

Sevion Therapeutics, Inc.  
Form 10-Q  
November 16, 2015

**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, 2015**

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File No. 001-31326

**SEVION THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

**84-1368850**

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(State or other jurisdiction of incorporation or organization) (IRS Employer Identification No.)

**4045 Sorrento Valley Boulevard**

**San Diego, CA 92121**

(Address of principal executive offices)

**(858) 909-0749**

(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:

20,420,608 shares of the issuer's common stock, par value \$0.01 per share, were outstanding as of October 31, 2015.



SEVION THERAPEUTICS, INC. AND SUBSIDIARIES

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**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

## CONSOLIDATED BALANCE SHEETS

(unaudited)

	September 30, 2015	June 30, 2015
<b><u>ASSETS</u></b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$3,354,869	\$3,334,626
Prepaid expenses and other current assets	299,286	395,100
<b>Total Current Assets</b>	<b>3,654,155</b>	<b>3,729,726</b>
Equipment, furniture and fixtures, net	153,855	185,948
Acquired research and development	9,800,000	9,800,000
Goodwill	5,780,951	5,780,951
Security deposits	50,770	50,770
<b>TOTAL ASSETS</b>	<b>\$19,439,731</b>	<b>\$19,547,395</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$174,356	\$232,033
Accrued expenses	398,812	408,705
Other current liabilities	102,324	137,778
<b>Total Current Liabilities</b>	<b>675,492</b>	<b>778,516</b>
Warrant and stock right liabilities	2,233,267	2,502,047
Deferred tax liability	3,920,000	3,920,000
Other liabilities	105,832	122,038
<b>TOTAL LIABILITIES</b>	<b>6,934,591</b>	<b>7,322,601</b>
<b>STOCKHOLDERS' EQUITY:</b>		
Convertible preferred stock, \$0.01 par value, authorized 5,000,000 shares		

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Series C shares 235,004 and 235,837 issued and outstanding, respectively (liquidation preference of \$2,350 and \$2,358 at September 30, 2015 and June 30, 2015, respectively)	2,350	2,358
Series A 10,297 shares issued and 380 shares outstanding (liquidation preference of \$399,000 and \$399,000 at September 30, 2015 and June 30, 2015, respectively)	4	4
Common stock, \$0.01 par value, authorized 500,000,000 shares, issued and outstanding 20,387,809 and 18,752,813 at September 30, 2015 and June 30, 2015, respectively	203,878	187,528
Capital in excess of par	119,810,996	119,217,880
Accumulated deficit	(107,512,088)	(107,182,976)
Total Stockholders' Equity	12,505,140	12,224,794
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 19,439,731</b>	<b>\$ 19,547,395</b>

See Notes to Condensed Consolidated Financial Statements



## SEVION THERAPEUTICS, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Three Months Ended	
	Ended September 30	
	2015	2014
Licensing Revenue	\$37,500	\$-
Operating expenses:		
General and administrative	587,273	774,600
Research and development	601,583	2,120,156
Impairment and write-off of patents	-	2,290,836
Total operating expenses	1,188,856	5,185,592
Loss from operations	(1,151,356 )	(5,185,592 )
Other non-operating income (expense)		
Change in fair value of stock right	22,334	-
Change in fair value of warrant liability	948,561	-
Interest income (expense) - net	(282 )	1,785
Net loss	(180,743 )	(5,183,807 )
Preferred dividends	(148,369 )	(14,500 )
Loss applicable to common shares	(329,112 )	(5,198,307 )
Other comprehensive loss	-	-
Comprehensive loss	\$(329,112 )	\$(5,198,307 )
Basic and diluted net loss per common share	\$(0.02 )	\$(0.38 )
Basic and diluted weighted-average number of common shares outstanding	20,006,451	13,846,361

See Notes to Consolidated Financial Statements

## SEVION THERAPEUTICS, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

As of September 30, 2015

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Capital in Excess of Par Value	Accumulated Deficit	Stockholders' Equity
Balance at June 30, 2015	236,217	\$ 2,362	18,752,813	\$ 187,528	\$ 119,217,880	\$(107,182,976)	\$ 12,224,794
Stock issued for Cash	66,667	667	959,996	9,600	1,142,130	-	1,152,397
Warrant Liability	-	-	-	-	(559,261 )	-	(559,261 )
Derivative Stock Right	-	-	-	-	(142,854 )	-	(142,854 )
Stock-based compensation	-	-	-	-	23,475	-	23,475
Preferred stock converted into common stock	(67,500 )	(675 )	675,000	6,750	(6,075 )	-	-
Deemed Dividend Preferred stock	-	-	-	-	135,701	(135,701 )	-
Dividends accrued and unpaid at Sept 30, 2015	-	-	-	-	-	(12,668 )	(12,668 )
Net loss	-	-	-	-	-	(180,743 )	(180,743 )
Balance at Sept 30, 2015	235,384	\$ 2,354	20,387,809	\$ 203,878	\$ 119,810,996	\$(107,512,088)	\$ 12,505,140

See Notes to Consolidated Financial Statements

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## SEVION THERAPEUTICS, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Three Months Ended	
	September 30	
	2015	2014
Cash flows from operating activities:		
Net loss	\$(180,743 )	\$(5,183,807)
Adjustments to reconcile net loss to net cash used in operating activities:		
Noncash income related to change in fair value		
- stock right	(22,334 )	-
- warrant liability	(948,561 )	-
Stock-based compensation expense	23,475	139,133
Depreciation and amortization	32,093	60,146
Write-off of intangibles	-	2,290,836
Write-off of prepaid research supplies	-	669,750
Deferred rent	(14,160 )	-
(Increase) decrease in operating assets:		
Prepaid expenses and other current assets	95,814	237,028
Increase (decrease) in operating liabilities:		
Accounts payable	(57,677 )	(288,160 )
Accrued expenses	(22,561 )	135,677
Deferred revenue	(37,500 )	-
Net cash used in operating activities	(1,132,154)	(1,939,397)
Cash flows from investing activities:		
Capitalized Patent costs	-	(260,477 )
Purchase of equipment, furniture and fixtures	-	(74,327 )
Net cash used in investing activities	-	(334,804 )
Cash flows from financing activities:		
Proceeds from issuance of common stock and warrants, net and exercise of warrants and options	1,152,397	-
Net cash provided by financing activities	1,152,397	-
Net (decrease) increase in cash and cash equivalents	20,243	(2,274,201)
Cash and cash equivalents at beginning of period	3,334,626	6,111,340
Cash and cash equivalents at end of period	\$3,354,869	\$3,837,139

Supplemental disclosure of non-cash transactions:

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Conversion of preferred stock into common stock	\$6,075	\$-
Allocation of equity proceeds to warrants	\$559,261	\$-
Allocation of equity proceeds to stock rights	\$142,854	\$-
Allocation of preferred stock proceeds to beneficial conversion feature	\$135,701	\$-
Dividends accrued on preferred stock	\$12,668	\$14,500
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$-	\$543

See Notes to 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, 2015.

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, 2015 and the results of its operations for the three months ended September 30, 2015 and cash flows for the three months ended September 30, 2015.

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 \$107,512,088 and has generated minimal revenues by licensing its technology 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.

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As of September 30, 2015, the Company had cash and cash equivalents in the amount of \$3,354,869, which consisted of checking accounts and money market funds. The Company estimates that its cash and cash equivalents as of September 30, 2015 will cover its expenses through at least June 30, 2016.

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 – Intangibles:

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 if the Company's review determines that the future undiscounted cash flows related to the groups, including these assets, will not be sufficient to recover their carrying value, the Company will reduce the carrying values of these assets down to the Company's estimate of fair value.

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,  
2015                      2014



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Common Stock to be issued upon conversion of convertible preferred stock - Series A	506,666	290,000
Common Stock to be issued upon conversion of convertible preferred stock - Series C	2,350,040	-
Outstanding warrants	8,698,634	7,237,774
Outstanding options	1,534,088	970,392
Total potentially dilutive shares of Common Stock	13,089,428	8,498,166

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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.

The Company did not issue any options during the three month period ended September 30, 2015.

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, 2015 is summarized as follows:

	Aggregate Number	Weighted Average Exercise Price	Exercise Price Range
Outstanding, June 30, 2015	1,626,919	\$ 4.45	\$ 0.54 - \$ 140.00
Granted	-	-	-
Exercised	-	-	-
Cancelled	(92,289 )	5.69	\$ .83 - \$ 140.00
Expired	(542 )	32.00	32.00
Outstanding, Sept 30, 2015	1,534,088	\$ 4.12	\$ 0.54 - \$ 140.00
Options exercisable at September 30, 2015	1,213,946	\$ 5.25	

As of September 30, 2015, the aggregate intrinsic value of stock options outstanding was \$1,343 with a weighted-average remaining term of 9.4 years. The aggregate intrinsic value of stock options exercisable at September 30, 2014 was \$0, with a weighted-average remaining term of 8.8 years. As of September 30, 2015, the Company has 3,383,582 shares available for future stock option grants.

Stock-based compensation expense for the three months ended September 30, 2015 and September 30, 2014 amounted to \$23,475 and \$139,133, respectively.

As of September 30, 2015, total stock-based compensation expense not yet recognized related to stock option grants amounted to approximately \$145,322 which will be recognized over the next 40 months.

**Note 6 – Income Taxes:**

No provision for income taxes has been made for the three months ended September 30, 2015 and 2014 given the Company's losses in 2015 and 2014 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, 2015 and June 30, 2015:

	Carrying Value	Fair Value Measurement at Sept 30, 2015		
		Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents	\$3,354,869	\$3,354,869	\$ -	\$-
Warrant Liabilities	\$2,233,267	\$-	\$ -	\$2,233,267

	Carrying Value	Fair Value Measurement at June 30, 2015		
		Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents	\$3,334,626	\$3,334,626	\$ -	\$-
Warrant Liabilities	\$2,502,047	\$-	\$ -	\$2,502,047

**For the quarter ended September 30, 2015**

Beginning Balance	\$2,502,047
Recognition of common stock warrant liability	559,261
Recognition of stock right	142,854
Change in fair value of warrant liabilities, net	(948,561 )
Change in fair value of stock right net	(22,334 )

Ending Balance \$2,233,267

**Note 8 – Warrant Liabilities:**

The warrant liabilities represent the fair value of Common Stock purchase warrants which have exercise price reset features estimated using a Monte Carlo valuation model. The Company computes a valuation using the Monte Carlo model for such warrants to account for the various possibilities that could occur due to changes in the inputs to the model as a result of contractually-obligated changes. These estimates of the likelihood of completing an equity raise that would meet the criteria to trigger the reset provisions are based on numerous factors, including the remaining term of the financial instruments and the Company's overall financial condition.

Changes in the unobservable input values would have likely caused material changes in the fair value of the Company's Level 3 financial instruments. The significant unobservable input used in the fair value measurement was the estimation of the likelihood of the occurrence of a change to the strike price of the warrants. A significant increase (decrease) in this likelihood would have resulted in a higher (lower) fair value measurement. The assumptions used to value the warrants at the date of issuance and at September 30, 2015 are as follows:

	Date of Issuance	September 30, 2015	
Estimated life in years	2.50	2.08	
Risk-free interest rate (1)	0.91	% 0.69	%
Volatility	108.60	% 105.40	%
Dividend paid	0.00	% 0.00	%

(1) Represents the interest rate on a U.S. Treasury security with a maturity date corresponding to that of the warrant term.

**Note 9 – Series C Preferred Stock.**

In connection with allocation of the gross proceeds to the issuance of the Series C Preferred Stock, the Company determined that the Series C Preferred Stock's conversion feature was considered to be beneficial. A beneficial conversion feature requires the Company to record a deemed dividend for a non-detachable conversion feature that is in the money at the issuance date. As a result, the Company recorded a deemed dividend amounting to \$135,701 as of the issuance date of the Series C Preferred Stock.

During the three months ended September 30, 2015, 67,500 shares of Series C Preferred Stock were converted into 675,000 shares of Common Stock.

**Note 10 – 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 May 2014, the FASB issued ASU No. 2014- 09, "Revenue from Contracts with Customers" ("ASU 2014-09"). ASU 2014-09 requires that a company recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which the company expects to be entitled for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP. The standard is effective for annual periods beginning after December 15, 2016, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). In July 2015, the FASB approved a proposal to defer the effective date of the guidance until annual and interim reporting periods beginning after December 15, 2017. The Company does not anticipate that the adoption of this standard will have a material impact on the Company's financial statements.

In June 2014, the FASB issued ASU No. 2014-12, "Compensation - Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide that a Performance Target Could be Achieved after the Requisite Service Period," ("ASU 2014-12"). ASU 2014-12 requires that a performance target that affects vesting, and that could be achieved after the requisite service period, be treated as a performance condition. As such, the

performance target should not be reflected in estimating the grant date fair value of the award. This update further clarifies that compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. The Company does not anticipate that the adoption of this standard will have a material impact on the Company's financial statements.

In August 2014, the FASB issued ASU No. 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," ("ASU 2014-15"). ASU 2014-15 amended existing guidance related to the disclosures about an entity's ability to continue as a going concern. These amendments are intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures. These amendments provide guidance to an organization's management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that are commonly provided by organizations in the financial statement footnotes. The amendments are effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. The Company does not anticipate that the adoption of this standard will have a material impact on the Company's financial statements.

In November 2014, the FASB issued ASU No. 2014-16, "Derivatives and Hedging (Topic 815), Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share Is More Akin to Debt or to Equity," ("ASU 2014-16"). All entities are required to use what is called the "whole instrument approach" to determine the nature of a host contract in a hybrid financial instrument issued in the form of a share. The guidance requires issuers and investors to consider all of a hybrid instrument's stated and implied substantive terms and features, including any embedded derivative features being evaluated for bifurcation. The guidance eliminates the "chameleon approach," under which all embedded features except the feature being analyzed are considered. The guidance is effective for fiscal years beginning after December 15, 2015, and interim periods within fiscal years beginning after December 15, 2016. The Company does not anticipate that the adoption of this standard will have a material impact on the Company's financial statements.

The Company has assessed other recently issued accounting pronouncements and has determined that they do not apply.

#### **Note 11 – Subsequent Events**

The Company has evaluated for any subsequent events through the date of issuance of the financial statements and has determined that no subsequent events have occurred.

## **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*

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 build and develop a portfolio of innovative therapeutics, from both internal discovery and acquisition, for the treatment of cancer and immunological diseases. The Company's product candidates are derived from multiple key proprietary technology platforms, such as: cell-based arrayed antibody discovery, ultralong antibody scaffolds and Chimerasome nanocages.

### **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 multispinning 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 is an ion channel blocking antibody that is potentially the first therapeutic antibody against this target class. SVN001 targets an ion channel, Kv1.3, which 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 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.

*Other Antibodies* - We have discovered fully human antibodies against additional oncology targets, including ErbB2, ErbB3, CXCR4, and GLP1R which have been engineered to have activity in in vitro systems. These cell surface proteins are validated, therapeutically high value targets in the disease fields of oncology and diabetes. Additionally, we have early stage antibodies against other undisclosed targets which were derived from our addressed library platform.

### *Research Program*

We are advancing SVN001 through preclinical development where it has demonstrated potent activity as well as advancing SVN002 through preclinical development. However, given the Company's limited capital resources, we have reduced our research and development spending on our antibody program until we are able to consummate a strategic transaction or a financing transaction.

On December 18, 2014, we entered into a Collaboration Agreement with CNA Development, LLC, an affiliate of Janssen Pharmaceuticals, Inc., or Janssen, to discover antibodies using our spatially addressed library platform. The collaboration, facilitated by the Johnson & Johnson Innovation Center in California, will include discovery of antibodies against multiple targets in several therapeutic areas. We and Janssen will jointly conduct research on antibodies discovered by us, and Janssen will have an option to an exclusive license to develop, manufacture, and commercialize candidates resulting from the collaboration. Under the terms of the agreement, we received an up-front payment and research support payments for activities conducted in collaboration with Janssen. For candidates licensed by Janssen, we would be eligible to receive payments upon the achievement of certain development and commercial milestones potentially totaling up to \$125 million as well as low single digit royalties on product sales.

In order to pursue the above research initiatives, as well as other research initiatives that may arise, we will use our cash reserves. 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.

### *Intellectual Property*

We continue to develop our intellectual property internally and by in-licensing certain intellectual property related to our antibody platforms and our chimerasome technology.



## Liquidity and Capital Resources

### *Overview*

For the three months ended September 30, 2015, net cash of \$1,132,154 was used in operating activities primarily due to a net loss of \$180,743 which was reduced by non-cash income \$929,485 and increased by changes in operating assets and liabilities in the amount of \$21,925.

The \$21,925 change in operating assets and liabilities was the result of a decrease in prepaid research supplies and expenses in the amount of \$95,814 and an increase in accounts payable and accrued expenses in the amount of \$117,741 due to the timing of expenses and payments.

During the three months ended September 30, 2015, no cash was used for investing activities related to the purchase of equipment, furniture and fixtures.

As of September 30, 2015, our cash balance totaled \$3,354,869, and we had working capital of \$2,978,663.

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 current cash balance at September 30, 2015, we will be able to fund our operations at least through June 30, 2016.

Over the next 9 months, we plan to fund our research and development and commercialization activities:

· by utilizing our current cash balance and investments,

· by raising capital through the placement of equity or debt instruments

by completing a strategic transaction, and / or

by raising capital through the 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**

Prior to the fourth quarter of fiscal 2015, certain patent related costs were capitalized. We concluded, based on historical write offs of patent cost, that the future beneficial value of our patent assets were uncertain and as such made a change to our accounting policy. This change is considered a change in estimate for accounting purposes and is reflected on a prospective basis beginning in the fourth quarter of fiscal 2015.

There have been no other 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, 2015.

**Results of Operations**Three Months Ended September 30, 2015 and Three Months Ended September 30, 2014

The net loss from operations for the three months ended September 30, 2015 was \$1,151,356. The net loss from operations for the three months ended September 30, 2014 was \$5,185,592. Such a change represents a decrease in net loss of \$4,034,236, or 78%. This decrease in net loss was primarily the result of reduction of research and development activities.

*Revenue*

There was \$37,500 in revenue during the three months ended September 30, 2015, which represented the amortization of deferred revenue for a collaboration and option agreement.

This compares to no revenue for the three months ended September 30, 2014

*General and Administrative Expenses (000's)*

	Three Months ended September 30			
	2015	2014	Change	%
Payroll and benefits	\$5	\$237	\$ (232 )	(97.9 )%
Professional fees	379	199	180	90.5 %
Delaware Franchise Tax	75	5	70	1400.0%
Consultants	45	32	13	40.6 %
Stock-based compensation	12	92	(80 )	(87.1 )%
Other general & Administrative Expenses	71	210	(139 )	(66.2 )%
Total G&A	\$587	\$775	\$ (188 )	(24.3 )%

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Payroll and benefits were lower as a result of the resignation of the CEO in FY 2015, and our new CEO's classification as a consultant instead of as a salaried employee.

Professional fees were higher primarily as a result of an increase in accounting fees due to the financial audit and SOX review, accounting staff including our CFO being paid as a consultant, and increased legal expense due to the complexity of the recent financing.

Delaware Franchise Tax increased due to the prepayment requirements on computed tax resulting from the reverse stock split effected during the prior fiscal year.

Consultant costs increased as a result of our treatment of our CEO, as compared to the quarter ended September 30, 2014, when our CEO was paid as an employee.

Stock-based compensation was lower primarily because options were not issued during the quarter ended September 30, 2015.

Other general and administrative expenses were lower due to reduced activity and fewer employees over the prior year.



*Research and Development Expenses (000's)*

	Three Months Ended September 30			
	2015	2014	Change	%
Payroll	\$281	\$353	\$(72 )	(20.4 )%
Patent Costs	112	75	37	49.3 %
Facility Rent	92	58	34	58.6 %
Research Supplies	36	92	(56 )	(60.9 )%
Depreciation and amortization	32	60	(28 )	(46.7 )%
Stock-based compensation	11	47	(36 )	(76.6 )%
Research Contract with the University of Waterloo	-	119	(119 )	(100.0)%
Write off Prepaid Research Supplies	-	670	(670 )	(100.0)%
Phase 1b/2a clinical trial	-	427	(427 )	(100.0)%
Other research and development	38	219	(181 )	(82.6 )%
Total research and development	\$602	\$2,120	\$(1,518)	(71.6 )%

Payroll and benefits were lower due to attrition with the closing of the New Jersey office in November 2014 partially offset by the addition of Fabrus research personnel.

Patent costs were higher as a result of the change in our accounting policies to now expense patent costs as incurred.

Rent was higher due to relocation of our principal offices to San Diego, California in October 2014.

Research supplies were lower primarily due to discontinuing development of our Factor 5A technology combined with the reduction of research costs and collaboration cost reimbursements.

Depreciation and amortization was lower due to the elimination of amortization of patent costs as a result of the change in our accounting policy to now expense patent costs as incurred.

Stock-based compensation was lower primarily because options were not issued during the quarter ended September 30, 2015.

Research contract expenses with the University of Waterloo were lower due to the suspension of the agreement in 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. No write-off was necessary in the quarter ended September 30, 2015.

Other research and development costs were lower primarily due to the SNS01-T clinical program being put on hold in 2014.

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

During the three months ended September 30, 2015, 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, 2015.

### **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 was terminated in 2014 and was 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*

Our exposure to market risks for interest rate changes is not significant. Interest rates on our short-term debt are subject to change, however, the effect of interest rate changes would not be material. 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, 2015. Based on that evaluation, management has concluded that as of September 30, 2015, our disclosure controls and procedures were not effective due to a material weakness in internal control over financial reporting as noted in the Company's Form 10-K for the year ended June 30, 2015 filed with the SEC on October 9, 2015. The material weakness identified relates to the review of the accounting and calculation surrounding its equity-linked financial instruments. The material weakness has not yet been remediated. We plan to remediate these control deficiencies by implementing changes to our internal control over financial reporting and will continue to review and make the changes necessary in order to improve the overall effectiveness of our internal controls over financial reporting. We have commenced steps to remediate the material weakness identified and to adequately and appropriately review all

equity-linked accounting instruments and related accounting issues. Notwithstanding the material weaknesses that existed as of June 30, 2015, our principal executive officer and principal financial officer have concluded that the financial statements included in this Quarterly Report on Form 10-Q present fairly, in all material aspects, the financial position, results of operations and cash flows of the Company in conformity with accounting principles generally accepted in the United States of America.

(b) Changes in internal controls.

As a result of the material weaknesses described above, there were changes (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934) in internal control over financial reporting during the three month period ended September 30, 2015 that have materially affected, or are reasonably likely to materially affect our internal control 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, 2015. 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, 2015, we believe we have enough cash to fund operations through at least June 30, 2016.

***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 \$107,512,088 at September 30, 2015. 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 June 30, 2016.

***If we are unable to successfully remediate the material weakness in our internal control over financial reporting, the accuracy and timing of our financial reporting may be adversely affected, which may adversely affect investor confidence in us and, as a result, the value of our common stock.***

In connection with the audit of our fiscal year 2015 consolidated financial statements, our auditors noted a material weakness in our internal controls, principally relating to the review of the accounting and calculation surrounding our equity-linked financial instruments. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting that results in more than reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. We cannot assure that any



measures that we take to correct this material weakness will fully remediate the deficiencies or material weakness described above. We also cannot assure you that we have identified all of our existing significant deficiencies and material weaknesses, or that we will not in the future have additional significant deficiencies or material weaknesses.

***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 preclinical studies and 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 preclinical studies and 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 discover and engineer monoclonal antibodies. 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 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 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 patients that receive our product candidates. 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, 2015, we had a cash balance of \$3,354,869 and working capital of \$2,978,663. Using our available reserves as of September 30, 2015, we believe that we can operate according to our current business plan at least through June 30, 2016.

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:

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- 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.

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, 2015, we had 458,287,101 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 industry, 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.

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.***

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 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 agricultural products or 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.

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. 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 of our product candidates 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 expect to perform clinical trials in connection with our product candidates, which are 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 product candidates may be unsuccessful, which could delay or prevent regulatory approval.***

Preclinical studies may reveal that one or more of our product candidates 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 product candidates 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. Additionally, 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, 2015, our executive officers and directors together beneficially own approximately 21% 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, 2015, 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, 2015, we had 20,387,809 shares of our common stock issued and outstanding, 380 shares of Series A convertible preferred stock outstanding which can convert into 506,666 shares of common stock and 235,004 shares of Series C Preferred Stock outstanding which can convert into 2,350,040 shares of common stock. 11,655,860 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 8,731,949 shares will begin to become eligible to be sold under SEC Rule 144 on April 30, 2016. In addition, we have registered 1,876,722 shares of our common stock underlying warrants previously issued and still outstanding and we registered 4,917,670 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, 2015, our common stock traded between \$0.55 and \$0.99 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 June 30, 2015, we have outstanding 380 shares of Series A convertible preferred stock which may convert into 506,666 shares of common stock, 235,004 shares of Series C convertible preferred stock outstanding which can convert into 2,350,040 shares of common stock and warrants to purchase 8,698,634 shares of our common stock. In

addition, as of September 30, 2015, we have reserved 4,917,670 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 4,852,080 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
4.1	Form of 2015 Common Stock Warrant. (Incorporated by reference to Exhibit 4.18 on our annual report on Form 10-K for the period ended June 30, 2015.)
10.1	Form of Registration Rights Agreement by and among Sevion Therapeutics, Inc. and certain investors. (Incorporated by reference to Exhibit 10.20 on our annual report on Form 10-K for the period ended June 30, 2015.)
10.2	Form of Subscription Agreement by and among Sevion Therapeutics, Inc. and certain investors. (Incorporated by reference to Exhibit 10.21 on our annual report on Form 10-K for the period ended

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June 30, 2015.)

- 10.3 Amendment to Form of Subscription Agreement, dated July 27, 2015, by and among Sevion Therapeutics, Inc. and certain investors. (Incorporated by reference to Exhibit 10.22 on our annual report on Form 10-K for the period ended June 30, 2015.)
- 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, 2015, filed on November 16, 2015, 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).

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**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 16, 2015 By: /s/ David Rector  
David Rector  
Chief Executive  
Officer  
(Principal Executive  
Officer)

DATE: November 16, 2015 By: /s/ James Schmidt  
James Schmidt  
Chief Financial  
Officer  
(Principal Financial  
and Accounting  
Officer)