SENESCO TECHNOLOGIES INC
Form 10-K
September 11, 2013
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

x ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the fiscal year ended June 30, 2013

OR

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.
For the transition period from _____ to _____

Commission file number: **001-31326**

SENESCO TECHNOLOGIES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**84-1368850**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

721 Route 202/206, Suite 130, Bridgewater, New Jersey	**08807**
(Address of principal executive offices)	(Zip Code)

(908) 864-4444

(Registrant's telephone number, including area code)

Securities registered under Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
None	

Securities registered under Section 12(g) of the Act:

Common Stock, $0.01 par value per share.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act . Yes ¨ No x

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 x 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 x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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 x

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

As of December 31, 2012, the aggregate market value of the registrant’s common stock held by non-affiliates of the registrant was $15,723,026, based on the closing sales price as reported on the OTCQB Marketplace on that date.

The number of shares outstanding of each of the registrant's classes of common stock, as of August 31, 2013:

Class	Number of Shares
Common Stock, $0.01 par value	231,901,368
Preferred Stock, $0.01 par value	665

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PART I

Item 1. Business.

Our Business

The primary business of Senesco Technologies, Inc., a Delaware corporation incorporated in 1999, and its wholly-owned subsidiary, Senesco, Inc., a New Jersey corporation incorporated in 1998, collectively referred to as "Senesco," "we," "us" or "our," is to utilize our patented and patent-pending technology related to certain genes, primarily eukaryotic translation initiation Factor 5A, or Factor 5A, and deoxyhypusine synthase, or DHS, and related technologies for human therapeutic applications to develop novel approaches to treat cancer and inflammatory diseases.

For agricultural applications, we have licensed applications of the Factor 5A, DHS and Lipase platforms to enhance the quality, productivity and stress resistance of agronomic crops and biofuel feedstock crops through the control of cell death, referred to herein as senescence, and growth in plants.

Human Therapeutic Applications

We believe that our Factor 5A gene regulatory technology could have broad applicability in the human therapeutic field, by either inducing or inhibiting programmed cell death, also known as apoptosis, which is the natural process the human body goes through in order to eliminate redundant or defective cells. Inducing apoptosis is useful in treating cancer where the defective cancer cells have failed to respond to the body's natural apoptotic signals. Conversely, inhibiting apoptosis may be useful in preventing, ameliorating or treating an exaggerated, acute immune response in a wide range of inflammatory and ischemic diseases attributable to or aggravated by premature apoptosis.

SNS01-T for Multiple Myeloma

We have developed a therapeutic candidate, SNS01-T, an improved formulation of SNS01, for the potential treatment of multiple myeloma and non-Hodgkin B-cell lymphomas. SNS01-T utilizes our Factor 5A technology and comprises two active components: a DNA plasmid, or pDNA, expressing human eIF5A containing a lysine to arginine substitution at amino acid position 50, or eIF5AK50R, and a small inhibitory RNA, or siRNA. These two components are combined in a fixed ratio with a polymer, polyethyleneimine, or PEI, which enables self-assembly of the DNA and RNA into nanoparticles with demonstrated enhanced delivery to tissues and protection from degradation in the blood stream. Under the control of a B cell selective promoter, SNS01-T's DNA plasmid up-regulates the apoptotic pathways within cancer cells by preferentially expressing the stable arginine form of the Factor 5A death message in target cells. The siRNA, by silencing the eIF5A gene, reduces expression of the hypusine form of Factor 5A that supports cell survival and proliferation. The silencing of the eIF5A gene by an eIF5A siRNA also down-regulates anti-apoptotic proteins, such as NFkB, ICAM and pro-inflammatory cytokines, which protect malignant cells from apoptosis and promote cell growth in multiple myeloma. The PEI, a cationic polymer, promotes auto-assembly of a nanoparticle with the other two components for intravenous delivery and protects the combination from degradation in the bloodstream until it is taken up by the tumor cell, where the siRNA and DNA plasmid are released.

We have performed efficacy, toxicological and dose-finding studies *in vitro* in non-human and human cells and *in vivo* in mice with SNS01. We have also completed our pivotal GLP toxicology studies in mice and dogs, employing SNS01-T, an improved formulation of SNS01, and have an open investigational new drug application, or IND, with the United States Food and Drug Administration, or FDA.

We have been granted orphan drug status for SNS01-T by the FDA for the potential treatment of multiple myeloma, mantle cell lymphoma (MCL) and diffuse large B-cell lymphoma (DLBCL) and are conducting a Phase 1b/2a clinical study with SNS01-T in patients with those indications. The clinical study is an open-label, multiple-dose, dose-escalation study, which is evaluating the safety and tolerability of SNS01-T when administered by intravenous infusion to relapsed or refractory multiple myeloma patients. The study design calls for four cohorts of three to six patients each. Patients in each cohort will receive twice-weekly dosing for six weeks followed by up to a four-week safety data review period before escalating to a higher dose level in the next cohort.

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

We have selected Mayo Clinic, University of Arkansas for Medical Sciences, the Randolph Cancer Center at West Virginia University, the Fred Hutchinson Cancer Research Center and the John Theurer Cancer Center at Hackensack University Medical Center as our clinical sites. During the fiscal year ended June 30, 2013, the agreement with the Company's contract research organization was amended to reflect the additional costs involved with adding the three additional clinical sites. We are also considering adding additional sites to increase the rate of enrollment.

We have completed our first and second cohorts and the third cohort is open for enrollment and dosing patients. The results of the first and second cohort showed that SNS01-T was safe and well tolerated and met the criteria for Stable Disease in 2 of the 6 evaluable patients.

We have demonstrated in human multiple myeloma cell lines that there may be an additional benefit to combining SNS01-T with other approved myeloma drugs, such as bortezomib and lenalidomide. We have shown, in vitro, that these drugs are up to forty (40) times more effective in inhibiting cell growth when used in combination with SNS01-T. These results further reinforce the significance of our target and will guide us in designing future clinical studies. We have demonstrated that a high level of tumor eradication in a mouse model of human multiple myeloma was achieved with a combination of SNS01-T and lenalidomide. While SNS01-T alone performed well by completely eliminating tumors in 40% of the animals, complete tumor eradication was achieved in five out of six or 83% of the treated animals that received SNS01-T combined with the optimal study dose of lenalidomide. This effect lasted throughout 6 weeks of observation after the end of treatment. Neither dose of lenalidomide used alone eliminated tumors in any of the treated mice. Most recently, we have demonstrated the benefits of combining SNS01-T with bortezomib. In a mouse model of human multiple myeloma, SNS01-T as a monotherapy achieved 59% tumor growth inhibition, which exceeded that of bortezomib alone at either the 0.2 mg/kg dose (22% inhibition) or at the 0.5 mg/kg dose (39% inhibition). However, the combination of SNS01-T with 0.5 mg/kg of bortezomib resulted in 89% tumor inhibition, which was significantly more effective than either SNS01-T or bortezomib alone.

SNS01-T used in combination with other drugs

We have demonstrated that the combination of lenalidomide and SNS01-T performs better than either treatment alone in mouse xenograft models of human mantle cell lymphoma. When SCID mice, implanted with an aggressive human mantle cell lymphoma cell line (JVM2), were treated with either 15 mg/kg lenalidomide (5 times weekly by intra-peritoneal injection) or 0.375 mg/kg SNS01-T (twice weekly by intravenous injection) there was a growth delay of 4 days and 14 days, respectively. Mice treated with a combination of both drugs using the same dose levels and dosing regimens exhibited a tumor growth delay of 27 days (p value = 0.0008).

The median survival of mice treated with control nanoparticles was 21 days. Mice treated with lenalidomide or SNS01-T had a median survival of 28 days (33 % increase) and 37 days (76 % increase), respectively. Mice treated with the drug combination had a median survival of 52 days, an increase in survival of 148 %. Survival analysis using the Kaplan-Meier method revealed that treatment of mice with the drug combination resulted in statistically significant increases in survival compared to both SNS01-T (p value = 0.002) and lenalidomide (p value = 0.007) alone. We believe that the results of these studies not only support moving forward in multiple myeloma, but also support extending our clinical evaluation of SNS01-T in other B-cell cancers.

We may consider other human diseases in order to determine the role of Factor 5A and SNS01-T. We may further expand our research and development program beyond the initiatives listed above to include other diseases and research centers.

Human Therapeutic Target Markets

We believe that our eIF5A platform technology may have broad applicability in the human therapeutic field, by either inducing or inhibiting apoptosis. Inducing apoptosis may be useful in treating certain forms of cancer where tumor cells do not respond to immune system signals to undergo apoptosis. Inhibiting apoptosis may be useful in preventing or treating a wide range of inflammatory and ischemic diseases attributed to premature apoptosis, including diabetes, diabetic retinopathy and lung inflammation.

We have advanced our research in multiple myeloma, MCL and DLBCL and are conducting a Phase 1b/2a clinical trial for those indications, and may select additional human therapeutic indications to investigate in clinical trials. We believe that the success of our future operations will likely depend on our ability to transform our research and development activities into commercial applications.

We anticipate that we may enter into a collaboration with a biotechnology or pharmaceutical company to support the further development of SNS01-T after we complete our Phase 1b/2a clinical trial in multiple myeloma, MCL and DLBCL. However, there can be no assurance that we will be able to enter into such a collaboration or that one will be available on terms satisfactory to us.

Human Therapeutic Research Program

Our human therapeutic research program, which consists of pre-clinical *in-vitro* and *in-vivo* experiments designed to assess the role and mode of action of Factor 5A in human diseases and a phase 1a/2b clinical trial, is being performed by third party researchers, at our direction, at Criterium, our contract research organization and the University of Waterloo and other facilities. Additionally, we outsource certain projects, such as our clinical trial, to other third party research organizations.

On September 1, 1998, we entered into, and have extended through August 31, 2013, a research and development agreement with the University of Waterloo and Dr. Thompson as the principal inventor. The Research and Development Agreement provides that the University of Waterloo will perform research and development under our direction, and we will pay for the cost of this work and make certain payments to the University of Waterloo. In return for payments made under the Research and Development Agreements, we have all rights to the intellectual property derived from the research.

Our research and development expenses incurred on human therapeutic applications were approximately $2,033,100, or 97%, of our total research and development expenses for the year ended June 30, 2013.

Our research and development expenses incurred on human therapeutic applications were approximately $2,286,511, or 89%, of our total research and development expenses for the year ended June 30, 2012.

Our research and development expenses incurred on human therapeutic applications were approximately $3,253,253, or 87%, of our total research and development expenses for the year ended June 30, 2011.

Since inception, the proportion of our research and development expenses on human therapeutic applications has increased, as compared to our research and development expenses on agricultural applications. This change is primarily due to the fact that our research focus on human therapeutics has increased and most of our research costs for plant applications have shifted to our license partners.

Our planned future research and development initiatives for human therapeutics include:

Multiple Myeloma, Mantle Cell Lymphoma and Diffuse Large B-Cell Lymphoma. Continue a Phase 1b/2a clinical trial. In connection with the clinical trial, we have engaged Criterium to manage the operational aspects of the Phase 1b/2a clinical study. We have also entered into an agreement with Mayo Clinic, University of Arkansas for Medical Sciences, the Randolph Cancer Center at West Virginia University, the Fred Hutchinson Cancer Research Center and the John Theurer Cancer Center at Hackensack University Medical Center to be our clinical sites. We may add additional clinical sites in order to accelerate patient enrollment into the trial. The trial opened in September 2011 and we are currently treating patients. We estimate that the trial will be completed in the first half of 2014.

We may consider targeting cancers in other tissues by modifying the structure of SNS01-T, e.g., liver cancer.

We are exploring the use of our Factor 5A technology in other disease applications in oncology and inflammation.

In order to pursue the above research initiatives, as well as other research initiatives that may arise, we completed placements common stock and warrants on January 4, 2013 and common stock on May 8, 2013. However, it will be necessary for us to raise a significant amount of additional working capital in the future. If we are unable to raise the necessary funds, we may be required to significantly curtail the future development of some or all of our research initiatives and we will be unable to pursue other possible research initiatives.

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

Human Therapeutic Suppliers

The materials for our lead therapeutic candidate, SNS01-T, for multiple myeloma consists of three parts: a pDNA expressing human eIF5A^{K50R}; an siRNA, whose sequence corresponds to an untranslated region of native eIF5A mRNA; and linear PEI which enables self-assembly of the nucleic acids into nanoparticles. We have entered into supply agreements for the components as follows:

On June 27, 2008, we entered into a supply agreement with VGXI, Inc., or VGXI, under which VGXI will supply us with the plasmid portion of the Company’s combination therapy, hereinafter referred to as the VGXI Product. The agreement has an initial term that commenced on the date of the agreement and runs for a period of five (5) years. The agreement shall, upon mutual agreement, renew for consecutive one (1) year periods thereafter. Our financial obligation under the agreement is dependent upon the amount of VGXI Product ordered by the Company.

On June 30, 2008, we entered into a supply agreement with Polyplus-transfection, or POLYPLUS, under which POLYPLUS will supply the Company with its “in vivo-jetPEI”, hereinafter referred to as the POLYPLUS Product, which is used in the formulation and systemic delivery of the Company’s combination therapy. The agreement has an initial term which commenced on the date of the agreement and runs until the eighth anniversary of the first sale of our product containing the POLYPLUS Product. The agreement shall automatically renew for consecutive one (1) year periods thereafter, except if terminated by either party upon six (6) months written notice prior to the initial or any subsequent renewal term. The Company’s financial obligation under the agreement is dependent upon the amount of POLYPLUS Product ordered by the Company.

On September 4, 2008, we entered into a supply agreement with Avecia Biotechnology, Inc., or AVECIA, under which AVECIA will supply the Company with the siRNA portion of the Company’s combination therapy consisting of the siRNA against Factor 5A, hereinafter referred to as the siRNA Product. The agreement had a term which commenced on the date of the agreement and terminated on the later of the completion of all services to be provided under the agreement or 30 days following delivery of the final shipment of the siRNA Product.

Effective June 4, 2013, the Company entered into a clinical supply agreement with The University of Iowa, or IOWA, under which IOWA will provide manufacturing, vialing and testing services for certain reagents that are used in SNS01-T. The agreement will terminate upon delivery of the delivery of the reagents, which is estimated to be approximately six months. The Company’s remaining financial obligation under the agreement is approximately $156,000.

Human Therapeutic Competition

Our competitors in human therapeutics that are presently attempting to distribute their technology have generally utilized one of the following distribution channels:

Entering into strategic alliances, including licensing technology to major marketing and distribution partners; or

Developing in-house production and marketing capabilities.

In addition, some competitors are established distribution companies, which alleviates the need for strategic alliances, while others are attempting to create their own distribution and marketing channels.

There are many large companies and development stage companies working in the field of apoptosis and B-cell cancer research including Celgene, Inc., Takeda/Millennium, ONYX Pharmaceuticals, Inc., Amgen Inc., Janssen Biotech, Inc., Novartis AG, and Pharmacyclics, Inc.

We do not currently have any commercialized products, and therefore, it is difficult to assess our competitive position in the market. However, we believe that if we are able to develop and commercialize a product or products under our patents to our Factor 5A platform technology, we will have a competitive position in the markets in which we will operate.

Agricultural Applications

Our agricultural research focuses on the discovery and development of certain gene technologies, which are designed to confer positive traits on fruits, flowers, vegetables, forestry species and agronomic crops.

We have licensed this technology to various strategic partners. We may continue to license this technology, as opportunities present themselves, to additional strategic partners and/or enter into joint collaborations or ventures.

Our ongoing research and development initiatives for agriculture include assisting our license partners to:

further develop and implement the DHS and Factor 5A gene technology in banana, canola, cotton, turfgrass, rice, alfalfa, corn, soybean, biofuels and trees; and

test the resultant crops for new beneficial traits such as increased yield, increased tolerance to environmental stress, disease resistance and more efficient use of fertilizer.

Agricultural Target Markets

In order to address the complexities associated with marketing and distribution in the worldwide market, we have adopted a multi-faceted commercialization strategy, in which we have entered into and plan to enter into, as the opportunities present themselves, additional licensing agreements or other strategic relationships with a variety of companies or other entities on a crop-by-crop basis. We anticipate revenues from these relationships in the form of licensing fees, royalties, usage fees, or the sharing of gross profits. In addition, we anticipate payments from certain of our partners upon their achievement of certain research and development benchmarks. This commercialization strategy allows us to generate revenue at various stages of product development, while ensuring that our technology is incorporated into a wide variety of crops. Our optimal partners combine the technological expertise to incorporate our technology into their product line along with the ability to successfully market the enhanced final product, thereby eliminating the need for us to develop and maintain a sales force.

Because the agricultural market is dominated by privately held companies or subsidiaries of foreign owned companies, market size and market share data for the crops under our license and development agreements is not readily available. Additionally, because we have entered into confidentiality agreements with our license and development partners, we are unable to report the specific financial terms of the agreements as well as any market size and market share data that our partners may have disclosed to us regarding their companies.

Agricultural Development and License Agreements

On February 8, 2012, we entered into a research and development agreement with BioCorp Ventures, LLC ("BCV"), a division of technology incubator US Equity Holdings, to use our proprietary eukaryotic translation initiation Factor 5A (eIF5A) technology platform for sustainable energy applications (the "Agreement"). BCV, a newly formed start-up company, will have a license to evaluate our technology for the development of plants and plant products suitable for use in the production of biofuel and biofuel feedstock, including all species of algae and all species in the genus Miscanthus (perennial grasses). Biofuels derived from these organisms include biodiesel and bioethanol. The companies will continue ongoing research and development as BCV works on commercializing the technology. BCV will be fully responsible for further assessing the potential of our technology for all biofuel applications and determining the route to the commercialization of biofuel products. Through our significant know-how at the University of Waterloo, we will be responsible for technology transfer and providing technical advice to facilitate BCV's operations. After the initial evaluation phase, the Agreement provides annual license maintenance payments to us and royalty payments in the mid-single digits if a product is commercialized by BCV. As part of the Agreement, after the initial evaluation phase, we will have a 15% equity interest in BCV and the right to appoint one member to BCV's advisory board.

In February 2013, BCV was in breach of the Agreement. Specifically, BCV did not make the payment required or issue our equity interest to us on the due date. On March 1, 2013, we sent BCV a notice of breach. As such breach had not been cured by April 1, 2013, the Agreement was terminated in its entirety. In May 2013, we entered into a new Biofuels Evaluation and License Agreement with the BCV under the same terms and conditions as the previous Biofuels Evaluation and License Agreement described above, except that the evaluation period was amended and the amount of the milestone payments was increased.

As of June 30, 2013, we have nine (9) active license agreements with established agricultural biotechnology companies.

Agricultural Research Program

Over the past year, our agricultural research and development has been performed by one (1) researcher, at our direction, at the University of Waterloo, where the technology was developed. Additional agricultural research and development is performed by our license or joint collaboration partners.

Agricultural Competition

Our competitors in agriculture that are presently attempting to distribute their technology have generally utilized one of the following distribution channels:

licensing technology to major marketing and distribution partners;
entering into strategic alliances; or
developing in-house production and marketing capabilities.

In addition, some competitors are established distribution companies, which alleviates the need for strategic alliances, while others are attempting to create their own distribution and marketing channels.

Our competitors in the field of delaying plant senescence are companies that develop and produce transformed plants with a variety of enhanced traits. Such companies include: Mendel Biotechnology; Renessen LLC; Exelixis Plant Sciences, Inc.; and Syngenta International AG; among others.

We do not currently have any commercialized products, and therefore, it is difficult to assess our competitive position in the market. However, we believe that if we or our licensees are able to develop and commercialize a product or products using our technology, we will have a competitive position in the markets in which we or our licensees operate.

Agricultural Development Program

Generally, projects with our licensees begin by transforming seed or germplasm to incorporate our technology. Those seeds or germplasm are then grown in our partners' greenhouses. After successful greenhouse trials, our partners will transfer the plants to the field for field trials. After completion of successful field trials, our partners may have to apply for and receive regulatory approval prior to initiation of any commercialization activities.

Generally, the approximate time to complete each sequential development step is as follows:

Seed Transformation	approximately 1 to 2 years
Greenhouse	approximately 1 to 2 years
Field Trials	approximately 2 to 5 years

The actual amount of time spent on each development phase depends on the crop, its growth cycle and the success of the transformation achieving the desired results. As such, the amount of time for each phase of development could vary, or the time frames may change.

The status of each of our projects with our partners is as follows:

Project	Partner	Status
Banana	Rahan Meristem	
- Shelf Life		Field trials
- Disease Resistance		Field trials
Trees	Arborgen	
- Growth		Field trials
Alfalfa	Cal/West	Field trials
Corn	Monsanto	Field trials
Cotton	Bayer	Greenhouse
Canola	Bayer	Field trials
Rice	Bayer	Greenhouse
Soybean	Monsanto	Field trials
Turfgrass	The Scotts Company	Greenhouse
Biofuels	BioCorp Ventures	Initial Evaluation

Commercialization by our partners may require a combination of traits in a crop, such as both shelf life and disease resistance, or other traits.

Based upon our commercialization strategy, we anticipate that there may be a significant period of time before plants enhanced using our technology reach consumers, if at all.

Intellectual Property

We have twenty-eight (28) issued patents from the United States Patent and Trademark Office, or PTO, and seventy-three (73) issued patents from foreign countries. Of our one hundred and one (101) domestic and foreign issued patents, sixty-two (62) are for the use of our technology in agricultural applications and thirty-nine (39) relate to human therapeutics applications.

In addition to our one hundred and one (101) patents, we have a wide variety of patent applications, including divisional applications and continuations-in-part, in process with the PTO and internationally. We intend to continue our strategy of enhancing these new patent applications through the addition of data as it is collected.

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

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

During our 2013, 2012 and 2011 fiscal years, we reviewed our patent portfolio in order to determine if we could reduce our cost of patent prosecution and maintenance. We identified several patents and patents pending that we believe we no longer need to maintain without having a material impact on the portfolio. We determined that we would no longer incur the cost to prosecute or maintain those patents or patents pending.

Government Regulation

At present, the U.S. federal government regulation of biotechnology is divided among three agencies: (i) the U.S. Department of Agriculture regulates the import, field-testing and interstate movement of specific types of genetic engineering that may be used in the creation of transformed plants; (ii) the Environmental Protection Agency regulates activity related to the invention of plant pesticides and herbicides, which may include certain kinds of transformed plants; and (iii) the FDA regulates foods derived from new plant varieties. The FDA requires that transformed plants meet the same standards for safety that are required for all other plants and foods in general. Except in the case of additives that significantly alter a food’s structure, the FDA does not require any additional standards or specific approval for genetically engineered foods but expects transformed plant developers to consult the FDA before introducing a new food into the market place.

In addition, our ongoing preclinical research with cell lines and lab animal models of human disease is not currently subject to the FDA requirements that govern clinical trials. However, use of our technology, SNS01-T, for human therapeutic applications, is subject to FDA regulation. Generally, 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 U.S., any products resulting from the application of our human therapeutic technology must be approved by the regulatory agencies of foreign governments. Prior to filing a new drug application or biologics license application with the FDA, we would have to perform extensive clinical trials, and prior to beginning any clinical trial, we need to perform extensive preclinical testing which could take several years and may require substantial expenditures.

Our current activities in human therapeutics related to our clinical trial in multiple myeloma, requires approval by the FDA. We have an open IND with the FDA for use of SNS01-T for the treatment of multiple myeloma and are subject to additional reporting to and monitoring by the FDA. Additionally, federal, state and foreign regulations relating to crop protection products and 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 genetically transformed plants and human therapeutic technology. In addition, our marketing partners who utilize our technology or sell products grown with our technology may be subject to government regulations. 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.

Employees

In addition to the seven (7) scientists and monitors performing funded research for us at our CRO, the University of Waterloo, and other commercial research facilities, we have four (4) employees and five (5) consultants, four (4) of whom are executive officers and who are involved in our management. We do not anticipate hiring any additional employees over the next 12 months.

The officers are assisted by a Scientific Advisory Board that consists of prominent experts in the fields of plant and human cell biology as follows:

Alan Bennett, Ph.D., who serves as the Chairman of the Scientific Advisory Board, is the Associate Vice Chancellor of the Office of Technology Transfer at the University of California. His research interests include the molecular biology of tomato fruit development and ripening, the molecular basis of membrane transport, and cell wall disassembly.

Charles A. Dinarello, M.D., who serves as a member of the Scientific Advisory Board, is a Professor of Medicine at the University of Colorado School of Medicine, a member of the U.S. National Academy of Sciences and the author of over 500 published research articles. In addition to his active academic research career, Dr. Dinarello has held advisory positions with two branches of the National Institutes of Health and positions on the Board of Governors of both the Weizmann Institute and Ben Gurion University.

James E. Mier, M.D., who serves as a member of the Scientific Advisory Board, is an Associate Professor of Medicine at Beth Israel Deaconess Medical Center, a teaching hospital of Harvard Medical School. He is also a practicing physician in the Division of Hematology-Oncology at Beth Israel. Dr. Mier's research is funded by the NIH and he is a member of numerous professional societies.

Furthermore, pursuant to the Research and Development Agreements, a substantial amount of our research and development activities are conducted at the University of Waterloo under the supervision of Dr. Thompson, our Executive Vice President and Chief Scientific Officer. We utilize the University's research staff including graduate and post-graduate researchers.

We may also contract research to additional university laboratories or to other companies in order to advance the development of our technology.

Safe Harbor Statement

The statements contained in this Annual Report on Form 10-K that are not historical facts are forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995. Such forward-looking statements may be identified by, among other things, the use of forward-looking terminology such as “believes,” “expects,” “may,” “will,” “should,” or “anticipates” or the negative thereof or other variations thereon or comparable terminology, or by discussions of strategy that involve risks and uncertainties. In particular, our statements regarding the anticipated growth in the markets for our technologies, the continued advancement of our research, the approval of our patent applications, the possibility of governmental approval in order to sell or offer for sale to the general public a genetically engineered plant or plant product, the successful implementation of our commercialization strategy, including the success of our agricultural partners, statements relating to our patent applications, the anticipated long term growth of our business, the results of our preclinical or clinical studies, if any, the quotation of the Company’s common stock on an over-the-counter securities market, and the timing of the projects and trends in future operating performance are examples of such forward-looking statements. The forward-looking statements include risks and uncertainties, including, but not limited to, our ability to recruit patients for its clinical trial, our limited operating history, our need for additional capital to fund our operations until we are able to generate a profit, the current economic environment, our dependence on a single principal technology, our outsourcing of our research and development activities, our significant future capital needs, our dependence on our patents and proprietary rights and the enforcement of these rights, the potential for our competitors or third parties to allege that we are infringing upon their intellectual property rights, the potential that our security measures may not adequately protect our unpatented technology, potential difficulty in managing our growth and expanding our operations, our lack of marketing or sales history and dependence on third-party marketing partners, our potential future dependence on joint ventures and strategic alliances to develop and market our technology, the intense competition in the human therapeutic and agricultural biotechnology industries, the various government regulations that our business is subject to, the potential that our preclinical studies and clinical trials of our human therapeutic applications may be unsuccessful, any inability to license from third parties their proprietary technologies or processes which we use in connection with the development of our technology, the length, expense and uncertainty associated with clinical trials for our human therapeutic technology, the potential that, even if we receive regulatory approval, consumers may not accept products containing our technology, our dependence on key personnel, the potential that certain provisions of our charter, by-laws and Delaware law could make a takeover difficult, increasing political and social turmoil, the potential that our management and other affiliates, due to their significant control of our common stock have the ability to significantly influence our actions, the potential that a significant portion of our total outstanding shares of common stock may be sold in the market in the near future, the limited trading market of our common stock, fluctuations in the market price of our common stock, our dividend policy and potential for our stockholders to be diluted.

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, 2013 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.

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 $74,425,835 at June 30, 2013. 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 through November 2013.

We may be adversely affected by the current economic environment.

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

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

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

We depend on a single principal technology and, if our technology is not commercially successful, we will have no alternative source of revenue.

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

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

We outsource all 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 all of our research and development activities. Our research and development efforts take place at the University of Waterloo in Ontario, Canada, where our technology was discovered, at other commercial research facilities and with our commercial partners. At this time, we do not have the 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, 2013, we had a cash balance of $1,602,294 and working capital of $309,572. Using our available reserves as of June 30, 2013, we believe that we can operate according to our current business plan through November 2013.

To date, we have generated minimal revenues and anticipate that our operating costs will exceed any revenues generated over the next several years. Therefore, we will be required to raise additional capital in the future in order to operate in accordance with our current business plan, and this funding may not be available on favorable terms, if at all. If we are unable to raise additional funds, we will need to do one or more of the following:

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

In addition, in connection with any funding, if we need to issue more equity securities than our certificate of incorporation currently authorizes we will need stockholder approval. If stockholder approval is not obtained or if adequate funds are not available, we may be required to curtail operations significantly or to obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies, product candidates, products or potential markets. Investors may experience dilution in their investment from future offerings of our common stock. For example, if we raise additional capital by issuing equity securities, such an issuance would reduce the percentage ownership of existing stockholders. In addition, assuming the exercise of all options and warrants outstanding and the conversion of the preferred stock into common stock, as of June 30, 2013, we had 113,332,828 shares of common stock authorized but unissued and unreserved, which may be issued from time to time by our board of directors. Furthermore, we may need to issue securities that have rights, preferences and privileges senior to our common stock. Failure to obtain financing on acceptable terms would have a material adverse effect on our liquidity.

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

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

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

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

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

As of June 30, 2013, we have been issued twenty-eight (28) patents by the PTO and seventy-three (73) patents from foreign countries. We have also filed numerous patent applications for our technology in the United States and in several foreign countries, which technology is vital to our primary business, as well as several continuations in part on these patent applications. Our success depends in part upon the grant of patents from our pending patent applications.

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

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

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

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

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

Patent law is still evolving relative to the scope and enforceability of claims in the fields in which we operate. We are like most biotechnology companies in that our patent protection is highly uncertain and involves complex legal and technical questions for which legal principles are not yet firmly established. In addition, if issued, our patents may not contain claims sufficiently broad to protect us against third parties with similar technologies or products, or provide us with any competitive advantage.

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

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

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

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

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

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

Our success depends upon know-how, unpatentable trade secrets, and the skills, knowledge and experience of our scientific and technical personnel. As a result, all employees agreed to a confidentiality provision in their employment agreement that prohibited the disclosure of confidential information to anyone outside of our company, during the term of employment and for five (5) years thereafter. The employment agreements have since been terminated, but the period of confidentiality is still in effect. We also require all employees to disclose and assign to us the rights to their ideas, developments, discoveries and inventions. 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. Although we do not presently conduct research and development activities in-house, we may undertake those activities in the future. 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