforms and our chimerasome technology

Our core human therapeutic technology patents are set to expire in 2021 in the United States and 2025 outside the United States, and our patents related to multiple myeloma are set to expire, both in and outside the United States in 2029. Our agricultural patents are generally set to expire in 2019 in the United States and 2025 outside the United States.

In October 2014, we decided to continue to develop our intellectual property only with respect to the human health therapeutic targets and would be reviewing such patents on a patent by patent basis to determine which specific ones to continue to develop.

Also, in October 2014, we decided to suspend all development of the Factor 5A technology based on our limited capital resources and the totality of the safety and efficacy data resulting from our Phase 1b/2a clinical trial. As we are unable to determine if or when the development will be resumed, we were unable to determine what the future undiscounted cash flows from these patents could be. Therefore, as of September 30, 2014, we determined that the carrying value of our patent and patent applications related to Factor 5A were impaired. Accordingly, we recorded an impairment of the full carrying value of our patents related to Factor 5A in the amount of \$2,290,836.

On June 13, 2013, the Supreme Court of the United States of America ruled that naturally-occurring DNA sequences are unpatentable because they are products of nature. The Supreme Court further found that cDNA sequences, which are copies of non-intron containing mRNA sequences created in the laboratory, are patent eligible. We believe that the Supreme Court ruling has little impact on our patent portfolio overall and no impact on our human therapeutic patents, which do not rely on claims on naturally-occurring DNA sequences. SNS01-T comprises two synthetic constructs, siRNA and a DNA plasmid, which are protected by composition of matter and method of use patent claims.

## Liquidity and Capital Resources

### *Overview*

For the three months ended September 30, 2014, net cash of \$2,274,201 was used in operating activities primarily due to a net loss of \$5,183,807 which was reduced by non-cash expenses of \$2,290,836. Cash used in operating activities was increased by changes in operating assets and liabilities in the amount of \$754,295.

The \$754,295 change in operating assets and liabilities was the result of a decrease in prepaid research supplies and expenses in the amount of \$906,778 which was partially offset by a decrease in accounts payable and accrued expenses in the amount of \$152,483 due to the timing of expenses and payments.

During the three months ended September 30, 2014, cash used for investing activities amounted to \$334,804, which was related to capitalized patent costs and the purchase of equipment, furniture and fixtures.

As of September 30, 2014, our cash balance totaled \$3,837,139, and we had working capital of \$2,356,231.

We expect our capital requirements to increase significantly over the next several years as we commence new research and development efforts, increase our business and administrative infrastructure and embark on developing in-house business capabilities and facilities. Our future liquidity and capital funding requirements will depend on numerous factors, including, but not limited to, the levels and costs of our research and development initiatives and the cost and timing of the expansion of our business development and administrative staff.

We anticipate that, based upon our cash balance at September 30, 2014, we will be able to fund our operations through at least March 31, 2015. Over such period, we plan to fund our research and development and commercialization activities by:

- utilizing our current cash balance and investments;
- the placement of additional equity or debt instruments; and
- the possible execution of additional licensing agreements for our technology.

We cannot assure you that we will be able to raise money through any of the foregoing transactions on favorable terms, if at all.

#### **Changes to Critical Accounting Policies and Estimates**

There have been no changes to our critical accounting policies and estimates as set forth in our Annual Report on Form 10-K for the fiscal year ended June 30, 2014.

## Results of Operations

### Three Months Ended September 30, 2014 and Three Months Ended September 30, 2013

The results of operations for the three months ended September 30, 2014, include the results of operations of Fabrus, Inc., our wholly owned subsidiary that was acquired on May 16, 2014. The results of operations for the three months ended September 30, 2013 do not include the results of operations of Fabrus, Inc.

The net loss for the three months ended September 30, 2014 was \$5,183,807. The net loss for the three months ended September 30, 2013 was \$1,784,333. Such a change represents an increase in net loss of \$3,399,474, or 190.5%. This increase in net loss was primarily the result of an increase in research and development expenses and patents written off, which was partially offset by a decrease in general and administrative expenses.

#### *Revenue*

There was no revenue during the three months ended September 30, 2014.

Total revenue in the amount of \$100,000 for the three months ended September 30, 2013 consisted of a milestone payment in connection with an agricultural license agreement.

We may receive future milestone payments in connection with our current license agreements. Additionally, we may receive future royalty payments from our license agreements when our partners commercialize their products containing our technology. However, it is difficult for us to determine our future revenue expectations because our future milestone payments are primarily contingent on our partners' successful implementation of their development plan, we have no history of receiving royalties and the timing and outcome of our experiments, the timing of signing new partner agreements and the timing of our partners moving through the development process into commercialization is difficult to accurately predict.

#### *General and Administrative Expenses*

Edgar Filing: Sevion Therapeutics, Inc. - Form 10-Q

Three Months Ended September 30,  
2014 2013 Change %  
(in thousands, except % values)

|                                  |        |        |          |         |   |
|----------------------------------|--------|--------|----------|---------|---|
| Payroll and benefits             | \$ 237 | \$ 145 | \$ 92    | 63.4    | % |
| Investor relations               | 73     | 379    | (306 )   | (80.7 ) | % |
| Professional fees                | 199    | 108    | 91       | 84.3    | % |
| Other general and administrative | 173    | 116    | 57       | 49.1    | % |
|                                  | 682    | 748    | (66 )    | (8.8 )  | % |
| Stock-based compensation         | 93     | 109    | (16 )    | (14.7 ) | % |
| Total general and administrative | \$ 775 | \$ 857 | \$ (82 ) | (9.6 )  | % |

Payroll and benefits were higher primarily as a result of hiring a new CEO in June 2014.

Investor relations fees were lower primarily due to the expenses incurred during the three months ended September 30, 2013 relating to an investor relations program that started in August 2013, the termination of an investor relations consulting agreement in September 2013 and a special meeting of stockholders held in August 2013. We entered into a new investor relations consulting agreement in September 2014.

Professional fees were higher primarily as a result of an increase in accounting fees due to the additional bookkeeping, consulting and auditing fees related to the acquisition of Fabrus, Inc. in May 2014.

Other general and administrative expenses were higher primarily due to an increase in consultants, travel and insurance.

Stock-based compensation was lower primarily because options were issued during the quarter ended September 30, 2013 but were not issued during the quarter ended September 30, 2014.

We expect cash-based general and administrative expenses to be lower over the next twelve months because on October 22, 2014, our board of directors decided to close the Bridgewater, New Jersey office and to terminate the research agreement with the University of Waterloo in order to consolidate all of our operations in our San Diego, California location.

#### *Research and Development Expenses*

Research and development expenses for the three months ended September 30, 2014 include costs incurred by Senesco, Inc. in the amount of \$1,562,000 and costs incurred by Fabrus, Inc. in the amount of \$558,000.

Research and development expenses for the three months ended September 30, 2013 do not include any costs incurred by Fabrus, Inc. as the Company acquired Fabrus, Inc. in May 2014.

|   | Three Months Ended September 30, |       |        |         |   |
|---|----------------------------------|-------|--------|---------|---|
|   | 2014                             | 2013  | Change | %       |   |
|   | (in thousands, except % values)  |       |        |         |   |
| Payroll and benefits                              | \$ 353                           | \$ 44 | \$ 309 | 702.3   | % |
| Phase 1b / 2a clinical trial                      | 427                              | 426   | 1      | .2      | % |
| Research supplies                                 | 92                               | 2     | 90     | 4500.0  | % |
| Research contract with the University of Waterloo | 119                              | 114   | 5      | 4.4     | % |
| Consultants                                       | 159                              | 116   | 43     | 37.1    | % |
| Rent  | 58                               | -     | 58     | -       |   |
| Legal   | 75                               | 10    | 65     | 650.0   | % |
| Depreciation and amortization                     | 60                               | 74    | (14 )  | (18.9 ) | % |
| Other research and development                    | 60                               | 9     | 51     | 566.7   | % |
|   | 1,403                            | 795   | 608    | 76.5    | % |
| Write-off of prepaid research supplies            | 670                              | -     | 670    | -       |   |
| Stock-based compensation                          | 47                               | 16    | 31     | 193.8   | % |

Edgar Filing: Sevion Therapeutics, Inc. - Form 10-Q

|                                |          |        |          |       |   |
|--------------------------------|----------|--------|----------|-------|---|
| Total research and development | \$ 2,120 | \$ 811 | \$ 1,309 | 161.4 | % |
|--------------------------------|----------|--------|----------|-------|---|

Payroll and benefits were higher primarily due to an increase in headcount due to the acquisition of Fabrus, Inc. in May 2014.

· Research supplies were higher primarily due to the acquisition of Fabrus, Inc. research programs in May 2014.

· Research contract with the University of Waterloo is higher due to an amendment to the agreement in February 2014.

Consultants were higher primarily due to the addition of consultants in connection with the acquisition of Fabrus, Inc. in May 2014.

Rent was higher due to the addition of lab space in San Diego, California in connection with the acquisition of Fabrus, Inc. in May 2014.

Legal was higher due to the impairment in the agricultural patent costs at June 30, 2014. As a result, the legal fees in connection with the prosecution of the agricultural patents are now being expensed as incurred instead of capitalized.

Depreciation and amortization was lower due to the impairment of the agricultural patents at June 30, 2014. As a result, we are no longer incurring amortization charges on those patents. This was partially offset by an increase in depreciation in connection with the equipment acquired in connection with the acquisition of Fabrus, Inc. in May 2014.

· Other research and development costs were higher primarily due to the acquisition of Fabrus, Inc. in May 2014.

During the quarter ended September 30, 2014, we concluded our Phase 1b /2a clinical trial but did not use all of the material purchased for the clinical trial. As we have put the clinical program for this product candidate on hold, we wrote-off the cost of the remaining material at September 30, 2014.

Stock-based compensation was higher primarily due to the Black-Scholes value of options issued in connection with the acquisition of Fabrus, Inc. in May 2014, which is being charged to operations over the vesting period.

#### *Write-off of patents*

In October 2014, we put the development of Factor 5A for human health applications on hold. As we do not know if or when the development will be resumed, we are unable to determine what the future undiscounted cash flows from these patents will be. As such, we have recorded an impairment to all of these patent costs in the net amount of \$2,290,836 at September 30, 2014 and will be expensing any future patent costs related to Factor FA as incurred.

#### **Contractual Obligations and Contingent Liabilities**

During the three months ended September 30, 2014, there were no material changes to our contractual obligations and commitments described under Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the fiscal year ended June 30, 2014.

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

We do not have any off balance-sheet arrangements.



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

*Foreign Currency Risk*

Our financial statements are denominated in United States dollars and, except for our agreement with the University of Waterloo, which is denominated in Canadian dollars, all of our contracts are denominated in United States dollars. Therefore, we believe that fluctuations in foreign currency exchange rates will not result in any material adverse effect on our financial condition or results of operations. In the event we derive a greater portion of our revenues from international operations or in the event a greater portion of our expenses are incurred internationally and denominated in a foreign currency, then changes in foreign currency exchange rates could affect our results of operations and financial condition.

*Interest Rate Risk*

We invest in high-quality financial instruments, primarily money market funds, with an effective duration of the portfolio of less than one year, which we believe are subject to limited credit risk. We currently do not hedge our interest rate exposure. Due to the short-term nature of our investments, we do not believe that we have any material exposure to interest rate risk arising from our investments.

**Item 4. Controls and Procedures.**

(a) Evaluation of disclosure controls and procedures.

The principal executive officer and principal financial officer have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) as of September 30, 2014. Based on this evaluation, they have concluded that our disclosure controls and procedures were effective to ensure that the information required to be disclosed by us in reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934 is accumulated and communicated to our management, including our principal executive and principal financial officers, to allow timely decisions regarding required disclosure.

(b) Changes in internal controls.

No change in our internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934) occurred during the three month period ended September 30, 2014 that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

## **PART II. OTHER INFORMATION.**

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

None.

### **Item 1A. Risk Factors.**

The more prominent risks and uncertainties inherent in our business are described below. However, additional risks and uncertainties may also impair our business operations. If any of the following risks actually occur, our business, financial condition or results of operations may suffer.

#### **Risks Related to Our Business**

*Recurring losses and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern and we may not be able to continue as a going concern.*

Our recurring losses from operations and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern and as a result, our independent registered public accounting firm included an explanatory paragraph in its report on our consolidated financial statements for the fiscal year ended June 30, 2014. Substantial doubt about our ability to continue as a going concern may create negative reactions to the price of the common shares of our stock and we may have a more difficult time obtaining financing.

We have prepared our financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should we be unable to continue in existence.

As of September 30, 2014, we believe we have enough cash to fund operations through at least March 31, 2015.

***We have a limited operating history and have incurred substantial losses and expect to incur future losses.***

We are a development stage biotechnology company with a limited operating history and limited assets and capital. We have incurred losses each year since inception and had an accumulated deficit of \$93,478,573 at September 30, 2014. We have generated minimal revenues by licensing our technology for certain crops to companies willing to share in our development costs. In addition, our technology may not be ready for commercialization for several years. We expect to continue to incur losses for the next several years because we anticipate that our expenditures on research and development and administrative activities will significantly exceed our revenues during that period. We cannot predict when, if ever, we will become profitable.

***We will need additional capital to fund our operations until we are able to generate a profit.***

Our operations to date have required significant cash expenditures. Our future capital requirements will depend on the results of our research and development activities, preclinical and clinical studies, and competitive and technological advances.

We will need to obtain more funding in the future through collaborations or other arrangements with research institutions and corporate partners, or public and private offerings of our securities, including debt or equity financing. We may not be able to obtain adequate funds for our operations from these sources when needed or on acceptable terms. Future collaborations or similar arrangements may require us to license valuable intellectual property to, or to share substantial economic benefits with, our collaborators. If we raise additional capital by issuing additional equity or securities convertible into equity, our stockholders may experience dilution and our share price may decline. Any debt financing may result in restrictions on our spending.

If we are unable to raise additional funds, we will need to do one or more of the following:

- delay, scale-back or eliminate some or all of our research and product development programs;
- provide licenses to third parties to develop and commercialize products or technologies that we would otherwise seek to develop and commercialize ourselves;
- seek strategic alliances or business combinations;
- attempt to sell our company;
- cease operations; or
- declare bankruptcy.

We believe that at the projected rate of spending we should have sufficient cash to maintain our present operations at least through March 31, 2015.

***We may be adversely affected by the current economic environment.***

Our ability to obtain financing, invest in and grow our business, and meet our financial obligations depends on our operating and financial performance, which in turn is subject to numerous factors. In addition to factors specific to our business, prevailing economic conditions and financial, business and other factors beyond our control can also affect our business and ability to raise capital. We cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

***Materials necessary to manufacture some of our compounds currently under development may not be available on commercially reasonable terms, or at all, which may delay our development and commercialization of these compounds.***

Some of the materials necessary for the manufacture of our compounds under development may, from time to time, be available either in limited quantities, or from a limited number of manufacturers, or both. Our contract manufacturers need to obtain these materials for our clinical trials and, potentially, for commercial distribution when and if we obtain marketing approval for these compounds. Suppliers may not sell us these materials at the time we need them or on commercially reasonable terms. If we are unable to obtain the materials needed to conduct our clinical trials, product testing and potential regulatory approval could be delayed, adversely affecting our ability to develop the product candidates. Similarly, if we are unable to obtain critical manufacturing materials after regulatory approval has been obtained for a product candidate, the commercial launch of that product candidate could be delayed or there could be a shortage in supply, which could materially affect our ability to generate revenues from that product candidate. If suppliers increase the price of manufacturing materials, the price for one or more of our products may increase, which may make our products less competitive in the marketplace. If it becomes necessary to change suppliers for any of these materials or if any of our suppliers experience a shutdown or disruption at the facilities used to produce these materials, due to technical, regulatory or other reasons, it could harm our ability to manufacture our products.

***We depend on a limited number of technologies and, if our technologies are not commercially successful, we will have no alternative source of revenue.***

Our primary business is the development and licensing of technology to (i) discover and engineer monoclonal antibodies and (ii) identify, isolate, characterize and promote or silence genes which control the death of cells in humans and plants. Our future revenue and profitability critically depend upon our ability, or our licensees' ability, to successfully develop apoptosis and senescence gene technology and later license or market such technology. We have conducted experiments on certain crops with favorable results and have conducted certain preliminary cell-line and animal experiments, which have provided us with data upon which we have designed additional research programs. However, we cannot give any assurance that our technology will be commercially successful or economically viable for any crops or human therapeutic applications.

In addition, no assurance can be given that adverse consequences might not result from the use of our technology such as the development of negative effects on humans or plants or reduced benefits in terms of crop yield or protection. Our failure to obtain market acceptance of our technology or the failure of our current or potential licensees to successfully commercialize such technology would have a material adverse effect on our business.

***We outsource much of our research and development activities and, if we are unsuccessful in maintaining our alliances with these third parties, our research and development efforts may be delayed or curtailed.***

We rely on third parties to perform much of our research and development activities. At this time, we have limited internal capabilities to perform our own research and development activities. Accordingly, the failure of third party research partners to perform under agreements entered into with us, or our failure to renew important research agreements with these third parties, may delay or curtail our research and development efforts.

***We have significant future capital needs and may be unable to raise capital when needed, which could force us to delay or reduce our research and development efforts.***

As of September 30, 2014, we had a cash balance of \$3,387,139 and working capital of \$2,356,231. Using our available reserves as of September 30, 2014, we believe that we can operate according to our current business plan at least through March 31, 2015.

To date, we have generated minimal revenues and anticipate that our operating costs will exceed any revenues generated over the next several years. Therefore, we will be required to raise additional capital in the future in order to

operate in accordance with our current business plan, and this funding may not be available on favorable terms, if at all. If we are unable to raise additional funds, we will need to do one or more of the following:

- delay, scale back or eliminate some or all of our research and development programs;
- provide a license to third parties to develop and commercialize our technology that we would otherwise seek to develop and commercialize ourselves;
- seek strategic alliances or business combinations;
- attempt to sell our company;
- cease operations; or
- declare bankruptcy.

In addition, in connection with any funding, if we need to issue more equity securities than our certificate of incorporation currently authorizes we will need stockholder approval. If stockholder approval is not obtained or if adequate funds are not available, we may be required to curtail operations significantly or to obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies, product candidates, products or potential markets. Investors may experience dilution in their investment from future offerings of our common stock. For example, if we raise additional capital by issuing equity securities, such an issuance would reduce the percentage ownership of existing stockholders. In addition, assuming the exercise of all options and warrants outstanding and the conversion of the preferred stock into common stock, as of September 30, 2014, we had 476,643,655 shares of common stock authorized but unissued and unreserved, which may be issued from time to time by our board of directors. Furthermore, we may need to issue securities that have rights, preferences and privileges senior to our common stock. Failure to obtain financing on acceptable terms would have a material adverse effect on our liquidity.

Since our inception, we have financed all of our operations through equity and debt financings. Our future capital requirements depend on numerous factors, including:

- the scope of our research and development;
- our ability to attract business partners willing to share in our development costs;
- our ability to successfully commercialize our technology;
- competing technological and market developments;
- our ability to enter into collaborative arrangements for the development, regulatory approval and commercialization of other products; and
- the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights.

***Our business depends upon our patents and proprietary rights and the enforcement of these rights. Our failure to obtain and maintain patent protection may increase competition and reduce demand for our technology.***

As a result of the substantial length of time and expense associated with developing products and bringing them to the marketplace in the biotechnology and agricultural industries, obtaining and maintaining patent and trade secret protection for technologies, products and processes is of vital importance. Our success will depend in part on several factors, including, without limitation:

· our ability to obtain patent protection for our technologies and processes;  
· our ability to preserve our trade secrets; and  
· our ability to operate without infringing the proprietary rights of other parties both in the United States and in foreign countries.

As of September 30, 2014, we have been issued thirty-one (31) patents by the PTO and eighty-one (81) patents from foreign countries. We have also filed numerous patent applications for our technology in the United States and in several foreign countries, which technology is vital to our primary business, as well as several continuations in part on these patent applications. Our success depends in part upon the grant of patents from our pending patent applications. In addition, we have licensed certain antibody technology from The Scripps Research Institute, or Scripps, pursuant to a license agreement dated August 8, 2014. If we are in breach of this license agreement, and Scripps elects to terminate the agreement, this termination could have a material adverse effect to our business in the future.

Although we believe that our technology is unique and that it will not violate or infringe upon the proprietary rights of any third party, we cannot assure you that these claims will not be made or if made, could be successfully defended against. If we do not obtain and maintain patent protection, we may face increased competition in the United States and internationally, which would have a material adverse effect on our business.

Since patent applications in the United States are maintained in secrecy until patents are issued, and since publication of discoveries in the scientific and patent literature tend to lag behind actual discoveries by several months, we cannot be certain that we were the first creator of the inventions covered by our pending patent applications or that we were the first to file patent applications for these inventions.

In addition, among other things, we cannot assure you that:

- our patent applications will result in the issuance of patents;
- any patents issued or licensed to us will be free from challenge and if challenged, would be held to be valid;
- any patents issued or licensed to us will provide commercially significant protection for our technology, products and processes;
- other companies will not independently develop substantially equivalent proprietary information which is not covered by our patent rights;
- other companies will not obtain access to our know-how;
- other companies will not be granted patents that may prevent the commercialization of our technology; or
- we will not incur licensing fees and the payment of significant other fees or royalties to third parties for the use of their intellectual property in order to enable us to conduct our business.

***Our competitors may allege that we are infringing upon their intellectual property rights, forcing us to incur substantial costs and expenses in resulting litigation, the outcome of which would be uncertain.***

Patent law is still evolving relative to the scope and enforceability of claims in the fields in which we operate. We are like most biotechnology companies in that our patent protection is highly uncertain and involves complex legal and technical questions for which legal principles are not yet firmly established. In addition, if issued, our patents may not

contain claims sufficiently broad to protect us against third parties with similar technologies or products, or provide us with any competitive advantage.

The PTO and the courts have not established a consistent policy regarding the breadth of claims allowed in biotechnology patents. The allowance of broader claims may increase the incidence and cost of patent interference proceedings and the risk of infringement litigation. On the other hand, the allowance of narrower claims may limit the scope and value of our proprietary rights.

The laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and many companies have encountered significant problems and costs in protecting their proprietary rights in these foreign countries.

We could become involved in infringement actions to enforce and/or protect our patents. Regardless of the outcome, patent litigation is expensive and time consuming and would distract our management from other activities. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we could because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of any patent litigation could limit our ability to continue our operations.

***If our technology infringes the intellectual property of our competitors or other third parties, we may be required to pay license fees or damages.***

The current patent landscape surrounding siRNA technology is unclear due to the recent proliferation of siRNA-related patent litigation and grants of third-party patents encompassing this technology. If any relevant claims of third party patents that are adverse to us are upheld as valid and enforceable, we could be prevented from commercializing our technology or could be required to obtain licenses from the owners of such patents. We cannot assure you that such licenses would be available or, if available, would be on acceptable terms. Some licenses may be non-exclusive and, therefore, our competitors may have access to the same technology licensed to us. In addition, if any parties successfully claim that the creation or use of our technology infringes upon their intellectual property rights, we may be forced to pay damages, including treble damages.

***Our security measures may not adequately protect our unpatented technology and, if we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology may be adversely affected.***

Our success depends upon know-how, unpatentable trade secrets, and the skills, knowledge and experience of our scientific and technical personnel. We require all employees to disclose and assign to us the rights to their ideas, developments, discoveries and inventions. All of the current employees have also entered into Non-disclosure, Non-competition and Invention Assignment Agreements. We also attempt to enter into similar agreements with our consultants, advisors and research collaborators. We cannot assure you that adequate protection for our trade secrets,

know-how or other proprietary information against unauthorized use or disclosure will be available.

We occasionally provide information to research collaborators in academic institutions and request that the collaborators conduct certain tests. We cannot assure you that the academic institutions will not assert intellectual property rights in the results of the tests conducted by the research collaborators, or that the academic institutions will grant licenses under such intellectual property rights to us on acceptable terms, if at all. If the assertion of intellectual property rights by an academic institution is substantiated, and the academic institution does not grant intellectual property rights to us, these events could limit our ability to commercialize our technology.

***As we evolve from a company primarily involved in the research and development of our technology into one that is also involved in the commercialization of our technology, we may have difficulty managing our growth and expanding our operations.***

As our business grows, we may need to add employees and enhance our management, systems and procedures. We may need to successfully integrate our internal operations with the operations of our marketing partners, manufacturers, distributors and suppliers to produce and market commercially viable products. We may also need to manage additional relationships with various collaborative partners, suppliers and other organizations. Expanding our business may place a significant burden on our management and operations. We may not be able to implement improvements to our management information and control systems in an efficient and timely manner and we may discover deficiencies in our existing systems and controls. Our failure to effectively respond to such changes may make it difficult for us to manage our growth and expand our operations.

***We are in the process of combining the assets and operations of Fabrus into our company, which will increase our infrastructure and reporting burden.***

The integration of the business and assets of Fabrus is of critical importance to our future success. The success of the integration will depend, in a large part, on our ability to realize the anticipated benefits, including synergies, cost savings, innovation and operational efficiencies, from combining Fabrus and Senesco. To realize these anticipated benefits, these businesses must be successfully integrated. The failure to integrate successfully and to manage successfully the challenges presented by the integration process may prevent us from achieving the anticipated benefits of this acquisition. Any difficulties in successfully integrating these businesses, or any delays in the integration process, could adversely affect our business, financial results and financial condition.

***We have no marketing or sales history and depend on third party marketing partners. Any failure of these parties to perform would delay or limit our commercialization efforts.***

We have no history of marketing, distributing or selling biotechnology products, and we are relying on our ability to successfully establish marketing partners or other arrangements with third parties to market, distribute and sell a commercially viable product both here and abroad. Our business plan envisions creating strategic alliances to access needed commercialization and marketing expertise. We may not be able to attract qualified sub-licensees, distributors or marketing partners, and even if qualified, these marketing partners may not be able to successfully market human therapeutic applications developed with our technology. If our current or potential future marketing partners fail to provide adequate levels of sales, our commercialization efforts will be delayed or limited and we may not be able to generate revenue.



***We will depend on joint ventures and strategic alliances to develop and market our technology and, if these arrangements are not successful, our technology may not be developed and the expenses to commercialize our technology will increase.***

In its current state of development, our technology is not ready to be marketed to consumers. We intend to follow a multi-faceted commercialization strategy that involves the licensing of our technology to business partners for the purpose of further technological development, marketing and distribution. We have and are seeking business partners who will share the burden of our development costs while our technology is still being developed, and who will pay us royalties when they market and distribute products incorporating our technology upon commercialization. The establishment of joint ventures and strategic alliances may create future competitors, especially in certain regions abroad where we do not pursue patent protection. If we fail to establish beneficial business partners and strategic alliances, our growth will suffer and the continued development of our technology may be harmed.

***Competition in the human therapeutic industry is intense and technology is changing rapidly. If our competitors market their technology faster than we do, we may not be able to generate revenues from the commercialization of our technology.***

There are many large companies working in the therapeutic antibody field and similarly may develop technologies related to antibody discovery. These companies include Genentech, Inc., Amgen, Inc., Biogen Idec, Inc., Novartis AG, Janssen Biotech, Inc., Sanofi-aventis U.S. LLC, Regeneron Pharmaceuticals, Inc., Bristol-Myers Squibb Company, Teva Pharmaceutical Industries Ltd, Pfizer, Inc., Takeda Pharmaceutical Company Limited, Kyowa Hokko Kirin Pharma, Inc., Daiichi Sankyo Company Limited, Astellas Pharma, Inc., Merck & Co. Inc., AbbVie, Inc., Seattle Genetics, Inc., and Immunogen, Inc.. Similarly, there are several small companies developing technologies for antibody discovery, including Adimab LLC, X-body Biosciences, Inc., Innovative Targeting Solutions, Inc., Heptares Therapeutics Ltd, Kymab Ltd., and Novimmune SA. Other companies are working on unique scaffolds, including Ablynx NV and ArGen-X N.V.

Many human therapeutic companies are engaged in research and development activities relating to apoptosis and senescence. We may be unable to compete successfully against our current and future competitors, which may result in price reductions, reduced margins and the inability to achieve market acceptance for products containing our technology. Some of our competitors that are involved in apoptosis research include: Celgene Corporation; Takeda/Millennium; ONYX Pharmaceuticals, Inc.; Amgen Inc.; Janssen Biotech, Inc.; Novartis AG; and Pharmacyclics, Inc. Many of these competitors have substantially greater financial, marketing, sales, distribution and technical resources than us and have more experience in research and development, clinical trials, regulatory matters, manufacturing and marketing. We anticipate increased competition in the future as new companies enter the market and new technologies become available. Our technology may be rendered obsolete or uneconomical by technological advances or entirely different approaches developed by one or more of our competitors, which will prevent or limit our ability to generate revenues from the commercialization of our technology.



***Our business is subject to various government regulations and, if we or our licensees are unable to obtain regulatory approval, we may not be able to continue our operations.***

Use of our technology, if developed for human therapeutic applications, is subject to FDA regulation. The FDA must approve any drug or biologic product before it can be marketed in the United States. In addition, prior to being sold outside of the United States, any products resulting from the application of our human therapeutic technology must be approved by the regulatory agencies of foreign governments. Prior to filing a new drug application or biologics license application with the FDA, we would have to perform extensive clinical trials, and prior to beginning any clinical trial, we would need to perform extensive preclinical testing which could take several years and may require substantial expenditures.

We have performed clinical trials in connection with our human therapeutic applications, which is subject to FDA approval. Additionally, federal, state and foreign regulations relating to human therapeutic applications developed through biotechnology are subject to public concerns and political circumstances, and, as a result, regulations have changed and may change substantially in the future. Accordingly, we may become subject to governmental regulations or approvals or become subject to licensing requirements in connection with our research and development efforts. We may also be required to obtain such licensing or approval from the governmental regulatory agencies described above, or from state agencies, prior to the commercialization of our human therapeutic technology. If unfavorable governmental regulations are imposed on our technology or if we fail to obtain licenses or approvals in a timely manner, we may not be able to continue our operations.

***Preclinical studies of our human therapeutic applications may be unsuccessful, which could delay or prevent regulatory approval.***

Preclinical studies may reveal that our human therapeutic technology is ineffective or harmful, and/or may be unsuccessful in demonstrating efficacy and safety of our human therapeutic technology, which would significantly limit the possibility of obtaining regulatory approval for any drug or biologic product manufactured with our technology. The FDA requires submission of extensive preclinical, clinical and manufacturing data to assess the efficacy and safety of potential products. Any delay in receiving approval for any applicable IND from the FDA would result in a delay in the commencement of the related clinical trial. Additionally, we could be required to perform additional preclinical studies prior to the FDA approving any applicable IND. Furthermore, the success of preliminary studies does not ensure commercial success, and later-stage clinical trials may fail to confirm the results of the preliminary studies.

***Our success will depend on the success of our clinical trials of our human therapeutic applications.***

It may take several years to complete the clinical trials of a product candidate, and failure of one or more of our clinical trials can occur at any stage of testing. We believe that the development of our product candidate involves significant risks at each stage of testing. If clinical trial difficulties and failures arise, our product candidate may never be approved for sale or become commercially viable.

There are a number of difficulties and risks associated with clinical trials. These difficulties and risks may result in the failure to receive regulatory approval to sell our product candidate or the inability to commercialize our product candidate. The possibility exists that:

- we may discover that the product candidate does not exhibit the expected therapeutic results in humans, may cause harmful side effects or have other unexpected characteristics that may delay or preclude regulatory approval or limit commercial use if approved;

- the results from early clinical trials may not be statistically significant or predictive of results that will be obtained from expanded advanced clinical trials;

- institutional review boards or regulators, including the FDA, may hold, suspend or terminate our clinical research or the clinical trials of our product candidate for various reasons, including noncompliance with regulatory requirements or if, in their opinion, the participating subjects are being exposed to unacceptable health risks;

- subjects may drop out of our clinical trials;

- our preclinical studies or clinical trials may produce negative, inconsistent or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials; and

- the cost of our clinical trials may be greater than we currently anticipate.

***Clinical trials for our human therapeutic technology will be lengthy and expensive and their outcome is uncertain.***

Before obtaining regulatory approval for the commercial sales of any product containing our technology, we must demonstrate through clinical testing that our technology and any product containing our technology is safe and effective for use in humans. Conducting clinical trials is a time-consuming, expensive and uncertain process and typically requires years to complete. In our industry, the results from preclinical studies and early clinical trials often are not predictive of results obtained in later-stage clinical trials. Some products and technologies that have shown promising results in preclinical studies or early clinical trials subsequently fail to establish sufficient safety and efficacy data necessary to obtain regulatory approval. At any time during clinical trials, we or the FDA might delay or halt any clinical trial for various reasons, including:

- occurrence of unacceptable toxicities or side effects;

ineffectiveness of the product candidate;

· negative or inconclusive results from the clinical trials, or results that necessitate additional studies or clinical trials;

· delays in obtaining or maintaining required approvals from institutions, review boards or other reviewing entities at clinical sites;

· delays in patient enrollment; or

· insufficient funding or a reprioritization of financial or other resources.

Any failure or substantial delay in successfully completing clinical trials and obtaining regulatory approval for our product candidates could severely harm our business.

***If our clinical trials for our product candidates are delayed, we would be unable to commercialize our product candidates on a timely basis, which would materially harm our business.***

Planned clinical trials may not begin on time or may need to be restructured after they have begun. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining an effective IND or regulatory approval to commence a clinical trial;
- negotiating acceptable clinical trial agreement terms with prospective trial sites;
- obtaining institutional review board approval to conduct a clinical trial at a prospective site;
- recruiting qualified subjects to participate in clinical trials;
- competition in recruiting clinical investigators;
- shortage or lack of availability of supplies of drugs for clinical trials;
- the need to repeat clinical trials as a result of inconclusive results or poorly executed testing;
- the placement of a clinical hold on a study;
- the failure of third parties conducting and overseeing the operations of our clinical trials to perform their contractual or regulatory obligations in a timely fashion; and
- exposure of clinical trial subjects to unexpected and unacceptable health risks or noncompliance with regulatory requirements, which may result in suspension of the trial.

We believe that our product candidates have significant milestones to reach, including the successful completion of clinical trials, before commercialization. If we have significant delays in or termination of clinical trials, our financial results and the commercial prospects for our product candidates or any other products that we may develop will be adversely impacted. In addition, our product development costs would increase and our ability to generate revenue could be impaired.

***Any inability to license from third parties their proprietary technologies or processes which we use in connection with the development of our technology may impair our business.***

Other companies, universities and research institutions have or may obtain patents that could limit our ability to use our technology in a product candidate or impair our competitive position. As a result, we would have to obtain licenses from other parties before we could continue using our technology in a product candidate. Any necessary licenses may not be available on commercially acceptable terms, if at all. If we do not obtain required licenses, we may not be able to develop our technology into a product candidate or we may encounter significant delays in development while we redesign methods that are found to infringe on the patents held by others.

***We face potential product liability exposure far in excess of our limited insurance coverage.***

We may be held liable if any product we or our collaborators develop causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing or sale. Regardless of merit or eventual outcome, product liability claims could result in decreased demand for our product candidates, injury to our reputation, withdrawal of patients from our clinical trials, substantial monetary awards to trial participants and the inability to commercialize any products that we may develop. These claims might be made directly by consumers, health care providers, pharmaceutical companies or others selling or testing our products. We have obtained limited product liability insurance coverage for our clinical trials; however, our insurance may not reimburse us or may not be sufficient to reimburse us for expenses or losses we may suffer. Moreover, if insurance coverage becomes more expensive, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for any of our product candidates, we intend to expand our insurance coverage to include the sale of commercial products, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, juries have awarded large judgments in class action lawsuits for claims based on drugs that had unanticipated side effects. In addition, the pharmaceutical and biotechnology industries, in general, have been subject to significant medical malpractice litigation. A successful product liability claim or series of claims brought against us could harm our reputation and business and would decrease our cash reserves.

***We depend on our key personnel and, if we are not able to attract and retain qualified scientific and business personnel, we may not be able to grow our business or develop and commercialize our technology.***

We are highly dependent on our scientific advisors, consultants and third-party research partners. Our success will also depend in part on the continued service of our key employees and our ability to identify, hire and retain additional qualified personnel in an intensely competitive market. Although we have a research agreement with Dr. John Thompson, this agreement may be terminated upon short or no notice. Additionally, except for our Chief Executive Officer, we do not have employment agreements with our key employees. We do not maintain key person life insurance on any member of management. The failure to attract and retain key personnel could limit our growth and hinder our research and development efforts.

***Certain provisions of our charter, by-laws, Delaware law and stock plans could make a takeover difficult.***

Certain provisions of our certificate of incorporation and by-laws could make it more difficult for a third party to acquire control of us, even if the change in control would be beneficial to stockholders. Our certificate of incorporation authorizes our board of directors to issue, without stockholder approval, 5,000,000 shares of preferred stock with voting, conversion and other rights and preferences that could adversely affect the voting power or other rights of the holders of our common stock.

In addition, we are subject to the Business Combination Act of the Delaware General Corporation Law which, subject to certain exceptions, restricts certain transactions and business combinations between a corporation and a stockholder owning 15% or more of the corporation's outstanding voting stock for a period of three years from the date such stockholder becomes a 15% owner. These provisions may have the effect of delaying or preventing a change of control of us without action by our stockholders and, therefore, could adversely affect the value of our common stock.

Furthermore, in the event of our merger or consolidation with or into another corporation, or the sale of all or substantially all of our assets in which the successor corporation does not assume our outstanding equity awards or issue equivalent equity awards, our current equity plans require the accelerated vesting of such outstanding equity awards.

### **Risks Related to Our Common Stock**

#### ***Penny stock regulations may impose certain restrictions on marketability of our securities.***

The SEC has adopted regulations which generally define a “penny stock” to be any equity security that has a market price of less than \$5.00 per share or an exercise price of less than \$5.00 per share, subject to certain exceptions. As a result, our common stock is subject to rules that impose additional sales practice requirements on broker dealers who sell such securities to persons other than established customers and accredited investors (generally those with assets in excess of \$1,000,000 or annual income exceeding \$200,000, or \$300,000 together with their spouse). For transactions covered by such rules, the broker dealer must make a special suitability determination for the purchase of such securities and have received the purchaser’s written consent to the transaction prior to the purchase. Additionally, for any transaction involving a penny stock, unless exempt, the rules require the delivery, prior to the transaction, of a risk disclosure document mandated by the SEC relating to the penny stock market. The broker dealer must also disclose the commission payable to both the broker dealer and the registered representative, current quotations for the securities and, if the broker dealer is the sole market maker, the broker dealer must disclose this fact and the broker dealer’s presumed control over the market.

Finally, monthly statements must be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. Broker-dealers must wait two business days after providing buyers with disclosure materials regarding a security before effecting a transaction in such security. Consequently, the “penny stock” rules restrict the ability of broker dealers to sell our securities and affect the ability of investors to sell our securities in the secondary market and the price at which such purchasers can sell any such securities, thereby affecting the liquidity of the market for our common stock.

Stockholders should be aware that, according to the SEC, the market for penny stocks has suffered in recent years from patterns of fraud and abuse. Such patterns include:

- control of the market for the security by one or more broker-dealers that are often related to the promoter or issuer;
- manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases;
- “boiler room” practices involving high pressure sales tactics and unrealistic price projections by inexperienced sales persons;
- excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and

the wholesale dumping of the same securities by promoters and broker-dealers after prices have been manipulated to a desired level, along with the inevitable collapse of those prices with consequent investor losses.

Our management is aware of the abuses that have occurred historically in the penny stock market.

***Our management and other affiliates have significant control of our common stock and could significantly influence our actions in a manner that conflicts with our interests and the interests of other stockholders.***

As of September 30, 2014, our executive officers and directors together beneficially own approximately 31% of the outstanding shares of our common stock, assuming the exercise of options and warrants which are currently exercisable or will become exercisable within 60 days of September 30, 2014, held by these stockholders. Additionally, there are four shareholders that each beneficially own more than 5% of the outstanding shares of our common stock. As a result, these stockholders, acting together, will be able to exercise significant influence over matters requiring approval by our stockholders, including the election of directors, and may not always act in the best interests of other stockholders. Such a concentration of ownership may have the effect of delaying or preventing a change in control of us, including transactions in which our stockholders might otherwise receive a premium for their shares over then-current market prices.

***A significant portion of our total outstanding shares of common stock may be sold in the market in the near future, which could cause the market price of our common stock to drop significantly.***

As of September 30, 2014, we had 13,846,361 shares of our common stock issued and outstanding and 580 shares of convertible preferred stock outstanding which can convert into 290,000 shares of common stock. 6,941,160 shares are registered pursuant to registration statements on Forms S-1 or S-3 or are either eligible to be sold under Rule 144 of the Securities Act of 1933, as amended, or are in the public float. An additional 6,905,201 shares will become eligible to be sold under SEC Rule 144 on November 16, 2014. In addition, we have registered 1,876,722 shares of our common stock underlying warrants previously issued and still outstanding and we registered 1,845,976 shares of our common stock underlying options granted or to be granted under our stock option plans. Consequently, sales of substantial amounts of our common stock in the public market, or the perception that such sales could occur, may have a material adverse effect on our stock price.

***Our common stock has a limited trading market, which could limit your ability to resell your shares of common stock at or above your purchase price.***

Our common stock is currently quoted on the OTCQB Marketplace, operated by the OTC Markets Group, or OTCQB, and our common stock currently has a limited trading market. We cannot assure you that an active trading market will develop or, if developed, will be maintained. As a result, our stockholders may find it difficult to dispose of shares of our common stock and, as a result, may suffer a loss of all or a substantial portion of their investment.

***The market price of our common stock may fluctuate and may drop below the price you paid.***

We cannot assure you that you will be able to resell the shares of our common stock at or above your purchase price. The market price of our common stock may fluctuate significantly in response to a number of factors, some of which are beyond our control. These factors include:

- quarterly variations in operating results;
- the progress or perceived progress of our research and development efforts;
- changes in accounting treatments or principles;
- announcements by us or our competitors of new technology, product and service offerings, significant contracts, acquisitions or strategic relationships;
- additions or departures of key personnel;
- future offerings or resales of our common stock or other securities;
- stock market price and volume fluctuations of publicly-traded companies in general and development companies in particular; and
- general political, economic and market conditions.

For example, during the quarter ended September 30, 2014, our common stock traded between \$1.28 and \$2.88 per share.

***Because we do not intend to pay, and have not paid, any cash dividends on our shares of common stock, our stockholders will not be able to receive a return on their shares unless the value of our common stock appreciates and they sell their shares.***

We have never paid or declared any cash dividends on our common stock, and we intend to retain any future earnings to finance the development and expansion of our business. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. Therefore, our stockholders will not be able to receive a return on their investment unless the value of our common stock appreciates and they sell their shares.

***Our stockholders may experience substantial dilution as a result of the conversion of convertible preferred stock, the exercise of options and warrants to purchase our common stock, or due to anti-dilution provisions relating to any on the foregoing.***

As of September 30, 2014, we have outstanding 580 shares of convertible preferred stock which may convert into 290,000 shares of our common stock and warrants to purchase 7,237,774 shares of our common stock. In addition, as

of September 30, 2014, we have reserved 1,845,976 shares of our common stock for issuance upon the exercise of options granted or available to be granted pursuant to our stock option plan, all of which may be granted in the future. Furthermore, in connection with the preferred stock agreements, we are required to reserve an additional 146,236 shares of common stock. The conversion of the convertible preferred stock and the exercise of these options and warrants will result in dilution to our existing stockholders and could have a material adverse effect on our stock price. The conversion price of the convertible preferred stock is also subject to certain anti-dilution adjustments.

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

None.

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

None.

**Item 4. Mine Safety Disclosures.**

None.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

Exhibits.

| Exhibit No. | Description   |
|-------------|---|
| 10.1        | Notice of Termination of Biofuels Evaluation and License Agreement by and between BioCorp Ventures LLC, Senesco Technologies, Inc. and Senesco, Inc. dated August 13, 2014. (Incorporated by reference to Exhibit 10.26 of Sevion Therapeutics, Inc. annual report on Form 10-K for the fiscal year ended June 30, 2014). |
| 10.2        | License Agreement by and between Fabrus, Inc. and The Scripps Research Institute, dated August 8, 2014. (Incorporated by reference to Exhibit 10.28 of Sevion Therapeutics, Inc. annual report on Form 10-K for the   |

fiscal year ended June 30, 2014).

10.3 Notice of extension of sublease agreement by and between Norris, McLaughlin & Marcus, P.A., as Sublandlord, and Senesco Technologies, Inc., as Subtenant, dated July 14, 2014. (Incorporated by reference to Exhibit 10.44 of Sevion Therapeutics, Inc. annual report on Form 10-K for the fiscal year ended June 30, 2014).

31.1 Certification of principal executive officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. (filed herewith).

31.2 Certification of principal financial and accounting officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. (filed herewith).

32.1 Certification of principal executive officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. 1350. (furnished herewith).

32.2 Certification of principal financial and accounting officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. 1350. (furnished herewith).

101.1 Financial Statements from the Quarterly Report on Form 10-Q of Sevion Therapeutics, Inc. for the quarter ended September 30, 2014, filed on November 14, 2014, formatted in XBRL: (i) the Condensed Consolidated Balance Sheets; (ii) the Condensed Consolidated Statements of Operations; (iii) the Condensed Consolidated Statements of Stockholder's Equity; (iv) the Condensed Consolidated Statements of Cash Flows and (v) the Notes to Condensed Consolidated Financial Statements. (filed herewith).

## **SIGNATURES**

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

### **SEVION THERAPEUTICS, INC.**

DATE: November 14, 2014 By: /s/ Ronald A. Martell  
Ronald A. Martell  
Chief Executive Officer  
(Principal Executive Officer)

DATE: November 14, 2014 By: /s/ Joel Brooks  
Joel Brooks  
Chief Financial Officer, Secretary and Treasurer  
(Principal Financial and Accounting Officer)

