

Star Scientific, Inc. is a technology-oriented company with a mission to promote maintenance of a healthy metabolism and lifestyle. Since the incorporation of our Rock Creek Pharmaceuticals subsidiary in 2007, our research has focused primarily on the utility of anatabine, one of the alkaloids found in the Solanaceae family of plants, which includes tomatoes, eggplants, peppers, potatoes, and tobacco. Initially, our research concentrated on the impact of anatabine in decreasing an individual's desire to smoke cigarettes or use other traditional tobacco products. More recently, Rock Creek Pharmaceuticals has been focusing on the anti-inflammatory aspects of anatabine, in an effort to develop a range of non-nicotine dietary supplements and related pharmaceutical products that could be beneficial in maintaining a healthy metabolism and in supporting good nutrition.

Currently, Rock Creek Pharmaceuticals manufactures and sells two nutraceutical dietary supplements: Anatabloc<sup>®</sup> Original and Anatabloc<sup>®</sup> Unflavored, for antiinflammatory support, and CigRx<sup>®</sup>, for assistance in fighting the urge to smoke cigarettes. In addition, Rock Creek Pharmaceuticals has been engaged in the development of other dietary supplements and pharmaceutical products, particularly products that have a botanical-based component and that are designed to provide nutritional support in a range of neurological conditions, including Alzheimer's disease, Parkinson's disease, schizophrenia, depression, and Hashimoto's thyroiditis. Rock Creek Pharmaceuticals also has been involved in the development of a line of cosmetic products that utilizes our anatabine compound to improve the appearance of the skin. These products consist of Anatabloc<sup>®</sup> Rare Cellular Facial Creme, Anatabloc<sup>®</sup> Revitalizing Facial Serum, and Anatabloc<sup>®</sup> Clarifying Facial Cleaser.

Since the 1990s, we also have sought to develop processes that significantly prevent the formation of one of the most abundant and significant groups of carcinogens, tobacco specific nitrosamines ("TSNA"), found in tobacco and tobacco smoke. Our development of technology for reducing levels of TSNA led us to focus on the development of non-nicotine tobacco-based pharmaceutical products and the non-nicotine dietary supplements that we are pursuing through Rock Creek Pharmaceuticals. As a result, we are uniquely positioned to pursue a range of world-wide licensing opportunities related to our underlying technology and products.

# SECURITIES AND EXCHANGE COMMISSION Washington, DC 20549

Received SEC

# **FORM 10-K**

NOV 200 2013

Washington, DC 20549

(Mark One)

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

For the fiscal year ended December 31, 2012

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: 000-15324** 

# **STAR SCIENTIFIC, INC.**

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)

4470 Cox Road, Suite 110, Glen Allen, VA 23060 (Address of principal executive offices)

52-1402131 (I.R.S. Employer **Identification No.)** 

(804) 527-1970 (Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

None

Securities registered pursuant to Section 12(g) of the Act: Common Stock, \$0.0001 par value (Title of Class)

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

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

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

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

Indicate by check mark 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 small reporting company.

Large accelerated filer

Accelerated filer

Small reporting company

Non-accelerated filer Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes 🗌 No 🔽

The aggregate market value of the Registrant's voting stock held by non-affiliates of the Registrant as of June 30, 2012 was approximately \$533.2 million. Shares of voting stock held by each executive officer and director and by each person who owns 10% or more of the Registrant's voting stock have been excluded in that such persons may be deemed affiliates of the Registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

Number of shares outstanding for each class common equity as of March 5, 2013, 166,491,509 shares of common stock, par value \$0.0001 per share.

# DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the Company's Definitive Proxy Statement relating to its 2013 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission no later than April 30, 2013, are incorporated by reference in Part III, Items 10-14 of this Annual Report on Form 10-K as indicated herein.

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# **CERTAIN DEFINITIONS**

Unless the context requires otherwise, all references in this annual report on Form 10-K, or this Report, to "Star Scientific," "Company," "we," "our," "us," "our company" and similar terms refer to Star Scientific, Inc. and its wholly owned subsidiaries Rock Creek Pharmaceuticals, Inc., a Delaware corporation, and Star Tobacco, Inc., a Virginia corporation, which also may be referred to in this Report as "Rock Creek" and "Star Tobacco," respectively.

# SPECIAL NOTE ON FORWARD-LOOKING STATEMENTS

Certain statements in this Report other than purely historical information, including estimates, projections, statements relating to our business plans, objectives, and expected operating results, and the assumptions upon which those statements are based, are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We have tried, whenever possible, to identify these forward-looking statements using words such as "anticipates," "believes," "estimates," "continues," "likely," "may," "opportunity," "potential," "projects," "will," "expects," "plans," "intends" and similar expressions to identify forward-looking statements, whether in the negative or the affirmative. These statements reflect our current beliefs and are based on information currently available to us. Accordingly, such forward-looking statements involve known and unknown risks, uncertainties and other factors which could cause our actual results, performance or achievements to differ materially from those expressed in, or implied by, such statements. These risks, uncertainties, factors and contingencies include, without limitation, the challenges inherent in new product development initiatives, including the continued development and market acceptance of our nutraceutical products, the effect of any competitive products, our ability to license and protect our intellectual property, our ability to raise additional capital in the future that is necessary to maintain our business, changes in government policy and/or regulation, potential litigation by or against us and any governmental review of our products or practices. Forward-looking statements reflect our management's expectations or predictions of future conditions, events or results based on various assumptions and management's estimates of trends and economic factors in the markets in which we are active, as well as our business plans. They are not guarantees of future performance. By their nature, forward-looking statements are subject to risks and uncertainties. Our actual results and financial condition may differ, possibly materially, from the anticipated results and financial condition indicated in these forward-looking statements. There are a number of factors that could cause actual conditions, events or results to differ materially from those described in the forward-looking statements contained in this Report. A discussion of factors that could cause actual conditions, events or results to differ materially from those expressed in any forward-looking statements appears in "Item 1A. Risk Factors."

Readers are cautioned not to place undue reliance on forward-looking statements in this Report or that we make from time to time, and to consider carefully the factors discussed in "Item 1A. Risk Factors" of this Report in evaluating these forward-looking statements. These forward-looking statements are representative only as of the date they are made, and we undertake no obligation to update any forward-looking statement as a result of new information, future events or otherwise.

#### ITEM 1. BUSINESS

# Overview

We are a technology-oriented company with a mission to promote maintenance of a healthy metabolism and lifestyle. Since the incorporation of our Rock Creek Pharmaceuticals subsidiary in 2007, we have focused on utilizing certain alkaloids found in the Solanacea family of plants, which includes potatoes, tomatoes, and eggplants, initially to address issues related to the desire to smoke or use of other traditional tobacco products. More recently, Rock Creek Pharmaceuticals has been concentrating on the anti-inflammatory aspects of one of those alkaloids, anatabine. We believe our research and development efforts relating to the anatabine alkaloid have positioned us to utilize our technology to develop a range of non-nicotine dietary supplements and potentially related pharmaceutical products that could be beneficial in maintaining a healthy metabolism and in supporting good nutrition.

Currently, Rock Creek Pharmaceuticals manufactures and sells two nutraceutical dietary supplements: Anatabloc<sup>®</sup>, for anti-inflammatory support, and CigRx<sup>®</sup>, for assistance in fighting the urge to smoke cigarettes. Since the introduction of Anatabloc<sup>®</sup>, our revenues have been derived almost exclusively from the sale of our anatabine based nutraceutical products and, more particularly, Anatabloc<sup>®</sup>. In addition, Rock Creek has been engaged in the development of other dietary supplements and pharmaceutical products, particularly products that have a botanical-based component and that are designed to provide nutritional support for a range of conditions, including Alzheimer's disease, Parkinson's disease, multiple sclerosis, schizophrenia, depression, and Hashimoto's autoimmune thyroiditis. Rock Creek also has been involved in the development of a cosmetic line of products that utilizes our anatabine compound to improve the appearance of the skin. We introduced Anatabloc<sup>®</sup> Facial Crème in September 2012.

Since the 1990s, we also have sought to develop processes that significantly prevent the formation of one of the most abundant and significant groups of carcinogens, tobacco specific nitrosamines, or TSNAs, found in tobacco and tobacco smoke. We initially utilized our company's technology in producing low-TSNA tobacco and related low-TSNA smokeless tobacco products as less harmful alternatives to cigarettes and traditional smokeless tobacco products and as a platform to provide a base of financial support for our intellectual property, licensing and development initiatives. However due to continuing operating losses we ceased selling any tobacco products as of December 31, 2012, although we continue to look for licensing opportunities related to our low-TSNA curing technology and our related products.

# **Our History**

We incorporated Rock Creek Pharmaceuticals in 2007 to pursue the use of tobacco, and particularly alkaloids found in tobacco including anatabine, based on prior research demonstrating the potential use of , certain tobacco-based monoamine oxidase inhibitors, or MAO agents, in treating neurological conditions. In August 2010 we introduced our first nutraceutical, dietary supplement CigRx<sup>®</sup> designed to temporarily reduce the desire to smoke. In August 2011 we introduced Anatabloc<sup>®</sup>, a second nutraceutical, dietary supplement for anti-inflammatory support and in September 2012 we introduced Anatabloc<sup>®</sup> Facial Crème as a cosmetic to improve the appearance of the skin. Since the introduction of Anatabloc<sup>®</sup> in August 2011, almost all of our revenues have been generated by the sales of Anatabloc<sup>®</sup> and, to a much lesser degree, CigRx<sup>®</sup>, each of which are manufactured and sold by Rock Creek. We currently expect this trend with respect to our mix of revenues to continue in 2013.

Star Tobacco ceased manufacturing and selling any tobacco products as of December 31, 2012. Star Tobacco was incorporated in 1990 and, until 1994, was primarily a contract manufacturer of cigars and cigarettes. From 1994 to 2007 we manufactured and sold our own cigarette brands. We exited the cigarette business in 2007. In late 1994, we commenced a research and development program relating to a range of tobacco products that deliver fewer toxins as well as tobacco cessation products. Thereafter, upon concluding that there was no way to develop a completely "safe cigarette," we shifted the near-term research by Star Tobacco to the development of very-low TSNA smokeless tobacco products containing lower levels of carcinogenic TSNAs, particularly NNNs and NNKs, that are formed principally during the curing of tobacco. We believe our very-low TSNA smokeless tobacco products contain the lowest TSNA levels of any marketed tobacco product. On December 14, 2012, our Board of Directors voted unanimously to discontinue the manufacturing and distribution of our company's dissolvable smokeless tobacco products, Ariva<sup>®</sup> and Stonewall Hard Snuff<sup>®</sup> as of December 31, 2012. Our Board was motivated to take this action in light of the continued losses and low sales for our dissolvable tobacco products over the last several years. It was also motivated by the fact that restrictions under the Family Smoking Prevention and Tobacco Control Act, or FDA Tobacco Act, which prohibits a company from making any statements about the comparative safety of various types of tobacco products made it extremely difficult to effectively market our dissolvable tobacco products, notwithstanding that they represented a less hazardous alternative to cigarettes and to traditional smokeless tobacco products has had a negative impact on our ability to interest leading scientific and medical research centers in undertaking clinical research related to our anatabine compound in managing excessive inflammation.

See Note 3 Discontinued Operations in Item 15 of this Report for complete details of the discontinuance of our dissolvable tobacco operations.

# **Our Strategy**

Our long-term focus, particularly in light of our decision to cease selling dissolvable smokeless tobacco products, is the research, development, manufacturing, distribution and sales of products and/or licensing of technology that are designed to generally assist consumers in maintaining a healthy metabolism. We have pursued these objectives through:

- the sale of nutraceutical, dietary supplements that focuses on anti-inflammatory support and decreasing the urge to smoke;
- the sale of a cosmetic product to enhance the appearance of the skin;
- ongoing research and development by Rock Creek of related dietary supplements and pharmaceutical products; and
- seeking to license our low-TSNA curing technology and related products.

Our recent research and development efforts have focused on the role that certain alkaloids found in the tobacco plant and other members of the Solanacea family of plants, such as potatoes, tomatoes and eggplants, play in maintaining or assisting individuals to maintain a healthy metabolism. This effort has resulted in our development of two non-nicotine, non-tobacco dietary supplements Anatabloc<sup>®</sup> and CigRx<sup>®</sup>. Based on the research activities of Rock Creek, we believe we are uniquely positioned to pursue the development of non-tobacco, non-nicotine products that are based on alkaloids found in tobacco, but that have a wider applicability to various health issues, including the maintenance of a healthy metabolism.

We have also developed a cosmetic product using our anatabine citrate compound, which is designed to enhance the appearance of the skin.

Since the late 1990s we also have sought to develop products that provide adult tobacco users with less toxic alternatives to cigarettes and traditional smokeless tobacco products. Given the reality of tobacco use, we continue to believe that there is an urgent need to reduce the toxicity of tobacco products to the maximum extent possible using available technology and to provide alternatives to those products for persons seeking to maintain a nicotine-free metabolism. Thus, while we ceased selling any tobacco products after December 31, 2012, we continue to look for licensing opportunities related to our dissolvable tobacco products and technology.

We believe the proprietary technology and manufacturing processes related to our dietary supplements and cosmetic products position us to be a leader in producing products designed to assist consumers in maintaining a healthy metabolism. Further, we believe that we are uniquely positioned to pursue the licensing of our patented low-TSNA tobacco curing technology and related tobacco products, given our role over the last decade in developing methods for producing low-TSNA tobacco and related products.

# **Our Technology**

# Our Intellectual Property Initiatives Relating to Anatabine and Anatabine Citrate Based Products

Since 2010 we have filed six United States patent applications relating to our dietary supplement products, uses of the products and product formulations. These included:

- two applications for therapeutic methods involving the administrations of anatabine, its isomers and derivatives thereof, or an isomer or salts thereof, for treating chronic inflammation that may be associated with disorders such as thyroiditis, cancer, arthritis, Alzheimer's disease, and multiple sclerosis,
- applications for our Anatabloc<sup>®</sup> and CigRx<sup>®</sup> formulations, as well as
- an application for the synthesis of anatabine and an application for a relapse prevention product.

We also filed an application for a design patent relating to the 20-piece container used for our CigRx<sup>®</sup> and Anatabloc<sup>®</sup> products and a divisional application for food grade salts of anatabine.

In June 2012, the United States Patent and Trademark Office, or PTO, issued a patent to Rock Creek for an improved method of synthesizing anatabine that facilitates large scale commercial production of high purity anatabine. Also, on August 14, 2012, the PTO issued a patent to Rock Creek for an anatabine citrate and yerba mate composition and uses thereof in assisting weight loss and curbing the urge for tobacco. In 2011, the PTO, issued a design patent to Rock Creek for the 20-piece dispenser used for our CigRx<sup>®</sup> and Anatabloc<sup>®</sup> products. We also have several foreign and international applications pending that relate to our Anatabloc<sup>®</sup> products, a relapse prevention product and the administration of anatabine, its isomers and any derivatives thereof for treating inflammatory mediated disorders generally, and also for autism and seizure indications.

# Our Intellectual Property Rights Relating to Curing Technology and Related Products

We are the exclusive licensee under a license agreement with Regent Court Technologies, LLC, or Regent Court, a company in which Jonnie R. Williams Sr., the technology's inventor, our founder, Chief Executive Officer and one of our largest stockholders, is a part owner. The license agreement with Regent Court grants us exclusive worldwide rights to and a right of sublicense for the StarCured<sup>®</sup> process, related patents covering the production of low-TSNA dissolvable smokeless tobacco products and the use of certain MAO agents in treating neurological conditions. Two of the patents under our license with Regent Court that relate to our method for producing low-TSNA tobacco had been the subject of our lawsuits against R. J. Reynolds Tobacco Company, or RJR, that were settled as part of the agreement entered into with RJR on September 21, 2012. The claims in both of these patents that were at issue in the litigation were affirmed by the Court of Appeals for the Federal Circuit and by the PTO as part of the litigation process. See Item 3 "Legal Proceedings" in this Report for further details of the resolution of the RJR litigation matters.

In December 2008, we filed a new United States patent application for a variant of our patented curing technology that results in the production of cured tobacco that contains virtually undetectable levels of carcinogenic TSNAs, as measured by prevailing standards and, in April 2012, the PTO issued a patent for this curing method. Also, in 2012 we filed utility applications for an enriched form of tobacco, an alkaloid composition for e-cigarettes and for a new tobacco product that are currently pending before the PTO. We believe that through the StarCured® process and our related technology we have the ability to reduce exposure to carcinogenic TSNAs, particularly the subgroups of nitrosamines commonly referred to as NNNs and NNKs, to very low levels (with carcinogenic NNNs and NNKs that measure 200 parts per billion and below) and that we have demonstrated that our process for curing tobacco using these processes can be scaled up to meet broad commercial needs in the United States and abroad. While we have discontinued the sale of tobacco products as of December 31, 2012, we continue to pursue means of collecting royalties for our curing technology through licensing arrangements and through monitoring of the curing practices of industry participants as applicable. For additional information related to our proprietary technology see "— Our Patents, Trademarks and Licenses."

## **Our Products**

## **Dietary Supplements**

We currently manufacture and market two nutraceutical, dietary supplements through Rock Creek. Our Anatabloc<sup>®</sup> product, which provides anti-inflammatory support, was introduced into the market in August 2011 and we introduced an unflavored version of Anatabloc<sup>®</sup> in mid-2012. Our CigRx<sup>®</sup> product, that is designed to curb the urge to smoke, was introduced in the market in August 2010. Both of these products utilize as the primary dietary ingredient anatabine citrate, a compound that is based on the anatabine alkaloid found in the tobacco plant and other members of the Solanacea family of plants. The development of both Anatabloc<sup>®</sup> and CigRx<sup>®</sup> grew out of our prior research and development efforts relating to tobacco alkaloids that were known to have certain MAO inhibiting properties. Since the introduction of Anatabloc<sup>®</sup>, sales of CigRx<sup>®</sup> have been de minimis.

Our Anatabloc<sup>®</sup> product is being sold through our interactive website, a customer service center and on a consignment basis through GNC, a retailer of dietary supplements. GNC began selling Anatabloc<sup>®</sup> through its online store in early 2012. In March 2012, GNC began carrying Anatabloc<sup>®</sup> at its company-owned stores and franchised retail locations and Anatabloc<sup>®</sup> is now available at GNC's more than 4,000 retail locations throughout the country. In February 2013 our company received GNC's 2012 top vendor award for product innovation in the "wellness" product category. Initially, marketing of Anatabloc<sup>®</sup> was directed toward physicians and other healthcare professionals. More recently we have been focusing our marketing efforts on athletes and other groups of individuals who regularly deal with issues relating to inflammation. CigRx<sup>®</sup> is being marketed through our interactive website and customer service centers and, to a lesser extent, at retail locations in the Richmond, Virginia metropolitan area and in the Northeast and Northwest regions of the country. See "— Our Sales and Marketing Efforts — *Dietary Supplement*" for a discussion of our manufacturing, storage, order processing and delivery arrangements with third parties related to Anatabloc<sup>®</sup> and CigRx<sup>®</sup>.

## Facial Cream

In September 2012, Rock Creek introduced Anatabloc<sup>®</sup> Facial Crème, an anatabine citrate based face cream designed to improve the appearance of the skin. This product is being sold on the Company's interactive website and promoted through select dermatology practices. In February 2013 GNC also began carrying the face cream on its website.

## Other Nutraceutical Products and Related Research Initiatives

Through Rock Creek, we are exploring the development of other related nutraceutical products that may assist in stabilizing metabolism, and development of pharmaceuticals for a range of conditions, including Alzheimer's disease, Parkinson's disease, multiple sclerosis, schizophrenia and depression. We are working with the Roskamp Institute and other research institutions to further our research on our anatabine compound. See below "Our Current Product Development Initiatives." In 2012 this research included:

- a multi-site clinical trial of Rock Creek's anatabine compound to examine its effect on chronic inflammation in individuals who have elevated blood levels of C-reactive protein, or CRP;
- an in-house clinical trial of approximately 100 smokers to determine the potential for Anatabloc<sup>®</sup> to lower CRP levels and curb the urge to smoke;
- A clinical study to determine the effect of Rock Creek's anatabine compound on Hashimoto's autoimmune thyroiditis;
- a clinical study of the effect of our anatabine compound on individuals with mild to moderate Alzheimer's diseases; and
- an initial dermatological study related to the use of our Anatabloc<sup>®</sup> Facial Crème.

We anticipate that the results of these clinical studies may be helpful in our marketing efforts for Anatabloc<sup>®</sup> and Anatabloc<sup>®</sup> Facial Crème, particularly marketing to physicians and other health care professionals. See "— Our Sales and Marketing Efforts — *Dietary Supplement*" for a discussion of our manufacturing, storage, order processing and delivery arrangements with third parties related to Anatabloc<sup>®</sup> and Anatabloc<sup>®</sup> Facial Crème.

## Smokeless Tobacco Products

Since the early 2000s, we have been engaged in the development of very low-TSNA, non-fermented smokeless tobacco products designed to provide adult tobacco users with a viable alternative to cigarettes and traditional smokeless tobacco products. However, for the reasons discussed above under "Overview" and "Our History", we discontinued the manufacture and distribution of our dissolvable tobacco products as of December 31, 2012 and we ceased selling any tobacco products as of that date.

# **Our Current Product Development Initiatives**

# Dietary Supplements and Pharmaceutical Products

Through our company's Rock Creek subsidiary, we are continuing to pursue the development of other anatabine based dietary supplements, as well as products to treat a range of conditions and human (clinical) trials examining the impact of supplementation with our company's anatabine citrate compound. Our development efforts in this regard have been focused on the anti-inflammatory aspects of anatabine and our company's earlier research which suggested the potential of certain MAO agents in tobacco to treat a range of conditions, including tobacco dependence. In addition to developing its own intellectual property portfolio Rock Creek operates pursuant to a sublicense under our exclusive license with Regent Court, which includes patents for the use of MAO inhibitors found in tobacco to treat various neurological conditions.

Since 2011, Rock Creek, the Roskamp Institute and researchers at John Hopkins University, have completed and reported on a number of studies designed to assess the ability of our anatabine citrate compound to lower chronic inflammation in a variety of pre-clinical (non-human) and clinical (human) settings. One study conducted by the Roskamp Institute and reported in the European Journal of Pharmacology showed that anatabine lowered levels of amyloid production both in the test tube and when administered to mice vulnerable to accumulation of amyloid which, at excessive levels, damages brain tissue. A second manuscript written by the same researchers and published online in the European Journal of Pharmacology in 2012 and in manuscript form in January 2013 further characterized the anti-inflammatory effects of anatabine in several types of animal tissues, in human cells, and in human whole blood. The Roskamp Institute also presented results of pre-clinical studies of anatabine in mouse models of multiple sclerosis, traumatic brain injury, and Alzheimer's disease at the Neuroscience 2012 conference held in New Orleans in October 2012. In January 2013 the results of the animal multiple sclerosis study were published in PLOS ONE under the title "Amelioration of Experimental Autoimmune Encephalomyelitis by Anatabine." Further, a pre-clinical investigator-initiated and independently funded study from Johns Hopkins that examined the effect of anatabine supplementation in a mouse model of autoimmune thyroiditis was published in September 2012 in an article entitled, "Anatabine Ameliorates Experimental Autoimmune Thyroiditis" in the Endocrine Society's journal, Endocrinology, (Endocrinology, 2012 Sep; 153(9):4580-7.)

In 2013 Rock Creek received positive results from a study investigating the effects of anatabine in an animal model of idiopathic inflammatory bowel disease, ulcerative colitis. It also received functional binding data that offers an explanation and a possible mechanism of action for some of the observed effects of Anatabloc<sup>®</sup>.

Rock Creek also has been involved in human (clinical) trials evaluating the impact of supplementation with anatabine citrate on an inflammatory marker c-reactive protein, or CRP, (which is believed to be an indicator of coronary heart disease), on Hashimoto's autoimmune thyroiditis, in individuals with mild to moderate Alzheimer's disease and in a multi-site study of Anatabloc<sup>®</sup> Facial Crème. In February 2012, Rock Creek reported research on the first clinical trial demonstrating that Anatabloc<sup>®</sup> lowers chronic inflammation measured by CRP levels in the blood. The reported results were obtained in connection with an in-house study undertaken by Rock Creek that involved a group of smokers who had been using Anatabloc<sup>®</sup> on an extended basis. In October 2012 Rock Creek reported on an interim look at the CRP study results. That interim look showed that 61% of diabetic subjects (11 of 18) taking metformin (the most common drug prescribed for diabetics) had a CRP reduction, as did 38% of the general trial population not taking metformin (31 of 81). Overall, 42 of 99 subjects (42%) had a decrease in CRP after one month of anatabine supplementation. On January 7, 2013 Rock Creek reported on the initial results for all study subjects who completed the Thyroid health study. Those results suggest that dietary supplementation with anatabine ameliorates the immune system's targeting of the thyroid gland in cases of autoimmune thyroiditis.

The Alzheimer's study that is being sponsored by Rock Creek and conducted at the Roskamp Institute began enrolling subjects at the end of August 2012 and is ongoing. As of March 8, 2013, 49 subjects have been screened and 37 subjects enrolled in the study. The Anatabloc<sup>®</sup> Facial Crème study is being conducted at three sites and began enrolling subjects in December 2012. As of March 8, 2013, 90 subjects have been screened and 85 subjects enrolled in the study.

In 2012, the Roskamp Institute also completed pharmacokinetics and dose response studies relating to anatabine citrate. Further, in 2012 Harvard University's McLean Hospital continued follow-up research relating to its initial assessment of the abuse potential for anatabine as an alkaloid of tobacco. In 2009 and 2010 our company completed initial research relating to anatabine citrate in connection with the development of our CigRx<sup>®</sup> dietary supplement.

We continue to work with the Roskamp Institute on the preparation of a drug development plan for a prescription product based on a version of anatabine citrate.

Rock Creek's research efforts are headed by Curtis Wright, MD, MPH who joined our company as Senior Vice President, Medical/Clinical Director of Rock Creek in 2008. Dr. Wright previously served as Vice President of Clinical and Regulatory Affairs for Adolor Corporation, Executive Director, Medical Affairs and subsequently Executive Director of Risk Assessment for Purdue Pharma and most recently, as Executive Vice President for Risk Management and Regulatory Affairs at Javelin Pharmaceuticals, Inc. Dr. Wright's career at the FDA, from 1989 through October 1997, included multiple senior scientific positions in the Center for Drug Evaluation and Research, including Deputy Director and Acting Director of his division.

Our ability to continue our research efforts, including advancement of the research and development activities of Rock Creek, will depend in large part on our working capital constraints and our ability to procure funding for these initiatives. See "Item 7. Management's Discussion and Analysis of Results of Operations — Liquidity and Capital Resources" and our consolidated financial statements included in "Item 15. Exhibits, Financial Statement Schedules" of this Report for further information on our working capital constraints and results of operations.

## Our Relationship with the Roskamp Institute

The Roskamp Institute is a private medical research organization in Sarasota, Florida whose stated purpose is understanding causes of and finding cures for neuropsychiatric and neurodegenerative disorders and addictions. In 2010 and 2011, respectively, Robert G. Roskamp, the founder of the Roskamp Institute, purchased from us for cash, (i) 769,230 shares of our common stock and warrants to purchase an additional 769, 230 shares at an exercise price of \$1.50 per share, and (ii) 254,452 shares and warrants to purchase an additional 254,452 shares at an exercise price of \$4.00 per share. We have entered into a Research and Royalty Agreement with an affiliate of the Roskamp Institute pursuant to which we pay royalties of 5% of Anatabloc<sup>®</sup> sales to this affiliate (such royalties being equal to \$301 thousand during 2012).

### **Discontinued Operations**

We exited the cigarette business in June 2007 and discontinued the sale of our low-TSNA smokeless tobacco products as of December 31, 2012. Although we no longer manufacture or sell any tobacco products, we continue to look for licensing opportunities related to our low-TSNA curing technology and our related products. See Note 3 to our Notes to Consolidated Financial Statements.

# **Prior Research and Development Efforts**

Since the mid-1990s we have developed several products and initiated research and development efforts based on our StarCured<sup>®</sup> low-TSNA tobacco technology which may provide potential for licensing opportunities relating to that technology and related products or may be useful to Rock Creek in its developmental efforts relating to anatabine and related alkaloids.

# Low-TSNA Tobacco and "modified risk tobacco products"

In the mid-1990s, we commenced research and development activities based on newly conceived technology for tobacco processing that substantially prevents the formation of TSNAs in cured tobacco. Our research and development efforts culminated in the development of our proprietary technology relating to

various aspects of the process for producing very low-TSNA tobacco and tobacco products. In 2008 we filed a patent application with the U.S. Patent and Trademark Office for a variant of our process for producing low-TSNA tobacco that results in even lower levels of carcinogenic TSNAs in cured tobacco and received a patent for that curing method in April 2012. For additional information related to our intellectual property, see "— Our Patents, Trademarks and Licenses."

In 2010 we filed applications with the FDA to have a version of our low-TSNA products (Ariva-BDL and Stonewall-BDL) designated by the FDA as "modified risk tobacco products" and we filed a similar application for a Stonewall Moist-BDL, a traditional moist snuff product, on February 1, 2011. In March 2011, the FDA'issued a decision holding that it currently does not have jurisdiction over Ariva-BDL and Stonewall-BDL products. The decision by the FDA clears the way for the marketing of the Ariva-BDL and Stonewall-BDL products without the regulatory restrictions applicable to tobacco products over which the FDA has asserted jurisdiction.

#### Low-TSNA Moist and Dry Snuff Products

In September 2001, we introduced our first two very low-TSNA snuff products (a moist and dry snuff) under the brand name Stonewall<sup>®</sup>. In light of our focus on dissolvable hard tobacco products, we discontinued the manufacture of Stonewall<sup>®</sup> moist snuff. In January 2011, we filed an application with the FDA for the designation of Stonewall Moist-BDL, a moist snuff product, as a "modified risk tobacco product." Stonewall Moist-BDL is a variant of our original Stonewall<sup>®</sup> moist snuff product. We voluntarily withdrew that application in August 2011.

#### Advance<sup>®</sup> Low-TSNA Cigarettes

We launched the first low-TSNA cigarette, Advance<sup>®</sup>, in October 2000. Advance<sup>®</sup> was the first conventional cigarette specifically manufactured to diminish the amount of exposure to highly carcinogenic TSNAs. The Advance<sup>®</sup> cigarette reduced additional toxic smoke constituents through a unique activated carbon/acetate filter. Advance<sup>®</sup> also provided adult tobacco consumers with enhanced health warnings beyond those required by the Surgeon General on the back of the package, and through "onserts" that contained comparative content information and additional health-related information.

# INDs for a Low-TSNA Cigarette and a Tobacco-Flavored Chewing Gum

In 1997, we submitted an Investigational New Drug Application, or IND, for a cigarette product made from low-TSNA flue-cured tobacco to the FDA as an investigational drug. This product was designed to offer a low-TSNA product to help patients, who had relapsed after a trial of smoking cessation, prepare for another cessation attempt. A Phase I study, under an FDA-reviewed protocol, was completed at the Virginia Commonwealth University, which demonstrated that reductions of TSNA levels in tobacco resulted in reduced levels of TSNAs in the human body when study subjects smoked cigarettes containing tobacco with reduced levels of TSNAs.

In the 1990s, we also sought to develop a gum product designed to help patients who had relapsed after a trial of smoking cessation to prepare for another cessation attempt. Although we secured an additional IND from the FDA for this product, we determined that further testing and submission of required marketing applications to the FDA would not only be overly costly and time consuming, but also would require a major scientific infrastructure which we neither had in place nor could afford at the time. As noted above, in June 2007, we formed Rock Creek to pursue the development of a range of pharmaceutical products, including products having a tobacco-based component, designed to treat tobacco related dependence and certain neurological conditions and related products such as dietary supplements.

#### **Our Sales and Marketing Efforts**

#### **Dietary Supplements**

Our Rock Creek subsidiary currently manufactures and sells a nutraceutical, dietary supplement Anatabloc<sup>®</sup> as well as an unflavored version of Anatabloc<sup>®</sup>. Our Anatabloc<sup>®</sup> product is being sold through our interactive website, a customer service center and on a consignment basis through GNC, a retailer of dietary supplements. GNC began selling Anatabloc<sup>®</sup> through its online store in early 2012. In March 2012, GNC began carrying Anatabloc<sup>®</sup> at its company-owned stores and franchised retail locations. Anatabloc<sup>®</sup> is now available at GNCs more than 4,000 retail locations throughout the country and in February 2013 our Company received GNC's 2012 top vendor award for product innovation in the "wellness" product category. Initially, marketing of Anatabloc<sup>®</sup> was directed toward physicians and other healthcare professionals. More recently we have been focusing our marketing efforts on athletes and other groups of individuals who regularly deal with issues relating to inflammation.

In February 2012, we entered into an endorsement agreement with Fred Couples, a member of the PGA golf tour, under which Mr. Couples has acted as our initial brand ambassador for Anatabloc<sup>®</sup> and has been active in promoting Anatabloc<sup>®</sup> at various PGA golf events and other settings. On January 7, 2013 we announced that tennis pro John Isner, who has been a member of the ATP tour since 2007, had become our second brand ambassador for Anatabloc<sup>®</sup>. The selection of John Isner as our company's second brand ambassador is consistent with our focus on the use of Anatabloc<sup>®</sup> in dealing with the type of muscle soreness that typically is experienced by professional athletes and others who regularly are engaged in vigorous physical activity. Mr. Couples, who will be inducted into the World Golf Hall of Fame this year, continues to be the principal brand ambassador for Anatabloc<sup>®</sup>.

CigRx<sup>®</sup>, our non-nicotine, non-tobacco dietary supplement, which is designed to temporarily reduce the desire to smoke, was introduced into the market in August 2010. CigRx<sup>®</sup> is being sold through our interactive website and through retail outlets in the Richmond, Virginia metropolitan area and in the New England and the mountain west states through arrangements with distributors who have an active presence in these geographic areas. Since the introduction of Anatabloc<sup>®</sup> sales of CigRx<sup>®</sup> have been de minimis.

Anatabloc<sup>®</sup> Facial Crème was introduced on September 10, 2012 as a cosmetic to improve the appearance of the skin. We currently sell our cosmetic product through our interactive website and a customer service center. Beginning in February 2013, GNC also began carrying our Anatabloc<sup>®</sup> Facial Crème on its website.

# Our Availability of Raw Materials, Manufacturing and Distribution Capabilities

## **Dietary Supplements and Cosmetic Products**

We obtain all of the raw materials and packaging supplies for the manufacture of our Anatabloc<sup>®</sup>, Anatabloc<sup>®</sup> Facial Crème and CigRx<sup>®</sup> products from various vendors and we maintain an inventory of critical raw materials and packaging at the manufacturing location where these products are produced. We believe that the vendors from whom we obtain raw materials and packaging have sufficient capacity to meet our supply needs on a timely basis and to allow us to maintain inventory levels adequate to meet expected sales volume for the foreseeable future.

We have outsourced the product manufacturing for Anatabloc<sup>®</sup>, Anatabloc<sup>®</sup> Facial Crème and CigRx<sup>®</sup> to companies who we believe comply with FDA requirements of current Good Manufacturing Practices, or cGMP, that have sufficient capacity to provide us finished product on a timely basis and at quantities necessary to fulfill expected product sales volume for the foreseeable future. To facilitate this contract manufacturing arrangement, we purchased and installed, at the manufacturing location for our Anatabloc<sup>®</sup> and CigRx<sup>®</sup> products, certain dedicated packaging equipment that is used in conjunction with the production of Anatabloc<sup>®</sup> and CigRx<sup>®</sup> in our patented 20-piece dispensing packs. All other packaging configurations are packed on standard machinery owned by the contract manufacturers. The special packing machinery used to pack our 20-piece dispensing packs, while located at the contract manufacturer's facility, remains titled in our company's name.

We have outsourced the storage, order processing and delivery of Anatabloc<sup>®</sup>, Anatabloc<sup>®</sup> Facial Crème and CigRx<sup>®</sup> through contracts and arrangements with a number of third party suppliers. We anticipate that the arrangements which have been put in place with these various entities should be sufficient to meet our storage and distribution needs for Anatabloc<sup>®</sup>, Anatabloc<sup>®</sup> Facial Crème and CigRx<sup>®</sup> for the foreseeable future.

### **Our Competition**

# Dietary Supplements, Pharmaceuticals and Other Products and Services

Anatabloc<sup>®</sup> competes with other dietary supplements that are marketed for anti-inflammatory support and for use in maintaining a healthy metabolism. Also, while Anatabloc<sup>®</sup> is intended to support the body's natural anti-inflammatory properties, there are a number of dietary supplements and prescription and non-prescription

products that are marketed for pain relief that, in many cases, may be due in part to excessive inflammation. While Anatabloc<sup>®</sup> is not a pain relief medication; it is possible that by providing anti-inflammatory support, Anatabloc<sup>®</sup> may be viewed as competing with these products to the extent that the use of Anatabloc<sup>®</sup> supports the body's natural regulation of inflammation.

CigRx<sup>®</sup> is a dietary supplement product that allows individuals to use a non-tobacco, non-nicotine product in situations where they are not in a position to use tobacco or wish to have an alternative to a tobacco product. Smoking cessation products that are approved by the FDA for sale in the United States are designed to wean the smoker from nicotine addiction over a period of time ranging from 30 days to six weeks. These products are referred to as "nicotine replacement therapies." Some of these products are sold over the counter and others are available by prescription. Although such pharmaceutical products are not intended to be substitutes for tobacco products, we believe that many smokers use such products for nicotine maintenance and that CigRx<sup>®</sup> may compete with such products.

Anatabloc<sup>®</sup> Facial Crème was introduced on September 10, 2012 as a cosmetic to improve the appearance of the skin. Anatabloc<sup>®</sup> Facial Crème competes with other cosmetic products that are marketed as providing an improvement in the appearance of the skin and an improvement to the look and feel of the skin.

There can be no assurance that in the future our competitors will not succeed in developing technologies and products that are more effective than the products we develop, or that would render our products obsolete or non-competitive. In addition, our competitors may have far greater resources and access to capital to fund their businesses, which may put us as a competitive disadvantage.

# Our Patents, Trademarks and Licenses

## **Our Recent Intellectual Property Initiatives**

Since 2010 we have filed six United States patent applications relating to our dietary supplement products, uses of the products and product formulations. These included:

- two applications for therapeutic methods involving the administrations of anatabine, its isomers and derivatives thereof, an application relating to the administration of anatabine, or an isomer or salts thereof, for treating chronic inflammation that may be associated with disorders such as thyroiditis, cancer, arthritis, Alzheimer's disease, and multiple sclerosis,
- an application for our CigRx<sup>®</sup> and our Anatabloc<sup>®</sup> formulations, as well as
- an application for the synthesis of anatabine and an application for a relapse prevention product.

We also filed an application for a design patent relating to the 20-piece container used for our CigRx<sup>®</sup> and Anatabloc<sup>®</sup> products and a divisional application for food grade salts of anatabine.

In June 2012 the United States Patent and Trademark Office issued a patent to Rock Creek for an improved method of synthesizing anatabine that facilitates large scale commercial production of high purity anatabine. Also, in August 2012, the PTO issued a patent to Rock Creek for an anatabine citrate and yerba mate composition and uses thereof in assisting weight loss and curbing the urge for tobacco. In 2011 the PTO, issued a design patent to Rock Creek for the 20-piece dispenser used for our CigRx<sup>®</sup> and Anatabloc<sup>®</sup> products. We also have several foreign and international applications pending that relate to our Anatabloc<sup>®</sup> product, a relapse prevention product and the administration of anatabine, its isomers and any derivatives thereof for treating inflammatory mediated disorders generally, and also for autism and seizure indications.

# Our License Agreement with Regent Court and Related Technology

We are the exclusive licensee under a License Agreement with Regent Court that provides, among other things, for the grant of an exclusive, worldwide, irrevocable license to us, with the right to grant sublicenses, to make, use and sell tobacco and tobacco containing products using Regent Court's patent rights and know-how relating to the processes for curing tobacco so as to substantially prevent the formation of TSNAs, whether such patent rights and know-how are now in existence or hereafter developed. The License Agreement provides us exclusive rights to any inventions of Regent Court and its affiliates during the term of the License Agreement relating to the production, treatment or curing of tobacco, or a method of manufacturing a product containing tobacco, and to any method of extracting one or more substances from

tobacco for the purpose of incorporating such substance or substances in a product or products. Absent a material breach, the License Agreement will continue until the expiration of the last of the applicable patents, which includes 13 U.S. patents and corresponding foreign patents, as well as any additional patents issued to Regent Court during the term of the License Agreement. Generally, patents have a term of 20 years from the initial date of filing of a patent application. The U.S. patents subject to the License Agreement expire at various dates between June 28, 2016 and December 23, 2028.

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We are obligated to pay to Regent Court a royalty of 2% on the net sales of our products and the products of any affiliated sub-licensees, and 6% on all fees and royalties received by us from unaffiliated sub-licensees, less any related research and development costs incurred by us as well as costs incurred in enforcing the patent rights. The License Agreement may be terminated by us upon 30 days written notice. Regent Court may terminate the License Agreement upon a default in the payment of royalties or a failure to submit a correct accounting continuing for at least 30 days after written notice from Regent Court, a material breach of any other of our obligations under the License Agreement continuing for at least 60 days after written notice from Regent Court, or in the event of a change of control resulting from the purchase of our stock or all or substantially all of our assets. The License Agreement obligates us to enforce and pay for United States and foreign patent rights and contains other provisions typically found in patent license agreements, such as provisions governing batent enforcement and the defense of any infringement claims asserted against us or our sub-licensees. The License Agreement further provides that any and all costs, obligations or liabilities related to patent infringement matters brought against us will be borne by us. We have agreed to indemnify and defend Regent Court and its affiliates against losses incurred in connection with our use, sale or other disposition of any licensed product or the exercise of any rights under the License Agreement. Regent Court has made no representations to us in any document regarding the efficacy of the licensed technology.

In December 2008, we filed a new United States patent application for a variant of our patented curing technology that results in the production of cured tobacco that contains virtually undetectable levels of carcinogenic TSNAs as measured by prevailing standards and in April 2012 the PTO issued a patent for this curing method. Also, in 2012 we filed utility applications for an enriched form of tobacco, an alkaloid composition for e-cigarettes and for a new tobacco product that are currently pending before the PTO. We believe that through the StarCured<sup>®</sup> process and our related technology we have the ability to reduce exposure to carcinogenic TSNAs, particularly the subgroups of nitrosamines commonly referred to as NNNs and NNKs, to very low levels (with carcinogenic NNNs and NNKs that measure 200 parts per billion and below) and that we have demonstrated that our process for curing tobacco using these processes can be scaled up to meet broad commercial needs in the United States and abroad. While we have discontinued the sale of tobacco products as of December 31, 2012, we continue to pursue means of collecting royalties for our curing technology through licensing arrangements and through monitoring of the curing practices of industry participants as applicable.

## Our Portfolio of Patents and Pending Patent Applications

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We believe that our patent portfolio through Rock Creek and under the License Agreement with Regent Court, along with our pending patent applications relating to uses of anatabine and products derived therefrom, establishes us as a world leader in the anti-inflammatory property of anatabine and for curing technology that consistently produces very low-TSNA tobacco. We currently have three (3) United States patents that have issued in the name of Rock Creek and we have exclusive rights to thirteen (13) United States patents issued to Regent Court and/or Jonnie R. Williams, Sr. under our license arrangement with Regent Court. There can be no assurances that the claims that have been or may be granted to us under these patents will be sufficient to protect the intellectual property licensed to us, or that we or Regent Court will develop or obtain the rights to any additional products or processes that are patentable. Further, no assurances can be given that any patents licensed to us will not be challenged, invalidated, infringed or circumvented, or that the rights granted thereunder will provide competitive advantages to us. The patents that Rock Creek has been issued or which our company has rights to under the exclusive license arrangement with Regent Court are set forth below;

Patent Number	Date of Issue	Description	<b>Expiration Date</b>
U.S. Patent No. 5,803,081	09/08/1998	Method of Treating Tobacco with Microwave Radiation to Prevent Formation of Nitrosamines	06/28/2016
U.S. Patent No. 5,845,647	12/08/1998	Tobacco Products Improved by the Use of Propolis	06/28/2016
U.S. Patent No. 6,135,121 (Reissued as RE 38,123 E)	10/24/2000	Tobacco Products Having Reduced Nitrosamine Content	06/28/2016
U.S. Patent No. 6,202,649	03/20/2001	Method of Preventing Nitrosamine Formation by Treating Tobacco in Controlled Environment	12/02/2016
U.S. Patent No. 6,311,695 B1	11/06/2001	Method of Treating Tobacco With High Frequency Energy to Prevent Nitrosamine Formation	06/28/2016
U.S. Patent No. 6,338,348 B1	01/15/2002	Method of Treating Tobacco With Microwave Energy to Prevent Nitrosamine Formation	06/28/2016
U.S. Patent No. 6,350,479 B1	02/26/2002	Method of Administering Alcohol Extracts of Tobacco	06/04/2019
U.S. Patent No. 6,425,401	07/30/2002	Method of Preventing Nitrosamine Formation By Treating Tobacco in Controlled Environment	12/02/2016
U.S. Patent No. 6,569,470 B2	,05/27/2003	Method of Administering Alcohol Extracts of Tobacco	06/04/2019
U.S. Patent No. 6,668,839 B2	12/30/2003	Smokeless Tobacco Products Made from Powdered Tobacco	05/06/2021
U.S. Patent No. 6,834,654	12/28/2004	Smokeless Tobacco Product Made from Compressed Powdered Tobacco	05/01/2021
U.S. Patent No. 6,929,811 B2	8/16/2005	Method of Modulating Monoamine Oxidase (MAO) Activity Using Tobacco Alkaloids	06/04/2019
U.S. Design Patent No. D639,178	6/07/2011	Dispenser	08/03/2024
U.S. Patent No. 8,151,804	4/10/2012	Tobacco Curing Method	12/23/2028
U.S. Patent No. 8,207,346	6/26/2012	Method of Synthesizing Anatabine	10/16/2030
U.S. Patent No. 8,241,680	8/14/2012	Nutraceutical Product Containing Anatabine and Yerba Mate	7/30/2030
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# **Our Trademarks**

We have obtained trademark protection for the brand names of the current products manufactured and sold by Rock Creek and other trade names associated with those products. Currently, we have a total of 22 registered trademarks and 7 marks that have been issued on "an intent to use" basis. In the case of our prior products, we have licensed three of our trademarks in connection with a license agreement entered into in 2007.

# **Government Regulation**

# FDA Regulation

The FDA has authority over the manufacture and sale of dietary supplements and drug products under the Food Drug and Cosmetic Act and the Dietary Supplement Health Education Act, or DSHEA.

Food Drug and Cosmetic Act. Under the Food, Drug and Cosmetic Act, the FDA has authority for reviewing and approving any new drug product prior to its introduction into commerce. The process of

seeking regulatory clearance or approval to market a pharmaceutical product is expensive and time consuming. The FDA-approval process involves, among other things, successfully completing clinical trials under an Investigational New Drug Application and obtaining a premarket approval after filing a New Drug Application, or NDA. The NDA process requires a company to prove the safety and efficacy of a new drug product to the FDA's satisfaction. Also, any FDA approved product is subject to continuing review and the labeling, packaging, adverse event reporting, storage, advertising and promotion of any such product is subject to extensive regulation. Violations of the Food, Drug, and Cosmetic Act can result in Warning Letters from FDA, injunctions, product seizure, and civil and criminal penalties. The FDA also has jurisdiction over cosmetic products and claims made for such products. Premarket approval is not required prior to the marketing of cosmetic products, however, the ingredients in such products must be recognized as being safe and appropriate for use in cosmetics and the FDA has authority with respect to the labeling, packaging and promotion of such products.

Dietary Supplement Health and Education Act. The Dietary Supplement Health and Education Act, provides the FDA with authority over the production and marketing of dietary supplements. In certain cases DSHEA also requires notification to the FDA before a company begins to market a dietary supplement and, if structure or function claims are made for a product in the product labeling, notification of such claims within 30 days of the introduction of the product into commerce. DSHEA requires that dietary supplements be manufactured under "good manufacturing practices" and that the label, labeling and advertising for such products meet specific requirements set forth in DSHEA and its implementing regulations. DSHEA does not require prior approval by the FDA for the introduction of dietary supplements into the market, but does require that dietary supplement products comply with the requirements of DSHEA prior to and after their introduction into commerce. If products are manufactured and sold as dietary supplements it is possible that FDA may challenge the status of a product classification. FDA may also challenge the types of claims made for a dietary supplement or its indications for use. Currently, we are marketing our Anatabloc<sup>®</sup> and CigRx<sup>®</sup> products as dietary supplements. We believe that we have appropriately marketed Anatabloc<sup>®</sup> and CigRx<sup>®</sup> as dietary supplements and only have made claims for those products that are consistent with those for dietary supplements. If Anatabloc<sup>®</sup> or CigRx<sup>®</sup> were determined to be a pharmaceutical product, as opposed to a dietary supplement, the affected product would need to be submitted to the FDA for approval as a new drug prior to its being sold in the United States. Also, in 2009 the FDA obtained jurisdiction over the manufacturing and sale of tobacco products under the FDA Tobacco Act. We had registered as a manufacture of low-TSNA smokeless tobacco products under the FDA Tobacco Act and the smokeless tobacco products we manufactured and sold through December 31, 2012 were required to comply with the requirements of the FDA Tobacco Act. Also, as a tobacco manufacture, we were taxed on the sale of our smokeless tobacco products pursuant to regulations promulgated by the Tax and Trade Bureau, under authority of the Internal Revenue Code of 1986, as amended. While we ceased manufacturing and selling any tobacco products as of December 31, 2102, we were obligated for Federal Excise taxes on all products sold prior to that date.

## **Product Liability**

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Prior to the introduction of Anatabloc<sup>®</sup>, Anatabloc<sup>®</sup> Facial Crème and CigRx<sup>®</sup>, we obtained product liability insurance for each of those products. This insurance covers claims arising from product defects or claims arising out of the sale, distribution and marketing of Anatabloc<sup>®</sup>, Anatabloc<sup>®</sup> Facial Crème and CigRx<sup>®</sup>. There have been no claims asserted with respect to our products to date. If any such claims are asserted in the future and ultimately result in liability that exceeds the limits of our insurance coverage, this could have a materially adverse effect on our financial condition.

In the United States, there have been numerous and well-publicized lawsuits against the largest manufacturers of cigarettes and, to a lesser extent, other tobacco products initiated by state and municipal governmental units, healthcare providers and insurers, individuals (for themselves and on a class-action basis) and by others. We believe that we have conducted our business in a manner that decreases the risk of liability in a lawsuit of the type described above because we, have attempted to consistently present to the public the most current information regarding the health risks of long-term smoking and tobacco use generally, have always acknowledged the addictive nature of nicotine, and have never targeted adolescent or young persons as customers.

In the past, we maintained product liability insurance for our tobacco products only with respect to claims that tobacco products manufactured by or for us contained any foreign object (i.e., any object that is not intended to be included in the manufactured product), but had not maintained that coverage for several years. The product liability insurance previously maintained did not cover health-related claims such as those that have been made against the major manufacturers of tobacco products. We do not believe that insurance for health-related claims can currently be obtained. Although, to date, no health-related lawsuit has ever been filed against us, a lawsuit based on such claims relating to products sold prior to December 31, 2012 could have a material adverse effect upon our company, notwithstanding the fact that we exited from the tobacco business as of December 31, 2012.

# **Our Employees and Consultants**

As of December 31, 2012, we employed 23 full-time employees, as compared to 39 employees as of December 31, 2011. The decrease is directly related to our decision to discontinue manufacturing and selling any smokeless tobacco products as of December 31, 2012.

From time to time, we engage temporary personnel to augment our regular employee staff. Further, we utilize the services of consultants, scientific and technical experts and, from time-to-time, independent contractors to provide key functions in the scientific, medical, public healthcare, compliance, technology, legal, communications, financial and related fields. The use of such third-party providers enables us to secure unique expertise on both a formal and informal basis in a wide variety of areas that we might otherwise not be in a position to obtain or which we would otherwise be required to obtain through the hiring of additional employees at a potentially greater cost to us. Substantially all of the our research and development efforts have been, and are expected to continue to be, conducted pursuant to contractual arrangements with universities, scientific, medical and public health consultants, independent investigators and research organizations.

## Internet Address and Internet Access to Periodic and Current Reports

Our Internet address is *www.starscientific.com*. You may obtain through our Internet website, free of charge, copies of our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and Proxy Statements on Schedule 14A, including any amendments to those reports or other information filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. These reports will be available as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the Securities and Exchange Commission, or SEC. You can also obtain these reports directly from the SEC at its website, *www.sec.gov*, or you may visit the SEC in person at the SEC's Public Reference Room at Station Place, 100 F. Street, N.E., Washington, DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. We will also provide a copy of our annual report on Form 10-K free of charge upon any written request by a shareholder.

Financial information about our business segments, product sales and research and development expenses are included in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the Notes to our Consolidated Financial Statements.

# **ITEM 1A. RISK FACTORS**

# We have incurred losses for the past ten years and operating expenses are likely to continue to be greater than operating revenues in the foreseeable future

We have incurred operating losses for ten consecutive fiscal years beginning with the year ended December 31, 2003. Our net losses were approximately \$(28.3) million for the year ended December 31, 2010, \$(38.0) million for the year ended December 31, 2011 and \$(22.9) million for the year ended December 31, 2012. Our accumulated deficit as of December 31, 2012 was approximately \$(231.5) million. For the past five years we have been focusing our efforts on the development of non-tobacco, non-nicotine dietary supplements and potentially pharmaceuticals through Rock Creek. In 2012 our dietary supplement products constituted the vast majority of our net sales. With the decision to cease manufacturing and selling any of our low-TSNA smokeless tobacco products and to exit from the tobacco business as of December 31, 2012, our future net sales will be derived almost exclusively from our dietary supplements and cosmetic products. Given the level of those sales to date, it would take a substantial increase in sales of these products for operating revenues to exceed expenses.

Our future prospects, therefore, are dependent on the expanded distribution and consumer acceptance of our dietary supplement products and cosmetic product. They also are dependent on the continued development of other dietary supplements and pharmaceutical products independently and through alliances with pharmaceutical companies and the licensing of our curing technology and related products, although we do not have any licenses in place for that technology at the present time.

# Our revenues are currently dependent almost exclusively on sales of our dietary supplement products (in particular, Anatabloc<sup>®</sup>).

For 2012, virtually all our dietary supplement revenues were derived from sales of our Anatabloc<sup>®</sup> dietary supplement. Our inability to increase our sales of Anatabloc<sup>®</sup> or any significant decline in sales for Anatabloc<sup>®</sup> from current levels (including for any of the reasons discussed in this "Item 1A. Risk Factors") could have a material adverse effect on our results of operations, financial condition and cash flows.

# In the future, we may not be able to secure financing necessary to operate and grow our business as planned.

The recurring losses generated by our operations continue to impose significant demands on our liquidity. Over the last several years our liquidity demands have been met principally by private placements of our common stock and from the exercise of related warrants and stock options. In 2012 our company received proceeds of approximately \$33.9 million through private placements and stock option and warrant exercises. See note 8 to our consolidated financial statements included in "Item 15. Exhibits, Financial Statement Schedules" for further details of these transactions. Absent the exercise of outstanding warrants and options for cash or a substantial improvement in sales and revenues and/or royalties, we believe that the recent funding will support our operations through the first quarter 2014. However, our business and operations may consume resources faster than we anticipate, and depending upon market conditions and the price of our common stock, we may decide to seek additional funds before that time. Additional financing may not be available on favorable terms, if at all. If adequate funds are not available on acceptable terms, we may be unable to fund our operations or the expansion of our sales and marketing and research and development efforts or take advantage of other opportunities, which could seriously harm our business and operating results. If we issue additional equity securities, existing stockholders will experience dilution.

#### We are responding to subpoenas in a government investigation.

In late January and February of this year, our company, directors and others received subpoenas from the United States Attorney's Office for the Eastern District of Virginia seeking documents. Our present understanding is that the investigation is principally focused on transactions involving our company's securities including certain private placements and related party transactions since 2006. We are responding to the subpoenas and intend to cooperate fully with the investigation. In addition, we engaged outside counsel (the international law firm of Chadbourne & Parke, LLP) to conduct an internal investigation of these matters.

We are unable to predict the duration of the internal investigation or the United States Attorney's investigation. No conclusion can be drawn at this time as to outcome, or whether these matters will result in

any materially adverse impact on our company. While the investigation is pending, we intend to remain focused on our core business activities, including expanding sales of our Anatabloc<sup>®</sup> product and continuing clinical and related research on our current development schedule. We do not intend, and disclaim any obligation, to provide continuing or updated disclosure regarding these requests and inquiries absent definitive developments unless otherwise required by law.

# If we are unable to protect our intellectual property rights, our competitive position could be harmed and we could be required to incur significant expenses to enforce our rights.

Our future success will depend in part on obtaining patent and other intellectual property protection for the technology related to our products, and on successfully defending our patents and other intellectual property against third-party challenges. In particular, this will include obtaining patent protection for the technology relating to the manufacture and uses of anatabine in our dietary supplement and cosmetic products based on the patents issued to date for the improved synthesis of anatabine and the composition used in our CigRx<sup>®</sup> product, utility applications filed to date and our success in commercially marketing the curing technology for which we have exclusive patent rights under our license arrangement with Regent Court. This will depend in large part on our ability to continue to protect the patents related to the synthesis of anatabine and our anatabine yerba mate composition as well as our low-TSNA tobacco curing technology and related products, to obtain further patent protection for our technology in the United States and other jurisdictions and to operate without infringing upon the patents and proprietary rights of others.

We do not know whether we will obtain the patent protection we seek through our existing patents or patent applications that are pending, or that the protection we do obtain will be found valid and enforceable, if challenged. If we fail to obtain adequate protection of our intellectual property, or if any protection we obtain is reduced or eliminated, others could use our intellectual property without compensating us, resulting in harm to our business. We may also determine that it is in our best interests to voluntarily challenge a third party's products or patents in litigation or administrative proceedings, including patent interferences or reexaminations. In the event that we seek to enforce any of our owned or exclusively licensed patents against an infringing party, it is likely that the party defending the claim will seek to invalidate the patents we assert. If successful this could result in the loss of the entire patent or the relevant portion of our patent, which would not be limited to any particular party. Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time-consuming and could divert the attention of our management and key personnel from our business operations. Our competitors may independently develop similar or alternative technologies or products without infringing any of our patents or other intellectual property rights, or may design around our proprietary technologies.

United States patents and patent applications may also be subject to interference proceedings and United States patents may be subject to reexamination proceedings and other post-grant challenges in the PTO. Foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent offices', and those proceedings could result in either loss of the patent or denial of the patent application, or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, reexamination and opposition proceedings may be costly. Thus, any patents that we own or license from others may provide limited or no protection against competitors. Our pending patent applications, those we may file in the future, or those we may license from third parties, may not result in patents being issued. If issued, they may not provide us with proprietary protection or competitive advantages against competitors with similar technology.

We may also rely on unpatented trade secrets and know-how to maintain our competitive position, that we seek to protect, in part, by confidentiality agreements with employees, consultants, suppliers and others. There can be no assurance that these agreements will not be breached or terminated, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by competitors. We intend to seek to create new products and distribution channels and expand existing distribution channels for our dietary supplements and cosmetic products and, for other products developed by Rock Creek. Our future growth is also heavily dependent upon increased consumer acceptance of our existing dietary supplements, Anatabloc<sup>®</sup> and CigRx<sup>®</sup>, our cosmetic product Anatabloc<sup>®</sup> Facial Crème, as well as the licensing of our low-TSNA curing technology and our related products.

Our long-term growth strategy includes an increased focus on the sale and marketing of our dietary supplements and cosmetic products, as well as the introduction of other dietary supplements and pharmaceuticals. It is also dependent, to a lesser degree, on the receipt of royalty fees for the licensing of our patented low-TSNA curing technology and related products, although at the present time we do not have any licenses agreements in place for that technology.

Additionally, our success will be dependent on our ability to develop other dietary supplements and cosmetic products that may be helpful to consumers in maintaining a healthy metabolism and improved skin appearance, as well as pharmaceutical products. The introduction of pharmaceutical products will require a substantial period of time in order to obtain FDA approval to market such products. As a result, we do not anticipate introducing any pharmaceutical products into the market for the foreseeable future, but will focus on the research and development aspects of a range of pharmaceuticals, in addition to the development of other dietary supplement products and cosmetics. Assuming that we are successful in introducing such products into the market, the success of those products like the success of our other dietary supplements and cosmetic products will depend on the willingness and ability of retail customers to market and sell our products to consumers, as well as our success in developing new distribution channels for those products. If we are not able to continue to market our dietary supplement and cosmetic products through our e-commerce initiatives or if retail customers were to reduce the quantity of the products they currently sell or stop selling our products, or if we are unable to open distribution channels for our new products, our financial condition and results of operations could be adversely affected.

It is not certain whether our dietary supplements or our cosmetic products will be accepted by the market in sufficient volume to support our operations. Consumers may decide not to purchase our products due to taste or other preferences, including a preference for our competitors' products. There can be no assurance that in the future our competitors will not succeed in developing technologies and products that are more effective than the products we develop or that would render our products obsolete or non-competitive. Further, our decision to exit from the tobacco business as of December 31, 2012, may negatively affect our ability to license our patented curing technology and related products.

# We may not be successful in expanding the market for our Anatabloc<sup>®</sup>, Anatabloc<sup>®</sup> Facial Crème and our CigRx<sup>®</sup> products.

We introduced Anatabloc<sup>®</sup> as a nutraceutical, dietary supplement for anti-inflammatory support in August 2011. As such, Anatabloc<sup>®</sup> competes with other dietary supplements that are marketed for anti-inflammatory support and for use in maintaining a healthy metabolism. While Anatabloc<sup>®</sup> is intended to support the body's natural anti-inflammatory properties, there are a number of dietary supplements, prescription and non-prescription products that are marketed for pain relief that, in many cases, may be due to excessive inflammation. While Anatabloc<sup>®</sup> is not a pain relief medication, it is possible that by providing anti-inflammatory support, Anatabloc<sup>®</sup> may be viewed as fungible with these products to the extent that the use of Anatabloc<sup>®</sup> supports the body's natural regulation of inflammation.

In August 2010, we introduced,  $CigRx^{\oplus}$  as a tobacco alternative designed to temporarily reduce the desire to smoke.  $CigRx^{\oplus}$  is a dietary supplement product that allows individuals to use a non-tobacco, non-nicotine product in situations where they are not in a position to use tobacco or wish to have an alternative to a tobacco product.  $CigRx^{\oplus}$  competes with smokeless tobacco products in the "When You Can't Smoke<sup>®</sup>" market. Also, to the extent that the FDA approves cessation products for nicotine maintenance, such products would compete with  $CigRx^{\oplus}$  in the future. Although FDA approved smoking cessation products are not labeled or approved for tobacco maintenance, it appears that those products may be used for that purpose and thus compete with  $CigRx^{\oplus}$  at the present time. Currently our  $CigRx^{\oplus}$  product does not have an established market as a tobacco alternative.

We currently market Anatabloc<sup>®</sup>, Anatabloc<sup>®</sup> Facial Crème and CigRx<sup>®</sup> through our interactive websites and customer service centers. We also market Anatabloc<sup>®</sup> through GNC's company-owned stores and franchised retail locations as well as through GNC's website. Further, we market CigRx<sup>®</sup> at selected retail locations in the Richmond, VA area and in the Northwest and Northeast, although sales of CigRx<sup>®</sup> have been de minimis since the introduction of Anatabloc<sup>®</sup>. Our success in marketing Anatabloc<sup>®</sup>, Anatabloc<sup>®</sup> Facial Crème and CigRx<sup>®</sup> will be dependent on consumer acceptance of these products and our ability to have the products sold to consumers through our websites and other avenues of distribution. If we are not able to attract interest in these products at the consumer level, expand on distribution channels or compete with other companies marketing alternatives to our dietary supplements and cosmetic products our financial condition and results of operations could be materially adversely affected.

# We may face disruptions relating to the manufacture and sale of Anatabloc<sup>®</sup>, Anatabloc<sup>®</sup> Facial Crème and CigRx<sup>®</sup> based on the fact that we have arranged for third parties to manufacture and distribute these products.

In order to facilitate the launch of Anatabloc<sup>®</sup>, Anatabloc<sup>®</sup> Facial Crème and CigRx<sup>®</sup> and limit capital expenditures, we have outsourced the manufacturing, storage, order processing and delivery of these products through contracts and arrangements with a number of third-party contractors. In a number of cases our arrangement with our contractors are on a sole source basis. If our contractors experience delays or disruptions that could adversely impact on their ability to meet our manufacturing and distribution needs. In the event that our third-party contractors are unable to meet our needs, we would need to find alternative sources for the manufacturing and/or distribution of Anatabloc<sup>®</sup>, Anatabloc<sup>®</sup> Facial Crème and CigRx<sup>®</sup>, which may be difficult to obtain in a timely and cost effective manner, or at all. Also, if sales volumes for Anatabloc<sup>®</sup>, Anatabloc<sup>®</sup> Facial Crème and CigRx<sup>®</sup> or if we are not able to obtain adequate amounts of Anatabloc<sup>®</sup>, Anatabloc<sup>®</sup> Facial Crème and CigRx<sup>®</sup> or if we are not able to supply product to consumers on a timely basis, our customers may seek to fulfill their supply needs by purchasing competing products, which, in turn, would reduce our market share and ability to successfully commercialize Anatabloc<sup>®</sup>, Anatabloc<sup>®</sup> Facial Crème and CigRx<sup>®</sup>, which could have a material adverse effect on our results of operations, financial position and cash flows.

# Our research and development efforts may not result in commercially viable products and may be curtailed by our lack of available research funds.

Our company's long-term focus is the research, development, manufacturing and licensing of technology that can promote maintenance of a healthy metabolism and, more generally, assist consumers in maintaining a healthy lifestyle. We have pursued these objectives through the production of our nutraceutical, dietary supplements Anatabloc<sup>®</sup> and CigRx<sup>®</sup> and our cosmetic product Anatabloc<sup>®</sup> Facial Crème and by our ongoing research and development efforts that are focused on the anti-inflammatory aspects of anatabine and related MAO agents in addressing a range of conditions, including Alzheimer's disease, Parkinson's disease, multiple sclerosis, schizophrenia and depression. Our current and future product development initiatives will be substantially dependent on our ability to continue our research initiatives and to obtain the funding necessary to support these initiatives. Our inability to continue these initiatives and initiate new research and development efforts could result in a failure to develop new products or to improve upon existing products, which could have a material and adverse impact on our sales, operating income and cash flows.

# We have many potentially dilutive derivative securities outstanding and the issuance of these securities as well as the future sales of our common stock could have a dilutive effect on current stockholders.

At March 5, 2013, we had outstanding options granted to directors, employees and consultants to purchase approximately 17,695,000 shares of our common stock, with a weighted-average exercise price of \$2.73 per share, of which options for 14,360,000 shares were exercisable at March 5, 2013. We also have outstanding warrants, which are currently exercisable into 16,492,501 shares of our common stock, with a weighted-average exercise price of \$1.79 per share. Exercise of outstanding stock options or warrants would cause dilution, which could adversely affect the market price of our common stock. If we issue additional shares of our common stock for sale (which has historically been our principal means of financing our

operations) in connection with future financings, our stockholders could experience further dilution. See Note 8, "Stockholders' Equity", to our Notes to Consolidated Financial Statements for information related to our outstanding securities that may become exercisable for future shares of our common stock.

# We may lose our key personnel or fail to attract and retain additional personnel.

We are highly dependent upon the continued services of our senior management team for our continued success. The loss of any one of Jonnie R. Williams, our Chief Executive Officer, Paul L. Perito, our Chairman, President and Chief Operating Officer, David M. Dean, our Vice President of Sales and Marketing, Park A. Dodd III, our Chief Financial Officer, Robert E. Pokusa, our General Counsel or Curtis Wright, M.D., MPH, Senior Vice-President Medical/Clinical Director of Rock Creek could have a serious negative impact on our business and operating results. The employment agreements for Messrs. Williams, Perito, Dodd, Dean and Pokusa are on a month-to-month basis.

Our future success depends in large part on our ability to attract and retain, on a continuing basis, consulting services from highly qualified scientific, technical, management, financial and marketing personnel. Competition for such personnel is intense and there can be no assurance that we will be able to attract and retain the personnel necessary for the development and operation of our business or that given the operating losses we have suffered over the past ten years we will have the financial ability to do so. The loss of the services of key personnel or the termination of relationships with independent scientific and medical investigators could have a material and adverse effect on our business.

# We are subject to risks inherent in new product development initiatives, particularly with respect to our goal of developing pharmaceutical products to treat certain conditions which are subject to FDA regulation and approval, and for related products such as dietary supplements and cosmetics.

Our future success is substantially dependent upon implementation of our business strategy related to our new product initiatives. Since the incorporation of Rock Creek in 2007, we have been focused on utilizing certain alkaloids found in the Solanacea family of plants, such as potatoes, tomatoes and eggplants, initially to address issues related to the desire to smoke or use other tobacco products. More recently, we have been focusing on the anti-inflammatory aspects of one of those alkaloids, anatabine. We believe our research and development efforts relating to the anatabine alkaloid have positioned us to utilize our technology to develop a range of non-nicotine dietary supplements, cosmetics and related pharmaceutical products that could be beneficial in maintaining a healthy metabolism and in treating a variety of diseases and conditions.

The ongoing product development initiatives of Rock Creek are subject to high levels of risk, uncertainties and contingencies, including the challenges inherent in new product development, FDA regulatory approval for any new pharmaceutical products that we develop and FDA regulatory oversight for dietary supplements and cosmetics.

DSHEA, provides the FDA with authority over the production and marketing of dietary supplements. In certain cases DSHEA also requires notification to the FDA before a company begins to market a dietary supplement and, if structure or function claims are made for a product in the product labeling, notification of such claims within thirty days of the introduction of the product into commerce. DSHEA also implements significant manufacturing and marketing requirements, including that dietary supplements be manufactured under "good manufacturing practices" and that the label, labeling and advertising for such products meet specific requirements set forth in the statute and implementing regulations. DSHEA does not require prior approval by the FDA for the introduction of dietary supplements into the market, but does require that the dietary supplement products being developed by Rock Creek comply with the requirements of DSHEA prior to and after their introduction into commerce. If products are manufactured and sold as dietary supplements it is possible that FDA may challenge the status of a product classification. FDA may also challenge the types of claims made for a dietary supplement or its indications for use and the FTC also has jurisdiction over advertising of dietary supplements and other OTC products.

In marketing our Anatabloc<sup>®</sup> and CigRx<sup>®</sup> dietary supplements, we will have to comply with the requirements of DSHEA, which could impact the time required to fully commercialize those products. We do not have any pharmaceutical products cleared or approved for commercialization and we do not expect to obtain approval for any drug products for the foreseeable future. The success of any future pharmaceutical,

and to a more limited extent, our dietary supplement, business will depend on our ability to obtain regulatory clearance or approval to market new drug products and our ability to comply with statutory and regulatory requirements for any dietary supplement products, create product sales, successfully introduce new products, establish our sales force and distribution network, and obtain access to additional working capital to finance our development initiatives, all of which we may be unable to realize. Additionally, if any dietary supplement developed by us is determined to be a pharmaceutical product, as opposed to a dietary supplement, the product would need to be submitted to the FDA for approval as a new drug prior to it being sold in the United States.

Even if we develop a viable pharmaceutical product, we may not obtain or maintain the necessary FDA approvals for our product, or such approvals may be delayed, which would mean that we would be unable to commercially distribute and market our product. The process of seeking regulatory clearance or approval to market a pharmaceutical product is expensive and time consuming and, notwithstanding the effort and expense incurred, clearance or approval is never guaranteed. Also, the FDA has substantial discretion in the drug approval process. We cannot market a drug product in the United States unless it has been approved by the FDA. The FDA approval process involves, among other things, successfully completing clinical trials under an IND and obtaining a premarket approval after filing an NDA. Clinical trials are expensive and uncertain. The NDA process would require us to prove the safety and efficacy of our product to the FDA's satisfaction. If our clinical trials fail to produce sufficient data to support an NDA, it will take us longer to ultimately commercialize a product and generate revenue, or the delay could result in our being unable to do so. Moreover, our development costs will increase if, to achieve sufficient data to support an NDA, we need to perform more or larger clinical trials than planned. Even if we are successful in developing a pharmaceutical product, if we are not successful in obtaining timely clearance or approval of the product from the FDA, we may never be able to generate sufficient revenue to support the successful commercialization of the product. Also, any FDA approved product will be subject to continuing review and the labeling, packaging, adverse event reporting, storage, advertising and promotion of any such product will be subject to extensive regulation.

The FDA also has jurisdiction over cosmetic products and claims made for such products. While premarket approval is not required prior to the marketing of cosmetic products, the ingredients in such products must be recognized as being safe and appropriate for use in cosmetics. In developing and marketing our cosmetic products we will be required to comply with the requirements relating to the manufacturing and marketing of such products and will be subject to continuing review by the FDA with respect to the labeling, packaging and promotion of such products.

# We have limited retail or independent distributors selling our dietary supplements Anatabloc<sup>®</sup> and CigRx<sup>®</sup> and our cosmetic, Anatabloc<sup>®</sup> Facial Crème, and a loss or material reduction in our existing distribution channels could result in reduced sales of our products.

Anatabloc<sup>®</sup>, which is intended to provide anti-inflammatory support, is currently being sold through our interactive website, a customer service center and on a consignment basis through GNC, a retailer of dietary supplements. GNC initially sold Anatabloc<sup>®</sup> through its online store and, beginning in late March 2012, GNC began carrying Anatabloc<sup>®</sup> at its company-owned stores and franchised retail locations. Initially, marketing of Anatabloc<sup>®</sup> was directed toward physicians and other healthcare professionals. More recently we have been focusing our marketing efforts on athletes and other groups of individuals who regularly deal with issues relating to inflammation. Through Rock Creek we have also been developing extensions of our Anatabloc<sup>®</sup> product line. We introduced an unflavored version of Anatabloc<sup>®</sup> in the second quarter 2012 and introduced into the market Anatabloc<sup>®</sup> Facial Crème in September, 2012 as a cosmetic to improve the appearance of the skin. Our success in marketing our dietary supplements and our cosmetic products will be dependent upon the willingness and ability of retail distributors to market and sell our products to consumers, as well as our success in developing new distribution channels for our dietary supplements and cosmetic products. If our distribution arrangement with GNC terminated or if GNC reduced the quantity of our products it carries or promotes, or if we are unable to open new distribution channels for our products, our financial condition and results of operations could be adversely affected.

Independent retailers and distributors generally purchase products from us on a purchase-order basis and do not have long-term contracts with us. Consequently, with little or no notice and without penalty, our

independent retail and independent distributors may terminate their relationships with us or materially reduce the level of their purchases of our products. If this were to occur with one or more retail or independent distributors, who purchase significant quantities of our products, it may be difficult for us to establish substitute relationships in a timely manner, which could have a material adverse effect on our financial condition and results of operations.

# We are dependent on domestic sales of our Anatabloc<sup>®</sup> and CigRx<sup>®</sup> dietary supplements and for sales of our Anatabloc<sup>®</sup> Facial Crème cosmetic product.

Virtually all of our revenues beginning January 1, 2013 are derived from sales of our dietary supplements, Anatabloc<sup>®</sup> and CigRx<sup>®</sup> and our cosmetic product Anatabloc<sup>®</sup> Facial Crème. While Anatabloc<sup>®</sup> is available for shipment to numerous foreign countries outside the United States, sales outside the United States have been limited and we do not have any direct distribution arrangements for Anatabloc<sup>®</sup> outside of the U.S. Prior to January 1, 2013, we also had been deriving revenue from the sale of our dissolvable tobacco products, although sales of those products had been de minimis over the last several years. However, we discontinued the manufacture and sale of any tobacco products as of December 31, 2012.

# If we experience product recalls, we may incur significant and unexpected costs and our business reputation could be materially adversely affected.

We may be exposed to product recalls and adverse public relations if our dietary supplement products or our cosmetic products are alleged to cause illness or injury, or if we are alleged to have violated governmental regulations. A product recall could result in substantial and unexpected expenditures, which could reduce operating profits and cash flow. In addition, a product recall may require significant management time and attention and may adversely impact on the value of our brands. Product recalls may lead to greater scrutiny by federal or state regulatory agencies and increased litigation, which could have a material adverse effect on our financial condition and results of operations.

# We have had substantial obligations under state laws adopted under the Master Settlement Agreement.

In November 1998, 46 states and the District of Columbia, or the Settling States, entered into the Master Settlement Agreement, or MSA, to resolve litigation that had been instituted against the major tobacco manufacturers. We did not join the MSA and while we manufactured and sold cigarette products we were required to satisfy certain escrow obligations pursuant to statutes that the MSA required the Settling States to adopt in order for such states to receive the full benefits of the settlement. We discontinued the sale of any cigarette products in June 2007 and we sold the rights, title and interest in and to all income from and reversionary interest in our MSA escrow accounts in May 2007. Although we sold the rights in and to all income for sales through 2006, these MSA escrow funds remain in our name and the principal amount of these accounts will be available to satisfy portions of any state judgments or settlements for the type of claims asserted against the major tobacco manufacturers in the suits that resulted in the negotiation of the MSA, notwithstanding that we stopped selling cigarettes in 2007 and exited from the tobacco industry completely as of December 31, 2012. Moreover, if such claims are successfully asserted in litigation against us in the future, the claims could exceed the amounts that have been deposited into escrow under the MSA which could adversely affect our operating income and cash flows.

# We may be assessed additional sales and use taxes by the Commonwealth of Virginia.

In 2002, the Virginia Department of Taxation asserted a Virginia Sales and Use Tax assessment for the period January 1, 1999, through March 31, 2002, against us with respect to our tobacco-curing barns in the amount of \$860,115. We applied for a correction of the assessment and a total abatement of the tax on the grounds that our barns are exempt from sales and use taxes under the industrial use and processing exemption and/or the agricultural exemption. In a letter dated October 7, 2004, our company received notification from the Commonwealth of Virginia that an adverse decision had been made by the Commissioner of Taxation with respect to the sales and use tax assessment previously issued to our company. On August 10, 2010 the Commonwealth of Virginia responded to our request for reconsideration of the state's sales and use tax assessment with respect to our tobacco curing barns. The Commonwealth disagreed with our position that the

barns are part of the manufacturing process and, therefore, exempt from sales and use taxes under the industrial use and processing exemption and/or the agricultural exemption, concluding that the barns are taxable under the Commonwealth's sales tax laws and regulation. We disagree with the ruling by the Commissioner and in July 2011 we filed a lawsuit in the Circuit Court for Mecklenburg County, VA seeking a correction of this assessment. The Commonwealth has filed an answer in that action asserting that the assessment was correct. The matter is currently pending. The sales and use tax assessment plus penalties and interest together, as of December 31, 2012, totaled approximately \$1.7 million. Interest will continue to accrue during our continued pursuit of a resolution of this matter.

# Lawsuits may affect our profitability and we have limited insurance coverage for any damages for which we may become liable.

Prior to the introduction of Anatabloc<sup>®</sup>, Anatabloc<sup>®</sup> Facial Crème and CigRx<sup>®</sup> we obtained product liability insurance for these products as dietary supplements and as a cosmetic. This insurance covers claims arising from product defects or claims arising out of the sale, distribution and marketing of our Anatabloc<sup>®</sup>, Anatabloc<sup>®</sup> Facial Crème and CigRx<sup>®</sup> products. There have been no claims asserted with respect to the manufacture, sale or use of these products to date. If any such claims are asserted in the future and ultimately result in liability that exceeds the limits of our insurance coverage, this could have a materially adverse effect on our financial condition.

We are not, nor have we ever been, named as a defendant in any legal proceedings involving claims arising out of the sale, distribution, manufacture, development, advertising, marketing and claimed health effects relating to the use of our tobacco products. While we exited the tobacco business as of December 31, 2012, we could have claims asserted against us in connection with our prior manufacture and sale of such products. While we believe the risk of being named a defendant in such a lawsuit is relatively low, we could be named as a defendant in such litigation, as there has been a noteworthy increase in the number of these cases pending. Punitive damages, often in amounts ranging into the hundreds of millions, or even billions of dollars, are asserted in a number of these cases in addition to compensatory and other damages. We currently do not have and do not believe that insurance coverage for health-related claims arising from the use of tobacco products can be obtained. If, in the future, we are named as a defendant in any actions related to our smoked or smokeless tobacco products, we will not have insurance coverage for damages relating to any such claims, which could have a material adverse effect on our financial condition.

# If we do not effectively manage our growth, we may be unable to successfully develop, market and sell our products.

Our future revenue and operating results will depend on our ability to manage the anticipated growth of our business. If we are successful in increasing market acceptance for our products, we will be required to manage substantial volume from our customers. To accommodate any such growth and compete effectively, we will be required to attract, integrate, motivate and retain additional highly skilled sales, technical and other employees. We face competition for these people. Also, we will have to maintain sufficient capacity for the contract manufacturing of our dietary supplement and cosmetic products. There can be no assurance that we can overcome the challenge of scaling up our processing and production operations, that our personnel, systems, procedures and controls will be adequate to support our future operations or that we will be able to increase or secure additional capacity through third-party contractors for the manufacturing, sale and distribution of our Anatabloc<sup>®</sup>, Anatabloc<sup>®</sup> Facial Crème and CigRx<sup>®</sup> products. Any failure to implement and improve our operational, financial and management systems, to attract, integrate, motivate and retain additional employees required by future growth, if any, or to secure any needed capacity through third party contractors, if required, could have a material adverse effect on our business and prospects, financial condition and results of operations.

# Our directors and executive officers own a large percentage of our voting stock, which allows them to exercise significant control over us, and they may make decisions with which you disagree.

Based on stock ownership as of March 5, 2013, our directors and executive officers and their affiliates, own an aggregate of approximately 7.3% of our currently issued and outstanding common stock. As a result, these persons acting together may have the ability to influence matters submitted to our stockholders for

approval and to control the management and affairs of our company. This concentration of ownership may have the effect of delaying or preventing a change in control of our company, impede a merger, consolidation, or takeover or other business combination, or discourage a potential acquirer from attempting to obtain control. This concentration of control could also have a negative effect on the market price of our shares.

#### Levels of market volatility have been unprecedented in recent years.

The capital and credit markets experienced volatility and disruption at unprecedented levels in 2008 and 2009, which continued to a lesser extent in the period 2010 through 2012. In some cases, the markets have produced downward pressure on stock prices and credit availability for certain issuers without regard to those issuers' underlying financial strength. If market disruption and volatility worsen in the future, there can be no assurance that we will not experience an adverse effect, which may be material, on our ability to access capital and on our business, financial condition and results of operations.

# Our stock price has been and may continue to be volatile and an investment in our common stock could suffer a decline in value.

The trading price of the shares of our common stock has been, and may continue to be, highly volatile. Our stock has traded at prices ranging from \$1.56 to \$5.05 for the period January 1, 2012 to March 5, 2013. We receive only limited attention from securities analysts and may experience an imbalance between supply and demand for our common stock resulting from our trading volumes. The market price of our common stock may fluctuate significantly in response to a variety of factors, most of which are beyond our control, including the following:

- our success in marketing our Anatabloc<sup>®</sup> and CigRx<sup>®</sup> dietary supplements and Anatabloc<sup>®</sup> Facial Crème cosmetic and developing related dietary supplements designed to assist in maintaining a healthy metabolism as well as pharmaceutical products;
- developments related to our patents or other proprietary rights;
- developments in our efforts to license our low-TSNA curing technology and related products;
- announcements of new products, technological innovations, contracts, acquisitions, financings, corporate partnerships or joint ventures by us or our competitors;
- negative regulatory action or regulatory approval with respect to our products or our competitors' products; and
- market conditions in the dietary supplement, pharmaceutical and cosmetic industries in general.

The stock market from time to time, and in particular over the last several years, has experienced extreme price and volume fluctuations that have particularly affected the market prices for small companies, and which have often been unrelated to their operating performance or prospects for future operations. These broad fluctuations may adversely impact the market price of our common stock. In addition, sales of substantial amounts of our common stock in the public market could lower the market price of our common stock.

# **ITEM 1B. UNRESOLVED STAFF COMMENTS**

We have not received any written comments from the SEC staff regarding our company's Quarterly Reports on Form 10-Q or Current Reports on Form 8-K in the 180 days preceding December 31, 2012.

States and

# **ITEM 2. PROPERTIES**

Our executive, marketing and administrative offices are located in Glen Allen, Virginia, which is part of the greater Richmond, Virginia metropolitan area. We currently have 2.5 years remaining on a five year lease covering approximately 2,500 square feet of office space at the Glen Allen location.

We lease space in Washington, DC to support our executive, administrative and scientific activities for both Star Scientific and Rock Creek. The Washington, DC area was selected as the primary location for our executive, administrative, legal and scientific activities to provide our executives and scientific and medical consultants access to the FDA, National Institutes of Health and the United States National Medical Library, as well as access to the U.S. Congress, the Executive branch of the federal government and the various related federal agencies located in the greater Washington, DC area. Rock Creek also has scientific and research offices in Gloucester, MA. The lease on our Washington, DC office has 1.3 years remaining and our office lease in Gloucester, MA. has 1.2 years remaining.

We lease from the Mecklenburg County Industrial Development Authority approximately nine acres of land in Chase City, Virginia. This lease also includes a building containing approximately 91,000 square feet of space that accommodated our dissolvable tobacco manufacturing operations, an expanded testing facility and office space. We have approximately nine years remaining on a twenty-year lease for this facility. This facility was previously used for the manufacturing of our low-TSNA smokeless tobacco products and is not being actively used at the present time. We anticipate pursuing sublease arrangements to minimize our lease expense with respect to this facility.

We own the manufacturing equipment located at our dissolvable tobacco manufacturing facility in Chase City, Virginia, which was closed as part of our decision to exit the dissolvable tobacco business as of December 31, 2012. The ultimate disposition of this equipment has not been determined at this time.

We own specialized packaging equipment that has been installed at our dietary supplement contract manufacturing vendor to package CigRx<sup>®</sup> and Anatabloc<sup>®</sup> in their 20-piece container format. We have invested in equipment to process anatabine, the primary ingredient in CigRx<sup>®</sup>, Anatabloc<sup>®</sup> and Anatabloc<sup>®</sup> Facial Crème, at a separate contract manufacturer facility.

We believe our manufacturing arrangements will be sufficient to allow us to respond to the demand for our dietary supplements and cosmetic products for the foreseeable future.

#### **ITEM 3. LEGAL PROCEEDINGS**

## **RJR** Litigation

In May 2001, we filed a patent infringement action against RJR in the United States District Court for Maryland, Southern Division, or District Court, to enforce our company's rights under U.S. Patent No. 6,202,649 ('649 Patent), which claims a process for substantially preventing the formation of TSNAs in tobacco. On July 30, 2002, we filed a second patent infringement lawsuit against RJR in the District Court based on a new patent issued by the U.S. Patent and Trademark Office on July 30, 2002 (Patent No. 6,425,401) ('401 Patent). The new patent is a continuation of the '649 Patent, and on August 27, 2002, the two cases were consolidated.

The consolidated cases were tried to a jury in the District Court between May 18, 2009 and June 16, 2009. At the conclusion of the trial, the jury returned a verdict in favor of RJR holding that there was no infringement of the two patents at issue in the case and that the patents were invalid due to anticipation, obviousness, indefiniteness and failure to disclose best mode. On July 7, 2009, we filed a motion with the District Court for Judgment as a Matter of Law or, in the Alternative, for a New Trial. That motion was denied on December 21, 2009 and judgment was entered on the jury verdict that day. We filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit Court of Appeals on December 22, 2009 and our opening brief was filed on May 5, 2010. After full briefing, Oral argument on the appeal was held

before a three-judge Panel of the Federal Circuit Court of Appeals on January 11, 2011. In a decision issued on August 26, 2011, the Court of Appeals reversed the jury finding as to the patent defenses of anticipation, obviousness, indefiniteness and failure to disclose best mode and reconfirmed the validity of the patent claims at issue in the litigation. At the same time the Court of Appeals affirmed the jury finding of non-infringement for the growing years at issue in the litigation. On November 29, 2011 the Federal Circuit denied RJR's Petition for Rehearing and Rehearing en Banc and the case was remanded to the District Court on December 15, 2011. On January 26, 2012, following a conference with counsel, the District Court issued an order referring this action and our second RJR case to a magistrate judge for mediation/settlement discussions. On September 21, 2012 our company and RJR reached a settlement of the consolidated cases and, as part of the settlement, joint stipulations of dismissals with prejudice were filed in each of the consolidated cases and were entered by the District Court on September 24, 2012.

On March 28, 2012, RJR filed a petition for certiorari with the Supreme Court to review the Federal Circuit Court of Appeals decision as to the definiteness of the patents at issue in the RJR litigation. Our Company's response to the petition for certiorari was filed on May 29, 2012. As part of the settlement between our company and RJR, RJR's petition for certiorari was dismissed on joint motion of the parties prior to consideration of the petition for certiorari by the Supreme Court.

On November 30, 2009, RJR filed a motion for a bill of costs for \$442,388.05. RJR also filed a motion requesting the District Court to determine that this is an "exceptional" case under 35 U.S.C. §285 and award attorneys' fees of approximately \$35 million under that provision and/or under 28 U.S.C. §1927 on the basis that attorneys' fees were unreasonably multiplied during the litigation. As part of Orders issued on December 21, 2009, the District Court stayed the motion for attorneys' fees until after a ruling on the pending appeal and the reexamination before the U.S. Patent and Trademark Office. The Court on January 8, 2010, stayed any further briefing on the renewed petition for a bill of cost that RJR filed on December 30, 2009. The stipulations of dismissal filed in the two consolidated cases pending in the District Court as part of the RJR settlement provided that each side in those actions would bear its own costs and attorneys' fees. With the entry of dismissals by the District Court, RJR's motion for attorneys' fees and costs in the consolidated cases became moot.

On May 29, 2009, we filed a new complaint against RJR for patent infringement during the period beginning 2003 through the filing date of the complaint. In an Order dated January 8, 2010, the Court stayed any further action in this case until after a ruling on the appeal in the initial infringement actions against RJR. As noted above, this case was referred to a magistrate judge for mediation/settlement discussions under the Court order issued on January 26, 2012. As part of the settlement between our company and RJR, a joint stipulation of dismissal with prejudice was filed with the District Court in this case and entered by the District Court on September 24, 2012. The stipulations of dismissal provided that each side in that action would bear its own costs and attorneys' fees.

With the entry of the stipulations of dismissals in these cases, all of the outstanding patent litigation matters between our company and RJR were resolved and extinguished.

## Virginia Sales and Use Tax Assessment

In 2002, the Virginia Department of Taxation asserted a Virginia Sales and Use Tax assessment for the period January 1, 1999, through March 31, 2002, against us with respect to our tobacco-curing barns in the amount of \$860,115. We applied for a correction of the assessment and a total abatement of the tax on the grounds that our barns are exempt from sales and use taxes under the industrial use and processing exemption and/or the agricultural exemption. In a letter dated October 7, 2004, our company received notification from the Commonwealth of Virginia that an adverse decision had been made by the Commissioner of Taxation with respect to the sales and use tax assessment previously issued to our company. On August 10, 2010 the Commonwealth of Virginia responded to our request for reconsideration of the state's sales and use tax assessment with respect to our tobacco curing barns. The Commonwealth disagreed with our position that the barns are part of the manufacturing process and, therefore, exempt from sales and use taxes under the industrial use and processing exemption and/or the agricultural exemption, concluding that the barns are taxable under the Commonwealth's sales tax laws and regulation. On July 14, 2011 we filed a lawsuit in the Circuit Court for Mecklenburg County, Virginia seeking a determination that the purchase of our company's

curing barns was exempt from Virginia sales and use tax and an abatement of all taxes and interest assessed against our company by Virginia's Commissioner of Revenue. The Commonwealth of Virginia filed an answer to our complaint on July 29, 2011 asserting that the assessment amount was properly determined. The matter is currently pending. The sales and use tax assessment plus penalties and interest together, as of December 31, 2012, totaled approximately \$1.7 million. Interest will continue to accrue during our company's pursuit of a resolution of this matter.

# CigRx<sup>®</sup> Trademark Litigation

On September 14, 2012, we filed an action in the United States District Court for the Central District of California against Cigirex, LLC alleging infringement of our company's registered trademark CigRx<sup> $\oplus$ </sup> and related claims and seeking a declaratory judgment as to such infringement, injunctive relief and damages. That action is currently pending. Also, prior to filing the action against Cigirex in Federal District Court, we had been opposing the registration of the Cigirex mark in the PTO. After filing our District Court action against Cigirex, LLC, we filed a motion in the PTO proceeding seeking to have that proceeding suspended pending the outcome of the District Court case. That motion was granted by the PTO on November 26, 2012.

# ITEM 4. MINE SAFETY DISCLOSURES

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# PART II

# ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our company's common stock, par value \$0.0001 per share, is traded on the NASDAQ Global Market under the symbol "STSI". On March 5, 2013, the closing price of our common stock as reported on the NASDAQ Global Market was \$1.98. Set forth below are the high and low sales prices for each full quarterly period during 2012 and 2011, as reported by NASDAQ. From time to time, during the periods indicated, trading activity in our common stock was infrequent. As of March 5, 2013, there were approximately 600 registered holders of our common stock.

	2012		2011	
	High	Low	High	Low
Quarter				· ,
First	\$4.18	\$2.13	\$4.19	\$1.56
Second	4.96	2.66	5.35	2.97
Third	5.05	3.21	4.60	1.50
Fourth	3.58	1.56	3.20	2.00

We have never paid dividends on our common stock, and our Board of Directors currently intends to retain any earnings for use in our business for the foreseeable future. Any future determination as to the payment of such cash dividends would depend on a number of factors including future earnings, results of operations, capital requirements, our financial condition and any restrictions under credit agreements outstanding at the time, as well as such other factors as the Board of Directors might deem relevant. No assurance can be given that we will pay any dividends in the future.

## Securities Authorized for Issuance Under Equity Compensation Plan

The following table provides certain information as of December 31, 2012, with respect to our equity compensation plans under which our common stock is authorized for issuance:

Plan Category	Number of Shares to be Issued Upon Exercise of Outstanding Options and Rights	Weighted-Average Exercise Price of Outstanding Options and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding Column (a))	
	(a)	(b)	(c)	
Equity Compensation Plans				
Approved by Shareholders	17,595,000	\$2.73	2,053,141	

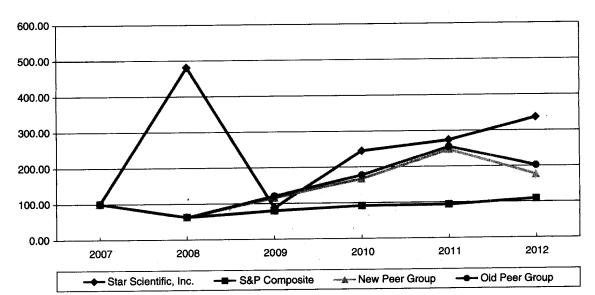
Subsequent to December 31, 2012 we issued a combination of 225,685 in stock and stock option grants. As a result, the number of securities remaining available under the plans at March 5, 2013 is 1,827,456.

#### **Option Grants and Stock Awards**

In 2012, we granted our directors, or the Purchaser Class, options to purchase our common stock as described in our Quarterly Reports on Form 10-Q filed during 2012 or during the fourth quarter of 2012 from our company's 2008 Incentive Plan. On December 16, 2011 our shareholders approved the grant of stock options previously issued to Jonnie R. Williams, our CEO, and Paul L. Perito, our President and COO, for 4.9 million and 4.0 million option shares respectively. Those stock options have a strike price of \$2.95 and an aggregate stock compensation of \$22.3 million. As of December 31, 2012 sixty-five percent of the stock options, constituting 5,785,000 option shares, had vested. The aggregate stock compensation of the vested shares was \$14.5 million and was recognized in the fourth quarter 2011. The compensation value of the remainder of the stock options will be recognized in the quarter in which any of the remaining stock options vest. On October 22, 2012, 50,000 options for shares of our common stock with an exercise price of \$3.20 were granted to one member of the Purchaser Class and on December 14, 2012, 50,000 options for shares of our common stock with an exercise price of \$3.26 were granted to another member of the Purchaser Class. On December 17, 2012, 50,000 shares of common stock with a value of \$3.17 per share were granted to a marketing consultant.

Five-year financial performance graph: 2008 - 2012

Comparison of five-year cumulative return among Star Scientific,, the S&P Composite and the peer group



Comparison of 5 Year Cumulative Total Return Assumes Initial Investment of \$100 December 2012

	FISCAL YEAR ENDING					
COMPANY/INDEX/MARKET	2007	2008	2009	2010	2011	2012
Star Scientific, Inc.	\$100.00	\$481.20	\$ 87.96	\$245.04	\$273.93	\$336.76
S&P Composite		\$ 62.99	\$ 79.65	\$ 91.64	\$ 93.58	\$108.56
New Peer Group		\$ 62.74	\$115.58	\$166.96	\$246.36	\$176.90
Old Peer Group	\$100.00	\$ 62.73	\$120.24	\$177.49	\$255.00	\$201.98

The New Peer Group consists of:

NU SKIN ENTERPRISES, INC HERBALIFE, LTD USANA HEALTH SCIENCES NATURE SUNSHINE PRODUCTS, INC. RELIVE INTERNATIONAL, INC. NATURAL ALTERNATIVES INTERNATIONAL, INC.

The Old Peer Group consisted of:

NU SKIN ENTERPRISES, INC HERBALIFE, LTD

# **USANA HEALTH SCIENCES**

The Stock Performance Graph shall not be deemed to be "soliciting materials" or to be "filed" with the SEC or subject to the liabilities of Section 18 under the Securities Exchange Act of 1934, as amended, or Exchange Act. In addition, it shall not be deemed incorporated by reference by any statement that incorporates this Annual Report on Form 10-K by reference into any filing under the Securities Act of 1933, as amended, or Securities Act, or the Exchange Act, except to the extent that we specifically incorporate this information by reference.

# ITEM 6. SELECTED FINANCIAL DATA

The selected consolidated financial data of our company, for and as of the end of each of the periods indicated in the five-year period ended December 31, 2012, have been derived from our company's audited consolidated financial statements. The selected consolidated financial data should be read in conjunction with "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included in "Item 15. Exhibits, Financial Statement Schedules" of this Report.

	Years Ended December 31,				
	2012	2011	2010	2009	2008
		(In thous	ands, except per	share data)	
Statement of Operations Data:					
Net sales	\$ 6,188	\$ 1,244	\$ 63	\$	<b>\$</b> —
Cost of goods sold (excludes federal excise					
tax)	3,566	1,861	405	470	456
Gross profit (loss)	2,622	(617)	(342)	(470)	(456)
Loss from continuing operations before					
income taxes	(18,100)	(35,893)	(25,829)	(17,369)	(12,775)
Loss from discontinued operations	(4,753)	(2,095)	(2,452)	(5,431)	(5,564)
Net loss	(22,853)	(37,988)	(28,281)	(22,800)	(18,339)
Basic and diluted loss per share:					
Continuing operations	\$ (0.12)	\$ (0.27)	\$ (0.22)	\$ (0.17)	\$ (0.14)
Discontinued operations	(0.03)	(0.01)	\$ (0.02)	\$ (0.05)	\$ (0.06)
Total basic and diluted loss per share	\$ (0.15)	\$ (0.28)	\$ (0.24)	\$ (0.22)	\$ (0.20)
Weighted average shares outstanding	146,997	133,640	118,384	101,907	89,844

	Years Ended December 31,					
· · · · · ·	2012	2011	2010	2009	2008	
	,	(In thousands, except per share data)				
Balance Sheet Data:						
Cash and cash equivalents	\$23,121	\$10,188	\$13,192	\$12,360	\$6,473	
Inventories	4,989	2,454	3,080			
Property and equipment	1,338	1,611	1,265	35	48	
MSA escrow funds	481	368	368	365	365	
Discontinued operations assets	314	1,061	1,296	1,345	2,700	
Total assets	31,924	17,077	20,285	13,889	9,552	
Long-term obligations		2,531	5,049	7,518	9,499	
Accounts payable and accrued						
liabilities	5,122	2,397	1,726	2,570	1,357	
Discontinued operations liabilities	1,761	190	283	826	367	
Stockholders' equity (deficit)	\$24,984	\$ 9,391	\$10,659	\$ (2,288)	\$ (498)	

# ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion provides an assessment of our consolidated results of operations, capital resources, and liquidity and should be read together with our consolidated financial statements and related notes in "Item 15. Exhibits, Financial Statement Schedules" of this Report, including note 17 thereof for information on the segment reporting for each of our operating subsidiaries. This discussion includes forward-looking statements based on current expectations that involve risks and uncertainties and should be read together with "Item 1A. Risk Factors" and "Special Note on Forward-Looking Statements" elsewhere in this Report.

# **Overview**

We are a technology-oriented company with a mission to promote the maintenance of a healthy metabolism and lifestyle. Since the incorporation of our Rock Creek Pharmaceuticals subsidiary in 2007, we have focused on utilizing certain alkaloids found in the Solanacea family of plants, which includes potatoes, tomatoes, and eggplants, initially to address issues related to the desire to smoke or use other traditional tobacco products. More recently, Rock Creek has been concentrating on the anti-inflammatory aspects of one of those alkaloids, anatabine. We believe our research and development efforts relating to the anatabine alkaloid have positioned us to utilize our technology to develop a range of non-nicotine dietary supplements and potentially related pharmaceutical products that could be beneficial in maintaining a healthy metabolism and in supporting good nutrition.

Currently, Rock Creek manufactures and sells two nutraceutical dietary supplements, Anatabloc<sup>®</sup>, for anti-inflammatory support, and CigRx<sup>®</sup>, for assistance in fighting the urge to smoke cigarettes. In addition, Rock Creek Pharmaceuticals has been engaged in the development of other dietary supplements and pharmaceutical products, particularly products that have a botanical- based component and that are designed to provide nutritional support for a range of conditions, including Alzheimer's disease, Parkinson's disease, multiple sclerosis, schizophrenia, depression, and Hashimoto's autoimmune thyroiditis. Rock Creek also has developed a cosmetic product that utilizes our anatabine compound to improve the appearance of the skin which was introduced as Anatabloc<sup>®</sup> Facial Crème in September 2012.

Since the 1990s, we also have sought to develop processes that significantly prevent the formation of one of the most abundant and significant groups of carcinogens TSNAs, found in tobacco and tobacco smoke. Our development of technology for reducing levels of TSNA led us to focus on the development of non-nicotine tobacco-based pharmaceutical products and the non-nicotine dietary supplements that we are pursuing through Rock Creek.

Following the introduction of our Anatabloc<sup>®</sup> dietary supplement in August 2011, our revenues have been derived almost exclusively from the sale of our anatabine based nutraceutical products and, in particular, our Anatabloc<sup>®</sup> product. Our Anatabloc<sup>®</sup> Facial Crème that also utilizes our anatabine compound has had diminius sales since introduction in September 2012. Although, we have not launched a full scale marketing campaign for this product while we are developing complementary products consisting of a cleanser and serum. GNC, in February 2013, began carrying our Anatabloc<sup>®</sup> Facial Créme on its website. We expect marketing and corresponding sales for the facial cream line of products to increase during 2013. As we worked to achieve our corporate objectives over the years, we initially utilized our company's technology in producing low-TSNA tobacco and related low-TSNA smokeless tobacco products as less harmful alternatives to cigarettes and traditional smokeless tobacco products and as a platform to provide a base of financial support for our intellectual property, licensing and development initiatives. However, since 2007, we shifted the focus of our research efforts to nutraceuticals and the development of related pharmaceutical products.

On September 21, 2012 our company and RJR entered into a confidential settlement agreement of our long standing RJR litigation matters. As part of the settlement, our company's remaining obligation to RJR for unsecured promissory notes with a principal balance of \$3.4 million as of August 1, 2012 and accrued interest on the notes was satisfied and extinguished and we received a one-time payment of \$5.0 million. In addition, the consolidated cases pending in the District Court of Maryland were dismissed with each party bearing their own costs and fees, which had the effect of extinguishing RJR's request of an award of costs in those cases in the amount \$0.4 million and its motion for an award of attorneys' fees of approximately \$35.0 million against our company. The benefit of the settlement to our company consisted of \$8.4 million in loan forgiveness and a cash payment, elimination of claimed court cost of approximately \$0.4 million and the avoidance of potential attorneys' fees owing to RJR of approximately \$35.0 million, totaling \$43.8 million. In considering the settlement, our company weighed the prospects for continued multi-year litigation, related appeals to the Federal Circuit Court of Appeals and the disruption of continued litigation, particularly given the shift in our focus to the dietary supplement portion of our business, and concluded that the resolution of the RJR litigation matters at this time was in the best interest of our company. While we have settled our ongoing litigation with RJR, we continue to pursue means of collecting royalties for our curing technology through licensing arrangements and through monitoring of the curing practices of industry participants other than RJR that may

infringe on our tobacco curing patents which were confirmed by the United States Court of Appeals for the Federal Circuit and the PTO during our RJR litigation.

In November, 2012, our CEO, Mr. Williams, voluntarily agreed to reduce his salary to \$1.00 per month beginning in January 2013 until our company becomes profitable and in February 2013, our Chairman, President and COO, Mr. Perito, voluntarily reduced his salary by \$500,000 until our company becomes profitable. Also, in February 2013, our General Counsel, Mr. Pokusa, and our CFO, Mr. Dodd, voluntarily agreed to reduce their salaries by \$100,000 and \$50,000 respectively until our company becomes profitable. Those decisions were ratified by the Compensation Committee and our Board in December 2012 as to our CEO, and in February 2013, as to our Chairman, President and COO, General Counsel and CFO.

On December 14, 2012, our Board of Directors voted to discontinue the manufacturing and distribution of our company's dissolvable smokeless tobacco products, Ariva<sup>®</sup> and Stonewall Hard Snuff<sup>®</sup> as of December 31, 2012 and we ceased selling any tobacco products as of that date. The discontinuation of our low-TSNA smokeless tobacco business was motivated in part by the continued losses and low sales for our dissolvable tobacco products over the last several years. It was also motivated by the fact that restrictions under the FDA Tobacco Act that prohibit a company from making any statements about the comparative safety of various types of tobacco products made it extremely difficult to effectively market our dissolvable tobacco products. Our action was further influenced by the fact that continuing to manufacture dissolvable tobacco products has had a negative impact on our ability to interest leading research centers in undertaking clinical research related to our anatabine compound and its potential for providing support in managing excessive inflammation.

#### **Prospects for Our Operations**

The recurring losses generated by our business continue to impose significant demands on our liquidity. Our future prospects will be dependent on the distribution and consumer acceptance of our dietary supplements, Anatabloc<sup>®</sup> and CigRx<sup>®</sup>, and our cosmetic product Anatabloc<sup>®</sup> Facial Crème and related line extensions. In particular, sales of Anatabloc<sup>®</sup> were responsible for virtually all of our dietary supplement revenue during 2012. In addition, we intend to continue to explore the development of new dietary supplements and pharmaceutical products independently and through alliances with pharmaceutical companies. We also will continue to seek to generate revenues through royalties from the patented tobacco curing process to which we are the exclusive licensee and for our related products.

We recognized net revenue of approximately \$6.2 million for 2012 and an operating loss from continuing operations of approximately \$(18.1) million. The recurring losses generated by our operations continue to impose significant demands on our company's liquidity. As of December 31, 2012, we had approximately \$22.3 million of working capital, of which approximately \$23.1 million was cash and cash equivalents. Absent the exercise of outstanding warrants and options for cash or a substantial improvement in sales and revenues and/or royalties, we believe the cash on hand at December 31, 2012 will support our operations through the first quarter 2014. However, depending upon market conditions and the price of the common stock, we may decide to seek additional funds before that date. There can be no assurance that any such financing would be available to us on favorable terms, if at all.

Dietary Supplements and Development of Tobacco-based Pharmaceutical Products. Anatabloc<sup>®</sup>, which is intended to provide anti-inflammatory support, is currently being sold through our interactive website, a customer service center and on a consignment basis through GNC, a retailer of dietary supplements. GNC initially sold Anatabloc<sup>®</sup> through its online store and, beginning in late March 2012, GNC began carrying Anatabloc<sup>®</sup> at its company-owned stores and franchised retail locations. Initially, marketing of Anatabloc<sup>®</sup> had been primarily directed toward physicians and other healthcare professionals. More recently we have been focusing our marketing efforts on athletes and other groups of individuals who regularly deal with issues relating to inflammation. In 2009, Rock Creek developed a non-nicotine, non-tobacco nutraceutical, CigRx<sup>®</sup>, that is intended to temporarily reduce the desire to smoke. We continue to market this product exclusively on our interactive website. Through Rock Creek we are exploring the development of other related nutraceutical products that may assist in stabilizing metabolism, pharmaceutical products with clinical claims, as well as pharmaceutical products for the treatment of a range of conditions, including Alzheimer's disease, Parkinson's disease, multiple sclerosis, schizophrenia and depression.

*Cosmetics.* We introduced our anatabine-based cosmetic product, Anatabloc<sup>®</sup> Facial Crème in September 2012. This product, which is intended to improve the appearance of the skin, is currently sold on our interactive website and a customer service center. Also, in February 2013 GNC began carrying our Anatabloc<sup>®</sup> Facial Crème on its website. To daté the sales have been relatively low since we have limited marketing for the product while we are developing complementary products consisting of a cleanser and serum. We anticipate increased marketing and sales for this product in 2013.

*Federal Regulations of Dietary Supplements, Drug Products and Cosmetics.* Under the Food, Drug and Cosmetic Act, the FDA has authority for reviewing and approving any new drug product prior to its introduction into commerce. The FDA approval process involves, among other things, successfully completing clinical trials under an Investigational New Drug Application and obtaining a premarket approval after filing a New Drug Application. The NDA process requires a company to prove the safety and efficacy of a new drug product to the FDA's satisfaction. The Dietary Supplement Health Education Act, provides the FDA with authority over the production and marketing of dietary supplements. In certain cases DSHEA also requires notification to the FDA before a company begins to market a dietary supplement. DSHEA does not require prior approval by the FDA for the introduction of dietary supplements into the market, but does require that such products comply with the requirements of DSHEA prior to and after their introduction into commerce. The FDA also has jurisdiction over cosmetic products and claims made for such products. While premarket approval is not required prior to the marketing of cosmetics and the FDA has authority with respect to the labeling, packaging and promotion of such products. See "Item 1. Business — Government Regulation" for more information relating to governmental regulation of products by the FDA.

Low-TSNA Curing Technology and Related Products. On December 14, 2012, our Board of Directors voted to discontinue the manufacturing, distribution and sale of our company's dissolvable smokeless tobacco products, Ariva® and Stonewall Hard Snuff® as of December 31, 2012 and we exited the tobacco business as of that date. The discontinuation of our low-TSNA smokeless tobacco business was motivated in part by the continued losses and low sales for our dissolvable tobacco products over the last several years. It was also motivated by the fact that restrictions under the FDA Tobacco Act that prohibited a company from making any statements about the comparative safety of various types of tobacco products made it extremely difficult to effectively market our dissolvable tobacco products. The Board's action was further influenced by the fact that continuing to manufacture dissolvable tobacco products has had a negative impact on our ability to interest leading research centers in undertaking clinical research related to our anatabine compound and its potential for providing support in managing excessive inflammation. While we ceased selling any tobacco products as of December 31, 2012, we continue to look for licensing opportunities related to our dissolvable tobacco products and our related curing technology.

Licensing and Intellectual Property. Since 2010 we have filed six United Sates patent applications relating to our dietary supplement products, uses of the products and product formulations. These included two applications for therapeutic methods involving the administrations of anatabine, its isomers and any derivatives thereof, an application relating to the administration of anatabine, or an isomer or salt thereof, for treating chronic inflammation that may be associated with disorders such as thyroiditis, cancer, arthritis, Alzheimer's disease, and multiple sclerosis, an application for our CigRx<sup>®</sup> formulation and our Anatabloc<sup>®</sup> formulation as well as an application for the synthesis of anatabine and an application for a relapse prevention product. We also filed an application for a design patent relating to the 20-piece container used for our CigRx<sup>®</sup> and Anatabloc<sup>®</sup> products and a divisional application for food grade salts of anatabine. In June 2012 the PTO, issued a patent to Rock Creek for an improved method of synthesizing anatabine that facilitates large scale commercial production of high purity anatabine. Also, on August 14, 2012, the PTO issued a patent to Rock Creek for an anatabine citrate and yerba mate composition and uses thereof in assisting weight loss and curbing the urge for tobacco. In 2011 the PTO, issued a design patent to Rock Creek for the 20-piece dispenser used for our CigRx<sup>®</sup> and Anatabloc<sup>®</sup> products. We also have several international applications pending that relate to inflammation-mediated disorders, our anatabine and yerba mate composition, a relapse prevention product and the administration of anatabine, its isomers and any derivatives thereof generally, and also for autism and seizure indications.

We are the exclusive licensee under a License Agreement with Regent Court which grants us exclusive worldwide rights to and a right of sublicense for the StarCured<sup>®</sup> process, related patents covering the production of low-TSNA dissolvable smokeless tobacco products and the use of certain MAO agents in treating neurological conditions. For additional information related to our proprietary curing process, see "— Our Patents, Trademarks and Licenses." Our proprietary StarCured<sup>®</sup> technology is applicable to the curing of Virginia flue-cured tobacco on a broad-scale commercial basis and, we believe, is also applicable to the curing of burley tobacco as well as other varieties of tobacco. This technology essentially arrests or eliminates microbial activity that normally occurs during curing, thereby preventing the formation of TSNAs.

In December 2008, we filed a new United Sates patent application for a variant of our patented curing technology that results in the production of cured tobacco that contains virtually undetectable levels of carcinogenic TSNAs as measured by prevailing standards and in April 2012 the PTO issued a patent for this curing method. Also in 2012, we filed utility applications for an enriched form of tobacco, an alkaloid composition for e-cigarettes and for a new tobacco product that are currently pending before the PTO. We believe that through the StarCured<sup>®</sup> process and our related technology we have the ability to reduce exposure to carcinogenic TSNAs, particularly the subgroups of nitrosamines commonly referred to as NNNs and NNKs, to very low levels (with carcinogenic NNNs and NNKs that measure 200 parts per billion and below) and that we have demonstrated that our process for curing tobacco using these processes can be scaled up to meet broad commercial needs in the United States and abroad. While we have discontinued the sale of tobacco products as of December 31, 2012, we continue to pursue means of collecting royalties for our curing technology through licensing arrangements and through monitoring of the curing practices of industry participants as applicable.

#### **Critical Accounting Policies and Estimates**

Accounting principles generally accepted in the United States of America, or GAAP, require estimates and assumptions to be made that affect the reported amounts in our company's consolidated financial statements and accompanying notes. Some of these estimates require difficult, subjective and/or complex judgments about matters that are inherently uncertain and, as a result, actual results could differ from those estimates. Due to the estimation processes involved, the following summarized accounting policies and their application are considered to be critical to understanding our business operations, financial condition and results of operations.

#### Inventories

Inventories are valued at the lower of cost or market. Cost is determined on the first-in, first-out (FIFO) method.

#### Revenue Recognition

Revenue is recognized when products are received by consumers or independent wholesalers from our third party fulfillment vendor based on orders entered by the customers or independent wholesalers on our interactive website and we have received confirmation of a valid credit card charge, which is the only payment option offered for sales on the interactive website. We also record appropriate provisions for rebates, discounts and credits for returns. These amounts are estimated due to the variability in credits as a result of temporary promotional programs, and allowances for product which may be returned by consumers after a sale is completed. In order to quantify these amounts, we make quarterly estimates in these areas based on the available quarterly information and historical experience.

Under certain retail agreements we have agreed to "pay on scan" terms of sale for our dietary supplement products. The "pay on scan" terms do not constitute a sale of the product until the product is sold to a consumer. Under these agreements revenue is recognized by us at the time the customer purchases the product from the consignee. The sales of products through these outlets are also subject to the same promotional and return credits discussed above. Our products that are sold on a "pay-on-scan" basis, whether in a warehouse or retail location, are considered consignment inventory and accordingly we retain all risk of loss until sale.

#### Sales Incentives Estimates

We record consumer incentives and trade promotion activities as a reduction of revenues based on amounts estimated as being due to customers and consumers at the end of a period. The estimates are based principally on historical utilization and redemption rates of our products. Such programs include discounts, coupons, rebates, slotting fees, in-store display incentives and volume-based incentives. To the extent that redemption rates exceed our estimates, this would increase our liability related to outstanding coupons in the period the estimate is revised.

#### Impairment of Long-Lived Assets

We review the carrying value of our amortizing long-lived assets whenever events or changes in circumstances indicate that the historical cost-carrying value of an asset may no longer be appropriate. We also assess recoverability of the asset by estimating the future undiscounted net cash flows expected to result from the asset, including eventual disposition. If the estimated future undiscounted net cash flows are less than the carrying value of the asset, an impairment loss is recorded equal to the difference between the asset's carrying value and its fair value. Non-amortizing intangibles (trademarks) are reviewed annually for impairment.

#### Depreciation Estimates

We generally determine depreciation based on the estimated useful lives of the assets and record depreciation on a straight-line method over such lives.

#### Commitment and Contingency Accounting

We evaluate each commitment and/or contingency in accordance with the accounting standards which state that if the item is probable then our company will record the liability in the financial statements. If not, we will disclose any material commitments or contingencies that may arise.

## Year Ended December 31, 2012 Compared to Year Ended December 31, 2011

Net Sales. For the year ended December 31, 2012, net sales (gross sales less cash discounts, product discounts and product return allowance) were approximately \$6.2 million compared to approximately \$1.2 million during the same period in 2011, an increase of approximately \$5.0 million. The improved net sales are attributable to increased sales volume of our Anatabloc<sup>®</sup> dietary supplement for anti-inflammatory support.

Gross Profit (Loss). We had a gross profit of \$2.6 million during the year ended December 31, 2012 compared to a gross loss of (0.6) million for the same period in 2011, an improvement of \$3.2 million. The increase in gross profit is attributable to increased Anatabloc<sup>®</sup> sales.

Total Operating Expenses. Total operating expenses were approximately \$27.2 million for the year ended December 31, 2012, a decrease of approximately \$7.9 million, or 22.3%, from approximately \$35.1 million for the same period in 2011. This change was attributable to decreases in general and administrative expenses of approximately \$12.8 million offset by increases in marketing and distribution costs of approximately \$3.6 million and increased research and development costs of approximately \$1.3 million. The increased research and development costs principally relate to clinical (human) trials and pre-clinical (non-human) studies of our Anatabloc<sup>®</sup> product or the principal dietary ingredient in Anatabloc<sup>®</sup>.

Marketing Expenses. Marketing and distribution expenses were approximately \$6.2 million for the year ended December 31, 2012, an increase of approximately \$3.6 million, or 140.8%, from approximately \$2.6 million for the same period in 2011. The increase in marketing costs during the year ended December 31, 2012 was attributable solely to the promotion of Anatabloc<sup>®</sup> as we decreased our spending on marketing for CigRx<sup>°</sup> during this period. Our Anatabloc<sup>®</sup> marketing has consisted of a mix of advertising on radio and television and in print media and through online channels as we attempt to reach a wider audience of potential consumers for Anatabloc<sup>®</sup>. We have varied the frequency of ads and changed content as we seek to better communicate the benefits of Anatabloc<sup>®</sup> to a wider audience. We expect to incur additional significant marketing and distribution expenses in 2013 related to the promotion of our products.

General and Administrative Expenses. General and administrative expenses were approximately \$16.5 million for the year ended December 31, 2012, a decrease of approximately \$12.8 million, or 43.7%,

from approximately \$29.3 million for the same period in 2011. During the year ended December 31, 2012, we had a non-cash charge of \$3.2 million for stock based compensation compared to a charge of \$17.3 million during the same period in 2011 for a net decrease of \$14.1 million during 2012. Also, we had an expense of \$0.3 million in connection with bonuses paid to certain employees who contributed to the successful launch of Anatabloc<sup>®</sup>, while no bonuses were paid in the comparable period in 2011. We recorded severance expense of approximately \$0.2 million in 2012 and had no comparable expense in the same period in 2011. During the year ended December 31, 2012, legal expenses increased approximately \$0.4 million compared to the prior period in 2011 in connection with our ongoing efforts to protect and expand the patented technology relating to our dietary supplements and the RJR litigation settlement. Various other expenses increased by a total of \$0.5 million.

Research and Development Expenses. During the year ended December 31, 2012, we expended approximately \$4.6 million primarily in connection with clinical (human) trials and pre-clinical (non-human) studies of our Anatabloc<sup>®</sup> product or the principal dietary ingredient in Anatabloc<sup>®</sup>. This included costs related to the development and testing of our Anatabloc<sup>®</sup> Facial Crème prior to its introduction into the market on September 10, 2012, as well as payment of royalties of 5% of Anatabloc<sup>®</sup> sales to an affiliate of the Roskamp Institute under the Research and Royalty Agreement entered into with that entity in 2010. For a description of our relationship with the Roskamp Institute, see "Part I — Item 1. Business — Our Current Product Development Initiatives — Our Relationship with the Roskamp Institute." During the year ended December 31, 2011, Rock Creek expended approximately \$3.2 million primarily in connection with the product development of Anatabloc<sup>®</sup>. Given our working capital constraints, our ability to continue such research efforts will depend on our ability to obtain funding for these initiatives through improved revenues from sales of our dietary supplements, the licensing of our technology or from other funding sources.

Interest Income and Expense. We had interest income of \$17 thousand and interest expense of \$104 thousand for the year ended December 31, 2012, for a net interest expense of \$87 thousand during the period. For the same period in 2011, we had interest income of \$46 thousand and interest expense of \$263 thousand, for a net interest expense of \$217 thousand. The lower interest expense for the year ended December 31, 2012 reflected lower outstanding principal of our long-term debt and the extinguishment of our RJR long-term debt obligation pursuant to the terms of the September 21, 2012 settlement agreement with RJR (see "Part I — Item 3. Legal Proceedings" and Note 14 of the Financial Statements in this Report for further details of the resolution of the RJR litigation matters). The lower interest income during the year ended December 31, 2012 was primarily due to lower cash balances in the period.

Other Income and Expense. We had other income for the year ended December 31, 2012 in the net amount of \$6.6 million, primarily in connection with the resolution of the RJR litigation matters. This consisted of the satisfaction and forgiveness of unsecured promissory notes in the amount of \$3.4 million as of August 1, 2012 that has been payable to RJR following its combination with B&W in 2004 and a separate cash payment of \$5.0 million for a total amount of \$8.4 million. This amount was partially offset by \$1.3 million in connection with a contingent fee arrangement with counsel relating to this litigation, although we anticipate negotiating the final amount of any fees payable (see Note 14 of the financial statements included in this Report for more details relating to RJR litigation matters). We had \$0.5 million in other expenses during 2012.

Income Tax Expense. During the year ended December 31, 2012, we had no income tax obligation due to our net operating losses.

Discontinued Operations. During the year ended December 31, 2012 we elected to close our dissolvable tobacco business and exited the tobacco business as of December 31, 2012. We incurred a charge of (3.1) million in connection with the discontinuation of those operations and losses from operations of (1.7) million for a total discontinued operations charge of (4.8) million. During the comparable period in 2011 discontinued operations related to the tobacco business was (2.2) million.

*Net Loss.* We had a net loss from continuing operations of approximately (18.1) million for the year ended December 31, 2012 compared to a net loss from continuing operations of approximately (35.9) million in 2011. The net loss after discontinued operations for the year ended December 31, 2012 was (22.9) million compared to the net loss after discontinued operations of (38.0) million for the same period in 2011. The

results for the year ended December 31, 2012 included miscellaneous one-time income of \$6.6 million primarily as a result of the resolution of the RJR litigation matters (see "Part I — Item 3. Legal Proceedings" and Note 14 of the Financial Statements included in this Report for further details of the resolution of the RJR litigation matters). While we had an increase in gross profit of \$3.2 million for the year ended December 31, 2012, that increase was offset by increased marketing costs of \$3.6 million for Anatabloc<sup>®</sup>, severance expense of \$0.2 million, bonuses paid to certain employees in connection with the successful launch of Anatabloc<sup>®</sup> amounting to \$0.3 million, increased legal expenses of approximately \$0.4 million and increased research and development expenses of \$1.3 million. These increases were offset by decreased charges for stock based compensation awards of \$14.1 million.

For the year ended December 31, 2012, our basic and diluted loss per share from continuing operations was (0.12) compared to a basic and diluted loss per share from continuing operations of (0.27) for the year ended December 31, 2011. For the year ended December 31, 2012, our basic and diluted loss per share, including (0.03) from discontinued operations, was (0.15). This compared to a basic and diluted loss per share, including (0.01) from discontinued operations, of (0.28) for the year ended December 31, 2012. However, on a pro-forma basis, excluding the net gain from the resolution of the RJR litigation matters and the discontinued operations, our net loss per share, both basic and diluted, would have been (0.17) for the year ended December 31, 2012. We believe that this non-GAAP measure is important to an investor's understanding of our net losses from core business operating results, and that the net gain from the resolution of the RJR litigation reflects a one-time event that will not recur in future periods.

<b>Reconciliation of GAAP to Non-GAAP earnings per share</b>		<u>.</u>	
/ / / / / / / / / / / / / / / /	Year ended December 31,		
	2012	2011	
	unaudited		
Basic and diluted net loss per common share GAAP basis continuing operations	\$(0.12)	\$(0.27)	
Basic and diluted gain from RJR settlement	\$ 0.05	<u></u>	
Basic and diluted net (loss) per common share Non-GAAP basis	<u>\$(0.17)</u>	<u>\$(0.27)</u>	

#### Year Ended December 31, 2011 Compared to Year Ended December 31, 2010

Please refer to "Item 5. Selected Financial Data" elsewhere in this Report to view the five-year comparison of our results of operations and selected financial data. The amounts in this analysis have been restated for discontinued operations resulting from the closing of our dissolvable tobacco business.

Sales. Net sales were \$1.2 million in 2011, reflecting a \$1.1 million increase from 2010 gross sales of \$0.1 million. All of the increase in net sales was related to volume increases from our dietary supplement products, primarily Anatabloc<sup>®</sup>.

Gross Profit. In 2011, overall gross margin loss (net revenue less costs of goods sold) increased by 0.3 million to (0.6) million in 2011 from (0.3) million in 2010. The increased gross margin loss was due to packaging obsolescence offset in part by margin increases from our dietary supplement products.

Total Operating Expenses. Total operating expenses increased by \$9.9 million, or 39.1%, to \$35.1 million in 2011 from \$25.2 million in 2010. This included increases in marketing and distribution expenses of \$0.8 million, general and administrative expenses of \$8.6 million, and research and development expenses of \$0.4 million.

Marketing Expenses. Marketing and distribution expenses for 2011 totaled \$2.6 million compared to \$1.8 million in 2010. The increase related to efforts to expand our dietary supplements market.

General and Administrative Expenses. General and administrative expenses were approximately \$29.3 million in 2011, an increase of approximately \$8.6 million from approximately \$20.6 million in 2010. The increase was attributable to an \$8.7 million increase in stock based compensation costs due primarily to stock options granted our Chairman of the Board and CEO. On December 16, 2011 our shareholders approved the grant of stock options previously issued to Jonnie R. Williams, Sr., our CEO, and Paul L. Perito, our President and COO, for 4.9 million and 4.0 million option shares respectively. Those stock options have a strike price of \$2.95 and an aggregate stock compensation of \$22.3 million. As of December 16, 2011

sixty-five percent of the stock options, constituting 5,785,000 option shares, had vested. The aggregate stock compensation of the vested shares was \$14.5 million and was recognized in the fourth quarter 2011. The compensation value of the remainder of the stock options will be recognized in the quarter in which any of the remaining stock options vest. Absent stock compensation costs in either year our general and administrative costs would have decreased \$0.2 million in 2011 primarily due to lower legal costs associated with our RJR patent litigation.

Research and Development Expenses. Research and Development costs in 2011 increased approximately  $0.4 \text{ million to } 3.2 \text{ compared to our expenditure of approximately } 80.4 \text{ million in 2010. During 2011 our research efforts were focused on our Anatabloc<sup>®</sup> product development and associated clinical trials, while our expenditures in 2010 focused on the development of our CigRx<sup>®</sup> product.$ 

Other Income/Expense. In 2011, we had other income/expense of \$0.2 million which primarily consisted of interest expense associated with our long-term debt to RJR. Interest income was de minimis due to lower average cash balances and lower interest rates. Other income/expense in 2010 totaled \$0.3 million, which was comprised of \$0.4 million interest expense associated with our long-term debt to RJR, offset by interest income of \$0.1 million earned on our available cash balances.

*Discontinued Operations.* The discontinued operations for 2011 and 2010 are related to our exiting from the smokeless tobacco business in 2012.

Income Tax Benefit/Expense. Due to a history of recurring operating losses, we had no income tax expense or benefit for the year ended December 31, 2011.

Net Loss. Our company had a net loss from continuing operations of approximately \$(35.9) million in 2011 compared to approximately \$(25.8) million in 2010. The net loss in 2011 of approximately \$(38.0) million after discontinued operations, compared to a net loss of \$(28.3) million in 2010 after discontinued operations, reflected the increased cost related to the non-cash stock based compensation charge of approximately \$17.3 million in 2011.

In 2011, our company had basic and diluted net loss per share from continuing operations of (0.27) compared to basic and diluted net loss per share from continuing operations of (0.22) in 2010. The basic and diluted net loss per share in 2011 including discontinued operations was (0.28) compared to (0.24) for the same period in 2010.

#### Liquidity and Capital Resources

We have been operating at a loss for the past ten years. Our future prospects will depend on our ability to generate and sustain increased revenue levels in future periods, which will largely be dependent on increased distribution and consumer acceptance of:

- Anatabloc<sup>®</sup>, our nutraceutical, dietary supplement for anti-inflammatory support introduced in August 2011; and CigRx<sup>®</sup>, our non-nicotine, non-tobacco nutraceutical dietary supplement designed to temporarily decrease the desire to smoke
- Anatabloc<sup>®</sup> Facial Crème introduced in September 2012; and
- The licensing of our low-TSNA curing technology and related products.

Since the introduction of Anatabloc<sup>®</sup>, our revenues have been derived almost entirely from the sales of our anatabine based nutraceutical products and, more particularly, Anatabloc<sup>®</sup>. Our future prospects also will be dependent on Rock Creek's ability to develop additional nutraceutical products and pharmaceutical products and to a lesser extent, on our ability to begin generating income through royalties from the patented tobacco curing process to which we are the exclusive licensee.

For additional information with respect to our prospects of operations, see "— Prospects for Our Operations."

In February 2012, through a private placement offering, our company received proceeds of approximately \$12.0 million from the sale of 410,000 shares of common stock and new warrants to purchase up to 410,000 shares of common stock as well as the exercise for cash of warrants to purchase 5,815,254 shares of common

stock and the issuance of new warrants to purchase up to 5,815,254 shares of common stock. See our current report on Form 8-K, filed with the SEC on February 29, 2012, for a further description of these transactions.

In November 2012, the holders of previously issued warrants exercisable for 18,500,000 shares of our company's common stock with a weighted average exercise price of \$2.71 per share (the "Prior Warrants"), agreed to immediately exercise the Prior Warrants for cash in exchange for a reduction of the exercise price of the Prior Warrants to \$1.00 per share, which resulted in total proceeds to us of \$18,500,000. Our CEO, Jonnie Williams, Sr, at the same time also exercised 1,000,000 warrants previously issued to him in a prior transaction at the full warrant exercise price of \$1.50 per share for proceeds to our company \$1,500,000. These transactions resulted in total gross proceeds to our company of \$20,000,000. See our current report on Form 8-K, filed with the SEC on November 15, 2012, for a further description of these transactions.

During the year ended December 31, 2012, we received an additional \$2.9 million from the exercise of stock options and warrants.

Absent exercise of outstanding warrants and options for cash or a substantial improvement in revenues and/or royalties, we believe that we have sufficient funding to support our operations through the first quarter 2014. Depending upon sales levels, market conditions and the price of our common stock, it may be necessary for us to seek additional funds. There can be no assurance that we will be successful in obtaining such funding at commercially reasonable terms.

As of December 31, 2012, we had approximately \$22.3 million of working capital, of which approximately \$23.1 million was cash and cash equivalents. Future cash needs during 2013 will include funding of our company's operations in light of our continued operating losses.

We expect to continue to pursue opportunities for expanding the sales and marketing efforts for our dietary supplements and cosmetic products, continuing the work of Rock Creek in developing other dietary supplement products, pharmaceutical products and the licensing of our low-TSNA tobacco curing process and related technology. While we may seek to obtain funds in the future through debt financing, there may be limitations on our ability to obtain new debt financing given our recurring operational losses. Moreover, our ability to raise future financings on terms acceptable to us (including through the exercise of outstanding warrants) will depend on a number of factors, including the performance of our stock price and our operational performance. Any equity financing will be dilutive to our existing shareholders.

#### Summary of Balances and Recent Sources and Uses

Net Cash From Operating Activities. During the year ended December 31, 2012, approximately \$(17.7) million of cash was used in continuing operating activities compared to approximately \$(17.5) million of cash used in continuing operating activities during the same period in 2011. The increase in cash used in operations in 2012 compared to the same period in 2011 was favorably impacted by the receipt of a cash payment of \$5.0 million as part of our settlement with RJR (see Note 14 of the Financial Statements for further details of the resolution of the RJR litigation matters). Absent that payment, cash used in operations for the year ended December 2012 would have been \$(22.7) million, or \$(5.3) million higher than the same period in 2011. The increase in cash used in operations was attributable to higher net operating expenses as we invested in marketing for Anatabloc® and for increase in accrued liabilities which will be paid in future periods.

Net Cash From Investing Activities. During the year ended December 31, 2012, a total of \$(21) thousand of cash was used for investing activities, primarily the acquisition of property and equipment and to fund costs associated with our intellectual property. That amount was partially offset by funds received for the licensing of certain of our trademarks under an agreement entered into in 2007. During the twelve months ended December 31, 2011 we expended a net of \$0.5 million primarily for equipment to support our dietary supplement products production.

Net Cash From Financing Activities. During the year ended December 31, 2012, we generated net cash from financing activities of approximately \$32.2 million through the exercise of warrants and stock options, and the sale of stock generating proceeds of \$1.7 million and offset, in part, by debt payments of \$1.7 million. During the same period in 2011, we generated net cash from financing activities of approximately

\$16.9 million, primarily through the sale of common stock for gross proceeds of approximately \$10.0 million and the exercise of warrants and stock options of \$9.5 million offset, in part, by long-term debt payments of \$2.5 million.

Net Cash Used in MSA Escrow Payments. Given the fact that we discontinued the sale of cigarettes in June 2007, we do not have any ongoing obligation to make any deposits into escrow. During the year ended 'December 31, 2012, we deposited \$113 thousand into escrow for sales from 2006 in one MSA state based on an audit of cigarette sales for that year. During the year ended December 31, 2011, we did not make any deposits for the sale of cigarettes in the MSA states.

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#### Cash Demands on Operations

During the year ended December 31, 2012, we had losses from continuing operations that totaled (18.1) million and net losses of (22.9) million.

#### Contingent Liabilities and Cash Demands

Litigation Costs. We have paid or accrued all existing obligations. Also, as part of our fee arrangements in certain litigation matters, we had agreed to pay counsel a percentage of any damage award, a percentage of the resulting payments we actually received in the event that the litigation was resolved in our favor or a result fee in return for a cap on fee payments during the litigation. In connection with the settlement of the RJR litigation, we have accrued \$1.3 million in connection with a contingent fee arrangement with counsel relating to that litigation, although we anticipate negotiating the final amount of any fees payable.

Prior to the introduction of Anatabloc<sup>®</sup>, Anatabloc<sup>®</sup> Facial Crème and CigRx<sup>®</sup>, we obtained product liability insurance for each of our products. This insurance covers claims arising from product defects or claims arising out of the sale, distribution and marketing of these products. There have been no claims . A. A. asserted with respect to the manufacture, sale or use of our dietary supplement products to date. If any such claims are asserted in the future and ultimately result in liability that exceeds the limits of our insurance coverage, we would be liable for any such excess amount. In the past, we maintained product liability insurance only with respect to claims that tobacco products manufactured by or for us contained any foreign object (i.e., any object that is not intended to be included in the manufactured product). We currently do not maintain such insurance. The product liability insurance previously maintained did not cover health-related claims such as those that have been made against the major manufacturers of tobacco products. We do not believe that insurance for health-related claims can currently be obtained. We may be named as a defendant in such cases in the future notwithstanding that we ceased selling cigarettes in 2007 and exited from the tobacco business as of December 31, 2012. However, we believe that we have conducted our business in a manner that decreases the risk of liability in a lawsuit of the type described above, because we have attempted to consistently present to the public the most current information regarding the health risks of long-term smoking and tobacco use generally, have always acknowledged the addictive nature of nicotine and have never targeted adolescent or young persons as customers.

Virginia Sales and Use Tax Assessment. In 2002, the Virginia Department of Taxation asserted a Virginia Sales and Use Tax assessment for the period January 1, 1999, through March 31, 2002, against us with respect to our tobacco-curing barns in the amount of \$860,115. We applied for a correction of the assessment and a total abatement of the tax on the grounds that our barns are exempt from sales and use taxes under the industrial use and processing exemption and/or the agricultural exemption. In a letter dated October 7, 2004, our company received notification from the Commonwealth of Virginia that an adverse decision had been made by the Commissioner of Taxation with respect to the sales and use tax assessment previously issued to our company. On August 10, 2010 the Commonwealth of Virginia responded to our request for reconsideration of the state's sales and use tax assessment with respect to our tobacco curing barns. The Commonwealth disagreed with our position that the barns are part of the manufacturing process and, therefore, exempt from sales and use taxes under the industrial use and processing exemption and/or the agricultural exemption, concluding that the barns are taxable under the Commonwealth's sales tax laws and regulation. On July 14, 2011 we filed a lawsuit in the Circuit Court for Mecklenburg County, Virginia seeking a determination that the purchase of our company's curing barns was exempt from Virginia sales and use tax and an abatement of all taxes and interest assessed against our company by Virginia's Commissioner of Revenue. The Commonwealth of Virginia filed an answer to our complaint on July 29, 2011 asserting that the

assessment amount was properly determined. The sales and use tax assessment plus penalties and interest together, as of December 31, 2012, totaled approximately \$1.7 million. Interest will continue to accrue during our company's pursuit of a resolution of this matter.

Government Investigation. In late January and February of this year, our company, directors and others received subpoenas from the United States Attorney's Office for the Eastern District of Virginia seeking documents. Our present understanding is that the investigation is principally focused on transactions involving our company's securities including certain private placements and related party transactions since 2006. We are responding to the subpoenas and intend to cooperate fully with the investigation. In addition, we engaged outside counsel (the international law firm of Chadbourne & Parke, LLP) to conduct an internal investigation of these matters.

We are unable to predict the duration of the internal investigation or the United States Attorney's investigation. No conclusion can be drawn at this time as to outcome, or whether these matters will result in any materially adverse impact on our company. While the investigation is pending, we intend to remain focused on our core business activities, including expanding sales of our Anatabloc<sup>®</sup> product and continuing clinical and related research on our current development schedule. We do not intend, and disclaim any obligation, to provide continuing or updated disclosure regarding these requests and inquiries absent definitive developments unless otherwise required by law.

#### **Recent Transactions and Potential for Additional Financing**

See note 8 to our consolidated financial statements included in "Item 15. Exhibits, Financial Statement Schedules" of this Report.

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

Our company does not have any off-balance sheet arrangements as defined by Item 303(a)(4) of Regulation S-K.

#### **Contractual Obligations**

At December 31, 2012, our company's contractual cash obligations, with initial or remaining terms in excess of one year, were as follows (in thousands):

	ta da serie da serie Serie da serie da ser		Amount of Commi By Year Ended		More than
	TOTAL	Year ending	Three years ended	Two year ending	5 Years
	· · · · · · · · · · · · · · · · · · ·	12/31/2013	2016	2018	
Operating Leases	\$1,190	\$366	\$479	\$133	\$212

Our company had purchase commitments as of December 31, 2012 totaling \$0.7 million.

Employment contracts are not included in the above table. For information on employment contracts with obligations in excess of one year, see "Item 11. Executive Compensation-Employment and Severance Agreements."

#### **Accounting and Reporting Developments**

See note 1 to our consolidated financial statements included in "Item, 15 Exhibits, Financial Statement Schedules" of this Report.

## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our company has not entered into any transactions using derivative financial instruments or derivative commodity instruments and believes that our exposure to market risk associated with other financial instruments (such as investments and borrowings) and interest rate risk is not material.

## ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements and notes thereto and the Report of Cherry Bekaert LLP are included in "Item 15. Exhibits, Financial Statement Schedules" and are incorporated herein by reference.

## ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

#### **ITEM 9A. CONTROLS AND PROCEDURES**

(a) Disclosure Controls and Procedures.

As required by Rule 13a-15 under the Exchange Act management has evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Report. Disclosure controls and procedures refer to controls and other procedures designed to provide reasonable assurance that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding our required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management was required to apply its judgment in evaluating and implementing possible controls and procedures.

Our Chief Executive Officer and Chief Financial Officer have concluded, based on this evaluation, that as of December 31, 2012, the end of the period covered by this Report, our disclosure controls and procedures were effective at a reasonable assurance level.

#### (b) Management's Annual Report on Internal Control Over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting, as defined in rules promulgated under the Exchange Act, is a process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer and effected by our Board of Directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America, or GAAP. Internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and our Board of Directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Our internal control over financial reporting is evaluated on a regular basis by personnel in our organization. The overall goals of these various evaluation activities are to monitor our internal control over financial reporting and to make modifications as necessary, as disclosure and internal controls are intended to be dynamic systems that change (including improvements and corrections) as conditions warrant. Part of this evaluation is to determine whether there were any significant deficiencies or material weaknesses in our internal control over financial reporting, or whether we had identified any acts of fraud involving personnel who have a significant role in our internal control over financial reporting. Significant deficiencies are control issues that could have a significant adverse effect on the ability to record, process, summarize and report financial data in the financial statements. Material weaknesses are particularly serious conditions where the internal control over financial reporting does not reduce to a relatively low level the risk that misstatements

caused by error or fraud may occur in amounts that would be material in relation to the financial statements and not be detected within a timely period by employees in the normal course of performing their assigned functions.

Management conducted an assessment of the effectiveness of our company's internal control over financial reporting as of December 31, 2012, utilizing the framework established in "INTERNAL CONTROL — INTEGRATED FRAMEWORK" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management has determined that our internal controls over financial reporting as of December 31, 2012 were effective.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Cherry Bekaert LLP, an independent registered public accounting firm, has audited the effectiveness of our internal control over financial reporting as of December 31, 2012, as stated in their report, which appears on page F-2 of "Item 15, Exhibits, Financial Statement Schedules" of this Report.

#### (c) Changes in Internal Control Over Financial Reporting.

During the fourth quarter of 2012, in connection with the evaluation of internal controls described above in paragraph (b) of this Item 9A, there were no changes in our internal control over financial reporting for the year ended December 31, 2012 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### **ITEM 9B. OTHER INFORMATION**

None.

#### PART III

#### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

This information is incorporated by reference from our company's Proxy Statement with respect to the 2013 Annual Meeting of Stockholders to be filed with the SEC no later than April 30, 2013.

#### ITEM 11. EXECUTIVE COMPENSATION.

This information is incorporated by reference from our company's Proxy Statement with respect to the 2013 Annual Meeting of Stockholders.

#### ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

This information is incorporated by reference from our company's Proxy Statement with respect to the 2013 Annual Meeting of Stockholders.

# ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

This information is incorporated by reference from our company's Proxy Statement with respect to the 2013 Annual Meeting of Stockholders.

#### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

This information is incorporated by reference from our company's Proxy Statement with respect to the 2013 Annual Meeting of Stockholders.

### PART IV

## ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of this Report.

1. Consolidated Financial Statements

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Index to Consolidated Financial Statements	F-1
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Consolidated Balance Sheets as of December 31, 2012 and 2011	F-3
Consolidated Statements of Operations for the years ended December 31, 2012, 2011 and 2010	F-4
Consolidated Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2012, 2011 and 2010	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2012, 2011 and 2010	F-6
Notes to Consolidated Financial Statements	F-8
2. Financial Statements Schedules	
None.	:

## (b) Exhibits.

An index to exhibits has been filed as part of this Report beginning on page 46 and is incorporated herein by reference.

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### **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

STAR SCIENTIFIC, INC.

By: /s/ JONNIE R. WILLIAMS, SR.

Jonnie R. Williams, Sr. Chief Executive Officer

Date: March 18, 2013

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Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date		
/s/ Jonnie R. Williams, Sr.	Chief Executive Officer and Director	March 18 <sup>th</sup> , 2013		
Jonnie R. Williams, Sr.	(Principal Executive Officer)			
/s/ Paul L. Perito	Chairman of the Board, President and	March 18 <sup>th</sup> , 2013		
Paul L. Perito	Chief Operating Officer			
/s/ Park A. Dodd, III	Chief Financial Officer	March 18 <sup>th</sup> , 2013		
Park A. Dodd, III	(Principal Financial Officer and	,		
	Principal Accounting Officer)			
/s/ Christopher C. Chapman	Director	March 18 <sup>th</sup> , 2013		
Christopher C. Chapman				
/s/ Neil L. Chayet	Director	March 18th, 2013		
Neil L. Chayet		,		
/s/ Burton J. Haynes	Director	March 18 <sup>th</sup> , 2013		
Burton J. Haynes				
/s/ Ralph B. Everett	Director	March 18 <sup>th</sup> , 2013		
Ralph B. Everett	_			

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Item	Description
2.1	Asset Purchase Agreement between Star Scientific, Inc., a Delaware corporation and Eyetech, LLC, a Minnesota limited liability company, by Robert J. Fitzsimmons, an individual residing ir St. Paul, Minnesota, dated December 30, 1998. <sup>(1)</sup>
3.1	Eighth Amended and Restated Certificate of Incorporation of Star Scientific, Inc. <sup>(2)</sup>
3.2	Amended and Restated Bylaws of Star Scientific, Inc. <sup>(3)</sup>
10.1	License Agreement between Star Tobacco and Pharmaceuticals, Inc., as Licensee and Regent Court Technologies, Jonnie R. Williams, and Francis E. O'Donnell, Jr., M.D., as Licensor, dated January 5, 1998. <sup>(4)</sup>
10.2	Amendment No. 1 to License Agreement between Regent Court Technologies, Jonnie R. Williams, Francis E. O'Donnell, Jr., M.D. and Star Tobacco and Pharmaceuticals, Inc., dated August 3, 1998. <sup>(5)</sup>
10.3	1998 Stock Option Plan, as amended. <sup>(6)</sup>
10.4	2000 Equity Incentive Plan, as amended. <sup>(7)</sup>
10.5	Second Amended and Restated 2008 Incentive Award Plan.
10.6	Qualified Stock Option Agreement dated as of April 27, 1999 between Star Scientific, Inc. and Paul L. Perito. <sup>(8)</sup>
10.7	Lease and Purchase Option Contract between Star Scientific, Inc. and the Industrial Developmer Authority of the Town of Chase City, Virginia, dated March 10, 2000. <sup>(6)</sup>
10.8	Form of Director Indemnification Agreement. <sup>(6)</sup>
10.9	Form of Officer Indemnification Agreement. <sup>(6)</sup>
10.10	Executive Employment Agreement between Star Scientific, Inc. and David M. Dean, dated October 6, 2000. <sup>(7)</sup>
10.11	Restated Loan Agreement between Star Scientific, Inc., Star Tobacco and Pharmaceuticals, Inc. and Brown & Williamson Tobacco Corporation, dated August 21, 2000. <sup>(9)</sup>
10.12	Restated Security Agreement between Star Scientific, Inc. and Brown & Williamson Tobacco Corporation, dated August 21, 2000. <sup>(9)</sup>
10.13	Security Agreement between Star Tobacco and Pharmaceuticals, Inc. and Brown & Williamson Tobacco Corporation, dated August 21, 2000. <sup>(9)</sup>
10.14	Guaranty Agreement between Star Scientific, Inc. and Brown & Williamson Tobacco Corporation, dated August 21, 2000. <sup>(9)</sup>
10.15	Guarantee Agreement between Star Tobacco and Pharmaceuticals, Inc. and Brown & Williamso Tobacco Corporation, dated August 21, 2000. <sup>(9)</sup>
10.16	Amended and Restated Executive Employment Agreement dated as of March 15, 2001 between Star Scientific, Inc. and Christopher G. Miller. <sup>(7)</sup>
10.17	Executive Employment Agreement dated as of March 30, 2001 between Star Scientific, Inc. an Robert E. Pokusa. <sup>(7)</sup>
10.18	Restated Master Agreement, dated April 25, 2001, by and between Star Scientific, Inc. and Brown & Williamson Tobacco Corporation. <sup>(10)</sup>
10.19	First Amendment to Restated Loan Agreement dated April 25, 2001, among Star Scientific, Inc. Star Tobacco & Pharmaceuticals, Inc. and Brown & Williamson Tobacco Corporation. <sup>(10)</sup>
10.20	Trademark License and Royalty Agreement, dated April 25, 2001, between Star Scientific, Inc. and Brown & Williamson Tobacco Corporation. <sup>(10)</sup>
10.21	Other Low TSNA Tobacco Royalty Agreement, dated April 25, 2001 by and between Star Scientific, Inc. and Brown & Williamson Tobacco Corporation. <sup>(10)</sup>

## INDEX TO EXHIBITS

	Description
10.22	First Amendment to Regent/B&W License Agreement, dated April 25, 2001, by and among Regent Court Technologies, Jonnie R. Williams, Francis O'Donnell, Jr., Star Scientific, Inc. and Brown & Williamson Tobacco Corporation. <sup>(10)</sup>
10.23	Exclusive License Agreement dated as of March 16, 2001 by and among Regent Court Technologies and Star Scientific, Inc. <sup>(11)</sup>
0.24	Consent to Assignment dated March 16, 2001 by and among Regent Court Technologies, Jonnie R. Williams, Francis O'Donnell, Jr., M.D., Star Tobacco & Pharmaceuticals, Inc., Star Scientific, Inc. and Brown & Williamson Tobacco Corporation. <sup>(11)</sup>
0.25	Amendment No. 1 dated April 5, 2001 to Exclusive License Agreement by and among Regent Court Technologies and Star Scientific, Inc. <sup>(11)</sup>
0.26	Contract with Lease and Option to Purchase by and among The Industrial Development Authority of Mecklenburg County, Virginia, The Industrial Development Authority of the Town of Chase City, Virginia, and Star Scientific, Inc., dated April 10, 2002. <sup>(12)</sup>
0.27	Convertible Debenture, dated March 25, 2004, issued by Star Scientific, Inc. to Manchester Securities Corp. Debenture was amended and then converted. <sup>(13)</sup>
0.28	Warrant, dated March 25, 2004, issued by Star Scientific, Inc. to Manchester Securities Corp. <sup>(13)</sup>
0.29	Securities Purchase Agreement, dated March 25, 2004, between Star Scientific, Inc. and Manchester Securities Corp. <sup>(13)</sup>
0.30	Registration Rights Agreement, dated March 25, 2004, between Star Scientific, Inc. and Manchester Securities Corp. <sup>(13)</sup>
0.31	Common Stock Purchase Warrant, dated as of March 25, 2004, issued by Star Scientific, Inc. to Reedland Capital Partners, an Institutional Division of Financial West Group. <sup>(13)</sup>
0.32	Executive Employment Agreement, dated December 30, 2005 between Star Scientific, Inc. and Jonnie R. Williams. <sup>(14)</sup>
0.33	Second Amended and Restated Employment Agreement, dated December 30, 2005 between Star Scientific, Inc. and Paul L. Perito. <sup>(14)</sup>
0.34	Securities Purchase and Registration Rights Agreement, dated as of March 3, 2006, between Star Scientific, Inc. and Joseph L. Schwarz. <sup>(15)</sup>
0.35	Common Stock Purchase Warrant, dated as of March 3, 2006, issued by Star Scientific, Inc. to Joseph L. Schwarz. <sup>(15)</sup>
0.36	Securities Purchase and Registration Rights Agreement, dated July 14, 2006, by and between Star Scientific, Inc. and Iroquois Capital. <sup>(16)</sup>
0.37	Common Stock Purchase Warrant, dated July 14, 2006, issued by Star Scientific, Inc. to Iroquois Capital. <sup>(16)</sup>
0.38	Securities Purchase and Registration Rights Agreement, dated July 14, 2006, by and between Star Scientific, Inc. and Delaware Charter Guarantee and Trust Company, FBO Joseph L. Schwarz, IRA. <sup>(16)</sup>
0.39	Common Stock Purchase Warrant, dated July 14, 2006, issued by Star Scientific, Inc. to Delaware Charter Guarantee and Trust Company, FBO Joseph L. Schwarz IRA. <sup>(16)</sup>
0.40	First Amendment to Executive Employment Agreement, dated December 15, 2006 between Star Scientific, Inc. and Jonnie R. Williams. <sup>(3)</sup>
0.41	First Amendment to Second Amended Executive Employment Agreement, dated December 15, 2006 between Star Scientific, Inc. and Paul L. Perito. <sup>(3)</sup>
0.42	Escrow Releases Purchase Agreement dated March 14, 2007 by and among QVT Associates LP, Whitebox Hedged High Yield Partners, LP, Star Scientific, Inc. and Star Tobacco, Inc. <sup>(17)</sup>
0.43	Second Amendment to Second Amended Executive Employment Agreement, dated March 23, 2007 between Star Scientific, Inc. and Paul L. Perito. <sup>(18)</sup>

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Item	Description
10.44	License Agreement, dated May 10, 2007 between Star Tobacco, Inc., Star Scientific, Inc. and Tantus Tobacco, LLC. <sup>(19)</sup>
10.45	Securities Purchase and Registration Rights Agreement, dated June 29, 2007, by and between Star Scientific, Inc. and Joseph L. Schwarz. <sup>(20)</sup>
10.46	Common Stock Purchase Warrant dated June 29, 2007, issued by Star Scientific, Inc. to Pershing LLC, FBO Joseph L. Schwarz Roth IRA. <sup>(20)</sup>
10.47	Common Stock Purchase Warrant dated June 29, 2007 issued by Star Scientific, Inc. to Joseph L. Schwarz. <sup>(20)</sup>
10.48	Securities Purchase and Registration Rights Agreement, dated June 29, 2007 by and between Star Scientific, Inc. and Joseph Rice. <sup>(20)</sup>
10.49	Common Stock Purchase Warrant dated June 29, 2007 issued by Star Scientific, Inc. to Joseph Rice. <sup>(20)</sup>
10.50	Agreement dated October 10, 2007 by and between Christopher G. Miller and Star Scientific, Inc. <sup>(21)</sup>
10.51	Agreement dated October 10, 2007 by and between Park A. Dodd, III and Star Scientific, Inc. <sup>(21)</sup>
10.52	Securities Purchase and Registration Rights Agreement, dated March 13, 2008 by and between Star Scientific, Inc. and the several Investors party thereto, including the form of Warrant thereunder. <sup>(22)</sup>
10.53	Securities Purchase and Registration Rights Agreement, dated March 14, 2008 by and between Star Scientific, Inc. and the several Investors party thereto, including the form of Warrant thereunder. <sup>(22)</sup>
10.54	Securities Purchase and Registration Rights Agreement, dated May 12, 2008 by and between Star Scientific, Inc. and the several Investors party thereto, including the form of Warrant thereunder. <sup>(23)</sup>
10.55	Letter Agreement with Jonnie R. Williams, dated March 14, 2008. <sup>(23)</sup>
10.56	Executive Employment Agreement dated February 26, 2008 between Star Scientific, Inc. and Curtis Wright, M.D. MPH. <sup>(22)</sup>
10.57	Amendment to Executive Employment Agreement dated as of December 19, 2008 between Star Scientific, Inc. and Robert E. Pokusa. <sup>(24)</sup>
10.58	Securities Purchase and Registration Rights Agreement, dated March 2, 2009 by and between Star Scientific, Inc. and the several Investors party thereto, including the form of Warrant thereunder. <sup>(25)</sup>
10.59	Securities Purchase and Registration Rights Agreement, dated September 22, 2009 by and between Star Scientific, Inc. and the Investor party thereto, including the form of Warrant thereunder. <sup>(26)</sup>
10.60	Executive Employment Agreement dated January 1, 2010 between Star Scientific, Inc. and Park A. Dodd, III. <sup>(27)</sup>
10.61	Securities Purchase and Registration Rights Agreement, dated March 5, 2010, by and between Star Scientific, Inc. and the several Investors party thereto. <sup>(28)</sup>
10.62	Amended Warrant, dated March 5, 2010, by and between Star Scientific, Inc. and Iroquois Master Fund Ltd. <sup>(28)</sup>
10.63	Amended Warrant, dated March 5, 2010, by and between Star Scientific, Inc. and Iroquois Capital, LP. <sup>(28)</sup>
10.64	Securities Purchase and Registration Rights Agreement, dated March 9, 2010, by and between Star Scientific, Inc. and the several Investors party thereto. <sup>(29)</sup>
10.65	and the second s

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Item	Description
10.66	Amended Warrant No. 2, dated March 9, 2010, by and between Star Scientific, Inc. and Tradewinds Master Fund (BVI), Ltd. <sup>(29)</sup>
10.67	Amended Warrant No. 1, dated March 9, 2010, by and between Star Scientific, Inc. and Feehan Partners, L.P. <sup>(29)</sup>
10.68	Amended Warrant No. 2, dated March 9, 2010, by and between Star Scientific, Inc. and Feehan Partners, L.P. <sup>(29)</sup>
10.69	Amended Warrant No. 1, dated March 9, 2010, by and between Star Scientific, Inc. and PV Partners, L.P. <sup>(29)</sup>
10.70	Amended Warrant No. 2, dated March 9, 2010, by and between Star Scientific, Inc. and PV Partners, L.P. <sup>(29)</sup>
10.71	Securities Purchase and Registration Rights Agreement, dated March 9, 2010, by and between Star Scientific, Inc. and the several Investors party thereto, including the form of Warrant attached as Exhibit A thereon. <sup>(29)</sup>
10.72	Securities Purchase and Registration Rights Agreement, dated March 10, 2010, by and between Star Scientific, Inc. and the Investor party thereto, including the form of Warrant attached as Exhibit A thereon. <sup>(29)</sup>
10.73	Amended Securities Purchase and Registration Rights Agreement, dated March 12, 2010, by an between Star Scientific, Inc. and the Investor party thereto. <sup>(29)</sup>
10.74	Securities Purchase and Registration Rights Agreement, dated March 12, 2010, by and between Star Scientific, Inc. and the several Investor party thereto, including the form of Warrant attache as Exhibit A thereon. <sup>(29)</sup>
10.75	Securities Purchase and Registration Rights Agreement, dated November 5, 2010, by and between Star Scientific, Inc. and the several Investors party thereto, including the form of Warrant attached as Exhibit A thereon. <sup>(30)</sup>
10.76	Securities Purchase and Registration Rights Agreement, dated February 28, 2011, by and betwee Star Scientific, Inc. and the Investor party thereto, including the form of Warrant attached as Exhibit A thereon. <sup>(31)</sup>
10.77	Securities Purchase and Registration Rights Agreement, dated March 4, 2011, by and between Star Scientific, Inc. and the several Investors party thereto, including the form of Warrant attached as Exhibit A thereon. <sup>(31)</sup>
10.78	Executive Employment Agreement, dated March 14, 2011, between Star Scientific, Inc. and Jonnie R. Williams. <sup>(32)</sup>
10.79	Third Amended and Restated Executive Employment Agreement, dated March 14, 2011, betwe Star Scientific, Inc. and Paul L. Perito. <sup>(32)</sup>
10.80	Amended and Restated Executive Employment Agreement, dated March 14, 2011, between Sta Scientific, Inc. and Curtis Wright, IV, MD, MPH. <sup>(32)</sup>
10.81	Securities Purchase and Registration Rights Agreement, dated December 22, 2011, by and between Star Scientific, Inc. and the Investor party thereto, including the form of Warrant attached as Exhibit A thereon. <sup>(33)</sup>
10.82	Securities Purchase and Registration Rights Agreement, dated February 28, 2012, by and betwee Star Scientific, Inc. and the Investor party thereto, including the form of Warrant attached as Exhibit A thereon. <sup>(34)</sup>
10.83	Amendment to Third Amended and Restated Executive Employment Agreement, dated December 28, 2012 between Star Scientific, Inc. and Paul L. Perito.
10.84	Amendment to Executive Employment Agreement, dated December 28, 2012 between Star Scientific, Inc. and Jonnie R. Williams.

Item	Description
14.1	Corporate Code of Business Conduct and Corporate Ethics, dated March 2004. <sup>(13)</sup>
21.1	Subsidiaries of the Company.
23.1	Consent of Cherry Bekaert LLP.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002.
EX-101	INSTANCE DOCUMENT.
EX-101	SCHEMA DOCUMENT.
EX-101	CALCULATION LINKBASE DOCUMENT.
<b>EX-101</b>	LABELS LINKBASE DOCUMENT.
<b>EX-101</b>	PRESENTATION LINKBASE DOCUMENT.
<b>EX</b> -101	DEFINITION LINKBASE DOCUMENT.
_	orated by reference to Current Report on Form 8-K filed on March 3, 1999. orated by reference to Current Report on Form 8-K filed on December 18, 2012.
	orated by reference to Current Report on Form 8-K filed on December 21, 2006.
_	orated by reference to Quarterly Report on Form 10-QSB for the quarter ended March 31, 1998.
_	orated by reference to Current Report on Form 8-K filed on September 14, 1998.
	orated by reference to Annual Report on Form 10-K for the year ended December 31, 1999.
(7) Incorp	orated by reference to Annual Report on Form 10-K for the year ended December 31, 2000.
(8) Incorp	orated by reference to Quarterly Report on Form 10-QSB for the quarter ended June 30, 1999.
	orated by reference to Quarterly Report on Form 10-Q for the quarter ended September 30, 2000. orated by reference to Current Report on Form 8-K filed on May 17, 2001.
-	orated by reference to Quarterly Report on Form 10-Q for the quarter ended September 30, 2001.
-	orated by reference to Quarterly Report on Form 10-Q for the quarter ended June 30, 2002.
(13) Incorp	orated by reference to Annual Report on Form 10-K for the year ended December 31, 2003.
(14) Incorp	orated by reference to Current Report on Form 8-K filed on December 30, 2005.
(15) Incorp	orated by reference to Current Report on Form 8-K filed on March 7, 2006.
(16) Incorp	orated by reference to Current Report on Form 8-K filed on July 18, 2006.
(17) Incorp	orated by reference to Annual Report on Form 10-K for the year ended December 31, 2006.
(18) Incorp	orated by reference to Current Report on Form 8-K filed on March 28, 2007.
(19) Incorp	orated by reference to Quarterly Report on Form 10-Q for the quarter ended June 30, 2007.
(20) Incorpo	orated by reference to Current Report on Form 8-K filed on July 6, 2007.
(21) Incorpo	orated by reference to Quarterly Report on Form 10-Q for the quarter ended September 30, 2007.
-	prated by reference to Annual Report on Form 10-K filed for the year ended December 31, 2007.
	orated by reference to Quarterly Report on Form 10-Q for the quarter ended March 31, 2008.
-	orated by reference to Annual Report on Form 10-K for the year ended December 31, 2008.
(75) Incom	protect by reference to Current Deport on Form 9 K flad on March 2, 2000

(25) Incorporated by reference to Current Report on Form 8-K filed on March 3, 2009.

(26) Incorporated by reference to Current Report on Form 8-K filed on September 25, 2009.

(27) Incorporated by reference to Current Report on Form 8-K filed on January 28, 2010.

(28) Incorporated by reference to Current Report on Form 8-K filed on March 5, 2010.

(29) Incorporated by reference to Annual Report on Form 10-K for the year ended December 31, 2009.

(30) Incorporated by reference to Registration Statement on Form S-3 filed on December 10, 2010.

(31) Incorporated by reference to Current Report on Form 8-K filed on March 4, 2011.

- (32) Incorporated by reference to Annual Report on Form 10-K for the year ended December 31, 2010.
- (33) Incorporated by reference to Current Report on Form 8-K filed on December 28, 2011.
- (34) Incorporated by reference to Current Report on Form 10-Q for the quarter ending March 31, 2012

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## INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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2011 and 2010	F-5
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#### **REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of Star Scientific, Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of Star Scientific, Inc. and Subsidiaries (the "Company") as of December 31, 2012 and 2011, and the related statements of operations, stockholders' equity (deficit) and cash flows for each of the years in the three-year period ended December 31, 2012. We also have audited the Company's internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting included in Item 9A — Controls and Procedures in the Company's 2012 Annual Report on Form 10-K. Our responsibility is to express an opinion on these financial statements and an opinion on the Company's internal control over financial reporting based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Star Scientific, Inc. and Subsidiaries as of December 31, 2012 and 2011, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2012 in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion the Company maintained, in all material respects, effective control over financial reporting as of December 31, 2012, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

/s/ Cherry Bekaert LLP Richmond, Virginia March 18, 2013

### CONSOLIDATED BALANCE SHEETS DECEMBER 31, 2012 AND 2011 (\$ in thousands except per share data)

	2012	2011
ASSETS Current assets:		
Cash and cash equivalents	\$ 23,121	\$ 10,188
Receivable from sale of licensing rights	33	30
Inventories	4,989	2,454
Prepaid expenses and other current assets	1,089	737
Current assets of discontinued operations	51	324
Total current assets	29,283	13,733
Property and equipment, net	1,338	1,611
Intangible assets, net of accumulated amortization	541	578
Receivable from sale of licensing rights, less current maturities	18	50
MSA escrow funds	481	368
Assets held for sale of discontinued operations	263	737
Total assets	\$ 31,924	\$ 17,077
LIABILITIES AND STOCKHOLDERS' EQUITY	<u> </u>	
Current liabilities:		
Current maturities of long-term debt	¢ 7	<b>*</b> • • • • •
Accounts payable, trade	\$ 7	\$ 2,519
Accrued expenses	2,405	1,756
Due to stockholders	2,717	640
Current liabilities of discontinued operations	50	50
Total current liabilities	1,761	190
Long-term debt, less current maturities	6,940	5,155
Total liabilities		2,531
Commitments and contingencies (Note 14)	6,940	7,686
	·	
Stockholders' equity:		
Common stock <sup>(A)</sup>	17	14
Additional paid-in capital	256,498	218,055
Accumulated deficit	(231,531)	(208,678)
Total stockholders' equity <sup>(B)</sup>	24,984	9,391
Total liabilities and stockholders' equity	\$ 31,924	\$ 17,077
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(A) \$.0001 par value, 213,500,000 shares authorized; and 166,349,158 and 139,255,505 shares issued and outstanding as of December 31, 2012 and 2011, respectively.

(B) Class A, convertible, \$.01 par value, 4,000 shares authorized, no shares issued or outstanding; Series B, convertible; \$.01 par value 15,000 shares authorized, no shares issued or outstanding.

See notes to consolidated financial statements.

## CONSOLIDATED STATEMENTS OF OPERATIONS YEARS ENDED DECEMBER 31, 2012, 2011 AND 2010 (\$ and share in thousands except per share data)

, ·	2012	2012 2011		2010	
Net sales	\$ 6,188	\$	1,244	\$	63
Less:					
Cost of goods sold	3,566		1,861		405
Gross profit (loss)	2,622		(617)		(342)
Operating expenses:	6,186		2,569		1,786
Marketing	16,491		29,274		20,625
	4,558		3,211		2,786
Research and development	27,235		35,054		25,197
Total operating expenses	(24,613)		(35,671)		(25,539)
Operating loss from continuing operations	•				
Other income (expense):	17		46		73
Interest income	(104)		(263)		(366)
Interest expense			(5)		3
Other	6,513		(222)		(290)
Total other income (expense)	(18,100)		(35,893)		(25,829)
Loss from continuing operations before income taxes	(10,100)		· · · · · · · · · · · · · · · · · · ·		
Income tax benefit (expense)	(18,100)		(35,893)		(25,829)
Net loss from continuing operations	(10,100)				
Discontinued operations	(3,084)				
Loss on discontinued operations	(1,669)		(2,095)		(2,452)
Total discontinued operations	(4,753)		(2,095)		(2,452)
Net loss	\$ (22,853)	\$	(37,988)	<u>\$</u>	(28,281)
	<u> </u>				
Loss per common share; basic and diluted:	¢ (0.13)	)\$	(0.27)	\$	(0.22)
Continuing operations	\$ (0.12) (0.03)		(0.27)	Ψ	(0.02)
Discontinued operations			(0.28)	\$	(0.24)
Total basic and diluted	$\frac{(0.15)}{146,006,416}$	·	33,639,781	<u> </u>	8,383,969
Weighted average shares outstanding – basic and diluted	146,996,416				

See notes to consolidated financial statements.

#### **Common Stock** Additional Accumulated Total Paid-in Capital Deficit Shares Amount \$ 2,288 \$(142,409) 107,677 \$11 \$144.686 Balances, January 1, 2010 ..... 8,823 8,823 100 Stock-based compensation ..... 27,829 27,827 2 19.342 Issuance of common stock ..... (28,281) (28,281) Net loss \_\_\_\_\_ 10.659 (170,690)13 181,336 Balances, December 31, 2010 . . . . 127,119 17,262 17,262 Stock-based compensation ..... 7,458 7,458 Stock option and warrant exercise . . 5,025 12,000 11,999 7,111 1 Issuance of common stock . . . . . (37,988) (37,988) Net loss 9,391 (208, 678)218,055 Balances, December 31, 2011 . . . . 139,255 14 3.556 3,556 Stock-based compensation ..... 50 32,180 32,183 3 26,304 Stock option and warrant exercise . . 2,707 2,707 740 Issuance of common stock . . . . . . (22,853) (22, 853)Net loss \$(231,531) \$ 24,984 \$17 \$256,498 Balances, December 31, 2012 . . . . 166,349

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) YEARS ENDED DECEMBER 31, 2012, 2011 AND 2010 (\$ and shares in thousands except per share data)

See notes to consolidated financial statements.

## CONSOLIDATED STATEMENTS OF CASH FLOWS YEARS ENDED DECEMBER 31, 2012, 2011 AND 2010 (\$ in thousands except per share data)

	2012	2011	2010
Operating activities:			
Net loss from continuing operations	\$(18,100)	\$(35,893)	\$(25,829)
Adjustments to reconcile net loss to net cash flows from operating activities:			
Depreciation and amortization	332	195	137
Forgiveness of debt	(3,356)		
Loss (gain) on disposal of property and equipment		5	
Stock-based compensation expense	3,556	17,262	8,823
Provision for (recovery of) bad debts	(1)	1	
Provision for inventory write-off	178	823	88
Increase (decrease) in cash resulting from changes in:			
Accounts receivable, trade	2	(2)	
Inventories	(2,713)	(198)	(3,168)
Prepaid expenses and other current assets	(352)	(386)	19
Accounts payable, trade	647	371	(951)
Accrued expenses	2,105	300	108
Net cash flows from operating activities	(17,702)	(17,522)	(20,773)
Investing activities:			
Purchases of property and equipment	(19)	(65)	(933)
Proceeds from sale of licensing rights	30	27	25
Purchase of intangible assets	(32)	(18)	(65)
Deposits made on property and equipment	—	(415)	(307)
Net cash flows from investing activities	(21)	(471)	(1,280)
Financing activities:			
Payments on long-term debt and capital leases	(1,686)	(2,518)	(1,994)
Proceeds from exercise of stock options and warrants	32,193	7,458	
Proceeds from sale of stock	1,661	12,000	27,829
Net cash flows from financing activities	32,168	16,940	25,835
Deposits to MSA escrow fund	(113)		(3)
Cash increase(decrease) from continuing operations	14,332	(1,053)	3,779
Cash flows from discontinued operations:			
Net cash flows used in operating activities	(1,399)	(1,952)	(2,889)
Net cash flows used in investing activities		(-,) —	(57)
Net cash flows from financing activities			
Net cash flows from discontinued operations	(1,399)	(1,952)	(2,946)
Increase (decrease) in cash and cash equivalents	12,933	(3,005)	833
Cash and cash equivalents, beginning of year	10,188	13,193	12,360
Cash and cash equivalents, end of year	\$ 23,121	\$ 10,188	\$ 13,193
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See notes to consolidated financial statements.

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#### CONSOLIDATED STATEMENTS OF CASH FLOWS YEARS ENDED DECEMBER 31, 2012, 2011 AND 2010 (\$ in thousands except per share data)

	2012	2011	2010
Supplemental disclosure of cash flow information: Cash paid during the year for:			
Interest	<u>\$ 109</u>	<u>\$271</u>	<u>\$370</u>
Supplemental schedule of non-cash investing and financing activities:			
During the year ended December 31, 2010, the Company purchased a vehicle financed through long-term debt. (See note 5)	\$ —	\$	\$ 63
During the year ended December 31, 2012, RJR forgave the outstanding balance of the Company's long-term debt owed	\$3,356	¢.	¢
to them as part of the RJR settlement. (See note 14) During the year ended December 31, 2012, the Company granted 330,000 common shares to employees effected by the exit	<b>43,330</b>	ф —	
from the dissolvable tobacco business. (See note 3)	<u>\$1,036</u>	<u>\$                                    </u>	<u>\$ —</u>

## See notes to consolidated financial statements.

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#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 1. Nature of business and summary of significant accounting policies:

#### Nature of business:

Star Scientific is a technology-oriented company with a mission to promote the maintenance of a healthy metabolism and lifestyle. Since the incorporation of its Rock Creek Pharmaceuticals, or Rock Creek, subsidiary in 2007, it has focused on utilizing certain alkaloids found in the Solanacea family of plants, which includes potatoes, tomatoes, and eggplants, initially to address issues related to the desire to smoke or use other traditional tobacco products. More recently, Rock Creek has been concentrating on the anti-inflammatory aspects of one of those alkaloids, anatabine. The Company believes its research and development efforts relating to the anatabine alkaloid has positioned it to utilize its technology to develop a range of non-nicotine dietary supplements and potentially related pharmaceutical products that could be beneficial in maintaining a healthy metabolism and in supporting good nutrition. Over the last several years, the Company has been engaged in:

- the manufacture, sale, marketing and development of two non-nicotine nutraceutical, dietary supplements: Anatabloc<sup>®</sup>, for anti-inflammatory support; and CigRx<sup>®</sup>, for fighting the urge to smoke cigarettes;
- the manufacture, sale, marketing and development of its cosmetic product, Anatabloc Facial Crème, which was introduced in September 2012
- the development of other nutraceutical, dietary supplements and pharmaceutical products, particularly products that have a botanical-based component and that are designed to treat a range of conditions, including Alzheimer's disease, Parkinson's disease, multiple sclerosis, schizophrenia, depression and tobacco dependence.

Since the 1990s, the Company also has sought to develop processes that significantly prevent the formation of one of the most abundant and significant groups of carcinogens, tobacco specific nitrosamines, or TSNAs, found in tobacco and tobacco smoke. The Company utilized this technology in producing low-TSNA tobacco and related low-TSNA smokeless tobacco products as less harmful alternatives to cigarettes and traditional smokeless tobacco products and as a platform to provide a base of financial support for its intellectual property, licensing and development initiatives. However, due to continuing operating losses, the Company ceased selling any tobacco products as of December 31, 2012, although it continues to look for licensing opportunities related to its low-TSNA curing technology and related products. The Company's technological development of reducing TSNA levels led to the focus on the development of non-nicotine tobacco-based pharmaceutical products and the non-nicotine dietary supplements that it is pursuing through Rock Creek.

#### Principles of consolidation:

The accompanying consolidated financial statements include the accounts of Star Scientific and its wholly owned subsidiaries, Rock Creek and Star Tobacco. All intercompany accounts and transactions have been eliminated.

#### Cash and cash equivalents:

For purposes of the statements of cash flows, the Company classifies all highly liquid investments with an original maturity of three months or less as cash equivalents.

#### Inventories:

Inventories are valued at the lower of cost or market. Cost is determined on the first-in, first-out (FIFO) method.

The Company accounts for freight, handling and wasted materials costs as current period charges. The Company outsources the production and storage of all of its dietary supplement and cosmetic products. The cost charged by the outsourced vendors is included in inventory costs.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 1. Nature of business and summary of significant accounting policies: - (continued)

#### Property and equipment:

Property and equipment are recorded at cost. Depreciation is determined using the straight-line method over the estimated useful lives of three to seven years for office equipment and machinery and equipment and thirty-nine years for buildings and improvements. Assets held for sale are the equipment that was idled as a result of exiting the smokeless tobacco business. The ultimate disposition of the equipment has not been determined.

#### Intangible assets:

Intangible assets consist primarily of licensing costs, patents and trademarks and packaging design costs. Intangibles are amortized using the straight-line method over a period of seventeen years for patents and licensing costs and five years for packaging design costs (the assets' estimated lives). Substantially all trademarks owned by the Company have indefinite lives and, as such, the cost of trademarks are not amortized, but are evaluated annually for impairment.

#### The Master Settlement Agreement ("MSA" or Master Settlement Agreement") escrow fund:

Cash deposits to which the Company has not transferred its ownership rights and which are restricted pursuant to the MSA have been reflected as a non-current asset in the Company's consolidated financial statements. Amounts deposited into MSA escrow accounts are required to be held in escrow for 25 years. (See note 14 for contingency discussion.)

#### Income taxes:

Deferred income tax assets and liabilities are computed annually for differences between the financial statement and federal income tax bases of assets and liabilities that will result in taxable or deductible amounts in the future, based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

#### Employee stock-based compensation:

The Company uses a fair-value based method to determine compensation for all arrangements under which employees and others receive shares of stock.

## Impairment of long-lived assets:

The Company reviews the carrying value of its amortizing long-lived assets whenever events or changes in circumstances indicate that the historical cost-carrying value of an asset may no longer be appropriate.

The Company assesses recoverability of the asset by estimating the future undiscounted net cash flows expected to result from the asset, including eventual disposition. If the estimated future undiscounted net cash flows are less than the carrying value of the asset, an impairment loss is recorded equal to the difference between the asset's carrying value and its fair value. Non-amortizing intangibles (trademarks) are reviewed annually for impairment.

#### Loss per common share:

Basic loss per common share is computed using the weighted-average number of common shares outstanding.

Diluted loss per share is computed assuming conversion of all potentially dilutive stock options and warrants. Potential common shares outstanding are excluded from the computation if their effect is anti-dilutive (See Note 8).

#### **Revenue Recognition:**

Revenue for the Company's dietary supplements and cosmetic products that are shipped to our direct buying consumers is recognized upon delivery of the product to the consumer. The dietary supplement

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 1. Nature of business and summary of significant accounting policies: - (continued)

products are shipped once the Company has received confirmation of a valid credit card charge, which is the only payment option offered to consumers of the dietary supplements and cosmetic products purchasing through the Company's webstore.

Under certain retail agreements we have agreed to "pay on scan" terms of sale for our dietary supplement products. The "pay on scan" terms do not constitute a sale of the product until the product is sold to a consumer. Under these agreements revenue is recognized by us at the time the customer purchases the product from the consignee. We use weekly reports from the consignee to derive the revenue recorded. The sales of products through these outlets are also subject to the same promotional and return credits discussed above. All of our products sold on a "pay-on-scan" basis, whether in a warehouse or retail location, is considered consignment inventory and accordingly we retain all risk of loss until sale.

Star records consumer incentives and trade promotion activities as a reduction of revenues based on amounts estimated as being due to customers and consumers at the end of a period. The estimates are based principally on historical utilization and redemption rates of the Company's products. Such programs include discounts, coupons, rebates, slotting fees, in-store display incentives and volume-based incentives.

#### Cost of Goods Sold

Cost of Goods Sold consists of the direct and indirect costs to produce and distribute the Company's products. Inventory related costs include materials, inbound freight, production costs, inventory obsolescence and shrinkage. In addition to the aforementioned, the costs for the Company's dietary supplement products (Anatabloc<sup>®</sup> and CigRx<sup>®</sup>) and cosmetic product (Anatabloc<sup>®</sup> Facial Crème) include fulfillment partner fees, credit card processing fees, and costs of consumer support.

#### Shipping costs:

The Company's dietary supplement products and cosmetic product are currently offered to direct buying consumers and Anatabloc<sup>®</sup> is sold on consignment at certain retail locations. All shipping costs are paid for by the Company however, the Company offers some premium shipping in the United States and charges its customers additional fees. International customers are charged a shipping fee, which is included in the sales price. All shipping costs are included in the cost of goods sold.

#### Advertising Costs:

Advertising costs are expensed as incurred and are included in marketing and distribution expenses. Advertising costs for the years 2012, 2011 and 2010, were \$2.9, \$0.9, and \$0.6 million, respectively.

#### Use of estimates:

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of income and expenses during the reporting period. Actual results could differ from those estimates.

#### Research and Development:

Research and development costs are expensed as incurred.

#### Research and Development royalty contracts:

The Company entered into a contract under which royalty payments are due based on Anatabloc<sup>®</sup> product sales. The contracts require the other party to the contract to perform research and development services at a minimum investment level before royalties are payable. The royalty is a percentage of gross sales and recorded at the contracted rate, however the royalty is subject to adjustment annually based on the other party performing research and development services at a required minimum level. Changes in the estimated royalty to be paid are treated as changes in estimates and are recognized in the period of change.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 1. Nature of business and summary of significant accounting policies: - (continued)

#### Commitment and contingency accounting:

The Company evaluates each commitment and/or contingency in accordance with the accounting standards which state that if the item is probable to become a direct liability then the Company will record the liability in the financial statements. If not, it will disclose any material commitments or contingencies that may arise.

#### **Recent Accounting and Reporting Pronouncements:**

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies that may have an impact on the Company's accounting and reporting.

In July 2012, the FASB issued a proposed Accounting Standards update, or ASU, 2012-02 "Impairment Goodwill and Other (Topic 350)." This amendment would give us the option to first assess qualitative factors to determine whether the existence of an event or circumstance indicates that it is more likely than not that indefinite-lived intangible assets are impaired before having to determine the fair value using the current quantitative approach. This ASU is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after September 15, 2012. We adopted this ASU during the year ended December 31, 2012. We evaluate intangibles for impairment annually unless factors arise that would create the need to perform an evaluation during interim periods. For the year ended December 31, 2012 there were no factors that indicated any impairment.

The Company believes that all other recently issued accounting pronouncements and other authoritative guidance for which the effective date is in the future either will not have an impact on its accounting or reporting or that such impact will not be material to its financial position, results of operations, and cash flows when implemented.

#### 2. Liquidity and managements' plans:

The Company has been operating at a loss for the past ten years. Star Scientific's future prospects will depend on its ability to generate and sustain increased revenue levels in future periods, which will largely be dependent on increased distribution and consumer acceptance of:

- Anatabloc<sup>®</sup>, a nutraceutical dietary supplement for anti-inflammatory support introduced in August 2011 and CigRx<sup>®</sup>, a non-nicotine, non-tobacco nutraceutical dietary supplement to temporarily reduce the desire to smoke;
- Anatabloc® Facial Crème introduced in September 2012; and
- to a lesser degree, the licensing of its low-TSNA curing technology and related products.

Star Scientific introduced Anatabloc<sup>®</sup>, its dietary supplement for anti-inflammatory support, in August 2011 through an interactive website and a customer service center. Since the introduction of Anatabloc<sup>®</sup>, the Company's revenues have been derived almost exclusively from the sales of its anatabine-based dietary supplement and, more particularly, Anatabloc<sup>®</sup>.

The Company's future prospects also will be dependent on Rock Creek's ability to develop additional nutraceutical products and pharmaceutical products and to a lesser degree on its ability to begin generating revenues through royalties from the patented tobacco curing process for which it is the exclusive licensee. As of December 31, 2012, the Company had approximately \$22.3 million of working capital, of which approximately \$23.1 million was cash and cash equivalents. While the Company may seek to obtain funds in the future through debt financing there is no guarantee that these efforts would be successful or commercially feasible given its continued operating losses. Moreover, the Company's ability to raise future financings on terms acceptable to it (including through the exercise of outstanding warrants) will depend on a number of

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 2. Liquidity and managements' plans: - (continued)

factors, including the performance of the Company's stock price and its operational performance. Any equity financing will be dilutive to the Company's existing shareholders.

The Company believes it has sufficient funds to operate through the first quarter of 2014. Depending upon market conditions and the price of its common stock, the Company may decide to seek additional funds before that time. There can be no assurance that the Company will be successful in obtaining such funding at commercially reasonable terms.

#### 3. Discontinued Operations:

Since the 1990s, the Company has sought to develop processes that significantly prevent the formation of one of the most abundant and significant groups of carcinogens, tobacco specific nitrosamines, or TSNAs, found in tobacco and tobacco smoke. The Company utilized this technology in producing low-TSNA tobacco and related low-TSNA dissolvable smokeless tobacco products as less harmful alternatives to cigarettes and traditional smokeless tobacco products and as a platform to provide a base of financial support for its intellectual property, licensing and development initiatives.

On December 14, 2012, the Company's Board of Directors voted unanimously to discontinue the manufacturing, distribution and sale of the Company's dissolvable smokeless tobacco products, Ariva<sup>®</sup> and Stonewall Hard Snuff<sup>®</sup> as of December 31, 2012. The Board was motivated to take this action in light of the continued losses and low sales for its dissolvable tobacco products over the last several years. It was also motivated by the fact that restrictions under the Family Smoking Prevention and Tobacco Control Act which prohibit a company from making any statements about the comparative safety of various types of tobacco products made it extremely difficult to effectively market its dissolvable tobacco products, notwithstanding that they represented a meaningful alternative to cigarettes and traditional smokeless tobacco products. The Board's action was further influenced by the fact that continuing to manufacture dissolvable tobacco products has had a negative impact on its ability to interest leading research centers in undertaking clinical research related to its anatabine compound and its potential for providing support in managing excessive inflammation.

While the Company ceased selling any tobacco products as of December 31, 2012, it continues to look for licensing opportunities related to its dissolvable tobacco products and related technology.

The Company incurred severance costs in the form of salary continuation payments and continued health benefit costs under COBRA of approximately \$829,000, for employees transitioning from Star Tobacco. In addition, the Company issued stock awards under the Company's 2008 Incentive Award Plan in the aggregate amount of 330,000 shares to those employees transitioning form Star Tobacco, in recognition of their long-time service to the Company. The stock awards had a total fair value of approximately \$1.1 million as well as a gross up charge for taxes of approximately \$0.8 million. The total cost in connection with the discontinuance of the Company's dissolvable tobacco business was approximately \$3.1 million consisting of cash and non-cash items and was recorded in the fourth quarter 2012.

The following represents a summary of the Company's operating results and the loss on the disposition of the dissolvable tobacco operations.

	2012	2011	2010
Net sales	\$ 418	\$ 488	\$ 785
Cost of goods sold	1,358	1,318	1,556
Gross margin (loss)	(940)	(830)	(771)
Operating expenses	729	1,265	1,681
Operating loss	(1,669)	(2,095)	(2,452)
Loss on disposal (primarily severance \$2,684)	(3,084)		
Total discontinued operations	\$(4,753)	\$(2,095)	<u>\$(2,452)</u>

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 3. Discontinued Operations: - (continued)

Assets and liabilities of the discontinued operations consist of the following:

	2012	2011
Current assets:		
Accounts receivable, trade	\$ 51	\$ 39
Inventory		285
Assets held for sale	263	737
Total assets	\$ 314	\$1,061
Current liabilities:		
Accounts payable	—	92
Accrued expenses	1,761	98
Total current liabilities	\$1,761	<u>\$ 190</u>

The Company owns the manufacturing equipment located at its dissolvable manufacturing facility in Chase City, Virginia which is being held for sale as a result of the Company decision to exit the dissolvable business as of December 31, 2012.

#### 4. Inventories:

Inventories consist of the following:

\$ Thousands	2012	2011
Raw materials	\$ 3,100	\$1,178
Packaging materials	1,470	1,413
Work-in-process	158	96
Finished goods	1,350	679
Total inventories	6,078	\$3,366
Less obsolescence and overstock reserve	(1,089)	(912)
Net inventories	\$ 4,989	\$2,454

#### 5. Property and equipment:

Property and equipment consists of the following:

\$ Thousands	2012	2011
Leasehold improvements	\$	\$
Machinery and equipment	1,650	682
Vehicles	62	62
Office and sales equipment	141	132
Construction in Progress	_	986
Total property and equipment	1,853	1,862
Less accumulated depreciation	(515)	(251)
Property and equipment-net	\$1,338	\$1,611

The Company owns specialized packaging equipment that has been installed at its dietary supplement contract manufacturing vendor to package  $CigRx^{\oplus}$  and  $Anatabloc^{\oplus}$  in its 20 piece container format. The Company also has invested in equipment to process anatabine, the primary ingredient in Anatabloc<sup>®</sup>, Anatabloc<sup>®</sup> Facial Crème and CigRx<sup>®</sup>, at a separate contract manufacturer facility.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 5. Property and equipment: – (continued)

Depreciation expense is included in the consolidated statement of operations for the years ended December 31, 2012, 2011 and 2010, as follows:

\$ thousands	2012	2011	2010
Cost of goods sold	\$236	\$ 97	\$40
Operating expenses	28	31	33
Total depreciation expense	\$264	\$128	\$73

#### 6. Intangible assets:

Intangible assets consist of the following:

\$ thousands	2012	2011
Patents	\$1,178	\$1,147
Trademarks and other intangibles	83	83
	1,261	1,230
Less: Accumulated Amortization	(720)	(652)
	\$ 541	<u>\$ 578</u>

Amortization expense associated with the intangibles was \$68, \$67 and \$64 thousand in 2012, 2011 and 2010, respectively. An aggregate of \$83 thousand in trademarks have indefinite lives and are therefore not amortized. Expected future amortization of intangibles with finite lives is as follows:

Years ending December 31,	\$ thousands
2013	\$ 70
2014	70
2015	69
2016	68
2017	60
Thereafter	121
	\$458

#### 7. Long-term debt:

The Company's principal long-term debt consisted of unsecured promissory notes arising from its prior business relationship with Brown & Williamson Tobacco Co., or B&W. Following the combination of the operations of RJR and B&W in 2004, those notes were being paid to RJR and had a principal balance of \$3.4 million as of August 1, 2012. As part of the resolution of the RJR litigation, the outstanding principal balance of the debt (\$3.4 million), plus any accrued interest was satisfied and forgiven and the notes were returned to the Company as satisfied (see Note 14 for further details of the resolution of the RJR litigation).

The Company's remaining long-term debt, as of December 31, 2012, consists of an installment note secured by a vehicle purchased in 2010. The note is for a term of 36 months with monthly installment payments of \$1,700 and continues until April 2013. The annual interest rate on the note is fixed at 1.9% for the note term. The current balance outstanding is \$7 thousand and is reflected as the Company's current portion of long-term debt on the consolidated balance sheet.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 8. Stockholders' equity:

#### Warrants:

The Company grants common stock warrants in connection with direct equity shares purchased by investors as an additional incentive for providing long-term equity capital to the Company and as additional compensation to consultants and advisors. The warrants are granted at negotiated prices in connection with the equity share purchases and at the market price of the common stock in other instances. The warrants have been issued for various terms ranging from several months to ten years.

Common stock warrants issued, redeemed and outstanding during the years ended December 31, 2012, 2011 and 2010 are as follows:

	Number	Weighted Average Exercise Price Per Share
Warrants		
Warrants outstanding at January 1, 2010	17,311,889	\$ 2.11
Warrants issued during 2010	13,939,162	1.65
Warrants exercised during 2010	_	
Warrants expired during 2010	(210,526)	(2.38)
Warrants outstanding at December 31, 2010	31,040,525	\$ 1.65
Warrants issued during 2011	11,311,182	2.16
Warrants exercised during 2011	(6,400,000)	(1.30)
Warrants expired during 2011		
Warrants outstanding at December 31, 2011	35,951,707	\$ 1.87
Warrants issued during 2012	6,225,254	4.05
Warrants exercised during 2012	(25,667,794)	1.21
Warrants expired during 2012		<u> </u>
Warrants outstanding at December 31, 2012	16,509,167	\$ 1.79

Sale of equity securities and exercise of warrants 2010:

Between March 5 and March 12, 2010, the Company entered into Securities Purchase Agreements and Registration Rights Agreements ("the "Agreements") with accredited investors (individually "Investor" and collectively "Investors") for an aggregate of 11,727,120 shares of its common stock at the consolidated closing bid price and a combination of new warrants for an aggregate of 6,323,727 shares and the repricing of 5,403,393 shares of previously issued warrants. In the aggregate the transactions resulted in gross proceeds to the Company of \$13.8 million. The details of the transactions follow:

On March 5, 2010 the Company sold to Investors 3,649,007 shares of its Common Stock at \$1.05 per share and reduced the exercise price on 3,649,007 warrants previously issued to the Investors from \$3.50 to \$1.50 per warrant and on March 9, 2010 the Company sold to other Investors 1,754,386 shares of its Common Stock at \$1.14 per share and reduced the exercise price on 1,754,386 warrants previously issued to the investors from \$2.00 to \$1.50 per warrant. Additionally, the Agreements granted the Investor certain registration rights with respect to the Common Stock.

On March 9, 2010 the Company also entered into an Agreement with another Investor who purchased 4,385,965 shares of the Common Stock at \$1.14 per share and the investor received a warrant to purchase an equal number of warrant shares at an exercise price of \$1.50 per share. On the same day, a Company Insider purchased 2,371,541 shares of Common Stock at \$1.14 per share and, for a price of \$0.125 per share, purchased a warrant for an equal number of warrant shares at an exercise price of \$1.50 per share. On March 10, 2010, the Company also entered into an Agreement with an Investor who purchased 769,230 shares of the Common Stock at \$1.30 per share and received a warrant to purchase an equal number of warrant shares at an exercise price of \$1.50 per share. On March 12, 2010, the Company also entered into an Agreement with an Investor who purchased 769,230 shares of the Common Stock at \$1.50 per share. On March 12, 2010, the Company also entered into an Agreement with an investor who purchased 769,230 shares of the Common Stock at \$1.50 per share. On March 12, 2010, the Company also entered into an Agreement with an investor who purchased 769,230 shares of the Common Stock at \$1.50 per share. On March 12, 2010, the Company also entered into an

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## 8. Stockholders' equity: - (continued)

Agreement with an Investor who purchased 1,428,571 shares of the Common Stock at \$1.40 per share and received a warrant to purchase an equal number of warrant shares at an exercise price of \$1.50 per share. The warrants, in all cases, were first exercisable six months after the closing of the offering and expire five years after the date that the warrants were first exercisable. The warrants issued on March 9, 2010 and March 10, 2010 are callable by the Company if the price of the Common Stock exceeds \$3.00 per share as quoted on an approved market for twenty consecutive trading days. The warrants issued on March 12, 2010 are callable by the Company if the price of the Common Stock exceeds \$10.00 per share as quoted on an approved market for twenty consecutive trading days. Additionally, the Agreements grant the Investors certain registration rights with respect to the Common Stock and warrant shares.

On March 12, 2010, the Company and an Investor in the Second March 9 Offering agreed to amend the Second March 9 Agreement only to reduce each of the number of shares of Common Stock and warrants purchased by such Investor to 1,754,385 from 4,385,965 (the "Amended Agreement"). After giving effect to the Amended Agreement, the Second March 9 Offering resulted in gross proceeds to the Company of approximately \$2,000,000 and a reduction of the amount of the Second March 9 Offering by approximately \$3,000,000.

The Offering was made only to accredited investors, as such term is defined in Rule 501 of Regulation D promulgated under the Securities Act. The Company relied on the exemption from the registration requirements of the Securities Act set forth in Section 4(2) thereof and the rules and regulations promulgated thereunder.

On November 5, 2010, the Company entered into a Securities Purchase Agreement and Registration Rights Agreement (the "November Agreement") with certain accredited investor (the "Investors"), including several executive officers and directors of the Company (the "Executives"), to sell 7,615,000 shares of Common Stock at \$1.80 per share and warrants to purchase an aggregate of 7,615,000 shares of Common Stock at an exercise price of \$1.80 per share. In addition to purchasing their respective shares of Common Stock for \$1.80 per share, the executives and directors also paid the Company \$0.125 per warrant purchased in the offering. The offering resulted in gross proceeds to the Company of \$14.0 million. The warrants were first exercisable six months after the closing of the offering and expire five years after the date that the warrants are first exercisable. The warrants are also callable by the Company if the price of the Common Stock exceeds \$10.00 per share as quoted on an approved market for twenty consecutive trading days. Additionally, the November Agreement grants the Investors certain customary resale registration rights with respect to the Shares and shares of Common Stock underlying the warrants.

The offerings referred to above were made only to accredited investors, as such term is defined in Rule 501 of Regulation D promulgated under the Securities Act. The Company relied on the exemption from the registration requirements of the Securities Act set forth in Section 4(2) thereof and the rules and regulations promulgated thereunder in connection with this transaction. In accordance with the Company's related party transaction policy, the Executives intention to purchase shares and warrant shares of the Company's stock was considered by the Audit Committee at a meeting held on November 3, 2010 and was approved by the Audit Committee on that date and the Board of Directors at a meeting held on November 5, 2010.

The Company had no warrants exercised during the twelve months ended December 31, 2010. As of December 31, 2010 the Company had 31,040,525 warrants outstanding with a weighted average exercise price of \$1.65 per share.

### Sale of equity securities and exercise of warrants 2011:

On February 28, 2011, the Company entered into a Securities Purchase and Registration Rights Agreement (the "February 28 Agreement") with an accredited investor who held previously issued warrants (the "Warrant Holder") for 2,000,000 shares of the Company's common stock, par value \$0.0001 per share, at

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## 8. Stockholders' equity: - (continued)

an exercise price of \$1.00 per share (the "Prior Warrants"). Pursuant to the February 28 Agreement, the Warrant Holder exercised on the Prior Warrants and the Company granted the Warrant Holder new warrants with an exercise price of \$2.00 per share for the same amount of shares of common stock as the Prior Warrants (the "New Warrants"). The February 28 Agreement resulted in gross proceeds to the Company of \$2.0 million. The New Warrants were exercisable immediately into an aggregate of 2,000,000 shares of common stock and expire on February 28, 2016.

On March 4, 2011, the Company entered into a Securities Purchase and Registration Rights Agreement (the "March 4 Agreement") with certain accredited investors (the "March 4 Investors"), to sell 4,856,730 shares of common stock (the "March 4 Shares") and warrants to purchase an aggregate of 4,856,730 shares of common stock at an exercise price of \$2.00 per share (the "Warrants") (collectively, the "March 4 Offering"). The March 4 Offering resulted in gross proceeds to the Company of \$9.0 million. The Warrants were first exercisable on September 4, 2011 and expire on September 4, 2016.

On March 30, 2011, the Company entered into a Securities Purchase and Registration Rights Agreement (the "March 30 Agreement") with an accredited investor (the "March 30 Investor"), to sell 254,452 shares of common stock (the "March 30 Shares"), and warrants to purchase an aggregate of 254,452 shares of common stock at an exercise price of \$4.00 per share (the "Warrants") (collectively, the "March 30 Offering"). The March 30 Offering resulted in gross proceeds to the Company of \$1.0 million. The Warrants were first exercisable on September 30, 2011 and expire on September 30, 2016.

On June 4, 2011, 200,000 warrants were exercised resulting in proceeds to the Company of \$0.2 million.

On December 22, 2011, the Company entered into a Securities Purchase and Registration Rights Agreement (the "December 22 Agreement") with an accredited investor who held previously issued warrants (the "Warrant Holder") for 5,000,000 shares of the Company's common stock, par value \$0.0001 per share, at an exercise price of \$1.50 per share (the "Prior Warrants"). Pursuant to the December 22 Agreement, the Warrant Holder exercised on 4,200,000 of the Prior Warrant shares and the Company granted the Warrant Holder new warrants with an exercise price of \$2.32 per share for the same amount of shares of common stock as the exercised portion of the Prior Warrants (the "New Warrants"). The December 22 Agreement resulted in gross proceeds to the Company of \$6.3 million. The New Warrants were exercisable immediately into an aggregate of 4,200,000 shares of common stock and expire on December 22, 2016.

## Sale of equity securities and exercise of warrants 2012:

On February 28, 2012, the Company entered into a Securities Purchase and Registration Rights Agreement ("Agreement No. 1") with an accredited investor (the "Investor") who held previously issued warrants for: (i) 3,260,869 shares of the Company's common stock, par value \$0.0001 per share ("Common Stock"), at an exercise price of \$2.00 per share and (ii) 2,554,385 shares of the Company's Common Stock at an exercise price of \$1.50 per share (collectively, the "Prior Warrants").

Pursuant to Agreement No. 1, in order to induce the Investor to immediately exercise the Prior Warrants, the Company agreed to grant the Investor new warrants with an exercise price of \$4.05 per share for the same amount of shares of Common Stock as the Prior Warrants (the "New Warrants") in exchange for the exercise of the Investor's Prior Warrants for cash whereby the Investor purchased 5,815,254 shares of Common Stock for gross proceeds to the Company of \$10.4 million (collectively, the "First February 28 Transaction"). The New Warrants were exercisable immediately into an aggregate of 5,815,254 shares of Common Stock and expire on February 28, 2017.

Additionally, on February 28, 2012, the Company entered into a Securities Purchase and Registration Rights Agreement ("Agreement No. 2") with the Investor to sell 410,000 shares (the "Shares") of the Company's Common Stock at \$4.05 per share and warrants to purchase an aggregate of 410,000 shares of Common Stock at an exercise price of \$4.05 per share (the "Warrants") (collectively, the

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 8. Stockholders' equity: - (continued)

"Second February 28 Transaction"). The Second February 28 Transaction resulted in gross proceeds to the Company of \$1.7 million. The Warrants are first exercisable on August 28, 2012 and expire on August 28, 2017.

Pursuant to a warrant reset agreement, between November 13 and 15, 2012, holders of previously issued warrants exercisable for 18,500,000 shares of the Company's common stock, par value \$0.0001 per share ("Common Stock"), with a weighted average exercise price of \$2.71 per share (the "Prior Warrants"), agreed with the Company to immediately exercise the Prior Warrants for cash in exchange for a reduction of exercise price of the Prior Warrants to \$1.00 per share. Mr. Williams also exercised 1,000,000 warrants issued to him in a prior transaction at the full warrant exercise price of \$1.50 per share. The gross proceeds from the exercise of the Prior Warrants and Mr. Williams' exercise of his warrants resulted in gross proceeds to the Company of \$20 million. The exercise resulted in the issuance of 19,500,000 shares of Common Stock and the cancellation of warrants exercisable for 19,500,000 shares of Common Stock.

In addition to the warrants exercised noted above, 352,540 warrants were exercised during the year ended December 31, 2012 resulting in gross proceeds to the Company of \$0.5 million.

#### Stock option plans:

Prior to 2008 the Company adopted a 1998 Stock Option Plan, a 2000 Equity Incentive Plan, and in September 2008 it adopted a 2008 Incentive Award Plan (the "Plans"). The Plans provide for grants of options to those officers, key employees, directors and consultants whose substantial contributions are essential to the continued growth and success of the Company. In the aggregate the Plans provide for grants of both qualified and non-qualified stock options to purchase up to 24,900,000 shares at a purchase price equal to the fair market value on the date of grant in the case of qualified options granted to employees.

Common stock options issued, redeemed and outstanding during the years ended December 31, 2012, 2011 and 2010 are as follows:

	Number	Weighted Average Exercise Price Per Share	Grant Date Fair Value
Options			
Options outstanding at January 1, 2010	4,555,200	\$ 2.28	\$0.77
Options forfeited during 2010	(729,000)	(3.97)	
Options exercised during 2010			
Options issued during 2010	3,890,000	2.65	
Options outstanding at December 31, 2010	7,716,200	\$ 2.31	\$1.74
Options forfeited during 2011	(186,200)	(3.12)	
Options exercised during 2011	(625,000)	(1.53)	
Options issued during 2011	10,084,000	2.90	
Options outstanding at December 31, 2011	16,989,000	\$ 2.68	\$2.16
Options forfeited during 2012	(50,000)	(3.99)	
Options exercised during 2012	(664,000)	(2.10)	
Options issued during 2012	1,320,000	3.13	
Options outstanding at December 31, 2012	17,595,000	2.73	\$2.19

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## 8. Stockholders' equity: - (continued)

The following table summarizes information for options outstanding and exercisable at December 31, 2012.

	Options Outstanding			Exercisable			
Range of Prices	Number	Weighted Avg. Remaining Life Years	Weighted Avg. Exercise Price	Aggregate Intrinsic Value	Number	Weighted Avg. Exercise Price	Aggregate Intrinsic Value
\$0.74 - 2.00	2,925,000	4.0	1.68	\$2,934,350	2,925,000	1.68	\$2,934,350
2.01 - 3.00	13,070,000	7.9	2.88	114,000	9,805,000	2.85	114,000
3.01 – 4.00	1,295,000	8.1	3.23		1,245,000	3.23	·
4.01 – 4.95	305,000	3.0	4.43		285,000	4.46	
\$0.70 - 4.95	17,595,000			\$3,048,350	14,260,000		\$3,048,350

A summary of the status of the Company's non-vested stock options as of December 31, 2012, and changes during the year then ended, is presented below.

Non-vested Stock Options	Shares	Weighted Average Grant-Date Fair Value
Non-vested at December 31, 2011	3,395,000	\$ 2.95
Granted	150,000	2.45
Vested	(210,000)	(2.32)
Forfeited	·	·
Non-vested at December 31, 2012	3,335,000	\$ 2.51

As of December 31, 2012, there was approximately \$8.0 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plans. Of the \$8.0 million of unrecognized compensation costs \$7.8 million relates to performance based stock options granted to Mr. Williams and Mr. Perito in 2011, which will be recognized upon satisfaction of the performance goals outlined in the agreement approved by the shareholders in December 2011. The remaining \$0.2 million cost will be recognized over the next two years. There were 664,000 options exercised in the year ended December 31, 2012 with an intrinsic value of \$1.1 million.

The fair value of options was estimated on the date of grant issuance using the Black-Scholes option pricing model with the following weighted average assumptions:

	2012	2011	2010
Expected life of options based on			
simplified method for employees	2 – 5 years	2-5 years	2 – 5 years
Risk free interest rate	0.31 - 1.04%	0.92 - 2.06%	1.15 - 2.75%
Expected volatility	111.27 - 121.85%	123.85 - 128.76%	122.85 - 125.79%
Expected dividend yield	0%	0%	0%

Total stock-based compensation (stock and stock option) cost recognized is as follows:

\$ thousands	2012	2011	2010
Employee	\$3,121	\$15,733	\$8,320
Non-employee consultants and directors	1,471	1,529	229
	\$4,592	\$17,262	\$8,549

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 8. Stockholders' equity: - (continued)

In 2012 the Company issued a total of 330,000 shares of common stock to employees as part of a severance plan granted to long term employees who transitioned from the Company as a result of the discontinuation of its dissolvable tobacco business and 50,000 shares of common stock to a marketing consultant. The total of 380,000 shares of common stock had a fair value of \$1.2 million. These shares were issued from the Company's 2008 Incentive Award Plan.

### 9. Earnings per share:

The following table sets forth the computation of basic and diluted earnings per share for the years ended December 31:

\$ and shares in thousands except per share data	2012	2011	2010
Net Loss from continuing operations	\$(18,100)	\$ (35,893)	\$(25,829)
Discontinued operations	(4,753)	(2,095)	(2,452)
Net loss	\$(22,853)	<u>\$(37,988</u> )	<u>\$(28,281</u> )
Denominator for basic earnings per share – weighted average shares	146,996	133,640	118,384
Effect of dilutive securities: stock options and warrants outstanding <sup>(a)</sup>		۲ 	·
Denominator for diluted earnings per share – weighted average shares adjusted for dilutive securities	146,996	133,640	118,384
Net loss per common share from continuing operations basic and diluted	\$ (0.12)	· \$ (0.27)	\$ (0.22)
Discontinued operations basic and diluted	(0.03)	(0.01)	(0.02)
Loss per common share – basic and diluted	<u>\$ (0.15)</u>	<u>\$ (0.28)</u>	<u>\$ (0.24)</u>

(a) Securities outstanding that were excluded from the computation because they would have been anti-dilutive are as follows:

	2012	2011	2010
Stock options and warrants	 34,104,167	52,940,707	38,756,725

#### 10. Income taxes:

Net deferred tax assets and liabilities consist of the following:

\$ thousand	2012	2011
Deferred tax assets:		
Net operating loss carry-forwards (portions subject to annual limitation)	\$69,824	\$63,221
Credit carry-forward	477	449
Stock option compensation	11,834	11,104
Differing basis in property and equipment for tax and financial reporting		
purposes	(194)	(83)
Inventory Reserve	600	488
Accrued severance cost	651	—
Other	822	106
	84,014	75,285

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 10. Income taxes: - (continued)

\$ thousand	2012	2011
Deferred tax liabilities:		
MSA escrow payments taxable in future	(180)	(138)
Valuation Allowance*	(83,834)	(75,147)
· · · · · · · · · · · · · · · · · · ·	<del>\$</del> —	\$

\* Based on the information available, management believes the allowance is appropriate.
 Income tax benefit consists of the following:

	2012	2011	2010
Current:			
Federal	\$—	\$—	\$—
State			
Deferred benefit	<u> </u>		
	\$	\$	<b>\$</b> —

The provision for income tax expense varies from that which would be expected based on applying the statutory federal rate to pre-tax accounting loss as follows:

	2012	2011	2010
Statutory federal rate	(34.00)%	(34.00)%	(34.00)%
Permanent items	(0.27)	0.14	(0.33)
State tax provision, net of federal benefit	(3.45)	(3.45)	(3.45)
Valuation allowance	37.72	37.31	37.78
	(0.00)%	(0.00)%	(0.00)%

At December 31, 2012, the Company had net operating loss carry-forwards of approximately \$188.7 million, which expire from 2012 through 2031. As a result of previous ownership changes, an aggregate of \$532 thousand in Federal loss carry-forwards are limited to \$116 thousand annually.

#### 11. Related party transactions:

## Related party activity:

The Company has entered into certain transactions with companies that are owned by members of management and stockholders and with one Director. The following is a summary of the significant related party transactions for the year ended December 31:

\$ thousands		2012	2011	2010
Business travel – aircraft expense	······································	\$1,857	\$2,003	\$1,654

Effective September 1, 2008, the Company entered into an agreement for the use of the aircraft owned by Starwood Aviation, Inc., a company wholly owned by Mr. Williams, Star's CEO. The 2008 agreement with Starwood Aviation, Inc. was amended in May 2010 to clarify the types of items that would be included as "out of pocket" expenses and to recognize that certain costs, such as for fuel, would be variable depending on the actual cost of the item at the time of use.

## Related party license agreement:

Effective January 1, 1998, Star entered into an exclusive license agreement with Regent Court Technology, LLC, of which the Company's founder, Chief Executive Officer and one of the Company's shareholders, and the beneficiary of the O'Donnell Trust, are the owners. Pursuant to this license agreement, Star has the exclusive world-wide rights to produce and sell tobacco products with low-TSNA tobacco and to

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 11. Related party transactions: - (continued)

sublicense that technology to third parties. In connection with this agreement, Star is obligated to pay royalties equal to 2% of all product sales (less certain costs incurred by the Company) and 6% of any royalty income earned from sublicensing (less certain costs incurred by the Company). Since the costs incurred by the Company were in excess of the royalty obligations there were no royalties due under this agreement for 2012, 2011 or 2010.

#### Due (to) from stockholders:

Due (to) from Stockholders consists of unsecured non-interest bearing advances of \$(50) thousand as of December 31, 2012 and December 31, 2011.

#### Share purchase and warrant exercise:

On March 9, 2010 Mr. Williams purchased 2,371,541 shares of the Company's common stock at a price of \$1.14 per share and, for a price of \$0.125 per share, purchased a warrant for an equal number of warrant shares at an exercise price of \$1.50 per share and on November 5, 2010 Mr. Williams purchased 717,220 shares of our common stock at a price of \$1.80 per share and, for a price of \$0.125 per share, purchased a warrant for an equal number of warrant shares at an exercise price of \$1.80 per share and, for a price of \$1.80 per share, purchased a warrant for an equal number of warrant shares at an exercise price of \$1.80 per share. On November 5, 2010 Messrs. Chayet, Haynes and Perito purchased 2,000, 10,000 and 50,000 shares, respectively, of our common stock at a price of \$1.80 per share and, for a price of \$0.125 per share, purchased a warrant for an equal number of warrant shares at an exercise price of \$1.80 per share. In accordance with the Company's related party transaction policy, Mr. Williams' intention to purchase shares and warrant shares of our company's stock was considered by the Audit Committee at meetings held on March 9, 2010 and November 5, 2010 respectively and was approved by the Audit Committee and the Board of Directors on those dates. The purchase of shares by Messrs. Chayet, Haynes and Perito also was approved by the Audit Committee at the meeting held on November 5, 2010.

On March 4, 2011 Mr. Williams purchased 508,905 shares of our common stock at a price of \$1.84 per share and, for a price of \$0.125 per share, purchased a warrant for an equal number of warrant shares at an exercise price of \$2.00 per share. In accordance with the Company's related party transaction policy, Mr. Williams' intention to purchase shares and warrant shares of the Company's stock was considered and approved by the Audit Committee of the Board of Directors on March 4<sup>th</sup>. See Note 7, "Stockholders' Equity" for details of the transaction.

On November 15, 2012, Star Scientific CEO Jonnie R. Williams exercised 1,000,000 warrants previously issued to him in a prior transaction at the full warrant exercise price of \$1.50 per share for a personal investment of \$1,500,000.

#### Consulting Agreement:

On March 15, 2010, Rock Creek entered into a consulting agreement with Neil L. Chayet, Esquire, for Mr. Chayet to assist Rock Creek in the recruitment and recommendation of members to be appointed to a Scientific Advisor Board of Rock Creek and in communicating to the public health community and others information regarding Rock Creek's products and mission. The agreement ran for a period of one year from March 15, 2010 and was terminated on March 15, 2011. Under the agreement, Mr. Chayet acted as an independent contractor and received a consulting fee of \$6,000 per month and reimbursement for reasonable business expenses. The term of the agreement was one year renewable by the Board of Directors annually. Given Mr. Chayet's status as a Director of Star Scientific, the consideration of the consulting agreement and its potential impact on Mr. Chayet's status as an Independent Director was considered by the Company's Audit Committee as a related party transaction in accordance with the Company's related party transaction policy. At a meeting held on March 9, 2010, the Audit Committee approved the consulting agreement and recommended approval to the Board of Directors. The agreement was thereafter approved by the Board on March 15, 2010. This agreement was not renewed in 2011.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## 12. Employee benefit plan:

The Company is the sponsor of a defined contribution retirement plan under Section 401(k) of the Internal Revenue Code. The plan covers all employees who meet certain eligibility and participation requirements. Participants may contribute up to 15% of their annual compensation. The Company matches these contributions at a rate of 75% of the first 6% of pay that an employee contributes to the plan. The Company made contributions of approximately \$108, \$98, and \$83 thousand to the 401-K Plan in 2012, 2011 and 2010, respectively.

## 13. Fair value of financial instruments, concentrations and credit risk and major customer information:

#### Fair value of financial instruments:

The estimated fair value of cash and cash equivalents, trade receivables, licensing rights receivable, MSA escrow funds, due from and to stockholders and trade payables approximate the carrying value due to their short-term nature, variable interest rates or interest rates charged at rates at which the Company can currently borrow. On September 21, 2012 the Company and RJR reached a settlement of pending litigation matters and, as part of the settlement, the Company's long-term debt with RJR was forgiven.

Differences between fair value and carrying amount of long-term debt are primarily due to instruments that provide fixed interest or zero interest rates or contain fixed interest rate elements. Inherently, such instruments are subject to fluctuations in fair value due to subsequent movements in interest rates.

#### Credit risk and major customer information:

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents, accounts receivable and licensing rights receivable.

The Federal Deposit Insurance Corporation, insures up to \$250,000 for substantially all interest bearing depository accounts. During 2012 the Company had amounts on deposit which exceed these insured limits and as of December 31, 2012, had \$5.0 million which exceeded these insured limits.

Trade accounts receivable for the Company's smokeless tobacco products resulted from sales of tobacco products to various customers throughout the United States. Through December 31, 2012 credit was extended to customers after an evaluation for credit worthiness. With the discontinuation of the sale of any tobacco products after December 31, 2012 any credit will be limited to that granted for product sold prior to the end of 2012. As of December 31, 2012 there was \$51 thousand of tobacco related accounts receivable included in the discontinued assets. Subsequent to December 31, 2012 all of the net accounts receivable had been collected.

The receivable from the sale of licensing rights is collectible in monthly installments and \$3.1 million of the \$3.2 million due under the agreement had been collected by December 31, 2012. All required payments to date have been timely received. As such, management believes this receivable is fully collectible.

The Company's dietary supplement products, Anatabloc<sup>®</sup> and CigRx<sup>®</sup>, and its cosmetic product, Anatabloc<sup>®</sup> Facial Crème are sold directly to consumers through credit card transactions that are approved prior to shipment. Anatabloc<sup>®</sup> is also sold through retailers who maintain a stock of the product on a consignment basis. The Company is paid weekly for cash sales at these retail locations.

In 2012 the Company sold approximately 51% of it's Anatabloc<sup>®</sup> product through its consignment arrangement with GNC. Pursuant to this arrangement, the Company is paid weekly for sales from the previous week. The accounts receivable for consignment sales therefore is not outstanding for a period longer than 7 days.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 14. Commitments, contingencies, and other matters:

## **Operating** leases:

The Company leases a warehouse and manufacturing facility that was used for manufacturing of its dissolvable tobacco products through December 31, 2012. The cost for this lease, which expires in 2022, is approximately \$7 thousand per month. Because the lease is non-cancellable, the Company is obligated to continue the lease payments through the lease term; however, it will look for opportunities to sublease this facility. The Company also leases office space for its Rock Creek subsidiary in Gloucester, Massachusetts for approximately \$5 thousand per month, maintains space for Star Scientific and Rock Creek in the Washington, DC area at a cost of approximately \$12 thousand per month and began leasing office space in February 2010 in Glen Allen, Virginia for its corporate marketing and administrative activities for approximately \$3 thousand per month.

The following represents the future minimum rental payments required under operating leases that have initial or remaining non-cancelable terms in excess of one year as of December 31, 2012.

Year ending December 31,		۰.				\$ thousand
2013		• •	••	•	• ÷	\$ 366
2014				•	•	274
2015	•••	• •		•	•	114
2016						
2017		• •	•	•	• •	, <b>71</b>
Thereafter		• •		•	•	274
						<u>\$1,190</u>

Rent expense for all operating leases was approximately \$343, \$296 and \$258 thousand for the years ended December 31, 2012, 2011 and 2010, respectively.

#### Obligations under master settlement agreement:

In November 1998, 46 states and the District of Columbia, the Settling States, entered into the Master Settlement Agreement, or MSA, to resolve litigation that had been instituted against the major cigarette manufacturers. The Company was not named as a defendant in any of the litigation matters and chose not to become a participating manufacturer under the terms of the MSA. As a non-participating manufacturer, the Company was required to satisfy certain escrow obligations for cigarette sales pursuant to statutes that the MSA required the Settling States to adopt in order for such states to receive the full benefits of the settlement. On March 14, 2007, the Company sold the rights, title and interest in and to all income from and reversionary interest in its MSA escrow accounts, including its 2006 MSA escrow deposits made in April 2007. Although the Company sold the rights in and to all income from and reversionary interest in the funds deposited into the MSA escrow accounts for the years up to and including 2006, these MSA escrow funds remain in the Company's name and the principal amount of these accounts will be available to satisfy portions of any state judgments or settlements for the type of claims asserted against the major tobacco manufacturers in the suits that resulted in the negotiation of the MSA, if such claims are successfully asserted in litigation against the Company.

As of December 31, 2011, the Company had deposited into escrow a net amount of approximately \$368 thousand for sales of cigarettes in Settling States, in addition to deposits for which the Company previously sold its rights, title and interest as part of the March 2007 transaction noted above. The Company's total escrow obligation for 2007 sales (paid in April of 2008) was \$365 thousand. In May 2007, the Company entered into a license agreement for the exclusive licensing of its trademarks Sport<sup>®</sup>, MainStreet<sup>®</sup> and GSmoke<sup>®</sup> and ceased manufacturing cigarettes in June 2007. In 2010 deposited \$3 thousand into escrow for sales in 2006 and 2007 in the State of Tennessee, based on an audit of cigarette sales for those years. The Company made no deposits into escrow in 2011. In 2012 the Company deposited \$113 thousand as a result of an audit by the State of Tennessee. Given the discontinuation of the Company's cigarette operations in June 2007, the Company does not anticipate having any material MSA escrow obligations in the future.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 14. Commitments, contingencies, and other matters: - (continued)

## **RJR** Litigation

In May 2001, the Company filed a patent infringement action against RJR in the United States District Court for Maryland, Southern Division, or District Court, to enforce its rights under U.S. Patent No. 6,202,649 ('649 Patent), which claims a process for substantially preventing the formation of TSNAs in tobacco. On July 30, 2002, it filed a second patent infringement lawsuit against RJR in the District Court based on a new patent issued by the U.S. Patent and Trademark Office on July 30, 2002 (Patent No. 6,425,401) ('401 Patent). The new patent is a continuation of the '649 Patent, and on August 27, 2002, the two cases were consolidated.

The consolidated cases were tried to a jury in the District Court between May 18, 2009 and June 16, 2009. At the conclusion of the trial, the jury returned a verdict in favor of RJR holding that there was no infringement of the two patents at issue in the case and that the patents were invalid due to anticipation, obviousness, indefiniteness and failure to disclose best mode. On July 7, 2009, the Company filed a motion with the District Court for Judgment as a Matter of Law or, in the Alternative, for a New Trial. That motion was denied on December 21, 2009 and judgment was entered on the jury verdict that day. The Company filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit Court of Appeals on December 22, 2009 and its opening brief was filed on May 5, 2010. After full briefing, Oral argument on the appeal was held before a three-judge Panel of the Federal Circuit Court of Appeals on January 11, 2011. In a decision issued on August 26, 2011, the Court of Appeals reversed the jury finding as to the patent defenses of anticipation, obviousness, indefiniteness and failure to disclose best mode and reconfirmed the validity of the patent claims at issue in the litigation. At the same time the Court of Appeals affirmed the jury finding of non-infringement for the growing years at issue in the litigation. On November 29, 2011 the Federal Circuit denied RJR's Petition for Rehearing and Rehearing en Banc and the case was remanded to the District Court on December 15, 2011. On January 26, 2012, following a conference with counsel, the District Court issued an order referring this action and the second RJR case to a magistrate judge for mediation/settlement discussions. On September 21, 2012 the Company and RJR reached a settlement of the consolidated cases and, as part of the settlement, joint stipulations of dismissals with prejudice were filed in each of the consolidated cases and were entered by the District Court on September 24, 2012.

On March 28, 2012, RJR filed a petition for certiorari with the Supreme Court to review the Federal Circuit Court of Appeals decision as to the definiteness of the patents at issue in the RJR litigation. The Company's response to the petition for certiorari was filed on May 29, 2012. As part of the settlement between the Company and RJR, RJR's petition for certiorari was dismissed on joint motion of the parties prior to consideration of the petition for certiorari by the Supreme Court.

On November 30, 2009, RJR filed a motion for a bill of costs for \$442,388.05. RJR also filed a motion requesting the District Court to determine that this is an "exceptional" case under 35 U.S.C. §285 and award attorneys' fees of approximately \$35 million under that provision and/or under 28 U.S.C. §1927 on the basis that attorneys' fees were unreasonably multiplied during the litigation. As part of Orders issued on December 21, 2009, the District Court stayed the motion for attorneys' fees until after a ruling on the pending appeal and the reexamination before the U.S. Patent and Trademark Office. The Court on January 8, 2010, stayed any further briefing on the renewed petition for a bill of cost that RJR filed on December 30, 2009. The stipulations of dismissal filed in the two consolidated cases pending in the District Court as part of the RJR settlement provided that each side in those actions would bear its own costs and attorneys' fees. With the entry of dismissals by the District Court, RJR's motion for attorneys' fees and costs in the consolidated cases became moot.

On May 29, 2009, the Company filed a new complaint against RJR for patent infringement during the period beginning 2003 through the filing date of the complaint. In an Order dated January 8, 2010, the Court stayed any further action in this case until after a ruling on the appeal in the initial infringement actions against RJR. As noted above, this case was referred to a magistrate judge for mediation/settlement discussions under the Court order issued on January 26, 2012. As part of the settlement between the Company and RJR, a

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 14. Commitments, contingencies, and other matters: - (continued)

joint stipulation of dismissal with prejudice was filed with the District Court in this case and entered by the District Court on September 24, 2012. The stipulations of dismissal provided that each side in that action would bear its own costs and attorneys' fees.

With the entry of the stipulations of dismissals in these cases, all of the outstanding patent litigation matters between the Company and RJR were resolved and extinguished.

#### Virginia Sales and Use Tax Assessment

In 2002, the Virginia Department of Taxation asserted a Virginia Sales and Use Tax assessment for the period January 1, 1999, through March 31, 2002, against the Company with respect to its tobacco-curing barns in the amount of \$860,115. The Company applied for a correction of the assessment and a total abatement of the tax on the grounds that its barns are exempt from sales and use taxes under the industrial use and processing exemption and/or the agricultural exemption. In a letter dated October 7, 2004, the Company received notification from the Commonwealth of Virginia that an adverse decision had been made by the Commissioner of Taxation with respect to the sales and use tax assessment previously issued to the Company. On August 10, 2010 the Commonwealth of Virginia responded to the request for reconsideration of the state's sales and use tax assessment with respect to the tobacco curing barns. The Commonwealth disagreed with the Company's position that the barns are part of the manufacturing process and, therefore, exempt from sales and use taxes under the industrial use and processing exemption and/or the agricultural exemption, concluding that the barns are taxable under the Commonwealth's sales tax laws and regulation. On July 14, 2011 the Company filed a lawsuit in the Circuit Court for Mecklenburg County, Virginia seeking a determination that the purchase of the Company's curing barns was exempt from Virginia sales and use tax and an abatement of all taxes and interest assessed against the Company by Virginia's Commissioner of Revenue. The Commonwealth of Virginia filed an answer to the complaint on July 29, 2011 asserting that the assessment amount was properly determined. The matter is currently pending. The sales and use tax assessment plus penalties and interest together, as of December 31, 2012, totaled approximately \$1.7 million. Interest will continue to accrue during the Company's continued pursuit of a resolution of this matter.

#### CigRx<sup>®</sup> Trademark Litigation

On September 14, 2012, the Company filed an action in the United States District Court for the Central District of California against Cigirex, LLC alleging infringement of the Company's registered trademark CigRx<sup>®</sup> and related claims and seeking a declaratory judgment as to such infringement, injunctive relief and damages. That action is currently pending. Also, prior to filing the action against Cigirex in Federal District Court, the Company had been opposing the registration of the Cigirex mark in the PTO. After filing the District Court action against Cigirex, LLC, the Company filed a motion in the PTO proceeding seeking to have that proceeding suspended pending the outcome of the District Court case. That motion was granted by the PTO on November 26, 2012

#### **15. Restructure Charge**

In 2012, in conjunction with the discontinuation of the manufacture and sale of its low-TSNA dissolvable tobacco product, the Company incurred severance costs in the form of salary continuation payments and continued health benefit costs under COBRA of approximately \$829,000, for employees transitioning from Star Tobacco, Inc. as of December 31, 2012. In addition, the Company issued stock awards under the Company's 2008 Incentive Award Plan in the aggregate amount of 330,000 shares to those employees transitioning from Star Tobacco, in recognition of their long-time service to the Company. The stock awards had a total value of approximately \$1,1 million as well as a gross up charge for taxes of approximately \$0.8 million. The total cost in connection with the discontinuance of the Company's dissolvable tobacco business was approximately \$3.1 million consisting of cash and non-cash items all of which were recorded in the fourth quarter 2012.

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## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## 16. Subsequent Events:

#### Stock options issued

The Company granted 100,000 stock options and 125,685 shares of common stock to consultants to the Company on January 2, 2013. The stock options have a term of 5 years and vested immediately. The stock option grant has an exercise price of \$2.68. The Company recorded \$146 thousand as stock compensation expense computed using the Black-Scholes valuation method for those grants. The common stock was valued at \$2.68 per share or \$337 thousand for the aggregate of 125,685 shares.

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#### 17. Quarterly results (unaudited):

The following is a summary of quarterly unaudited results of operations for the years ended December 31, 2012, 2011 and 2010.

\$ thousands except per share date	March	June	September	December
2012			·	
Revenues	\$ 1,069	\$ 1,448	\$ 1,704	\$ 1,966
Gross profit (loss)	446	705,	696	777
Discontinued operations	(453)	(355)	(543)	(3,402)
Net loss	(5,171)	(7,996)	365	(10,051)
EPS – discontinued operations				(0.02)
EPS – net loss basic and diluted	(0.04)	(0.06)		(0.07)
2011				
Revenues	<b>\$</b> 46	\$ 131	\$ 279	\$ 789
Gross profit (loss)	(102)	(57)	(827)	369
Discontinued operations	(519)	(557)	(595)	(424)
Net loss	(6,085)	(5,000)	(6,565)	(20,341)
EPS – discontinued operations		_		_
EPS – net loss basic and diluted	(0.05)	(0.04)	(0.05)	(0.15)
2010				
Revenues	\$ —	<b>\$</b> —	\$ 28	\$ 35
Gross profit (loss)	(62)	(62)	(104)	(107)
Discontinued operations	(680)	(568)	(858)	(346)
Net loss	(4,925)	(13,501)	(4,822)	(4,952)
EPS – discontinued operations	(0.01)	<u> </u>	_	
EPS – net loss basic and diluted	(0.04)	(0.11)	(0.04)	(0.04)

Per share amounts for each quarter are required to be computed independently and, therefore, may not equal amounts computed on an annual basis.

#### **18. Segment Information**

The Company operated in two segments during 2012, 2011 and 2010 dietary supplements and dissolvable tobacco. However, in December 2012 the Company discontinued its operations in the dissolvable tobacco business and accordingly, has restated prior years information related to that business as discontinued operations on the face of the respective years financial statements. As of December 31, 2012 the Company only operates in one business segment, the results of which are presented in the financial statements. Accordingly, the Company has no segment information to present in footnote form in this Report.

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#### SECURITIES AND EXCHANGE COMMISSION Washington, DC 20549

#### FORM 10-K/A Amendment No. 1

# (Mark One)

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

For the fiscal year ended December 31, 2012 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: 000-15324

## **STAR SCIENTIFIC, INC.**

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

4470 Cox Road, Suite 110, Glen Allen, VA 23060 (Address of principal executive offices) 52-1402131 (I.R.S. Employer Identification No.)

(804) 527-1970 (Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: None Securities registered pursuant to Section 12(g) of the Act: Common Stock, \$0.0001 par value (Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined by Rule 405 of the Securities Act. Yes  $\Box$  No  $\checkmark$ 

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  $\square$  No  $\checkmark$ 

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  $\bigvee$  No  $\square$ 

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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  $\bigvee$  No  $\square$ 

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.  $\Box$ 

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a small reporting company.

Large accelerated filer	Accelerated filer 🔽
Non-accelerated filer	Small reporting company

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

The aggregate market value of the Registrant's voting stock held by non-affiliates of the Registrant as of June 30, 2012 was approximately \$533 million. Shares of voting stock held by each executive officer and director and by each person who owns 10% or more of the Registrant's voting stock have been excluded in that such persons may be deemed affiliates of the Registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes. Number of shares outstanding for each class common equity as of April 15, 2013, 166,491,509 shares of common stock, par value \$0.0001 per share.

#### **DOCUMENTS INCORPORATED BY REFERENCE:**

None

## EXPLANATORY NOTE — AMENDMENT

This Amendment No. 1 on Form 10-K/A (this "Amendment No. 1") amends our Annual Report on Form 10-K for the fiscal year ended December 31, 2012 (the "Original 10-K Filing"), as initially filed with the Securities and Exchange Commission on March 18, 2013. In accordance with General Instruction G to Form 10-K, the information required by Items 10, 11, 12, 13 and 14 of Part III was omitted from the Original 10-K Filing and, as indicated in the Original 10-K Filing, was to be filed as part of an amendment to the Original 10-K Filing not later than 120 days after the close of the Company's fiscal year ended December 31, 2012. Accordingly, we are filing this Amendment No. 1 solely for the purpose of providing the information required by Items 10, 11, 12, 13 and 14 of Part III of Form 10-K.

In addition, pursuant to Rule 12b-15 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), this Amendment No. 1 also contains new certifications by our principal executive officer and principal financial officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Accordingly, Item 15 of Part IV has also been amended to include the currently dated certifications as exhibits, and to reference the financial statements filed with the Original 10-K Filing. Because no financial statements have been included in this Amendment No. 1 and this Amendment No. 1 does not contain or amend any disclosure with respect to Items 307 and 308 of Regulation S-K under the Exchange Act, paragraphs 3, 4 and 5 of the certifications have been omitted. In addition, we have omitted the certifications required pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 because this Amendment No. 1 does not contain any financial statements.

Other than as described above, the Original 10-K Filing is unchanged and is not reproduced in this Amendment No. 1. Unless otherwise expressly stated, this Amendment No. 1 does not reflect events occurring after the filing of the Original 10-K Filing, nor does this Amendment No. 1 modify or update in any way disclosures contained in the Original 10-K Filing, including the Company's financial statements and the footnotes thereto. Accordingly, this Amendment No. 1 should be read in conjunction with the Original 10-K Filings.

#### PART III ITEM 10. Directors, Executive Officers and Corporate Governance 2 ITEM 11. Executive Compensation ..... 8 ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters 21 ITEM 13. Certain Relationships and Related Transactions, and Director Independence 23 ITEM 14. Principal Accountant Fees and Services ..... 24 PART IV ITEM 15. Exhibits, Financial Statement Schedules 25 SIGNATURES ..... 26 INDEX TO EXHIBITS 27

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#### **CERTAIN DEFINITIONS**

Unless the context requires otherwise, all references in this annual report on Form 10-K/A, or this Report, to "Star Scientific," "Company," "we," "our," "us," "our company" and similar terms refer to Star Scientific, Inc. and its wholly owned subsidiaries Rock Creek Pharmaceuticals, Inc., a Delaware corporation, and Star Tobacco, Inc., a Virginia corporation, which also may be referred to in this Report as "Rock Creek" and "Star Tobacco," respectively.

## SPECIAL NOTE ON FORWARD-LOOKING STATEMENTS

Certain statements in this Report other than purely historical information, including estimates, projections, statements relating to our business plans, objectives, and expected operating results, and the assumptions upon which those statements are based, are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We have tried, whenever possible, to identify these forward-looking statements using words such as "anticipates," "believes," "estimates," "continues," "likely," "may," "opportunity," "potential," "projects," "will," "expects," "plans," "intends" and similar expressions to identify forward-looking statements, whether in the negative or the affirmative. These statements reflect our current beliefs and are based on information currently available to us. Accordingly, such forward-looking statements involve known and unknown risks, uncertainties and other factors which could cause our actual results, performance or achievements to differ materially from those expressed in, or implied by, such statements. These risks, uncertainties, factors and contingencies include, without limitation, the challenges inherent in new product development initiatives, including the continued development and market acceptance of our nutraceutical products, the effect of any competitive products, our ability to license and protect our intellectual property, our ability to raise additional capital in the future that is necessary to maintain our business, changes in government policy and/or regulation, potential litigation by or against us and any governmental review of our products or practices. Forward-looking statements reflect our management's expectations or predictions of future conditions, events or results based on various assumptions and management's estimates of trends and economic factors in the markets in which we are active, as well as our business plans. They are not guarantees of future performance. By their nature, forward-looking statements are subject to risks and uncertainties. Our actual results and financial condition may differ, possibly materially, from the anticipated results and financial condition indicated in these forward-looking statements. There are a number of factors that could cause actual conditions, events or results to differ materially from those described in the forward-looking statements contained in this Report. A discussion of factors that could cause actual conditions, events or results to differ materially from those expressed in any forward-looking statements appears in "Item 1A. Risk Factors" of our 10-K Report filed on March 18, 2013.

Readers are cautioned not to place undue reliance on forward-looking statements in this Report or that we make from time to time, and to consider carefully the factors discussed in "Item 1A. Risk Factors" of our 10-K Report in evaluating these forward-looking statements. These forward-looking statements are representative only as of the date they are made, and we undertake no obligation to update any forward-looking statement as a result of new information, future events or otherwise.

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## Part III

## ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

#### Directors

The following table and text set forth the name, age and positions of each of our directors elected by our common stockholders:

Name	Age	Position
Burton J. Haynes <sup>(1)(2)(3)</sup>	65	Director
Christopher C. Chapman, Jr., M.D. <sup>(1)(2)(3)</sup>	60	Director
Neil L. Chayet <sup>(1)(2)</sup>	74	Director
Ralph B. Everett <sup>(3)</sup>	61	Director
Paul L. Perito	76	Chairman, President and Chief Operating Officer
Jonnie R. Williams, Sr.	57	Chief Executive Officer

(1) Member of the Audit Committee.

(2) Member of the Compensation Committee.

(3) Member of the Nominating Committee.

Set forth below is biographical information for each director of our company.

Christopher C. Chapman, Jr., 60, has served as a member of our Board of Directors since September 2005. Since its inception in 1999, Dr. Chapman has served as Chairman and Chief Executive Officer of Chapman Pharmaceutical Consulting, Inc., which provides expert medical consultation on the development and management of domestic and global product development programs for biotech, pharmaceutical and medical device products. He served as Senior Director of Medical Affairs with Quintiles/BRI, the largest contract research organization in the U.S., from 1995 until 2000. In that capacity, Dr. Chapman had oversight responsibility for the support of new drug applications, clinical studies and device submissions to the FDA for approval. From 1992 until 1994, Dr. Chapman was Medical Director at Regeneron Pharmaceuticals. He currently serves as Chairman of the Chapman Pharmaceutical Health Foundation. Dr. Chapman is a graduate of the Georgetown University School of Medicine in Washington, DC.

Dr. Chapman was nominated to serve on our Board of Directors at the time that our company was seeking to establish a pharmaceutical subsidiary that would focus on a range of non-nicotine nutraceutical products and pharmaceutical products, as well as expanding the acceptance of our very-low TSNA smokeless tobacco products as a viable alternative to more toxic forms of tobacco. Dr. Chapman's training as a physician and his experience in the biotech and pharmaceutical areas, particularly his experience in dealing with new drug applications, clinical studies and device submissions, led our Board of Directors to conclude that he could provide valuable assistance in connection with the development of both our very low-TSNA smokeless tobacco products and the anticipated activities of a new subsidiary that would focus on pharmaceuticals, nutraceuticals and related products. Consistent with Dr. Chapman's areas of expertise, he has served as a director of Rock Creek, since its incorporation in 2007 and has been active in advising our company on issues relating to new drug development and the potential for the expansion of our company's mission in the area of pharmaceutical and nutraceutical products.

Neil L. Chayet, 74, has served as a member of our Board of Directors since September 2007. Mr. Chayet is President of Chayet Communications Group, Inc., a consulting organization that addresses difficult public policy issues, including those related to health care, mental health services, and communications. Mr. Chayet is a member of the faculty of the Harvard Medical School, serving in the Department of Psychiatry and at McLean Hospital. He is also a member of the faculty of the Cummings School of Veterinary Medicine at Tufts University and a member of the Board of the Tisch College of Citizenship and Public Service at Tufts. Mr. Chayet also serves as a member of the Board of Directors of the Whitehead Institute for Biomedical research at M.I.T., and is Co-Chair of its Board of Associates. He is President of the Harvard Law School Association of Massachusetts, and Co-Chair of the HLSA Senior Advisory Network. He is also a member of the Board of Directors of Mass INC, and a member of the Massport Security Advisory Council. He previously served as Chairman of the Massachusetts Mental Health Institute, Inc., a member of the Research Grants Review Committee for the Studies of Narcotic Drug Abuse at the National Institute of Mental Health, and a delegate to the U.N. Conference on Psychotropic Substances, which followed the Single Convention on Narcotic Drugs. Since 1976, Mr. Chayet has hosted a daily radio feature, "Looking at the Law", which is syndicated by CBS, and he frequently lectures on topics related to the intersection of health, science and the law. Mr. Chayet earned an undergraduate degree from Tufts University in 1960 and a law degree from Harvard Law School in 1963. In April 2007, Mr. Chayet received the Civic Achievement Award from the American Jewish Committee and in 2008 received the Tufts Distinguished Service Award.

Mr. Chayet was nominated to serve on our Board of Directors shortly after our company formed its pharmaceutical subsidiary, Rock Creek. As part of his legal and consulting practice, Mr. Chayet for many years has been involved with issues relating to the healthcare field and the intersection of health, science and the law. Given the public health aspects of tobacco use, the related mission of our company to reduce the harm associated with tobacco use and the expectation that Congress would eventually grant the FDA authority over tobacco products, our Board of Directors believed that Mr. Chayet could provide unique insight and assistance to our company as we sought to grow our pharmaceutical business and continue the development of very low-TSNA smokeless tobacco products. Like Dr. Chapman, Mr. Chayet has provided valuable counsel and guidance as a member of the Board of Rock Creek, in addition to serving as a member of our Board of Directors.

Ralph B. Everett, 61, was elected as a member of our Board of Directors by our stockholders at the Annual Meeting held on December 14, 2012. Since January 2007, Mr. Everett has served as President and CEO of the Joint Center for Political and Economic Studies, widely acknowledged as the nation's leading think tank for policy analysis and research on issues of concern to African Americans and other people of color. Since his appointment to that position, he has led an effort to expand the organization's research and influence into key policy areas, which has resulted in the establishment of two new centers of excellence — the Joint Center Media and Technology Institute and the Civic Engagement and Governance Institute - as well as an Energy and Environment Program. From 1989 through 2006, Mr. Everett was a partner at Paul, Hastings, Janofsky & Walker LLP, a leading international law firm with offices throughout Europe, Asia and the United States. He was the first African American partner at Paul Hastings and during his 17-year tenure specialized in telecommunications and transportation policy. He served as Managing Partner of the Washington office from 1993 until 1996 and was also Co-Chair of the firm's Federal Legislative Practice Group and a Policy Committee member. Mr. Everett has a 34-year track record of pioneering leadership in the nation's capital. He served as Staff Director and Chief Counsel of the U.S. Senate Committee on Commerce, Science and Transportation from 1987 to 1989. There, he played a pivotal role in cable, broadcast and common carrier legislative reforms, as well as regulatory reform of the airline, truck, railway and bus industries. Prior to assuming the role of Chief Counsel of the full Committee, he served as Democratic Staff Director and Minority Chief Counsel from 1982 to 1986 and as a legislative assistant to U.S. Senator Ernest Hollings from 1977 to 1982. In 1998, President Clinton appointed Mr. Everett as U.S. Ambassador to the International Telecommunication Union's Plenipotentiary Conference. That year, he also was chosen to lead the U.S. Delegation to the Second World Telecommunication Development Conference in Malta, joining participants from more than 190 nations. In Malta, he was elected Vice Chairman of the world proceedings. In 2008, Mr. Everett was a team leader for the Obama-Biden Transition Project Agency Review Working Group responsible for overseeing the Department of Commerce. Mr. Everett currently serves on the AT&T Consumer Advisory Panel, is Co-Chair of the Commission to Engage African Americans on Climate Change and is a member of the Economic Club of Washington, Alpha Phi Alpha Fraternity and Sigma Pi Phi Fraternity. He has served on the Duke University Law School's Board of Visitors since 1994. He also serves as Vice Chair of the Board for Independent Sector, as a Director of the National Coalition on Black Civic Participation and, since 1998, as a Director of Cumulus Media Inc. Mr. Everett's community service has included six years on the National Urban League Board and over a decade on the Board of the Center for National Policy, where he was Secretary. He has served on the President's Board of Advisors for Historically Black Colleges and Universities and as Vice Chairman of the Commonwealth of Virginia's Waste Management Board. He also chaired the Board of Trustees of the historic Alfred Street Baptist Church, one of the oldest African American Baptist Churches in the United States. A native of Orangeburg, South Carolina, Mr. Everett graduated Phi Beta Kappa from Morehouse College in 1973 and received his law degree from Duke University Law School

in 1976. At Duke University, he held the honor of being named Earl Warren Legal Scholar. He is a member of the District of Columbia and North Carolina Bars as well as a member of the Supreme Court Bar. *Ebony* magazine has named Mr. Everett one of the nation's "150 Most Influential African Americans."

Mr. Everett was nominated to serve on our Board of Directors based on his extensive experience in dealing with regulated industries both in the context of legislative initiatives in the public sector and in advising and leading companies in the private sector in dealing with legal issues before the legislative and administrative branches of government. Mr. Everett also has had extensive experience in advising companies on an array of business issues both as an attorney advisor, executive and member of the board of directors of numerous companies and organizations. Mr. Everett's familiarity with the legislative and regulatory processes at the Federal government level, his educational training and his diverse business background were viewed by our Board of Directors as being valuable in dealing with the type of regulatory issues that our company encounters on a regular basis and, particularly, as we continue to transition and focus our efforts on the development and sale of nutraceutical dietary supplements and potentially pharmaceutical products.

Burton J. Haynes, 65, has served as a member of our Board of Directors since October 22, 2010. Since 1997, Mr. Haynes has served as the sole principal in Burton J. Haynes PC, a law firm specializing in income tax matters, estate and tax planning and complex civil and criminal tax cases. Between 1988 and 1996, Mr. Haynes practiced law as a named partner in the law firm of Bodzin, Haynes & Golub, specializing in civil and criminal tax cases. Mr. Havnes was a partner at the law firm of Finley, Kumble, Wagner, Heine, Underberg, Manley, Myerson & Casey from 1981 to 1988. Prior to entering private practice, Mr. Haynes served as a Special Agent, IRS Criminal Investigation Division from 1973 to 1981. As a Special Agent, Mr. Haynes worked closely with the FBI and U.S. Attorney's Office on criminal investigations and was named criminal investigator of the year in 1980 by the Association of Federal Investigators. Mr. Haynes received his Bachelor of Arts Degree in Business Administration from the University of Maryland in 1972 and received a Master's Degree in Business Administration from the University of Maryland Graduate School in 1975. He received his law degree in 1979 from the University of Maryland, where he was the recipient of the W. Calvin Chestnut award and the John L. Thomas prize for outstanding scholarship and was elected Order of the Coif. Mr. Havnes is a member of the bars of the District of Columbia, Maryland and Virginia and is a Certified Public Accountant (although his CPA license is in inactive status because his primary focus is on the practice of law). He served as an adjunct professor from 1979 to 1981 at Towson State University.

Mr. Haynes was nominated to serve on our Board of Directors based on his extensive experience in business, legal and complex tax, litigation and regulatory matters. His background as an accountant and attorney provides a unique combination of disciplines as does his long career in dealing with complex civil and criminal tax matters. Our Board of Directors viewed Mr. Haynes' combination of training and experience as a valuable source of expertise, particularly in the areas of financial analysis and planning. Mr. Haynes' expertise is also valuable in dealing with the type of regulatory issues facing our company in connection with our ongoing efforts relating to the development and marketing of pharmaceutical and nutraceutical products.

Paul L. Perito, 76, is our company's President and Chief Operating Officer, or COO, and has served in that capacity since November 1999. He has served as a member of our Board of Directors since December 1999 and as the Chairman of our Board of Directors since August 2000. Mr. Perito served as our company's Executive Vice President, General Counsel, and Chief Ethics Officer from June 1999 through November 1999. Previously, Mr. Perito was a senior partner in the law firm of Paul, Hastings, Janofsky & Walker LLP, or PHJ&W, from July 1991 until June 1999 when he became a senior counsel to the firm at the time he joined our company. Mr. Perito resigned his position as senior counsel to PHJ&W as of March 31, 2001, after serving as National Co-Chair of the White Collar Corporate Defense Practice Group at PHJ&W since 1991, and Chair of the Litigation Department in that firm's Washington, DC office since 1995. Prior to his re-entry into private practice, he served as Chief Counsel and Deputy Director of the White House Special Action Office on Drug Abuse Prevention from 1971 to 1973. Mr. Perito was confirmed by the Senate for that position in March 1972. From 1970 to 1971, Mr. Perito served as Chief Counsel and Staff Director to the U.S. House of Representatives Select Committee on Crime. Immediately prior to serving the Congress, Mr. Perito was an Assistant United States Attorney in the Southern District of New York, U.S. Department of Justice from 1966 to 1970. Mr. Perito graduated from Tufts University, Magna Cum Laude and Phi Beta Kappa, and from the Harvard Law School. Mr. Perito was a Rotary International Scholar at the Victoria

University of Manchester in Manchester, England, and in Lund University, Lund, Sweden, in P.P.E. in 1960 – 1961 before entering Harvard Law School. Mr. Perito graduated from Harvard Law School (LLB/JD), as an Edward John Noble Scholar, in 1964 and was thereafter admitted to the Bar of the Commonwealth of Massachusetts. He is also a member of the District of Columbia Bar and is admitted to practice in numerous federal District Courts, Courts of Appeal, and the United States Supreme Court. Mr. Perito was the President of the Harvard Law School Association of the District of Columbia from 1990 to 2010 and is now Chair Emeritus. He is also a member of the Executive Committee of the Harvard Law School Association and was Secretary to the Harvard Law School Association for approximately 15 years. In June 2010, Mr. Perito was elected First Vice President of the Harvard Law School Association in June 2012 for a two-year term. He served as Chairman of the Harvard Law School Class of 1964 Reunion and Fund Committees from 1995 to 2010 and served as Co-Chair of the World Alumni Congress in 2006 – 2007, and Class Agent for the Harvard Law School Fund in 2006 – 2007. Mr. Perito was Chair of the Harvard Law School 45<sup>th</sup> Reunion Committee and Co-Chair of the Gift Committee Class of 1964. Mr. Perito is a member of the International Board of Overseers of Tufts University and a former member of the Board of Georgetown Visitation Preparatory School in Washington, DC.

Prior to joining our company's Board of Directors, Mr. Perito had a long and distinguished legal and governmental career that focused not only on highly complex litigation matters, but also a variety of health related regulatory and legal matters, including issues relating to addiction and harm reduction as part of his service in the Legislative and Executive branches of government. Given our company's recent focus in the area of non-nicotine nutraceutical and pharmaceutical products and our focus since the late 1990s on tobacco harm reduction, as well as our emerging intellectual property portfolio related to these initiatives, it was evident to our Board of Directors that our company would benefit from having Mr. Perito's legal and management skills and expertise in coordinating our company's intellectual property and litigation efforts as well as his input on how best to interact at the highest levels of the federal government on a wide variety of healthcare and legal issues related to the regulation of tobacco products and more recently nutraceutical and pharmaceutical and regulatory matters facing our company, the need for the type of expertise and experience possessed by Mr. Perito has remained. Additionally, given our increased emphasis on non-nicotine nutraceuticals and related products and the expanded focus of our company in seeking to promote the maintenance of a healthy metabolism Mr. Perito's expertise has become more essential to our company's business strategy.

Jonnie R. Williams, 57, has served as our company's Chief Executive Officer, or CEO, since November 1999 and has served as a member of our Board of Directors since October 1998. Mr. Williams was one of the original founders of Star Tobacco, our company's wholly owned subsidiary, and served as its Chief Operating Officer and Executive Vice President until July 1999. On July 1, 1999, in order to concentrate on the expanding demands of our company's sales and new product development, Mr. Williams resigned from his positions with Star Tobacco initially to assume the primary responsibilities of Director of Product Development and Sales of our company and then the position of CEO. Mr. Williams, a principal stockholder of our company, is also the inventor of the StarCured<sup>®</sup> tobacco curing process for preventing or significantly retarding the formation of TSNAs in tobacco and tobacco smoke. He also has been actively involved in our recent product initiatives involving the use of anatabine citrate as a dietary ingredient and potentially as a pharmaceutical ingredient, Mr. Williams has been involved in venture capital start-up bio-tech companies for over a decade where he has been either a major shareholder or a co-founder of the following companies: LaserSight, LaserVision and VISX. Mr. Williams is also one of the owners of Regent Court Technologies LLC and was a principal in Jonnie Williams Venture Capital Corp.

Mr. Williams has played a prominent role in our company since its inception as the inventor of the StarCured<sup>®</sup> tobacco curing process, as a significant contributor to our new product initiates in the pharmaceutical and nutraceutical areas and, since 1999, as our CEO. Also, he has been active in capital raising initiatives and related interactions with investors. Given his activities and skills in these areas, it was evident to our Board of Directors that Mr. Williams' guidance as a director would be beneficial to our company in each of these areas and in assessing the direction and focus of our company as we have moved forward with our mission of promoting the maintenance of a healthy metabolism and in supporting good nutrition.

#### **Executive Officers**

The following table sets forth certain information with respect to our executive officers, other than Messrs. Paul L. Perito and Jonnie R. Williams, whose information is set forth above under the caption "— Directors."

Name	Age	Position
David M. Dean	53	Vice President of Sales and Marketing
Park A. Dodd, III	60	Chief Financial Officer
Robert E. Pokusa	62	General Counsel
Curtis Wright, MD, MPH	63	Senior Vice President, Medical/Clinical Director of Rock
· · · · · · · · · · · · · · · · · · ·		Creek Pharmaceuticals, Inc.

Set forth below is biographical information for each executive officer of our company who is not also a director.

David M. Dean, 53, has served as Vice President of Sales and Marketing of our company since November 1999 and as President of Star Tobacco since February 2010. From 1998 to October 1999, he served as a Principal of Group Insurance Concepts of Virginia, L.L.C., an employee benefits consulting firm and an affiliate of Northwestern Mutual. From 1984 to 1998, Mr. Dean was employed with Trigon Blue Cross/Blue Shield in Richmond, Virginia, where he held a variety of executive positions over a 14 year period, including Vice President of the Eastern Region from 1994 to 1996, Vice President of Sales from 1996 to 1997, and Vice President of Sales and Account Management for the Eastern and Western Regions from 1997 to 1998. Trigon Blue Cross/Blue Shield was the largest health insurer in Virginia and was purchased during 2002 by Anthem. Mr. Dean is a graduate of Elon College.

Park A. Dodd, III, 60, has served as our company's Chief Financial Officer, Treasurer, and Assistant Secretary since October 2007. Mr. Dodd was a special advisor to our company from May 2007 until assuming the role as Chief Financial Officer in October 2007. Mr. Dodd's experience includes a thirty-two year career in strategic financial planning and accounting. From 1980 to 2000 he held a number of management positions with Philip Morris, Inc. with increasing responsibilities in accounting and reporting, business decision support, financial planning and analysis during that time, including his service as Senior Manager and Director of Financial Planning and Analysis from 1992 to 1998 and Director of Finance Reengineering and Technology Upgrade from 1998 to 2000. Mr. Dodd was special advisor to the Chief Financial Officer of the United States Olympic Committee during 2000, and from 2001 to 2005 he served as Director in Accounting and Reporting of Capital One Financial Corporation in Richmond, Virginia. Between 2005 and the end of 2009, Mr. Dodd was a partner with Tatum, LLC, a national executive services firm that specializes in providing interim financial leadership to client organizations. Mr. Dodd received an undergraduate degree in Accounting from Virginia Tech in 1975 and an MBA from Virginia Commonwealth University in 1986. He is a licensed Certified Public Accountant in the State of Virginia.

Robert E. Pokusa, 62, has served as our company's General Counsel and Secretary since March 2001. From 1991 until joining our company, he was associated with Paul, Hastings, Janofsky & Walker LLP during which time he worked on a number of matters for our company and concentrated his practice in the areas of complex civil litigation and administrative law. From 1980 to 1991, Mr. Pokusa was associated with the law firms of Perito, Duerk & Carlson; Finley, Kumble, Wagner, Hiney, Underburg, Manley, Meyerson & Casey, and Washington, Rerito and Dubuc. Mr. Pokusa received his Bachelor of Arts Degree from Montclair State University and his law degree from The American University, Washington College of Law. He is a member of the Virginia and District of Columbia bars.

*Curtis Wright, MD, MPH*, 63, has served as Senior Vice-President, Medical/Clinical Director of our pharmaceutical subsidiary, Rock Creek Pharmaceuticals, Inc. since February 2008. Dr. Wright previously served as Vice President of Clinical and Regulatory Affairs for Adolor Corporation from 1997 to 1998, and Executive Director, Medical Affairs and subsequently Executive Director of Risk Assessment for Purdue Pharma from 1998 to 2004. Immediately prior to joining Rock Creek Pharmaceuticals, Inc., Dr. Wright served as Executive Vice President for Risk Management and Regulatory Affairs at Javelin Pharmaceuticals, Inc., Cambridge, MA from 2004 to 2008. Dr. Wright's career at the FDA, from 1989 through October 1997,

included multiple senior scientific positions in the Center for Drug Evaluation and Research, including Deputy Director and subsequently Acting Director of his division. Dr. Wright received his medical degree, with distinction, from George Washington University and received a master's degree in Public Health from the John Hopkins University.

## Section 16 (a) Beneficial Ownership Reporting Compliance

Section 16 of the Securities Exchange Act of 1934, as amended, requires directors and executive officers and persons, if any, owning more than ten percent of a class of our company's equity securities to file with the Securities and Exchange Commission initial reports of ownership and reports of changes in ownership of our company's equity and equity derivative securities. Based solely upon a review of the copies of such reports and written representations from reporting persons, we believe that all Section 16(a) filing requirements applicable to our officers, directors and greater than ten percent stockholders were complied with on a timely basis for the year ended December 31, 2012, except that certain gifts of our common stock made by Mr. Williams during 2012 were not timely reported on or before the 45<sup>th</sup> day after December 31, 2012.

#### **Code of Ethics**

We have adopted a Code of Ethics that applies to all of our company's directors, officers (including our Chief Executive Officer, Chief Financial Officer, Controller and any person performing similar functions) and employees. We have filed a copy of this Code of Ethics as Exhibit 14.1 to this Report. We also have made the Code of Ethics available on our company's website at: www.starscientific.com. Information contained on our website is not part of this Report and is not incorporated in this Report by reference.

## **Audit Committee**

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We currently maintain an Audit Committee which has responsibility for the appointment of our independent registered public accountants, reviews our internal accounting procedures and financial statements, and consults with and reviews the services provided by our independent registered public accountants, including the results and scope of their audits. The Audit Committee is currently comprised of Messrs. Chapman, Haynes and Chayet, each of whom are independent under the applicable rules of the Securities and Exchange Commission and The NASDAQ Global Market. The Board of Directors has determined that Burton J. Haynes, who is the Chairman of the Audit Committee, also qualifies as an "Audit Committee Financial Expert" as defined by the rules of the Securities and Exchange Commission.

## **ITEM 11. EXECUTIVE COMPENSATION**

## **Compensation Discussion and Analysis**

Our company's Named Executive Officers are Jonnie R. Williams, Sr., our CEO, Park A. Dodd, III, our Chief Financial Officer, or CFO, Paul L. Perito, our Chairman, President and COO, Robert E. Pokusa, our General Counsel and David M. Dean, our Vice President for Sales and Marketing. We collectively refer to these executive officers as the "Named Executives." The following discussion summarizes the compensation awarded to the Named Executives or other executive officers during 2012.

#### **Overview**

Our mission as it has developed over the past several years has been to move away from the production of tobacco products in favor of promoting the use of certain alkaloids found in tobacco that appear to be beneficial in assisting in maintaining a healthy metabolism and potentially in treating a range of neurological and other conditions. In this regard, we have been focused on the development of non-nicotine, non-tobacco dietary supplements that provide viable alternatives to tobacco products and anti-inflammatory support, related pharmaceutical products and the licensing of our company's low-TSNA curing technology and our other technology. In particular, over the last several years we have been engaged in the production of several nutraceutical, dietary supplements that are marketed under the brand names Anatabloc® and CigRx® and the development of related pharmaceutical products that are designed to treat a range of conditions including Alzheimer's disease, Parkinson's disease, multiple sclerosis, schizophrenia, depression and tobacco dependence. We ceased manufacturing and selling our low tobacco specific nitrosamine, or TSNA, dissolvable tobacco products as of December 31, 2012 and are no longer manufacturing or selling any tobacco products. However, based on our prior work in this area we believe we are uniquely positioned to pursue a range of licensing opportunities relating to our patented tobacco curing technology and low-TSNA products.

Currently, our revenues are being derived almost exclusively from the sale of our anatabine-based nutraceutical products and a cosmetic line of products that also utilizes our anatabine compound. As we have worked to achieve our corporate objectives over the years, we initially utilized our company's technology in producing low-TSNA tobacco as a platform to provide a base of financial support for our intellectual property, licensing and development initiatives. Since 2007, we have shifted the focus of our efforts to nutraceuticals and the development of related pharmaceutical products.

Over the years we also have sought to develop a sophisticated superstructure for our innovative, technology-based company that could interact at all levels of the government, regulatory, medical and industrial sectors on a broad range of issues relating to the promotion of a healthy metabolism and lifestyle. To achieve this objective, our company sought a Chief Executive Officer, or CEO, in 1999 who could oversee our company's existing business and facilitate the kind of capital raising initiatives and investor support necessary to promote an aggressive and far-ranging approach to the issues facing our company, including the potential of certain alkaloids found in tobacco to play a role in maintaining a healthy metabolism and in the treatment of a range of neurological and other conditions.

Our company also made efforts to identify and hire a President and Chief Operating Officer, or COO, with a substantial legislative, regulatory and litigation background and who had relationships with the relevant scientific and research communities that are critical to our goals and objectives. We felt that this individual should be able to coordinate our company's intellectual property and litigation efforts, interact at the highest levels of the federal government on a wide variety of health and legal issues including those involved in the regulation of products by the Food and Drug Administration, and be in a position to enlist other individuals as employees and consultants to assist in those initiatives. With the incorporation of our Rock Creek subsidiary in 2007, we also sought to identify and hire an individual who could spearhead our development of nutraceuticals and pharmaceuticals which had evolved from our prior investigation of certain alkaloids in tobacco. Further, we worked to staff key executive positions in sales and marketing, finance, legal, investor relations and medical research with individuals who would complement our company's senior management and provide a level of expertise that would minimize the need to procure those services through external third parties. Because we initially set out to be a force for change in the tobacco industry and to promote a healthy metabolism, we understood that our company needed to be able to attract and maintain a high-caliber group of executives to further these goals and objective.

#### **Compensation** Objectives

In establishing compensation for our company's executive officers, we have sought to:

- attract and retain individuals of superior ability and managerial talent;
- ensure that the compensation for senior executive officers is aligned with our company's corporate strategies, business objectives and long term interests; and
- enhance the incentive of our company's executive officers to maximize shareholder value by providing opportunities for direct ownership in our company through awards of stock options and stock grants.

Over the last ten years our company has experienced operating losses on an annual basis, and, accordingly, since 2002 we have chosen to maintain our executive officers base salary at levels that existed at that time or at levels that were established when certain of our executive officers first joined our company (see "Base Salary" below for a discussion of recent voluntary reductions in base salary levels for certain of our Named Executives). As a result during the period 2002 through April 2012, we had not utilized an incentive-based salary structure as a means of determining salary levels for our executive officers or other employees. Except for nominal amounts, and for an initial signing bonus in the case of Curtis Wright, MD, MPH, who joined our company in March 2008 as Senior Vice President, Medical/Clinical Director of Rock Creek, no cash bonuses were paid to executive officers during the period 2002 to April 2012. In April 2012 our Board of Directors, upon recommendation of the Compensation Committee, approved the payment of cash bonuses in an aggregate amount of \$270,000 to ten of our employees, including four of our executive officers, in recognition of their efforts in connection with the successful introduction of our Anatabloc<sup>®</sup> dietary supplement. This included awards of \$75,000 to David Dean, \$10,000 to Robert E. Pokusa and \$5,000 to Park A. Dodd, III, three of our Named Executives. The Board of Directors also approved an incentive bonus plan for David Dean under which, beginning in March 2012, he is receiving a commission of one-half of one percent of gross sales of our Anatabloc<sup>®</sup> product and will be entitled to target bonuses of \$10,000, \$20,000, \$50,000 and \$100,000 when Anatabloc<sup>®</sup> sales reach gross revenues of \$10.0 million, \$20.0 million, \$50.0 million and \$100.0 million, respectively.

From 2003 until May 2008, we did not issue any stock options or stock grants to our company's executive officers, except as noted below in the case of Park A. Dodd, III and Dr. Wright, in each case upon their commencement of service to our company. However, in May 2008 and April 2010, our Board of Directors, based on the recommendation of the Compensation Committee, awarded a total of 1,625,000 and 3,590,000 stock options, respectively, to several employees, executive officers, one consultant and our Independent Board members. The 2010 awards included 1,250,000 stock options issued to Messrs. Perito and Williams, respectively, 200,000 stock options issued to Dr. Wright and 50,000 stock options issued to Mr. Dodd. Those stock options were awarded in recognition of their continued contributions towards our company's goals and objectives, particularly the product development initiatives of Rock Creek. On January 31, 2011 our Board of Directors on recommendation of the Compensation Committee awarded a total of 604,000 stock options to three employees who had an equal number of stock options expire during 2010. including one of our Named Executives, David Dean. Also, on March 14, 2011 our Board of Directors, upon recommendation of the Compensation Committee, approved an additional award of stock options to Messrs. Perito and Williams, and Dr. Wright in the amount of 4,000,000, 4,900,000 and 300,000 stock options respectively, as part of new employment agreements entered into with them at that time. Each of those stock options was subject to performance based vesting criteria and, in the case of the stock option grants to Messrs. Perito and Williams, stockholder approval. In 2011 the stock option grant to Dr. Wright vested with the introduction of our Anatabloc<sup>®</sup> dietary supplement and sixty-five percent of the stock options granted to Messrs. Perito and Williams vested based on their meeting performance criteria in their employment agreement and stockholder approval of the grants which occurred at our Annual Meeting held on December 16, 2011. As of December 31, 2012 the remaining thirty-five percent of the stock options granted to Messrs. Perito and Williams in 2011 had not vested. In April 2012 our Board of Directors, upon recommendation of the Compensation Committee, approved the award of an aggregate of 570,000 stock options in varying amounts to ten of our employees, including grants of 150,000 stock options to David Dean

and 35,000 stock options to each of Robert E. Pokusa and Park A. Dodd, III, three of our Named Executives, in recognition of their efforts in connection with the successful introduction of our Anatabloc<sup>®</sup> product.

In conducting our risk assessment analysis of employee compensation policies and practices, including those for our Named Executives, we have taken into account the fact that our compensation levels through April 2012 have been limited to base salary and benefits and have not been tied to additional compensation in the form of salary or cash bonus payments for meeting specific performance objectives. Since 2008 we have issued stock options to our Named Executives and other employees; however, except for the stock option grants to Messrs. Perito and Williams and Dr. Wright in 2011, those stock option grants have vested at the time of issuance and have not been tied to performance criteria. The stock options issued to Messrs. Perito and Williams and Dr. Wright in 2011 were subject to performance based vesting requirements, but those requirements were tied to corporate objects that were aligned to our company's overall corporate mission, as opposed to specific individual performance criteria. Further, the decision to issue performance based stock options was based, in part, on our company's determination that it would continue its previous policy of maintaining salary levels at prior year levels and, in the case of Messrs. Williams and Perito, providing our Board of Directors with the discretion to make any adjustment to their current salary levels as the Board deems appropriate. In the case of the incentive bonus plan established in April 2012 for David Dean, our Vice President of Sales and Marketing, that bonus plan is discretionary and may be terminated at any time by our Board of Directors. Also, these bonus payments are tied to sales of our Anatabloc® dietary supplement, which has been a principal focus of our company's sales efforts since the introduction of Anatabloc® in 2011, and increases in Anatabloc® sales are thus aligned to our company's overall corporate mission. Based on those considerations, we have concluded that our employee compensation policies and practices, including those applicable to our Named Executives, do not create risks that are reasonably likely to have a material adverse effect on us and do not result in an incentive for our Named Executives to take undue risk in order to increase their levels of compensation.

Our compensation determinations have been driven primarily by considerations relating to the ability to attract and retain individuals who could help our company carry out its long-term objectives to promote the maintenance of a healthy metabolism and lifestyle. The determinations also have involved an assessment of our company's progress in obtaining and protecting the intellectual property to which we are the exclusive owner or licensee, and the licensing of that technology, our success in introducing to the market nutraceuticals and pharmaceuticals through Rock Creek, and our success in generating revenue from the licensing of our proprietary technology.

Our Board of Directors has provided its Compensation Committee the primary authority to determine the compensation awards available to our company's executive officers and the Compensation Committee, in turn, makes recommendations on compensation levels to the Board for its approval after undertaking an analysis of appropriate levels of compensation for our executive officers. To aid the Compensation Committee in making its determinations, on a yearly basis the Compensation Committee is provided an analysis of the compensation levels of our executive officers based on the review of job functions and job responsibilities that have been assumed by particular executive officers and compensation ranges available in comparable positions for individuals with like training and experience. The analysis is prepared by our company's General Counsel working with our COO and with input from outside counsel. Our CEO and COO also provide recommendations, as appropriate, regarding compensation for all executive officers, including themselves. Our company has not engaged a compensation consultant to undertake this analysis. Given our company's unique position in the area of developing nutraceuticals and pharmaceuticals based on our experience in dealing with non-nicotine alkaloids found in tobacco, we have not used benchmarks from the tobacco industry in setting compensation levels for our company's most senior executives. Instead, the Compensation Committee has considered general market information for similar senior level executives in setting base compensation, including an analysis of salary levels and benefits for executives in the manufacturing sector in the relevant geographic markets (Richmond, Virginia, Washington, DC and Boston, Massachusetts).

We have utilized a comparison to the manufacturing sector since our company over the past decade has been involved in development and manufacturer of a number of novel products utilizing our low-TSNA curing technology as well as dietary supplements based on the anti-inflammatory properties of anatabine. In August 2010 through our Rock Creek subsidiary, we introduced our non-nicotine, non-tobacco nutraceutical (CigRx<sup>®</sup>) and in August 2011 introduced another non-nicotine nutraceutical for anti-inflammatory support (Anatabloc®). Currently sales of our dietary supplement products constitute the majority of our revenue. In addition to Rock Creek's sale of Anatabloc<sup> $\oplus$ </sup> and CigRx<sup> $\oplus$ </sup>, we intend in the future to manufacture other nutraceuticals and pharmaceuticals through Rock Creek and in September 2012 we introduced an Anatabloc® Facial Crème cosmetic. Given the current focus of our company on maintaining a healthy metabolism, going forward we expect we will consider the appropriate industry comparison based on the mix of products being sold by our company. In the case of our company's COO and General Counsel, the Compensation Committee also has undertaken an analysis of compensation for senior partners at major law firms in the Washington, DC area, given the background of our COO and General Counsel in the litigation, regulatory and legislative areas and their active involvement in implementing and coordinating our company's activities in these areas. The general market information is publicly available aggregated pooled data and, while the Compensation Committee reviews the general market information, it does not see the identity of any of the surveyed companies. Further, the analysis has focused on the extent to which executive officers have assumed multiple functions relating to various aspects of our company's mission and long-term objectives that in different circumstances likely would have been assumed by other employees. Also, the Compensation Committee considers other factors such as the seniority of our senior executives, and for newer hires, the executive's base salary at his/her prior place of employment, the duties and responsibilities that the individual will be assuming, the availability of other well-qualified candidates that would be available to carry out our company's goals and objectives, and the compensation level a potential executive would be able to demand in a similar position with another company or institution. The Compensation Committee reviews the information provided by management and makes its recommendation to the Board of Directors with respect to appropriate compensation levels.

In 2011, our company entered into new employment contracts with Messrs. Perito and Williams that had initial terms through December 31, 2012. Those contracts were continued on a month-to-month basis in December 2012, based on the recommendation of the Compensation Committee and the approval of our Board of Directors. At the same time, the Compensation Committee and Board of Directors ratified the voluntary decision of our CEO, Mr. Williams, to reduce his salary to \$1.00 per month beginning in January 2013 until our Company becomes profitable.

## **Base Salary**

In 2012, the base salary for each of our executive officers, except for Messrs. Perito and Williams and Dr. Wright, were set in accordance with the terms of contracts that were entered into in years prior to 2010 and have been continued without any change in base salary on a month-to-month basis. In Dr. Wright's case his base salary was increased by \$30,000 from \$300,000 to \$330,000 at the time our company entered into an amended and restated employment agreement with Dr. Wright in March 2011. In the case of Messrs. Perito and Williams their compensation is at the discretion of the Board and was initially set at \$1.0 million per year in March 2011, consistent with the terms of their prior agreements. In November, 2012, Mr. Williams voluntarily agreed to reduce his salary to \$1.00 per month beginning in January 2013 until our company becomes profitable and in February 2013, Mr. Perito voluntarily reduced his salary by \$500,000 until our company becomes profitable. Also, in February 2013, our General Counsel, Mr. Pokusa, and our CFO, Mr. Dodd, voluntarily agreed to reduce their salaries by \$100,000 and \$50,000 respectively until our company becomes profitable. Those decisions were ratified by the Compensation Committee and our Board in December 2012 as to our CEO, and in February 2013, as to our Chairmen, President and COO, General Counsel and CFO. As discussed above, in assessing compensation levels for all executive officers, the Compensation Committee has focused on the extent to which executive officers have been assuming multiple functions relating to our company's mission and long-term objectives. The Compensation Committee also has considered salary levels and benefits for executives in the manufacturing sector in the relevant geographic markets (Richmond, Virginia, Washington, DC and Boston, Massachusetts) and, in the case of our company's COO and General Counsel, compensation levels for senior partners at major law firms in the Washington, DC area.

## Ancillary Bonuses

In April 2012 three of our Named Executives, David Dean, Robert E. Pokusa and Park A. Dodd, III, received cash bonuses of \$75,000, \$10,000 and \$5,000 respectively as part of a one-time award of an aggregate of \$270,000 in cash bonuses paid to a total of ten of our employees in recognition of their efforts in connection with the successful introduction of our Anatabloc® dietary supplement. Previously, in 2008, an initial signing bonus in the amount of \$100,000 was paid to Dr. Curtis Wright at the time he joined our company as Senior Vice President, Medical/Clinical Director of Rock Creek. In January 2010 we entered into a new employment agreement with our CFO at the time he transitioned fully from Tatum Partners LLC. Under this agreement, Mr. Dodd received salary payments comparable to those that he received in 2009. Also, under his employment agreement to the Board/Compensation Committee that it consider a similar type of award to the CFO taking into account the differences in annualized salary and the contribution of the CFO to our company's success that resulted in the award to the CEO or COO.

On an annual-basis, we have paid an ancillary holiday bonus in the amount of \$1,500 to executive officers, except for our company's CEO, COO and at times our CFO. An identical bonus has been paid to our other employees. Such bonuses have been paid as part of a long-standing holiday bonus policy and are not based on executive officers meeting achievement or performance goals.

## Discretionary Equity Incentive Awards

While our Board of Directors believes compensating our executive officers with equity awards helps align the interests of our executive officers with that of our shareholders and enhances the incentive of our company's executive officers to maximize shareholder value, our Board of Directors recognizes that the number of our shares owned by any director or executive is a personal decision and has not adopted a policy requiring ownership by directors or executives of a minimum number of our shares.

Our executive officers, along with our other employees, are eligible to participate in the award of stock options or restricted stock grants or stock appreciation rights under our 2000 Equity Incentive Plan, or 2000 Plan, and our 2008 Incentive Award Plan. However, to date we have only granted stock options and not shares of restricted stock or stock appreciation rights to our executive officers.

On April 5, 2012 our Board of Directors, upon recommendation of our Compensation Committee, awarded a total of 570,000 stock options to ten of our employees, excluding our CEO and COO, in recognition of their efforts in connection with the successful launch of our Anatabloc<sup>®</sup> dietary supplement. The awards, each of which has an exercise price of \$3.02 per share, vested on the date of the grant and included awards of 150,000 stock options to David Dean and 35,000 stock options to each of Robert E. Pokusa and Park A. Dodd, III.

On January 31, 2011 our Board of Directors on recommendation of the Compensation Committee awarded a total of 604,000 stock options to three employees who had an equal number of stock options expire during 2010. Also, On March 14, 2011 our Board of Directors, upon recommendation of the Compensation Committee, approved an award of stock options to Messrs. Perito and Williams and Dr. Wright as part of new employment agreements entered into with these Named Executive Officers in the amount of 4,000,000, 4,9000,000 and 300,000 stock options respectively. The decision to grant Dr. Wright an additional stock option, as part of his amended and restated employment agreement, was based on the positive contributions made by Dr. Wright in terms of the development of our nutraceutical dietary supplements, the successful launch of CigRx® in August 2010 and his work in connection with the development and testing of our Anatabloc<sup>®</sup> product that was introduced into the market in August 2011. The award of stock options to Messrs. Perito and Williams was motivated by the fact that their March 2011 employment agreements do not include any provisions for incentive cash bonus awards, as opposed to earlier employment agreements, and left to the Board sole discretion to increase or decrease annual salary amounts for Messrs. Perito and Williams during the term of the agreements. Further given the fact that the Board of Directors had not authorized any incentive cash awards for either Mr. Perito or Mr. Williams since 2002, the Compensation Committee and the Board of Directors determined that it was appropriate to issue additional stock option awards to Messrs. Perito and Williams that would reward their continuing efforts on behalf of the Company and incentivize their future performance. Also, the Compensation Committee and the Board of Directors in making their award

determination took into account the fact that prior to 2008 Mr. Williams had never been granted stock options and that Mr. Perito prior to 2008 had never been granted stock options, except as part of his initial employment agreement entered into when he joined the Company in 1999.

Each of the stock options granted to Dr. Wright and Messrs. Perito and Williams in 2011 was subject to performance based vesting criteria and, in the case of the stock option grants to Messrs. Perito and Williams, stockholder approval. In 2011 the stock option grant to Dr. Wright vested with the introduction of our Anatabloc® dietary supplement and sixty-five percent of the stock options granted to Messrs. Perito and Williams vested based on their meeting two of the performance criteria in their employment agreements and upon stockholder approval of the stock option grants by a margin of 81.6% of the votes cast for this proposal at our Annual Meeting held on December 16, 2011. The stock option grants for Messrs. Perito and Williams provide the following criteria for vesting upon the attainment of the performance goals, provided that not more than 100% of the stock options may become vested:

Obj	ective	Percentage Allocation
•	The introduction of Anatabloc <sup>®</sup> into the market for sale as a dietary supplement, following a successful clinical trial of the product and a related clinical study report by an independent third party issued by such party	80%
•	Gross sales of CigRx <sup>®</sup> surpass \$1,000,000 on a cumulative basis	20%
•	Public stock of our company's common stock trades at above $5.00$ at close of NASDAQ market on any one trading day <sup>(a)</sup>	50%
•	Our company enters into an agreement with a major tobacco (including one of the top three US tobacco companies) company for licensing and/or sale of one of its three BDL smokeless products and/or the licensing or sale of the current versions of Stonewall or Ariva	25%
•	Our company enters into an agreement for the development of an isomer of its RCP006 compound as a drug product	20%
•	The United States Court of Appeals for the Federal Circuit reverses the jury verdict in favor of RJR and remands the case back to the Federal District Court for a retrial	40%
•	The Food & Drug Administration, after review and consideration, acts favorably on any one of the three (3) pending Modified Risk Applications under §911 of the Tobacco Act of 2009 for our company's low-TSNA smokeless tobacco products	20%
•	The PTO rules in our company's favor on the two pending Reexamination Petitions addressing claims in the '649 and '401 patents <sup>(b)</sup>	15%

(b) On March 10, 2011 the PTO upheld our claims in the two patents at issue in the reexamination petitions.

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At December 31, 2012, there were 17,595,000 options issued and outstanding with a weighted average exercise price of \$2.73 per share.

#### **Benefits** Plans

In order to attract and retain individuals who are capable of carrying out and enhancing our mission, we have provided certain benefits and perquisites to our senior executives that are comparable to those generally available to senior management and were available to those executives in previous positions. In the case of our CEO and COO these benefits and perquisites have included the items listed below. Where noted, such benefits also have been provided to other executive officers:

- reimbursement for life insurance coverage in the amount of \$10 million for our company's CEO,
  \$5 million for our COO and \$1 million for our General Counsel;
- additional disability insurance for our COO and General Counsel;
- a Company automobile and reimbursement for all costs associated with the operation of the automobile for our company's CEO and COO and reimbursement of automobile expenses for our company's Vice President of Sales and Marketing;
- monthly or annual club membership dues for our company's CEO and COO;
- a mobile phone and phone costs for our company's CEO, COO, CFO and Vice President of Sales and Marketing; and
- Reimbursement for the cost of outside counsel retained by our company's CEO and/or COO in connection with advice and counsel related to the negotiation, drafting, and execution of their employment agreements.

### **Employment and Severance Arrangements**

The executive employment agreements entered into with Messrs, Williams and Perito on March 14, 2011 continued through December 31, 2012 and contained identical severance provisions that provided for the payments of all salary, benefits, bonuses and other compensation that would be due through the term of the contract if the contract were terminated without "Cause" or if either Mr. Perito or Mr. Williams resigned for "Good Reason", as set forth in the employment agreements. In December 2012, the executive employment agreements were amended to continue on a month-to-month basis. Under the amendments the executive employment agreements may be terminated upon notice provided at least 15-days prior to the end of each monthly period. In the event of termination, Mr. Perito or Mr. Williams, as applicable, will be entitled to all salary, benefits, bonuses and other compensation that would be due thereunder through the end of the termination of his contract.

Under the terms of Mr. Pokusa's employment agreement, at the conclusion of the initial three-year term in 2004, the agreement continued in place, but on a month-to-month basis. Pursuant to the terms of his employment agreement, Mr. Pokusa is entitled to severance payments equal to six months' salary in the event of his termination without cause. Those payments would be due on a monthly basis. Mr. Pokusa's employment agreement has not been modified to eliminate severance because the agreement has continued under its original terms, although on a month-to-month basis. Under the terms of Mr. Dodd's employment agreement he is entitled to severance payments equal to six months base salary, based on his average salary over the past twelve months or lesser period as applicable, in the event the agreement is terminated without "Cause" or for "Good Reason", as defined in the agreement. Any severance payments would be made at the same time and in the same manner as salary payments would have been paid to Mr. Dodd during the term of his agreement. The executive employment agreement with Mr. Dean was modified to eliminate any severance payments when his contract was continued on a month-to-month basis after expiration and in connection with the decision to limit Mr. Dean's compensation at that time to his base salary payments and benefits.

Under the employment agreements with Messrs. Dean, Dodd, Perito, Pokusa and Williams, these Named Executives are subject to noncompetition covenants following the termination of employment as well as covenants relating to the treatment of confidential information disclosed to them during their employment with our company. The noncompetition covenants prohibit the Named Executives from owning a company or accepting employment with an entity that competes in the same field as our company or soliciting business of the same or similar type being carried on by our company for a period of one year following termination of employment.

We believe that written agreements are in the best interest of our company to retain our current executive officers, to attract prospective executive officers to our company and to provide such individuals with assurances of continued salary and benefits in the event of the termination of their employment relationship. Absent such provisions, we believe that we would have difficulty attracting and retaining the type of executive officers that we believe are critical to our mission and long-term objectives. When we are in a position to enter into new contracts with our other Named Executive or other executive officers in the future, it is expected that such contracts will be for multiple-year terms and will contain provisions for base salary, and provisions covering a combination of some or all of bonuses, equity incentive awards and severance provisions.

## Taxation of Executive Compensation

We seek to compensate our executive officers in a manner that is tax effective for our company. As appropriate, we seek to structure these compensation arrangements, to the extent applicable, to comply with the requirements of Section 162(m) of the Internal Revenue Code of 1986, as amended.

#### Consideration of "Say-on-Pay" Vote

Our Board of Directors recognizes the fundamental interest that our stockholders have in the compensation of our executive officers. At our 2012 annual meeting of stockholders, our stockholders approved, on an advisory basis, the compensation of our Named Executive Officers (a "say-on-pay proposal") as disclosed in the proxy statement for such meeting. Our stockholders approved the say-on-pay proposal by the affirmative vote of 92.8% of the shares cast on that proposal. The Compensation Committee believes that this illustrates our stockholders' support of our approach to executive compensation. The Compensation Committee will continue to consider the outcome of our company's say-on-pay proposals when making future compensation decisions for our executive officers. In addition, as previously disclosed, our company's Board of Directors has determined that it will hold an advisory vote on the compensation of our company's named executive officers annually until the next required vote on the frequency of stockholder votes on executive compensation, which will occur no later than our annual meeting of stockholders in 2017.

#### **Compensation Committee Report**

The Compensation Committee held four meetings during fiscal year ended December 31, 2012. Based on our company's introduction of our Anatabloc<sup>®</sup> dietary supplement in 2011 and progress in 2012 in meeting goals relating to our nutraceutical, dietary supplements and the ongoing research and development activities of our company's Rock Creek subsidiary, the Compensation Committee determined that our company's current compensation levels were appropriate, as were the additional cash bonuses and stock option awards issued in April 2012. The Compensation Committee also subsequently ratified the voluntary action by the Company's CEO, Chairman, President and COO, General Counsel and CFO to voluntarily reduce their salaries until our company is profitable and has reviewed and discussed with management the Compensation Discussion and Analysis for the year ended December 31, 2012. Based upon such review and discussion, the Compensation Committee recommended to our Board of Directors that the Compensation Discussion and Analysis section be included in this Report. Additionally, based on such review, the Compensation has determined that the current levels of compensation of our executive officers are appropriate given their experience, job responsibilities and the diverse management roles that have been assumed by the executive officers.

Christopher C. Chapman, M.D. (Chairman) Neil L. Chayet, Esquire Burton J. Haynes, Esquire

The foregoing report shall not be deemed incorporated by reference by any general statement incorporating by reference this proxy statement into any filing under the Securities Act of 1933 or under the Securities Exchange Act of 1934, as amended (together, the "Acts"), except to the extent that our company specifically incorporates this information by reference, and shall not otherwise be deemed filed under the Acts.

The following table summarizes the compensation paid to the Named Executives employed by our company during 2010, 2011 and 2012, for services rendered in all capacities to our company and its subsidiaries.

## **SUMMARY COMPENSATION TABLE FOR 2012**

Name and Principal Position	Year	Salary (\$)	<b>Bonus</b> (\$) <sup>(1)</sup>	Options (\$) <sup>(2)</sup>	All Other Compensation (\$)	Total (\$)
Jonnie R. Williams, Sr.	2010	1,000,000		2,858,625	95,158	3,953,783
Chief Executive Officer	2011	1,000,000		7,971,363	117,641	9,089,004
	2012	1,000,000			148,443 <sup>(3)</sup>	1,148,443
Park A. Dodd, III Chief	2010	221,483	1,500	114,345	5,342	342,670
Financial Officer	2011	246,019	1,500	<u> </u>	11,025	247,519
	2012	279,791	6,500	83,755	12,750 <sup>(4)</sup>	382,796
Paul L. Perito Chairman,	2010	1,000,000	_	2,858,625	236,833	4,095,458
President and Chief	2011	1,000,000		6,507,235	220,750	7,727,985
Operating Officer	2012	1,000,000			338,180 <sup>(5)</sup>	1,338,180
Robert E. Pokusa	2010	385,000	1,500		. 17,815	404,315
General Counsel	2011	385,000	1,500		17,290	403,790
	2012	385,000	11,500	83,755	18,763 <sup>(6)</sup>	509,013
David Dean Vice President	2010	295,000	1,500		25,842	322,342
Sales and Marketing	2011	295,000	1,500	451,500	28,977	776,977
. · · · · · · · · · · · · · · · · · · ·	2012	295,000	100,761	358,950	63,007 <sup>(7)</sup>	817,718

(1) Represents our company's yearly Holiday bonus of \$1,500 paid to all employees, except our CEO and COO. Also our Chief Financial Officer, General Counsel and Vice President of Sales and Marketing received one time performance bonuses in 2012 of \$75,000, \$10,000 and \$5,000 respectively relating to the successful introduction of Anatabloc<sup>®</sup> and our Vice President Sales and Marketing also received \$24,261 in sale commission for Anatabloc<sup>®</sup> sales.

(2) Amounts represent the grant date fair value of the stock options issued in the respective year. For the assumptions used in calculating the value of this award, see Note 8 to our consolidated financial statements included in Item 15 of our Annual Report on Form 10-K filed on March 18, 2013.

- (3) Represents \$65,670 in automobile expenses, \$55,130 in life insurance premiums and \$27,643 in club memberships.
- (4) Represents matching contributions by our company under our 401(k) Plan.
- (5) Represents \$49,042 in automobile expenses, \$266,762 in life and disability insurance premiums and \$22,376 in club memberships.
- (6) Represents \$6,013 in life and disability insurance premiums and \$12,750 of matching contributions by our company under our 401(k) Plan.
- (7) Represents \$63,007 in automobile expenses.

#### **Grants of Plan Based Awards During 2012**

The table below summarizes information relating to the grants to our Named Executives in 2012.

Name	Options Grant Date	Number of Securities Underlying Unexercised Options	Option Exercise Price	Option Expiration Date	Grant Date Fair Value of Options Award
David Dean	4/5/2012	150,000	\$3.02	4/5/2022	\$358,950
Park Dodd	4/5/2012	35,000	\$3.02	4/5/2022	\$ 83,755
Robert Pokusa	4/5/2012	35,000	\$3.02	4/5/2022	\$ 83,755

For the assumptions used in calculating the value of these awards, see Note 8 to our consolidated financial statements included in "Item 15. Exhibits, Financial Statement Schedules" of our Annual Report on Form 10-K filed on March 18, 2013.

## **Outstanding Equity Awards as of December 31, 2012**

The following table provides information regarding the stock options held by the Named Executives as of December 31, 2012. All stock options were fully vested and exercisable as of December 31, 2012, except for those granted to Messrs. Perito and Williams in 2011. In connection with those grants 3,185,000 of the 4,900,000 option shares granted to Jonnie R. Williams and, 2,600,000 of the 4,000,000 option shares granted to Paul L. Perito vested in 2011. In connection with those grants, 1,715,000 and 1,400,000 stock options, respectively, remain unvested for Messrs. Williams and Perito.

	Number of Securities Underlying Unexercised Options (#) Exercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price (\$)	Option Expiration Date
Jonnie R. Williams, Sr.	125,000		\$1.89	5/6/13
	500,000	·	\$1.72	5/6/18
	1,250,000	_	\$2.72	4/5/20
	3,185,000	1,715,000 <sup>(1)</sup>	\$2.95	3/14/21
Park A. Dodd, III	250,000		\$1.19	10/10/17
	50,000	·	\$1.72	5/6/18
	50,000	<u> </u>	\$2.72	4/5/20
	35,000	s a <sup>1</sup> a a <del></del> a	\$3.02	4/5/22
Paul L. Perito	625,000		\$1.72	5/6/18
	1,250,000		\$2.72	4/5/20
	2,600,000	1,400,000 <sup>(1)</sup>	\$2.95	3/14/21
Robert E. Pokusa	225,000	. —	\$1.72	5/6/18
	35,000		\$3.02	4/5/22
David Dean	350,000		\$2.00	1/31/21
	150,000		\$3.02	4/5/22

(1) These stock options are subject to performance based vesting criteria. For a description of the vesting schedule upon the attainment of the applicable performance goals, see "Compensation Discussion and Analysis — Discretionary Equity Incentive Awards."

#### **Option Exercises and Stock Vested During 2012**

The following table provides information regarding the exercise of options by our Named Executives during the year ended December 31, 2012. No shares of our common stock held by our Named Executives became vested during 2012.

;

Name	· .	1. A.		Number of Shares Acquired on Exercise (#) <sup>(1)</sup>	Value Realized on Exercise (\$) <sup>(2)</sup>
Jonnie R. William	ıs Śr	 	· · · · · · · · · · · · · · · · · · ·	<u> </u>	
Park A. Dodd, III	· · · · · · · · ·	 			· · · · · · · · · · · · · · · · · · ·
Robert E. Pokusa		 		100,000	\$286,000
David Dean		 			

(1) Represents the gross number of shares of our common stock acquired upon exercise of vested options without taking into account any shares that may be withheld to cover option exercise price or applicable tax obligations:

(2) The amount shown represents the value of exercised options calculated by multiplying (i) the gross number of shares of our common stock acquired upon exercise by (ii) the excess of the fair market value of our common stock on the date of exercise over the exercise price of the option.

## Potential Payments Upon Termination or Change of Control

As noted below, our Named Executives are entitled to severance upon a termination of employment but are not entitled to any payments solely as a result of agreements that were in effect as of December 31, 2012. The employment agreements for the Named Executives are described above under "--- Employment and Severance Arrangements". The following chart sets forth the severance the Named Executives would be entitled to receive upon certain terminations of employment, assuming the relevant event occurred on December 31, 2012.

Name	Description of Severance	Termination without Cause
Park A. Dodd, III <sup>(1)</sup>	Salary Continuation	\$100,000
Robert E. Pokusa <sup>(1)</sup>	Salary Continuation	\$192,500

(1) The Named Executives would also be entitled to receive the above salary continuation payments upon a termination of employment by them for "Good Reason," as defined in their employment agreements effective as of December 31, 2012, to generally mean (i) a material diminution in their position, duties, responsibilities, functions or status with us, or the removal, or our failure to re-elect them to, any of such positions, (ii) a material reduction by us of their base salary or benefits or (iii) any other material breach by us of their employment agreement, which breach is not cured within 20 days of notice.

#### **Board of Director Compensation**

In compensating directors, our company has sought to use a combination of payments for participation in director and committee meetings, initial anniversary stock option grants and periodic stock option grants. The combination of payments for meeting attendance and stock option grants is intended to motivate and align the interest of the directors with that of our company. Also, given our company's mission to promote maintenance of a healthy metabolism and to reduce the harm associated with the use of tobacco at every level, we have sought to use the combination of payments to directors for attendance at meetings and stock option grants to attract directors who have particular skills and expertise that would complement our company's mission, particularly in the area of finance, new product development, medical research, and other health-related areas.

Each of our company's independent directors, as so classified by our Board of Directors, or the Independent Directors, is granted a stock option to purchase up to 50,000 shares of our common stock on the date such Independent Director is first elected to the Board of Directors, vesting in equal installments on each of the first two anniversaries of the date of grant. As an annual retainer, each Independent Director additionally receives a stock option to purchase up to 50,000 shares of our common stock granted on each anniversary of such Independent Director's initial election to the Board of Directors, exercisable immediately. Each Independent Director also receives a payment of \$4,500 for his participation in each meeting of the Board of Directors and any committee meeting attended personally and \$3,500 for his participation in each meeting of the Board of Directors and any committee meeting attended telephonically, subject to a cap of \$6,000 for multiple in-person or telephonic meetings on the same day. Additionally, the chairman of the Audit Committee is to receive a separate fee of \$20,000 per year for services in that capacity, although the fee has been waived at times in the past, and the chairman of the Compensation Committee is to receive a separate fee of \$15,000 per year for services in that capacity.

Messrs. Chapman, Chayet, Everett and Haynes have been designated as our current Independent Directors. This designation of independence is intended solely for the purpose of clarifying which directors are entitled to compensation for their services as directors. Directors not designated as Independent Directors generally are those who in the past have been employees of our company, or who have waived their right to receive director compensation. Directors who are employees of our company receive compensation in their capacity as employees but do not receive any compensation for board or committee meetings, nor do they receive the "options package" made available to individuals serving as Independent Directors. Our CEO does not, and has not, served as the Chairman of our Board of Directors. Since 2000 our Chairman has been Mr. Perito, who serves as our company's President and COO.

The following table sets forth, for our company's Independent Directors, certain information regarding fees earned and equity awards granted during the year ended December 31, 2012.

Name	Fees Earned or Paid in Cash (\$) <sup>(1)</sup>	Option Grant Date Fair Value (\$) <sup>(2)</sup>	All Other Compensation	Total (\$)
Burton J. Haynes	\$84,000	\$246,150		\$330,150
Christopher C. Chapman, MD	80,500	274,950	_	355,450
Neil L. Chayet	44,500	269,150	_	313,650
Ralph B. Everett	6,000	139,922	_	145,922
Mario V. Mirabelli <sup>(3)</sup>	42,500	279,150		321,650

(1) This column represents the amount of compensation earned by each Independent Director during 2012 in the form of director fees.

(2) Amounts represent the grant date fair value of the stock options issued in the respective year. For the assumptions used in calculating the value of this award, see Note 8 to our consolidated financial statements included in Item 15 of our Report on Form 10-K filed on March 18, 2013.

(3) Mr. Mirabelli did not stand for re-election to the Board at the annual meeting held on December 14, 2012.

Name	Options Granted 2012	2012 Vested Options	Option Exercise Price (\$)	Option Expiration Date	Total Options outstanding as of December 31, 2012
Burton J. Haynes	50,000	50,000	3.02	4/5/22	
	50,000	50,000	3.20	10/22/22	200,000
Christopher C. Chapman, M.D.	50,000	50,000	3.02	4/5/22	
	50,000	50,000	3.93	9/22/22	525,000
Neil L. Chayet	50,000	50,000	3.02	4/5/22	•
-	50,000	50,000	3.78	9/7/22	425,000
Ralph B Everett	50,000	_	3.26	12/14/22	50,000
Mario V. Mirabelli <sup>(1)</sup>	50,000	50,000	3.02	4/5/22	
	50,000	50,000	4.03	7/8/22	200,000

The following represents the number of options granted to each Independent Director in 2012 and the total number of options held by each Independent Director as of December 31, 2012.

(1) Mr. Mirabelli did not stand for re-election to the Board at the annual meeting held on December 14, 2012.

# **Compensation Committee Interlocks and Insider Participation**

No member of our Board of Director's Compensation Committee, each of whom is listed under "--- Compensation Committee Report," has served as one of our officers or employees at any time. None of our executive officers served during 2012 as a member of the board of directors or as a member of a compensation committee of any other company that has an executive officer serving as a member of our Board of Directors or Compensation Committee.

#### ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth as of April 15, 2013, certain information with respect to the beneficial ownership of our company's common stock by each beneficial owner of more than 5% of our company's voting securities, each director and each Named Executive Officer, and all directors and executive officers of our company as a group. As of April 15, 2013, there were 166,491,509 shares of our company's common stock outstanding.

	Shares	
Name	Beneficially Owned <sup>(1)</sup>	Percentage Owned <sup>(2)</sup>
Named Executive Officers		
Park A. Dodd, III <sup>(3)</sup>	395,000	*
Paul L. Perito <sup>(4)</sup>	6,455,000	3.7%
Robert E. Pokusa <sup>(5)</sup>	273,558	* .
Jonnie R. Williams, Sr. <sup>(6)</sup>	17,486,210	10.0%
David Dean <sup>(7)</sup>	891,398	: <b>*</b>
Directors Who Are Not Named Executive Officers		
Christopher C. Chapman, Jr., M.D. <sup>(8)</sup>	525,000	*
Neil Chayet <sup>(9)</sup>	429,000	*
Ralph B. Everett <sup>(10)</sup>	0	*
Burton J. Haynes <sup>(11)</sup>	244,700	*
All Directors and Executive Officers as a Group (10 Persons) <sup>(12)</sup>	27,449,866	15.1%
Other Beneficial Owners of 5% or More of the Outstanding Common Stock of the Company	ан со	1. 1 4.
Tradewinds Investment Management, LP <sup>(13)</sup>	21,825,492	13.1%
John Joseph McKeon <sup>(14)</sup>	14,473,000	8.7

\* Denotes less than 1% beneficial ownership.

(5) Includes 13,558 shares held by Mr. Pokusa and 260,000 shares that Mr. Pokusa has the right to acquire upon exercise of stock options.

<sup>(1)</sup> Beneficial ownership is determined in accordance with rules of the SEC and includes shares over which the indicated beneficial owner exercises voting and/or investment power. Shares of common stock subject to options or warrants currently exercisable or exercisable within 60 days are deemed outstanding for purposes of computing the percentage ownership of the person holding such securities, but not deemed outstanding for purposes of computing the percentage ownership of any other person. Except as indicated, and subject to community property laws where applicable, the persons named in the table above have sole voting and investment power with respect to all shares of voting stock shown as beneficially owned by them. Unless otherwise noted, the address for each of the above stockholders is c/o Star Scientific, Inc., 4470 Cox Road, Suite 110, Glen Allen, Virginia 23060.

<sup>(2)</sup> The "Percentage Owned" calculations are based on the outstanding shares of our common stock as of April 15, 2013.

<sup>(3)</sup> Includes 385,000 shares that Mr. Dodd has the right to acquire upon exercise of stock options and 10,000 shares held by Mr. Dodd.

<sup>(4)</sup> Includes 1,881,000 shares held by Mr. Perito, 50,000 shares that Mr. Perito has the right to acquire upon exercise of a warrant, 4,475,000 shares which Mr. Perito has the right to acquire upon exercise of stock options, and an aggregate of 49,000 shares held by his children or in trust for the benefit of his children, of which Mr. Perito disclaims beneficial ownership.

- (6) Includes 9,828,544 shares held by Mr. Williams, 2,597,666 shares that Mr. Williams has the right to acquire upon exercise of warrant, and 5,060,000 shares that Mr. Williams has the right to acquire upon exercise of stock options. Mr. Williams' beneficial ownership is based solely on publicly available information as filed with the SEC and our company records. In addition, we are aware that according to note and pledge agreements dated June 26, 2009, December 16, 2010 and December 19, 2012, Mr. Williams pledged a total of 8,327,468 shares of our common stock under the notes. The status of Mr. Williams' beneficial ownership is currently being reviewed.
- (7) Includes 151,742 shares held by Mr. Dean, 1,100 shares held by Mr. Dean's wife, 238,556 shares held in an individual retirement account, and 500,000 shares that Mr. Dean has the right to acquire upon exercise of stock options.
- (8) Includes 525,000 shares that Mr. Chapman has the right to acquire upon exercise of stock options.
- (9) Includes 2,000 shares held by Mr. Chayet, 2,000 shares that Mr. Chayet has the right to acquire upon exercise of a warrant and 425,000 shares that Mr. Chayet has the right to acquire upon exercise of stock options.
- (10) Mr. Everett was granted a stock option for 50,000 shares upon his election to our Board of Directors at our Annual Meeting held on December 14, 2012. Those option shares will vest in 25,000 share increments on December 14, 2013 and December 14, 2014 respectively.
- (11) Includes 10,000 shares held by Mr. Haynes, 10,000 shares that Mr. Haynes has the right to acquire upon exercise of a warrant, 24,700 shares held by Mr. Haynes in an individual retirement account and 200,000 shares that Mr. Haynes has the right to acquire upon exercise of stock options.
- (12) Includes 12,210,200 shares of common stock, 12,580,000 shares of common stock that the directors and officers have the right to acquire upon the exercise of options and 2,659,666 shares of common stock that the directors and officers have the right to acquire upon exercise of warrants.
- (13) Based solely on reported filings and representation from Tradewinds Management and other filings, includes 21,825,492 shares for which Tradewinds Master Fund (BVI) Ltd., Feehan Partners, L.P. and 2. P.V. Partners, L.P. share voting and dispositive power. Robert W. Scannell is a director of Tradewinds Master Fund (BVI) Ltd. and the General Partner of Feehan Partners, L.P. and has voting and investment power over each entity's respective securities. Mr. Peters is a director of Tradewinds Master Fund (BVI) Ltd. and the General Partner of P.V. Partners, L.P. and has voting and investment power over each entity's respective securities. Tradewinds Master Fund (BVI) Ltd. is a business company organized in the British Virgin Islands. Tradewinds Investment Management, L.P. is its investment manager pursuant to an investment management agreement over which Messrs. Scannell and Peters exercise voting and investment authority and control. Mr. Peters disclaims beneficial ownership of and receives no pecuniary interest from the securities held by Feehan Partners, L.P., which are held for the benefit of Mr. Scannell, and Mr. Scannell disclaims beneficial ownership of and receives no pecuniary interest from the securities held by P.V. Partners, L.P. and the securities held in Mr. Peters' retirement accounts, in each case, which are held for the benefit of Mr. Peters. The address for these stockholders is c/o Tradewinds Investment Management, L.P. Three Harbor Drive, Suite 213, Sausalito, California 94965.
- (14) Based solely on the reporting person's Schedule 13G/A filed on January 22, 2013, reflecting 14,473,000 shares for which Mr. McKeon has sole voting or dispositive power. The address for this stockholder, as set forth in the Schedule 13G/A, is 2630 Harbourside Dr., Longboat Key, FL 34228.

#### Equity Compensation Plan Information

The following table provides certain information as of December 31, 2012, with respect to our equity compensation plans under which our common stock is authorized for issuance:

Shares to be Issued Upon Weighted-Average Exercise of Exercise Price of	Future Issuance Under Equity
Number of	Securities Remaining Available for

Subsequent to December 31, 2012 we issued a combination of 225,685 in stock and stock option grants and 175,000 stock options expired. As a result, the number of securities remaining available under the plan at April 15, 2013 is 2,002,456.

# ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

#### **Transactions with Related Persons**

Our company is the licensee under a license agreement, or License Agreement, with Regent Court Technologies, LLC, of which Jonnie R. Williams, Sr., our company's CEO, and Francis E. O'Donnell, Jr., M.D., the beneficiary of the O'Donnell Trust, are the owners. The License Agreement provides, among other things, for the grant of an exclusive, worldwide, irrevocable license to our company, with the right to grant sublicenses, to make, use and sell tobacco and products containing tobacco under the licensor's patent rights and know-how relating to the processes for curing tobacco so as to significantly prevent the formation of certain toxic carcinogens present in tobacco and tobacco smoke, namely Tobacco Specific Nitrosamines, and to develop products containing such tobacco, whether such patent rights and know-how are now in existence or hereinafter developed. Our company is obligated to pay to Regent Court a royalty of 2% on all net sales of products by us and any affiliated sub-licensees, and 6% on all fees and royalties received by us from unaffiliated sub-licensees, less any related research and development costs incurred by our company. The License Agreement expires with the expiration of the last of any applicable patents. Thirteen United States patents have been issued, and additional patent applications are pending. To date, our company has paid no royalties under the License Agreement. The License Agreement may be terminated by our company upon thirty days written notice or by Regent Court if there is a default in paying royalties or a material breach by our company or the purchase of our company's stock or assets.

Effective September 1, 2008, we entered into an agreement for our company's use of an aircraft owned by Starwood Aviation, a Company that is owned solely by Mr. Williams. Under this agreement, we agreed to pay an hourly rate for the use of the aircraft of approximately \$3,970 each month until the monthly fixed rental cost for the aircraft of approximately \$51,000 has been met. If the aircraft was used beyond the monthly fixed cost, we were required to pay an hourly rate of approximately \$1,200 to cover related costs. In accordance with our company's related party transaction policy, the agreement with Starwood Aviation was recommended for approval to the Board of Directors by our company's Audit Committee, and it was approved by the Board of Directors at a meeting held on October 6, 2008. As of May 5, 2010, the agreement with Starwood Aviation was amended to clarify the types of items that would be included as "out of pocket" expenses and to recognize that certain costs, such as for fuel, would be variable depending on the actual cost of the item at the time of use. Payments made by our company to Starwood or Starwood Aviation with respect to related expenses were \$1.9 million in 2012, \$2.0 million in 2011, \$1.7 million in 2010, and were billed at cost. In 2013, Starwood Aviation sold the aircraft that was the subject of our prior agreement for aircraft use. On March 9, 2010, Mr. Williams purchased 2,371,541 shares of our common stock at a price of \$1.14 per share and, for a price of \$0.125 per share, purchased a warrant for an equal number of warrant shares at an exercise price of \$1.50 per share and on November 5, 2010, Mr. Williams purchased 717,220 shares of our common stock at a price of \$1.80 per share and, for a price of \$0.125 per share, purchased a warrant for an equal number of warrant shares at an exercise price of \$1.80 per share. On November 5, 2010, Messrs. Chayet, Haynes and Perito purchased 2,000, 10,000 and 50,000 shares respectively of our common stock at a price of \$1.80 per share and, for a price of \$0.125 per share, purchased a warrant for an equal number of warrant shares at an exercise price of \$0.125 per share. On November 5, 2010, Messrs. Chayet, Haynes and Perito purchased 2,000, 10,000 and 50,000 shares respectively of our common stock at a price of \$1.80 per share and, for a price of \$0.125 per share, purchased a warrant for an equal number of warrant shares at an exercise price of \$1.80 per share. In accordance with our company's related party transaction policy, Mr. Williams' intention to purchase shares and warrant shares of our company's stock was considered by the Audit Committee at meetings held on March 9, 2010 and November 5, 2010 respectively and was approved by the Audit Committee and the Board of Directors on those dates. The purchase of shares by Messrs. Chayet, Haynes and Perito also was approved by the Audit Committee at the meeting held on November 5, 2010. On November 14, 2012, Mr. Williams exercised 1,000,000 warrant shares at the granted exercise price of \$1.50 per share of the warrants that were issued on March 9, 2010, as part of a stock purchase transaction on the same date.

Jonnie R. Williams, Jr., the son of our CEO and who is employed as our Director of Marketing received total compensation in 2012 in the amount of \$184,904.57. This consisted of salary of \$75,000, a \$75,000 bonus and payment allowance for an automobile and related use and maintenance cost in the amount of \$34,904.57.

#### **Procedures for Approval of Related Party Transactions**

Pursuant to the charter of our Audit Committee, all transactions between us and any of our directors, executive officers or related parties are subject to the review by our Audit Committee.

#### **Director Independence**

The standards relied upon by our Board of Directors in affirmatively determining whether a director is "independent" in compliance with the rules of The NASDAQ Global Market are the standards set forth in the NASDAQ Marketplace Rules and the applicable listing requirements thereof. In addition, no director will qualify as independent unless our Board of Directors affirmatively determines that the director has no relationship that may interfere with the director's exercise of independent judgment.

Our Board of Directors, in applying the above-referenced standards, has affirmatively determined that our current independent directors are: Messrs. Chapman, Chayet, Haynes and Everett. As part of the Board of Director's process in making such determination, each such director has provided responses to questionnaires confirming that (i) all of the above-cited objective criteria for independence are satisfied and (ii) he has no other relationship that could interfere with his ability to exercise independent judgment.

# ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The Audit Committee has established its pre-approval policies and procedures, pursuant to which the Audit Committee approved the following audit services, provided by Cherry Bekaert LLP in 2012. Consistent with the Audit Committee's responsibility for engaging our company's independent auditors, all audit and permitted non-audit services require pre-approval by the Audit Committee. The full Audit Committee approves proposed services and fee estimates for these services. The Audit Committee chairperson or his designee has been designated by the Audit Committee to approve any services arising during the year that were not pre-approved by the Audit Committee at its next regular meeting and the Audit Committee reviews services and fees for the fiscal year. Pursuant to these procedures, the Audit Committee approved the following audit services provided by Cherry Bekaert LLP:

#### Audit Fees;

Cherry Bekaert LLP billed our company \$158 thousand for professional services for the audits of our company's annual consolidated financial statements and the effectiveness of internal control over financial reporting for the year ended December 31, 2012, the reviews of the interim financial statements included in our company's Forms 10-Q filed during the fiscal year ended December 31, 2012, and other required Securities Act filings.

Cherry Bekaert LLP billed our company \$157 thousand for professional services for the audits of our company's annual consolidated financial statements, the effectiveness of internal control over financial reporting for the year ended December 31, 2011, the reviews of the interim financial statements included in our company's Forms 10-Q filed during the fiscal year ended December 31, 2011, and other required Securities Act filings.

#### Audit-Related Fees:

None.

#### Tax Fees:

Cherry Bekaert LLP billed our company \$22 thousand for services related to tax compliance (federal and state tax reporting and tax planning) in 2012.

Cherry Bekaert LLP billed our company \$23 thousand for services related to tax compliance (federal and state tax reporting, tax planning and tax consulting services in connection with an analysis of the impact on net operating loss carryovers due to changes in Company ownership) in 2011.

All Other Fees:

None.

#### Part IV

#### **ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

(a) Documents filed as part of this Report.

1. Consolidated Financial Statements

Our financial statement (and related notes) were contained in the Original 10-K Filing. Please refer to the Original 10-K Filing.

(b) Exhibits.

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An index to exhibits has been filed as part of this Report beginning on page 27 and is incorporated herein by reference.

# SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

# STAR SCIENTIFIC, INC.

By: /s/ JONNIE R. WILLIAMS, SR.

Jonnie R. Williams, Sr. Chief Executive Officer

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Date: April 30, 2013

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#### Description Item Asset Purchase Agreement between Star Scientific, Inc., a Delaware corporation and Eyetech, 2.1 LLC, a Minnesota limited liability company, by Robert J. Fitzsimmons, an individual residing in St. Paul, Minnesota, dated December 30, 1998.<sup>(1)</sup> Eighth Amended and Restated Certificate of Incorporation of Star Scientific, Inc.<sup>(2)</sup> 3.1 Amended and Restated Bylaws of Star Scientific, Inc.<sup>(3)</sup> 3.2 License Agreement between Star Tobacco and Pharmaceuticals, Inc., as Licensee and Regent Court 10.1 Technologies, Jonnie R. Williams, and Francis E. O'Donnell, Jr., M.D., as Licensor, dated January 5, 1998.<sup>(4)</sup> Amendment No. 1 to License Agreement between Regent Court Technologies, Jonnie R. Williams, 10.2 Francis E. O'Donnell, Jr., M.D. and Star Tobacco and Pharmaceuticals, Inc., dated August 3, 1998.(5) 1998 Stock Option Plan, as amended.<sup>(6)</sup> 10.3 2000 Equity Incentive Plan, as amended.<sup>(7)</sup> 10.4 Second Amended and Restated 2008 Incentive Award Plan. 10.5 Qualified Stock Option Agreement dated as of April 27, 1999 between Star Scientific, Inc. and 10.6 Paul L. Perito.<sup>(8)</sup> Lease and Purchase Option Contract between Star Scientific, Inc. and the Industrial Development 10.7 Authority of the Town of Chase City, Virginia, dated March 10, 2000.<sup>(6)</sup> Form of Director Indemnification Agreement.<sup>(6)</sup> 10.8 Form of Officer Indemnification Agreement.<sup>(6)</sup> 10.9 Executive Employment Agreement between Star Scientific, Inc. and David M. Dean, dated 10.10 October 6, 2000.<sup>(7)</sup> Restated Loan Agreement between Star Scientific, Inc., Star Tobacco and Pharmaceuticals, Inc. 10.11 ' and Brown & Williamson Tobacco Corporation, dated August 21, 2000.<sup>(9)</sup> Restated Security Agreement between Star Scientific, Inc. and Brown & Williamson Tobacco 10.12 Corporation, dated August 21, 2000.<sup>(9)</sup> Security Agreement between Star Tobacco and Pharmaceuticals, Inc. and Brown & Williamson 10.13 Tobacco Corporation, dated August 21, 2000.<sup>(9)</sup> Guaranty Agreement between Star Scientific, Inc. and Brown & Williamson Tobacco Corporation, 10.14 dated August 21, 2000.<sup>(9)</sup> Guarantee Agreement between Star Tobacco and Pharmaceuticals, Inc. and Brown & Williamson 10.15 Tobacco Corporation, dated August 21, 2000.<sup>(9)</sup> Amended and Restated Executive Employment Agreement dated as of March 15, 2001 between 10.16 Star Scientific, Inc. and Christopher G. Miller.<sup>(7)</sup> Executive Employment Agreement dated as of March 30, 2001 between Star Scientific, Inc. and 10.17 Robert E. Pokusa.<sup>(7)</sup> Restated Master Agreement, dated April 25, 2001, by and between Star Scientific, Inc. and 10.18 Brown & Williamson Tobacco Corporation.<sup>(10)</sup> First Amendment to Restated Loan Agreement dated April 25, 2001, among Star Scientific, Inc., 10.19 Star Tobacco & Pharmaceuticals, Inc. and Brown & Williamson Tobacco Corporation.<sup>(10)</sup>

#### INDEX TO EXHIBITS

Item	Description
10.20	Trademark License and Royalty Agreement, dated April 25, 2001, between Star Scientific, Inc. an Brown & Williamson Tobacco Corporation. <sup>(10)</sup>
10.21	Other Low TSNA Tobacco Royalty Agreement, dated April 25, 2001 by and between Star Scientific, Inc. and Brown & Williamson Tobacco Corporation. <sup>(10)</sup>
10.22	First Amendment to Regent/B&W License Agreement, dated April 25, 2001, by and among Regent Court Technologies, Jonnie R. Williams, Francis O'Donnell, Jr., Star Scientific, Inc. and Brown & Williamson Tobacco Corporation. <sup>(10)</sup>
10.23	Exclusive License Agreement dated as of March 16, 2001 by and among Regent Court Technologies and Star Scientific, Inc. <sup>(11)</sup>
10.24	Consent to Assignment dated March 16, 2001 by and among Regent Court Technologies, Jonnie R. Williams, Francis O'Donnell, Jr., M.D., Star Tobacco & Pharmaceuticals, Inc., Star Scientific, Inc. and Brown & Williamson Tobacco Corporation. <sup>(11)</sup>
10.25	Amendment No. 1 dated April 5, 2001 to Exclusive License Agreement by and among Regent Court Technologies and Star Scientific, Inc. <sup>(11)</sup>
10.26	Contract with Lease and Option to Purchase by and among The Industrial Development Authority of Mecklenburg County, Virginia, The Industrial Development Authority of the Town of Chase City, Virginia, and Star Scientific, Inc., dated April 10, 2002. <sup>(12)</sup>
10.27	Convertible Debenture, dated March 25, 2004, issued by Star Scientific, Inc. to Manchester Securities Corp. Debenture was amended and then converted. <sup>(13)</sup>
10.28	Warrant, dated March 25, 2004, issued by Star Scientific, Inc. to Manchester Securities Corp. <sup>(13)</sup>
10.29	Securities Purchase Agreement, dated March 25, 2004, between Star Scientific, Inc. and Manchester Securities Corp. <sup>(13)</sup>
10.30	Registration Rights Agreement, dated March 25, 2004, between Star Scientific, Inc. and Manchester Securities Corp. <sup>(13)</sup>
10.31	Common Stock Purchase Warrant, dated as of March 25, 2004, issued by Star Scientific, Inc. to Reedland Capital Partners, an Institutional Division of Financial West Group. <sup>(13)</sup>
10.32	Executive Employment Agreement, dated December 30, 2005 between Star Scientific, Inc. and Jonnie R. Williams. <sup>(14)</sup>
10.33	Second Amended and Restated Employment Agreement, dated December 30, 2005 between Star Scientific, Inc. and Paul L. Perito. <sup>(14)</sup>
10.34	Securities Purchase and Registration Rights Agreement, dated as of March 3, 2006, between Star Scientific, Inc. and Joseph L. Schwarz. <sup>(15)</sup>
10.35	Common Stock Purchase Warrant, dated as of March 3, 2006, issued by Star Scientific, Inc. to Joseph L. Schwarz. <sup>(15)</sup>
10.36	Securities Purchase and Registration Rights Agreement, dated July 14, 2006, by and between Star Scientific, Inc. and Iroquois Capital. <sup>(16)</sup>
10.37	Common Stock Purchase Warrant, dated July 14, 2006, issued by Star Scientific, Inc. to Iroquois Capital. <sup>(16)</sup>
10.38	Securities Purchase and Registration Rights Agreement, dated July 14, 2006, by and between Star Scientific, Inc. and Delaware Charter Guarantee and Trust Company, FBO Joseph L. Schwarz IRA. <sup>(16)</sup>

Item	Description
10.39	Common Stock Purchase Warrant, dated July 14, 2006, issued by Star Scientific, Inc. to Delaware Charter Guarantee and Trust Company, FBO Joseph L. Schwarz IRA. <sup>(16)</sup>
10.40	First Amendment to Executive Employment Agreement, dated December 15, 2006 between Star Scientific, Inc. and Jonnie R. Williams. <sup>(3)</sup>
10.41	First Amendment to Second Amended Executive Employment Agreement, dated December 15, 2006 between Star Scientific, Inc. and Paul L. Perito. <sup>(3)</sup>
10.42	Escrow Releases Purchase Agreement dated March 14, 2007 by and among QVT Associates LP, Whitebox Hedged High Yield Partners, LP, Star Scientific, Inc. and Star Tobacco, Inc. <sup>(17)</sup>
10.43	Second Amendment to Second Amended Executive Employment Agreement, dated March 23, 2007 between Star Scientific, Inc. and Paul L. Perito. <sup>(18)</sup>
10.44	License Agreement, dated May 10, 2007 between Star Tobacco, Inc., Star Scientific, Inc. and Tantus Tobacco, LLC. <sup>(19)</sup>
10.45	Securities Purchase and Registration Rights Agreement, dated June 29, 2007, by and between Star Scientific, Inc. and Joseph L. Schwarz. <sup>(20)</sup>
10.46	Common Stock Purchase Warrant dated June 29, 2007, issued by Star Scientific, Inc. to Pershing LLC, FBO Joseph L. Schwarz Roth IRA. <sup>(20)</sup>
10.47	Common Stock Purchase Warrant dated June 29, 2007 issued by Star Scientific, Inc. to Joseph L. Schwarz. <sup>(20)</sup>
10.48	Securities Purchase and Registration Rights Agreement, dated June 29, 2007 by and between Star Scientific, Inc. and Joseph Rice. <sup>(20)</sup>
10.49	Common Stock Purchase Warrant dated June 29, 2007 issued by Star Scientific, Inc. to Joseph Rice. <sup>(20)</sup>
10.50	Agreement dated October 10, 2007 by and between Christopher G. Miller and Star Scientific, Inc. <sup>(21)</sup>
10.51	Agreement dated October 10, 2007 by and between Park A. Dodd, III and Star Scientific, Inc. <sup>(21)</sup>
10.52	Securities Purchase and Registration Rights Agreement, dated March 13, 2008 by and between Star Scientific, Inc. and the several Investors party thereto, including the form of Warrant thereunder. <sup>(22)</sup>
10.53	Securities Purchase and Registration Rights Agreement, dated March 14, 2008 by and between Star Scientific, Inc. and the several Investors party thereto, including the form of Warrant thereunder. <sup>(22)</sup>
10.54	Securities Purchase and Registration Rights Agreement, dated May 12, 2008 by and between Star Scientific, Inc. and the several Investors party thereto, including the form of Warrant thereunder. <sup>(23)</sup>
10.55	Letter Agreement with Jonnie R. Williams, dated March 14, 2008. <sup>(23)</sup>
10.56	Executive Employment Agreement dated February 26, 2008 between Star Scientific, Inc. and Curtis Wright, M.D. MPH. <sup>(22)</sup>
10.57	Amendment to Executive Employment Agreement dated as of December 19, 2008 between Star Scientific, Inc. and Robert E. Pokusa. <sup>(24)</sup>
10.58	Securities Purchase and Registration Rights Agreement, dated March 2, 2009 by and between Star Scientific, Inc. and the several Investors party thereto, including the form of Warrant thereunder. <sup>(25)</sup>

Item	Description
10.59	Securities Purchase and Registration Rights Agreement, dated September 22, 2009 by and between Star Scientific, Inc. and the Investor party thereto, including the form of Warrant thereunder. <sup>(26)</sup>
10.60	Executive Employment Agreement dated January 1, 2010 between Star Scientific, Inc. and Park A. Dodd, III. <sup>(27)</sup>
10.61	Securities Purchase and Registration Rights Agreement, dated March 5, 2010, by and between Star Scientific, Inc. and the several Investors party thereto. <sup>(28)</sup>
10.62	Amended Warrant, dated March 5, 2010, by and between Star Scientific, Inc. and Iroquois Master Fund Ltd. <sup>(28)</sup>
10.63	Amended Warrant, dated March 5, 2010, by and between Star Scientific, Inc. and Iroquois Capital, LP. <sup>(28)</sup>
10 <b>.64</b>	Securities Purchase and Registration Rights Agreement, dated March 9, 2010, by and between Star Scientific, Inc. and the several Investors party thereto. <sup>(29)</sup>
10.65	Amended Warrant No. 1, dated March 9, 2010, by and between Star Scientific, Inc. and Tradewinds Master Fund (BVI), Ltd. <sup>(29)</sup>
10.66	Amended Warrant No. 2, dated March 9, 2010, by and between Star Scientific, Inc. and Tradewinds Master Fund (BVI), Ltd. <sup>(29)</sup>
10.67	Amended Warrant No. 1, dated March 9, 2010, by and between Star Scientific, Inc. and Feehan Partners, L.P. <sup>(29)</sup>
10.68	Amended Warrant No. 2, dated March 9, 2010, by and between Star Scientific, Inc. and Feehan Partners, L.P. <sup>(29)</sup>
10.69	Amended Warrant No. 1, dated March 9, 2010, by and between Star Scientific, Inc. and PV Partners, L.P. <sup>(29)</sup>
10.70	Amended Warrant No. 2, dated March 9, 2010, by and between Star Scientific, Inc. and PV Partners, $L.P.^{(29)}$
10.71	Securities Purchase and Registration Rights Agreement, dated March 9, 2010, by and between Star Scientific, Inc. and the several Investors party thereto, including the form of Warrant attached as Exhibit A thereon. <sup>(29)</sup>
10.72	Securities Purchase and Registration Rights Agreement, dated March 10, 2010, by and between Star Scientific, Inc. and the Investor party thereto, including the form of Warrant attached as Exhibit A thereon. <sup>(29)</sup>
10.73	Amended Securities Purchase and Registration Rights Agreement, dated March 12, 2010, by and between Star Scientific, Inc. and the Investor party thereto. <sup>(29)</sup>
10.74	Securities Purchase and Registration Rights Agreement, dated March 12, 2010, by and between Star Scientific, Inc. and the several Investor party thereto, including the form of Warrant attached as Exhibit A thereon. <sup>(29)</sup>
10.75	Securities Purchase and Registration Rights Agreement, dated November 5, 2010, by and between Star Scientific, Inc. and the several Investors party thereto, including the form of Warrant attached as Exhibit A thereon. <sup>(30)</sup>
10.76	Securities Purchase and Registration Rights Agreement, dated February 28, 2011, by and between Star Scientific, Inc. and the Investor party thereto, including the form of Warrant attached as Exhibit A thereon. <sup>(31)</sup>

Item	Description
10.77	Securities Purchase and Registration Rights Agreement, dated March 4, 2011, by and between Star Scientific, Inc. and the several Investors party thereto, including the form of Warrant attached as Exhibit A thereon. <sup>(31)</sup>
10.78	Executive Employment Agreement, dated March 14, 2011, between Star Scientific, Inc. and Jonnie R. Williams. <sup>(32)</sup>
10.79	Third Amended and Restated Executive Employment Agreement, dated March 14, 2011, between Star Scientific, Inc. and Paul L. Perito. <sup>(32)</sup>
10.80	Amended and Restated Executive Employment Agreement, dated March 14, 2011, between Star Scientific, Inc. and Curtis Wright, IV, MD, MPH. <sup>(32)</sup>
10.81	Securities Purchase and Registration Rights Agreement, dated December 22, 2011, by and between Star Scientific, Inc. and the Investor party thereto, including the form of Warrant attached as Exhibit A thereon. <sup>(33)</sup>
10.82	Securities Purchase and Registration Rights Agreement, dated February 28, 2012, by and between Star Scientific, Inc. and the Investor party thereto, including the form of Warrant attached as Exhibit A thereon. <sup>(34)</sup>
10.83	Amendment to Third Amended and Restated Executive Employment Agreement, dated December 28, 2012 between Star Scientific, Inc. and Paul L. Perito. <sup>(35)</sup>
10.84	Amendment to Executive Employment Agreement, dated December 28, 2012 between Star Scientific, Inc. and Jonnie R. Williams. <sup>(35)</sup>
14.1	Corporate Code of Business Conduct and Corporate Ethics, dated March 2004. <sup>(13)</sup>
21.1	Subsidiaries of the Company. <sup>(35)</sup>
23.1	Consent of Cherry Bekaert LLP. <sup>(35)</sup>
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. §1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002. <sup>(35)</sup>
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. §1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002. <sup>(35)</sup>
EX-101	INSTANCE DOCUMENT. <sup>(35)</sup>
EX-101	SCHEMA DOCUMENT. <sup>(35)</sup>
EX-101	CALCULATION LINKBASE DOCUMENT. <sup>(35)</sup>
EX-101	LABELS LINKBASE DOCUMENT. <sup>(35)</sup>
EX-101	PRESENTATION LINKBASE DOCUMENT. <sup>(35)</sup>
EX-101	DEFINITION LINKBASE DOCUMENT. <sup>(35)</sup>
(1) Inco	rporated by reference to Current Report on Form 8-K filed on March 3, 1999.
	rporated by reference to Current Report on Form 8-K filed on December 18, 2012.
(3) Incom	rporated by reference to Current Report on Form 8-K filed on December 21, 2006.

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(4) Incorporated by reference to Quarterly Report on Form 10-QSB for the quarter ended March 31, 1998.

(5) Incorporated by reference to Current Report on Form 8-K filed on September 14, 1998.

(6) Incorporated by reference to Annual Report on Form 10-K for the year ended December 31, 1999.

(7) Incorporated by reference to Annual Report on Form 10-K for the year ended December 31, 2000.

(8) Incorporated by reference to Quarterly Report on Form 10-QSB for the quarter ended June 30, 1999.

(9) Incorporated by reference to Quarterly Report on Form 10-Q for the quarter ended September 30, 2000.

(10) Incorporated by reference to Current Report on Form 8-K filed on May 17, 2001.

(11) Incorporated by reference to Quarterly Report on Form 10-Q for the quarter ended September 30, 2001.

(12) Incorporated by reference to Quarterly Report on Form 10-Q for the quarter ended June 30, 2002.

(13) Incorporated by reference to Annual Report on Form 10-K for the year ended December 31, 2003.

(14) Incorporated by reference to Current Report on Form 8-K filed on December 30, 2005.

(15) Incorporated by reference to Current Report on Form 8-K filed on March 7, 2006.

(16) Incorporated by reference to Current Report on Form 8-K filed on July 18, 2006.

(17) Incorporated by reference to Annual Report on Form 10-K for the year ended December 31, 2006.

(18) Incorporated by reference to Current Report on Form 8-K filed on March 28, 2007.

(19) Incorporated by reference to Quarterly Report on Form 10-Q for the quarter ended June 30, 2007.

(20) Incorporated by reference to Current Report on Form 8-K filed on July 6, 2007.

(21) Incorporated by reference to Quarterly Report on Form 10-Q for the quarter ended September 30, 2007.

(22) Incorporated by reference to Annual Report on Form 10-K filed for the year ended December 31, 2007.

(23) Incorporated by reference to Quarterly Report on Form 10-Q for the quarter ended March 31, 2008.

(24) Incorporated by reference to Annual Report on Form 10-K for the year ended December 31, 2008.

(25) Incorporated by reference to Current Report on Form 8-K filed on March 3, 2009.

(26) Incorporated by reference to Current Report on Form 8-K filed on September 25, 2009.

(27) Incorporated by reference to Current Report on Form 8-K filed on January 28, 2010.

(28) Incorporated by reference to Current Report on Form 8-K filed on March 5, 2010.

(29) Incorporated by reference to Annual Report on Form 10-K for the year ended December 31, 2009.

(30) Incorporated by reference to Registration Statement on Form S-3 filed on December 10, 2010.

(31) Incorporated by reference to Current Report on Form 8-K filed on March 4, 2011.

(32) Incorporated by reference to Annual Report on Form 10-K for the year ended December 31, 2010.

(33) Incorporated by reference to Current Report on Form 8-K filed on December 28, 2011.

(34) Incorporated by reference to Current Report on Form 10-Q for the quarter ending March 31, 2012.

(35) Incorporated by reference to Annual Report on Form 10-K for the year ended December 31, 2012

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### Executive, Scientific and Regulatory Affairs Offices

1255 23rd Street NW Suite 875 Washington, DC 20037 (202) 887-5100

# <u>Corporate, Sales and</u> <u>Marketing Offices</u>

4470 Cox Road Suite 110 Glen Allen, VA 23060 (804) 527-1970

### Rock Creek Pharmaceuticals, Inc.

55 Blackburn Center Gloucester, MA 01930 (978) 283-1372

# **Corporate Counsel**

K&L Gates 1601 K Street, NW Washington, DC 20006-1600

# Transfer Agent

Wells Fargo Shareowner Services 1110 Centre Point Curve Suite 101 Mendota Heights, MN 55120 (800) 468-9716

# Star Scientific, Inc.

# BOARD OF DIRECTORS

Paul L. Perito, Esquire, *Chairman* Jonnie R. Williams Christopher C. Chapman, MD Neil L. Chayet, Esquire Ralph B. Everett, Esquire Burton J. Haynes, Esquire

# OFFICERS

Jonnie R. Williams – CEO Paul L. Perito, Esquire – President, COO Park A. Dodd III – Chief Financial Officer Robert E. Pokusa, Esquire – General Counsel David M. Dean – Vice President of Sales & Marketing Howard N. (Sonny) Jones, III – Vice President of Operations Talhia T. Tuck – Vice President of Communications and Investor Relations

# **Rock Creek Pharmaceuticals, Inc.**

# BOARD OF DIRECTORS

Paul L. Perito, Esquire, *Chairman* Christopher C. Chapman, MD Neil L. Chayet, Esquire

# OFFICERS

Paul L. Perito, Esquire – CEO Curtis Wright IV, MD – Senior Vice President & Medical/Clinical Director Park A. Dodd III – Chief Financial Officer



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