

Sevion Therapeutics, Inc.
Form S-1
October 09, 2015

As filed with the Securities and Exchange Commission on October 9, 2015

Registration No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

SEVION THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

2834

84-1368850

(State or other jurisdiction of

(Primary Standard Industrial

(I.R.S. Employer

incorporation or organization) *Classification Code Number)* *Identification
Number)*

**4045 Sorrento Valley Boulevard
San Diego, CA 92121
(858) 909-0749**

(Address, including zip code and telephone number, including area code, of registrant's principal executive offices)

David Rector

Chief Executive Officer

Sevion Therapeutics, Inc.

4045 Sorrento Valley Boulevard

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(858) 909-0749

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Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this registration statement, as shall be determined by the selling stockholders identified herein.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company
 (Do not check if a smaller reporting company)

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered (1)	Proposed Maximum Aggregate Offering Price Per Share (2)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee
Common Stock, par value \$0.01 per share underlying the warrants	9,842,992	\$ 0.60	\$ 5,905,796	\$ 595
Total	9,842,992	(3)	\$ 5,905,796	\$ 595

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(1) Represents shares offered by the selling stockholders. Includes an indeterminable number of additional shares of common stock, pursuant to Rule 416 under the Securities Act of 1933, as amended, that may be issued to prevent dilution from stock splits, stock dividends or similar transactions that could affect the shares to be offered by selling stockholders.

(2) Estimated pursuant to Rule 457(c) under the Securities Act of 1933, as amended, for the purpose of calculating the registration fee based on the average of the high and low prices per share of the registrant's common stock as reported on the OTCQB Marketplace on October 2, 2015.

(3) Represents 200% of 4,921,496 shares of common stock that may be issued upon the exercise of the warrants.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. The selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is declared effective. This prospectus is not an offer to sell these securities and it is not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion, dated October 9, 2015

Preliminary Prospectus

SEVION THERAPEUTICS, INC.

9,842,992 Shares of Common Stock,

This prospectus relates to the resale of up to 9,842,992 shares of our common stock by the selling stockholders named herein. From May 2015 to July 2015, we entered into separate subscription agreements with certain accredited investors whereby we sold units of our securities with each unit consisting of one share of our common stock, or, at the election of the investor, shares of our Series C Convertible Preferred Stock, and a warrant to purchase one half of one share of our common stock at an exercise price of \$1.50 per share, referred to herein as the Warrants. Each unit was sold for \$0.75 per unit. Pursuant to the terms of the registration rights agreement, or Registration Rights Agreement, we entered into with the investors in connection with these transactions, we are required to register 200% of the number of shares of common stock underlying the Warrants. To the extent that one or more investors elects to exercise their respective Warrants to acquire shares of our common stock, this prospectus may be used by the selling stockholders named under the section “Selling Stockholders” to resell their shares. We are not selling any securities under this prospectus and will not receive any of the proceeds from the sale of shares by any selling stockholders, however, we will receive proceeds upon exercise of the Warrants, and any such proceeds received will be used for general corporate purposes and for working capital.

The selling stockholders may sell their respective shares of common stock described in this prospectus in a number of different ways and at varying prices. We provide more information about how the selling stockholders may resell their respective shares of our common stock in the section titled “Plan of Distribution.” Each selling stockholder may be deemed to be an “underwriter” within the meaning of the Securities Act in connection with such sales within the

meaning of the Securities Act of 1933, as amended, with respect to any shares resold under this prospectus by such selling stockholder. Although we will pay the expenses incurred in registering the shares, we will not be paying any underwriting discounts or commissions in connection with the resale of the shares.

We will pay the expenses incurred in registering the shares, including legal and accounting fees. See “Plan of Distribution.”

Our common stock is listed for quotation on the OTCQB Marketplace, operated by the OTC Markets Group, under the symbol “SVON.” There is limited trading in our common stock. The last reported sale price of our common stock on the OTCQB Marketplace on October 8, 2015 was \$0.65 per share.

You should understand the risks associated with investing in our common stock. Before making an investment, read the “Risk Factors,” which begin on page 5 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is _____, 2015.

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We have not authorized anyone to provide you with information different from, or in addition to, that contained in this prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell or seeking offers to buy these securities in any jurisdiction where, or to any person to whom, the offer or sale is not permitted. The information in this prospectus is accurate only as of its date regardless of the time of delivery of this prospectus or of any sale of our common shares. Our business, financial condition, results of operations and future growth prospects may have changed since those dates.

For investors outside the United States, we have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus outside of the United States.

This prospectus includes estimates, statistics and other industry and market data that we obtained from industry publications, research, surveys and studies conducted by third parties and publicly available information. Such data involves a number of assumptions and limitations and contains projections and estimates of the future performance of the industries in which we operate that are subject to a high degree of uncertainty. This prospectus also includes data based on our own internal estimates. We caution you not to give undue weight to such projections, assumptions and estimates.

PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus. Because it is only a summary, it does not contain all of the information that you should consider before investing in our securities and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere in this prospectus. You should read the entire prospectus carefully, especially the section entitled “Risk Factors” and our consolidated financial statements and related notes, before deciding to buy our securities. Unless otherwise stated, all references to “us,” “our,” “we,” “Sevion,” the “Company” and similar designations refer to Sevion Therapeutics, Inc. and its subsidiaries Senesco, Inc and Fabrus, Inc.

Company Overview

Sevion Therapeutics, Inc., a Delaware corporation, is a development stage company. We do not expect to generate significant revenues for several years, during which time we will engage in significant research and development efforts. Our primary business is to build and develop a portfolio of innovative therapeutics, from both internal discovery and acquisition, for the treatment of cancer and immunological diseases. Our product candidates are derived from multiple key proprietary technology platforms, such as: cell-based arrayed antibody discovery, ultralong antibody scaffolds and Chimerasome nanocages.

Our protein biologics technology comprises (i) a platform to discover and engineer human antibodies directly on the cell surface, (ii) antibodies derived from cows that contain ultralong binding regions that may be useful in binding certain therapeutic epitopes, and (iii) a chimerasome nanocage capable of encapsulating therapeutic payloads for drug delivery.

Our preclinical antibody development program comprises an antibody against the ion channel Kv1.3, which is an important molecule in regulating T-cell activation in a number of autoimmune diseases. We have performed experiments showing that this antibody potently blocks activation of human T-cells in vitro. Future development efforts will include a Phase I clinical trial.

Risk Factors

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are described in more detail in the “Risk Factors” section of this prospectus immediately following this prospectus summary. These risks include the following:

We have not experienced positive cash flow from our operations, and the ability to achieve positive cash flow from operations will depend on increasing sales of our products, which may not be achievable.

Our business is subject to continuing regulatory compliance by the FDA and other authorities, which is costly and could result in negative effects on our business.

Failure to protect our intellectual property rights could result in costly and time consuming litigation and our loss of any potential competitive advantage.

The price of our common shares could be highly volatile due to a number of factors, which could lead to losses by investors and costly securities litigation.

Corporate Information

We were incorporated under the laws of Delaware in 1999. Our principal executive offices are located at 4045 Sorrento Valley Boulevard, San Diego, CA 92121 and our telephone number is (858) 909-0749. Our website address is www.seviontherapeutics.com. We have included our website address in this prospectus solely as an inactive textual reference. The information contained on, or that can be accessed through, our website is not part of this prospectus.

Recent Developments

On May 1, 2015, May 7, 2015, May 29, 2015, June 10, 2015, June 24, 2015, and July 27, 2015 we entered into separate subscription agreements, collectively referred to as the Subscription Agreements, with certain accredited investors, whereby we sold units of our securities, the Units, with each Unit consisting of one share of our common stock or, at the election of the investor, shares of our newly designated 0% Series C Convertible Preferred Stock, or the Preferred Stock, and a warrant to purchase one half of one share of Common Stock at an exercise price of \$1.50 per share, referred to herein as the Warrants. This offering is referred to as the Private Placement. Each Unit was sold for \$0.75 per Unit. We received net proceeds of approximately \$5,979,966 from the Private Placement, after paying placement agent fees and estimated offering expenses, which we will use to fund our research and development and for working capital purposes.

Laidlaw & Company (UK) Ltd., or Laidlaw, acted as the lead placement agent for the Private Placement. As compensation for the services of Laidlaw and the other participating placement agents, we paid a total of approximately \$424,542 of placement agent fees, and issued to the placement agents common stock purchase warrants to purchase up to 555,521 shares of our common stock with an initial exercise price of \$0.75. The shares underlying the warrants that we issued to the placement agents are included in this prospectus.

In connection with the Private Placement, we entered into a registration rights agreement with the investors pursuant to which we are obligated to file a registration statement to register the resale of up to 200% of the shares of common stock issuable upon exercise of the warrants. In addition, pursuant to the terms of our agreement with the placement agents, the warrants issued to the placement agents are given the same registration rights as those delivered to the investors pursuant to the Subscription Agreements.

The Offering

Up to 9,842,992 shares, consisting of:

Common stock offered by the selling stockholders 4,921,496 shares issuable upon the exercise of the Warrants; and

· 4,921,496 shares issuable upon the exercise of additional Warrants that we may be obligated to issue to the investors pursuant to the Subscription Agreements.

Common stock offered by us None

Common stock currently outstanding 20,389,809 shares (1)

Common stock to be outstanding after giving effect to the total issuance of 9,842,992 shares registered in this Registration Statement 30,232,801 shares (2)

Use of proceeds We will not receive any proceeds from the sale of the common stock offered hereby. However, we may receive up to a maximum of approximately \$13,931,205 (which number includes the additional warrants that we may be required to issue pursuant to the Subscription Agreements) of gross proceeds from the exercise of the warrants issued in the Private Placement, which proceeds we expect to use for general working capital. No assurances can be given, however, that all or any portion of such warrants will ever be exercised.

Current trading on OTCQB Marketplace Our common stock currently trades on the OTCQB Marketplace under the symbol "SVON."

Risk factors You should read the "Risk Factors" section of this prospectus for a discussion of factors to consider carefully before deciding to invest in our common shares.

1) The number of shares of common stock outstanding after this offering is based on 20,389,809 shares of common stock outstanding as of September 15, 2015, and excludes:

1,626,919 shares of common stock issuable upon the exercise of options outstanding as of June 30, 2015 at a weighted average exercise price of \$4.45 per share;

3,780,137 shares of common stock issuable upon the exercise of warrants outstanding as of June 30, 2015 at a weighted average exercise price of \$4.70 per share;

506,666 shares of common stock issuable upon the conversion of 380 shares of Series A Convertible Preferred Stock outstanding as of June 30, 2015;

2,358,370 shares of common stock issuable upon the conversion of 235,837 shares of Series C Convertible Preferred Stock outstanding as of June 30, 2015; and

3,290,751 additional shares of common stock available for future issuance as of June 30, 2015 under our Sevion Therapeutics, Inc. 2008 Stock Incentive Plan.

2) Assumes the exercise of all warrants by the selling stockholders.

Unless otherwise specifically stated, information throughout this prospectus does not assume the exercise of outstanding options or warrants to purchase shares of common stock or conversion of outstanding shares of preferred stock.

RISK FACTORS

Investing in our common shares involves a high degree of risk. Before you decide to invest in our securities, you should consider carefully the risks described below, as well as the other information contained in this prospectus. The risks described below are not the only ones facing us. Additional risks not presently known to us or that we currently deemed immaterial may also impair our business operations.

If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common shares could decline, and you may lose all or part of your investment.

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.

Based on the cash on hand as of June 30, 2015 and the aggregate net proceeds from the issuance of preferred stock, common stock and warrants on July 27, 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 \$107,182,976 at June 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.

Based on the cash on hand as of June 30, 2015 and the aggregate net proceeds from the issuance of preferred stock, common stock and warrants on July 27, 2015, we believe we have enough cash to fund operations through at least June 30, 2016.

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 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 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 any 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 June 30, 2015, we had a cash balance of \$3,334,626 and working capital of \$2,951,210. Using our available reserves as of June 30, 2015, and the aggregate net proceeds from the issuance of preferred stock, common stock and warrants on July 27, 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:

- 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 June 30, 2015, we had 461,262,961 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 product candidates.

It may take several years to complete the clinical trials of a product, 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;