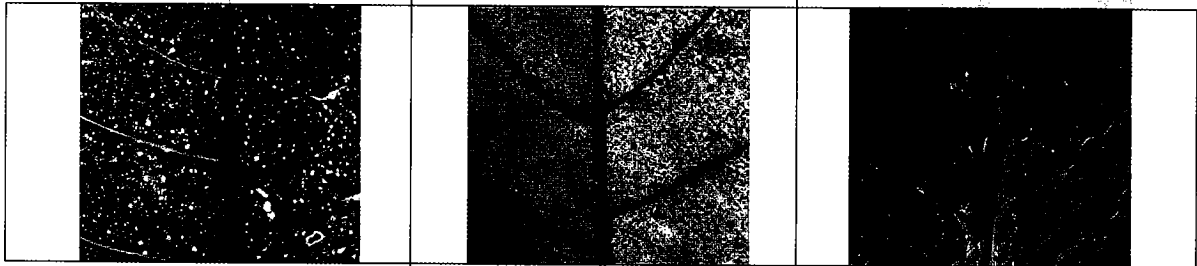




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STAR SCIENTIFIC, INC



ANNUAL REPORT
ON 2010

Policy Statement for Star Scientific, Inc.

Responsible standards for changing certain prevalent views in the tobacco industry

- ❖ **STAR SCIENTIFIC accepts and supports effective measures at the national, state and local levels to ensure that tobacco products are not distributed, sold, or marketed to children and adolescents.**
- ❖ **STAR SCIENTIFIC accepts the findings and conclusions of the Surgeon General of the United States, as well as the informed public health community, that conventionally cured tobacco is a major factor in disease and addiction and that those who use tobacco products who wish to quit should be given incentives and opportunities to do so.**
- ❖ **STAR SCIENTIFIC acknowledges that the use of tobacco products generally poses health hazards and that no known tobacco product or process, even the process that Star has developed, while virtually eliminating nitrosamines, eliminates all health hazards associated with the smoking of tobacco.**
- ❖ **STAR SCIENTIFIC supports having the Food & Drug Administration (FDA) as the lead regulatory agency charged with overseeing the implementation of fair and meaningful regulations over the manufacture, sale, distribution, labeling and marketing of all tobacco-containing products.**
- ❖ **STAR SCIENTIFIC supports increased biomedical and allied research by the private sector, as well as such federal agencies as the FDA, NIH, CDC, and the USDA, that will continue to identify and understand the complexities of what causes the diseases associated with tobacco use and work to find ways of reducing and/or eliminating these causes, and setting standards and “benchmarks” for the development of reduced risk and less hazardous tobacco products.**
- ❖ **STAR SCIENTIFIC believes that it has a corporate responsibility to continue to expand research and development efforts to manufacture tobacco products that are as safe as is technologically possible to address the serious public health problems associated with tobacco use, and to respond to the needs of adult tobacco users who continue to consume tobacco products notwithstanding the broad range of health risks associated with using such products.**
- ❖ **STAR SCIENTIFIC believes that adults who choose to smoke and/or make an adult choice regarding the use of any tobacco products should be fully and completely informed about the dangers of the tobacco products they choose to use, including specific information regarding ingredients and constituents of tobacco and tobacco smoke and the levels of such toxic constituent elements in tobacco and tobacco smoke. This should include any scientifically established information that indicates that a product may or will reduce certain exposure to major toxic elements associated with tobacco use.**
- ❖ **STAR SCIENTIFIC is committed to working with the public health community, the FDA, and other federal regulatory agencies in seeking to prevent the use of tobacco products by children and adolescents and in the scientific development of products that have the potential for lessening or even eliminating the incidence of disease, death and addiction associated with tobacco use.**
- ❖ **STAR SCIENTIFIC believes that the time has come for health groups, researchers, scientists, policy makers, senior government officials, tobacco farmers and responsible tobacco companies to sit down and talk about the future of tobacco and the tobacco industry, including an articulation of reasonable parameters under which new products that will reduce exposure to certain toxic constituents in tobacco and tobacco smoke can be developed, evaluated and marketed.**

SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

SEC
Mail Processing
Section

NOV 14 2011

Washington, DC
125

(Mark One)

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

For the fiscal year ended December 31, 2010

**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)

52-1402131

(I.R.S. Employer
Identification No.)

4470 Cox Road, Suite 110, Glen Allen, VA 23060

(Address of principal executive offices)

(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.

Larger 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, 2010 was approximately \$140 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 15, 2011 — 134,026,053 shares of common stock, par value \$0.0001 per share.

DOCUMENTS INCORPORATED BY REFERENCE:

None.

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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 Star Tobacco, Inc., a Virginia corporation, and Rock Creek Pharmaceuticals, Inc., a Delaware corporation, which also may be referred to in this Report as “Star Tobacco” and “Rock Creek”, 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 through Star Tobacco and Rock Creek, the uncertainties inherent in the progress of scientific research, our ability to raise additional capital in the future that is necessary to maintain our business, potential disputes concerning our intellectual property, risks associated with litigation regarding such intellectual property, uncertainties associated with the development, testing and regulatory approvals of our low-TSNA tobacco, related tobacco products and pharmaceutical and nutraceutical products, market acceptance of our new smokeless tobacco products and nutraceutical and pharmaceutical products, competition from companies with greater resources than us, our dependence on key employees and on our prior strategic relationships with Brown & Williamson Tobacco Corporation in light of its combination with R.J. Reynolds Tobacco Company, Inc.

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.

PART I

ITEM 1. BUSINESS

Overview

We are a technology-oriented company with a mission to reduce the harm associated with the use of tobacco at every level. We are primarily engaged in:

- the development, implementation and licensing of our proprietary technology for the curing of tobacco so as to substantially prevent the formation of carcinogenic toxins present in tobacco and tobacco smoke, primarily the tobacco-specific nitrosamines, or TSNA's;
- the manufacture, sales, marketing and/or development of very low-TSNA dissolvable smokeless tobacco products that carry enhanced warnings beyond those required by the Surgeon General, including ARIVA® compressed powdered tobacco cigarette® pieces and STONEWALL Hard Snuff® and "modified risk tobacco products" as defined in the Family Smoking Prevention and Tobacco Control Act of 2009, or the FDA Tobacco Act;
- the development of pharmaceutical products, particularly products that have a botanical, tobacco-based component, that are designed to treat tobacco dependence and a range of neurological conditions, including Alzheimer's disease, Parkinson's disease, schizophrenia and depression; and
- the manufacture, sale, marketing and development of non-nicotine and non-tobacco nutraceutical products designed to assist individuals who are seeking a smoking alternative as well as related nutraceutical products that are designed to promote the maintenance of a healthy metabolism.

Since the 1990s, we have sought to develop processes and products that significantly reduce the levels of toxins, principally TSNA's, in tobacco compared to traditional smoked and smokeless tobacco products. Our development of technology for reducing TSNA levels has led to our focus on the development of tobacco-based pharmaceutical products and non-nicotine nutraceuticals that we are pursuing through our Rock Creek subsidiary. Given our long-term focus on reducing the levels of toxins in tobacco and the harm associated with tobacco use, we believe we are uniquely positioned to pursue a range of very-low TSNA smokeless tobacco products as "modified risk products" under the FDA Tobacco Act. We also believe we are positioned to utilize our technology to produce a range of non-nicotine nutraceuticals and tobacco-based pharmaceuticals furthering our mission to reduce the harm associated with tobacco use at every level as well as to develop related products that are designed to promote the maintenance of a healthy metabolism.

The following discussion of our historical results of operations and financial condition should be read in conjunction with our consolidated financial statements and the notes thereto included in "Item 15. Exhibits, Financial Statement Schedules" of this Report. In August 2010, our Rock Creek subsidiary introduced a non-nicotine, non-tobacco nutraceutical designed to curb the urge to smoke. Beginning in our quarterly report on Form 10-Q for the period ended September 30, 2010, we began utilizing segment reporting for each of our operating subsidiaries. See note 17 to our consolidated financial statements included in "Item 15. Exhibits, Financial Statement Schedules" of this Report for further information on our segment reporting.

Our History

Since December 1998, our primary corporate focus has centered on the sales, marketing and development of tobacco products that expose adult tobacco users to lower levels of toxins and, beginning in 2007, tobacco-based pharmaceuticals and related non-nicotine nutraceutical products.

Until 2007, our revenues were generated principally through the sale of discount cigarettes by our company's wholly owned subsidiary Star Tobacco. Star Tobacco was incorporated in 1990 and, until 1994, was primarily a contract manufacturer of cigars and cigarettes. In late 1994, we commenced development and commercialization of its own brands of discount cigarettes using primarily Virginia flue-cured tobacco, which

competed principally on the basis of price. Around the same time, we commenced a research and development program relating to a range of tobacco products that deliver fewer toxins as well as tobacco cessation products. Shortly 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. In connection with that effort, we announced that our company would seek to transition from the sale of cigarette products as soon as practically possible. To facilitate that transition, in May 2007 we entered into an agreement with Tantus Tobacco LLC, or Tantus, for the exclusive license of our cigarette trademarks Sport®, MainStreet® and GSmoke® and discontinued manufacturing any cigarette products as of June 2007. Since 2007 our tobacco revenues have been generated exclusively through the sale of our low-TSNA smokeless tobacco products. In August 2010 we introduced into the market CigRx®, our non-nicotine, non-tobacco dietary supplement and we have been generating revenue from the sale of CigRx® since that time.

Our Strategy

Our long-term focus is the research, development, manufacturing and licensing of technology that can lessen reliance on and the impact of the use of all forms of tobacco, reduce the range of serious health hazards associated with the use of smoked and smokeless tobacco and more generally assist consumers in maintaining a healthy metabolism. We have pursued these objectives through:

- the production of very low-TSNA tobacco;
- dissolvable smokeless tobacco products that expose adult tobacco users to substantially lower levels of toxins as compared to other smoked and smokeless tobacco products;
- the development of non-nicotine, non-tobacco nutraceuticals;
- the submission of applications to have variants of our low-TSNA smokeless products designated as “modified risk tobacco products” under the FDA Tobacco Act; and
- the ongoing research and development efforts of Rock Creek on related non-nicotine nutraceuticals and pharmaceutical products.

We fully accept the evidence that links smoking tobacco with a variety of diseases and premature death. We believe it is highly unlikely that the health risks of smoked tobacco can be completely eliminated, and that no safe cigarettes will ever be manufactured. We believe we were the first company to state unequivocally that “there is no such thing as a safe cigarette.” Further, we were the first company to affix to the back of the package of our first premium low-TSNA product, Advance®, a package “onsert” that contained not only scientifically verified comparative product content data, but also additional health warnings beyond those required by the Surgeon General. Despite worldwide efforts to curb tobacco use, the American Cancer Society continues to report that an estimated 1.3 billion people smoke and use other conventional 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.

Over the last several years, we have expended significant time and resources: (i) on our ongoing patent infringement litigation with R.J. Reynolds Tobacco Company, or RJR, a wholly owned subsidiary of Reynolds American, Inc., or RAI, which we are continuing to pursue on appeal following an unsuccessful verdict in our jury trial in that case which took place between May 18 and June 16, 2009 in the United States District Court for the District of Maryland, or District Court, (see “Item 3. Legal Proceedings” for further details) (ii) the development of ARIVA® and STONEWALL Hard Snuff®, our low-TSNA dissolvable smokeless tobacco products and, more recently, “modified risk tobacco products” under the FDA Tobacco Act, (iii) the licensing of low-TSNA products and the technology behind our StarCured® tobacco curing process, and (iv) the efforts of Rock Creek in developing botanical tobacco-based pharmaceutical products, non-nicotine nutraceuticals and related products. Our future success will depend largely on the successful results of these initiatives. While

product licensing royalties and smokeless tobacco sales have been de minimis to date, we intend to continue our efforts to develop and sell low-TSNA smokeless tobacco products, develop pharmaceutical products to treat tobacco addiction and a range of neurological conditions and related non-nicotine nutraceuticals, and to pursue licensing arrangements for those products and related technology.

We believe our proprietary technology related to the curing of very-low TSNA tobacco and the development of related products, including tobacco-based pharmaceuticals and non-nicotine nutraceuticals, positions us to be a leader in producing products designed to lower the harm associated with the use of tobacco at all levels.

Our Technology

Our Current Intellectual Property Rights

Our proprietary technology for producing low-TSNA tobacco which is utilized in ARIVA® and STONEWALL Hard Snuff®, our low-TSNA dissolvable smokeless tobacco products, has been licensed exclusively from 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® process, related patents covering the production of low-TSNA dissolvable smokeless tobacco products and the use of certain tobacco-based monoamine oxidase inhibitors, or MAO, agents in treating neurological conditions. For additional information related to our proprietary curing process, see "— Our Patents, Trademarks and Licenses." Two of the patents under our license with Regent Court that relate to our method for producing low-TSNA tobacco are the subject of our ongoing lawsuit against RJR. Accordingly, we have dedicated substantial time and resources to defend and enforce our proprietary rights with respect to these patents. See "Item 3. Legal Proceedings." It is our objective to achieve widespread acceptance of our tobacco curing technology as a standard for the manufacture of less toxic and potentially less harmful smoked and smokeless tobacco products and, in the future, as a basis for the use of very low-TSNA tobacco in the production of smoking cessation products.

Our Recent Intellectual Property Initiatives

In December 2008, we filed a new U.S. 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. In 2010 Rock Creek filed three patent applications relating to our CigRx® product, and a patent application for a relapse prevention product. Rock Creek also has several provisional patent applications pending that we expect to mature into one or more non-provisional patent applications 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.

The StarCured® Process

The process of curing or drying tobacco so that it is suitable for use in the production of tobacco products begins immediately upon harvesting of the tobacco leaf. The two principal varieties of tobacco leaf in the United States are Virginia flue-cured tobacco and burley tobacco, both of which are typically used in American-made cigarettes to produce what is referred to as an American blend.

Under conventional curing methods used in the production of Virginia flue-cured tobacco, the leaves are placed in enclosed barns and are then exposed to gas-fired heat, while burley tobacco undergoes a curing process where the leaves are hung in sheds to dry naturally. The curing process for Virginia flue-cured tobacco takes approximately five to seven days, and the curing process used with burley tobacco generally last a month or more. Our proprietary StarCured® 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. Our proprietary curing process essentially arrests or eliminates microbial activity that normally occurs during curing, thereby preventing the formation of TSNAs. Our StarCured® curing technology does not, however, alter or affect taste, color or the nicotine content of tobacco. We make no claim or

representation that our StarCured® tobacco curing process precludes the formation of harmful chemical constituents found in tobacco and tobacco smoke, other than TSNAs. Additionally, we make no claim that the elimination of TSNAs reduces the risk of disease. We have been careful not to make any health claims, directly or indirectly, even though peer-reviewed scientific literature continues to emerge pointing out that a reduction of these carcinogens in smokeless tobacco can be expected to reduce health risks.

We believe that through our StarCured® process we have the technology 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 the StarCured® method can be scaled up to meet broad commercial needs in the United States and abroad. Our focus on very low-TSNA, non-fermented smokeless tobacco products, and the licensing of our technology, is based, in part, on the fact that there is broad agreement among tobacco researchers that tobacco smoke contains over 4,000 constituents, 65 of which are known carcinogens. While TSNAs are considered to be one of the most significant groups of carcinogens in tobacco and tobacco smoke, they are recognized as being the only major or biologically significant group of carcinogenic toxins in smokeless tobacco. In December 2008 we filed a new U.S. patent application for a variant of our patented curing technology that results in the production of cured tobacco that consistently contains virtually undetectable levels of carcinogenic TSNAs as measured by prevailing standards. We are using tobacco cured by this process in the products included in the applications that we submitted to the FDA for the “modified risk tobacco” designation. The use of this tobacco allows us to produce a tobacco product that has levels of the carcinogenic TSNA comparable to those found in nicotine replacement therapy products.

Our Current Products

Smokeless Tobacco Products

Over the past nine years, 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 in situations and environments where they cannot or choose not to use such products. This development effort was encouraged by our company’s Scientific Advisory Board and other independent scientific, medical and public health advisors who in 1999 and in 2000 urged us to accelerate the development of smokeless products using 100% StarCured® very low-TSNA tobacco because our smokeless products have far fewer toxins than conventional cigarettes and traditional smokeless tobacco products. This position is supported by a 2002 report issued by the Royal College of Physicians in Great Britain that concluded the “consumption of non-combustible tobacco is of the order of 10-1,000 times less hazardous than smoking, depending on the product.” It is broadly agreed among tobacco researchers that cigarette smoke contains more than 4,000 chemical compounds, 65 of which are known to be carcinogenic. In contrast, it is generally recognized that the only major or biologically significant carcinogenic toxins in non-fermented smokeless tobacco are the TSNAs, particularly the NNNs and NNKs.

In November 2001, we introduced ARIVA® cigarette pieces, or ARIVA®, as our first dissolvable hard tobacco smokeless tobacco product. ARIVA® is a compressed powdered tobacco product designed to dissolve completely in the mouth without leaving any residue or requiring expectoration. During the second quarter of 2003, in an effort to market a dissolvable hard tobacco product to adult users of traditional smokeless tobacco products such as moist snuff, we introduced a non-fermented spit-free “hard tobacco” product called STONEWALL Hard Snuff®. Both ARIVA® and STONEWALL Hard Snuff® are made from non-fermented 100% low-TSNA StarCured® tobacco plus natural and artificial flavorings, as well as other ingredients. In 2007, we introduced two new blends of STONEWALL Hard Snuff®, “Natural” and “Java” in addition to the original “Wintergreen” blend. We introduced a “Java” blend of ARIVA® in 2008 and in the first quarter of 2010 we introduced “Cinnamon”, “Mint” and “Citrus” blends of ARIVA® and a new packaging format (10-piece sleeves) for ARIVA®.

ARIVA® and STONEWALL Hard Snuff® have been marketed nationwide through tobacco distributors and wholesalers who have direct arrangements with several national retail chains and through other national distributors

experienced with consumer products. In 2009 we restructured our smokeless tobacco operations to reduce costs while concentrating our efforts on a more narrow geographic area and continuing sales to our established regional and national retail chain customers. Our domestic sales of ARIVA® and STONEWALL Hard Snuff® have been de minimis to date and we did not have any international sales in 2010. We believe that in order to successfully market ARIVA® and STONEWALL Hard Snuff® on a broad basis we must develop additional distribution channels for these products. We also will be required to expend substantial funds on the marketing of these products to consumers, which we will need to obtain from external financing, the availability of which cannot be assured. For additional information relating to our liquidity, see “Item 6. Management’s Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources.”

CigRx®

CigRx®, our non-nicotine, non-tobacco nutraceutical intended to temporarily reduce the desire to smoke, was introduced into the market in August 2010 in the Richmond, Virginia area. Since its introduction, we have been working with InVentiv Health to develop awareness for the CigRx® product through an outreach program involving visits to physicians and other health care professionals. We also market CigRx® through an interactive website, infomercials and limited direct advertising at the consumer level. In late February 2011, we began testing CigRx® on a national basis through expanded infomercials and radio spots. We believe that these marketing avenues will allow us to increase sales of CigRx® and provide a viable platform for the expansion of CigRx® sales on a national basis. See “— Our Sales and Marketing Efforts — Dietary Supplement-CigRx®” for a discussion of our manufacturing, storage, order processing and delivery arrangements with third parties related to CigRx®.

Our Current Product Development Initiatives

Pharmaceutical Products and Nutraceuticals

Through our company’s Rock Creek subsidiary, we are pursuing the development of botanical based products for the treatment of tobacco dependence, as well as products that would utilize certain MAO agents in tobacco to treat a range of neurological conditions, including Alzheimer’s disease, Parkinson’s disease, schizophrenia and depression. Rock Creek also has been involved in developing non-nicotine nutraceutical products that may assist persons who have ceased using tobacco or who are in the process of stopping tobacco use maintain a balanced metabolism and related non-nicotine products that may be helpful to consumers in maintaining a healthy metabolism. Rock Creek operates pursuant to a sublicense under our exclusive license with Regent Court, which includes patents for producing tobacco with very low-TSNA levels. The sublicense also covers patents for the use of MAO inhibitors in tobacco to treat various neurological conditions.

These 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.

Low-TSNA Tobacco and “modified risk tobacco products”

In the mid-1990s, we commenced research and development activities based on newly conceived technology for the processing of tobacco that substantially prevents the formation of TSNA 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 TSNA in cured tobacco. For additional information related to our intellectual property, see “— Our Patents, Trademarks and Licenses.” Two of the

patents that relate to our method for producing low-TSNA tobacco are the subject of our ongoing lawsuit against RJR. See “Item 3. Legal Proceedings” for further details.

In 2009 and 2010 we developed Ariva-BDL™ and Stonewall-BDL™, variants of our ARIVA® and STONEWALL Hard Snuff® smokeless tobacco products, that have significantly lower levels of carcinogenic TSNA as well as other toxins compared to conventional tobacco products and which are at a levels comparable to those found in nicotine replacement therapy products. These products use tobacco cured by our StarCured® tobacco processes. We filed applications with the FDA in 2010 to have Ariva-BDL™ and Stonewall-BDL™ designated as “modified risk tobacco products” under the FDA Tobacco Act. On February 1, 2011, we filed a third application with the FDA for a modified risk moist snuff product, Stonewall Moist-BDL™. If our application for the designation of Ariva-BDL™, Stonewall-BDL and Stonewall Moist-BDL™ as “modified risk tobacco products” are approved by the FDA, we believe our company will gain an advantage in marketing our very-low TSNA smokeless tobacco products, because we would be able to provide information to tobacco users on the levels of such toxins in those products. Absent receiving an order approving a product’s designation as a “modified risk tobacco product”, the FDA Tobacco Act prohibits a company from making any claims relating to a product’s reduced levels of toxins or reduced risk.

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, ability to procure funding for these initiatives, and the successful outcome of our ongoing patent infringement litigation with RJR. 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.

Discontinued Products

We exited from the cigarette business in June 2007. Prior to that time, the majority of our revenues were derived from the sale of discount cigarettes. Although we retain the right to manufacture and sell other branded cigarettes, we plan to continue to focus our efforts in the tobacco area on the sale of our low-TSNA dissolvable smokeless tobacco products, as opposed to cigarettes.

Our Prior Research and Development Efforts

In the past we have developed several products and initiated several research and development efforts based on our StarCured® low-TSNA tobacco technology which, although not currently active, we believe could serve as the basis for future product development efforts.

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®. In light of our focus on dissolvable hard tobacco products, we discontinued the manufacture of Stonewall® moist snuff and we have not sought to continue to market Stonewall® dry 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® moist snuff product and we are also considering filing an application with the FDA for this same designation for a Stonewall Dry Snuff-BDL™, a variant of our original Stonewall® Dry Snuff product.

Advance® Low-TSNA Cigarettes

We launched the first low-TSNA cigarette, Advance®, in October 2000. Advance® was the first conventional cigarette specifically manufactured to diminish the amount of exposure to highly carcinogenic TSNA. The Advance® cigarette reduced additional toxic smoke constituents through a unique activated carbon/acetate filter. Advance® 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. The study contrasted our test product that had TSNA levels of about 100 parts per billion with conventional brands of cigarettes in terms of breath levels of carbon monoxide, blood levels of nicotine and urinary levels of TSNA. With regard to the test product, blood nicotine levels were somewhat higher and carbon monoxide was substantially lower. The subjects' urinary levels of TSNA (as measured by NNAL) were reduced substantially, consistent with published data showing that TSNA leave the body over 90 to 120 days in an initial rapid phase and then in a slower phase during this period. The results of this study were significant in demonstrating that reductions of TSNA levels in tobacco resulted in reduced levels of TSNA in the human body when study subjects smoked cigarettes containing tobacco with reduced levels of TSNA.

Prior to the decision to concentrate on the development of tobacco products that incorporate very low-TSNA StarCured® tobacco, 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 nutraceuticals.

Our Sales and Marketing Efforts

Dissolvable Tobacco

Our dissolvable tobacco sales and marketing activities are lead by Mr. Jonnie R. Williams Sr., our Chief Executive Officer, Mr. David M. Dean, our Vice President of Sales and Marketing and Mr. Sheldon Bogaz, our Vice President of Trade Operations. We have a two-fold strategy with respect to selling our dissolvable tobacco products to retailers. We provide local distributors with product information and upon request point of sale material for our dissolvable tobacco products. We also market our products directly to large retail chains which order product and point of sale material directly from us. In late 2009 we restructured our tobacco operations by reducing our sales force outside of Virginia and concentrating our in-store sales effort on a more narrow geographic area in Virginia and contiguous states. At the same time we continue to service our established regional and national retail chain customers through employees working out of our offices in the Richmond, Virginia area.

We currently sell our smokeless tobacco products through approximately 107 tobacco distributors throughout the United States. The distributors and other customers maintain state and, where applicable, municipal government tobacco product licenses and apply state and/or local tax stamps when needed to resell our tobacco products. We deliver our products mainly by common carrier trucks. Our distributor customers primarily service convenience stores, gas stations, retail stores and other outlets.

Dietary Supplement-CigRx®

CigRx®, our dietary supplement, is manufactured and sold through our Rock Creek subsidiary. CigRx® currently is being sold through an interactive website, infomercials and, to a limited extent, through direct retail sales. We also have been working jointly with InVentiv Health to develop awareness for the CigRx® product through an outreach program involving visits to physicians and other health care professionals and through direct advertising at the consumer level. Our in-house marketing personnel also have been assisting on the CigRx® launch and associated marketing activities associated with the launch

In order to facilitate the launch of CigRx® and limit capital expenditures, we have outsourced the manufacturing, storage, order processing and delivery of CigRx® 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 manufacturing and distribution needs for CigRx® for the foreseeable future. We also believe that the current marketing initiatives we have put into place will allow us to increase sales of CigRx® as we move forward on the national test market of CigRx® that began in late February 2011.

Our Availability of Raw Materials and our Manufacturing Capabilities

Dissolvable Tobacco

All of the flue-cured tobacco used in our smokeless tobacco products has been or will be cured in specially manufactured curing barns using our StarCured® tobacco curing process. The StarCured® tobacco curing process involves controlling certain conditions in the tobacco curing barns, and in certain applications, uses microwave and/or electron beam technology. In March 2007, we sold approximately 990 of our tobacco curing barns. The sale of these barns was made exclusively to farmers who had been participants in our StarCured® tobacco curing program. We sold our 37 remaining StarCured® barns in late 2009 to growers who previously had participated in the StarCured® program. While we currently do not own any StarCured® barns, we have a significant amount of StarCured® tobacco in inventory and access to StarCured® tobacco through growers who previously participated in our StarCured® tobacco curing program. We believe that our existing inventory of StarCured® tobacco and our relationships with growers who maintain StarCured® barns will permit us to obtain sufficient amounts of StarCured® tobacco for our low-TSNA dissolvable smokeless tobacco products, and for other needs.

We have a high-speed manufacturing line at our leased facility in Chase City, Virginia, which is currently used for the production of our ARIVA® and STONEWALL Hard Snuff® dissolvable smokeless tobacco products. In 2009 we consolidated our manufacturing operations into a larger immediately adjacent facility, which we lease from the Mecklenburg County Industrial Development Authority. See “Item 2. Properties.” We do not anticipate ordering additional equipment for manufacturing our dissolvable smokeless tobacco products until the existing production line is operating at nearly full capacity. We believe both our current availability of StarCured® tobacco and our manufacturing facilities provide more than sufficient capacity to meet both the current demand for our very low-TSNA dissolvable smokeless products and our manufacturing needs in the foreseeable future.

Dietary Supplement—CigRx®

We obtain all of the raw materials and packaging supplies for the manufacture of CigRx® from various vendors and we maintain an inventory of critical raw materials and packaging at the manufacturing location where CigRx® is 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 maintain inventory levels adequate to meet expected sales volume for the foreseeable future.

We have outsourced the product manufacturing for CigRx® to a cGMP contract manufacturer which has sufficient capacity to provide us finished product timely 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, a dedicated packaging equipment line that is used in conjunction with the production of CigRx®. The machinery, while located at the contract manufacturer’s facility, remains titled in our company’s name.

Our Competition

Tobacco Products

Traditionally, tobacco products have been divided between smoked products (cigarettes, cigars, roll-your-own tobacco and pipe tobacco) and smokeless tobacco (moist snuff, chewing tobacco and dry snuff). The

predominant competitors in the smoked tobacco market have been the major tobacco companies, Philip Morris USA, Inc., or Phillip Morris, RJR, Lorillard, Inc. and, prior to its combination with RJR, Brown and Williamson Tobacco Corporation, or B&W. UST, Inc., or UST, has been the dominant manufacturer in the smokeless segment of the market, which also includes companies such as Conwood Company, LLC, or Conwood, a wholly owned subsidiary of RAI, and Swedish Match AB, or Swedish Match. In 2009 Altria Group, Inc., or Altria, Philip Morris's parent company expanded its role in the smokeless tobacco market through the acquisition of UST. As a result of the acquisition of UST by Altria Group, Inc and Conwood by RJR, those companies now control approximately ninety percent of the smokeless tobacco market. Recently, there has been increased competition between the smoked and smokeless tobacco markets as companies have begun to market smokeless tobacco as an alternative to cigarettes in situations where adult tobacco users cannot or choose not to smoke. Swedish Match has worked with selected varieties of tobacco under crop management environments and other methods in an effort to maintain low-TSNA levels in its smokeless tobacco products. In 2001, Swedish Match introduced a new smokeless tobacco product in the United States that claimed to have reduced levels of carcinogens. UST has also test marketed a pouch-style smokeless tobacco product, which it claimed has low levels of TSNA's. Industry analysts have reported that the smokeless tobacco market has been expanding at a rate of approximately 2-3% per year since 2003, while the cigarette market has been contracting over the same period. In 2007, both Philip Morris and RJR introduced smokeless tobacco pouch products that utilize their primary brand names (Marlboro Snus and Camel Snus, respectively) as alternatives to cigarettes and in 2009 RJR introduced several dissolvable smokeless tobacco products in test markets in the U.S.

ARIVA[®] compressed tobacco cigalett[®] pieces are intended to compete with conventional cigarettes and to be used by adult smokers in situations and environments when they cannot or choose not to smoke. Each ARIVA[®] compressed tobacco cigalett piece delivers approximately 1.5 mg of nicotine, approximately the same level of nicotine as a "light" cigarette. Accordingly, we believe ARIVA[®] primarily competes for market share against large tobacco manufacturers that dominate the cigarette industry, as opposed to our traditional competitors in the smokeless market. ARIVA[®] is priced competitively with cigarettes.

Our STONEWALL Hard Snuff[®] dissolvable tobacco product primarily competes with other smokeless tobacco companies such as UST, Conwood and Swedish Match, because STONEWALL Hard Snuff[®] is intended for use by adult users of moist snuff or other forms of smokeless tobacco. However, STONEWALL Hard Snuff[®] is also used by "heavy smokers" (those who smoke more than two packs of cigarettes a day) as an alternative to their traditional cigarette products. Each STONEWALL Hard Snuff[®] piece contains about 4.0 mg of nicotine, roughly the same as a pinch of snuff. STONEWALL Hard Snuff[®] is priced at a discount to traditional moist snuff products. Our sales of STONEWALL Hard Snuff[®] also face further competition with the recent introduction of smokeless tobacco products by Philip Morris and RJR.

The FDA Tobacco Act permits companies to apply to have products designated as "modified risk tobacco products", however, barring such designation, the FDA restricts the types of claims and descriptions that can be made with respect to various components in tobacco products, including any claims relating to reduced levels of toxins or reduced risk. In February 2010 we submitted an application to the FDA for the approval of Ariva-BDL[™] as the first modified risk tobacco product under the FDA Tobacco Act and we filed a similar application for Stonewall-BDL[™] in June 2010. In February 2011, we filed a third application with the FDA to have a moist snuff product, Stonewall Moist-BDL[™], designated as a "modified risk tobacco product". In 2002 the United States Department of Agriculture, or USDA, announced that it would provide full price supports only for flue-cured tobacco that was cured in a manner to reduce or limit the levels of TSNA's in the cured tobacco leaf, and the tobacco industry earlier had announced an initiative to facilitate the production of low-TSNA flue-cured tobacco. As a result, virtually all flue-cured tobacco grown in the United States since that time has been cured in a manner to reduce the levels of TSNA's. We believe that if we are successful in commercializing our unique low-TSNA tobacco products, enforcing the patents for the technology used to produce such products, to which we are the exclusive licensee, or obtaining approval to market our low-TSNA products as modified risk tobacco products under the FDA Tobacco Act, many of the major tobacco companies will also seek to market such low-TSNA tobacco products and may seek to sublicense the technology for producing low-TSNA tobacco from us.

Pharmaceuticals, Nutraceuticals and Other Products and Services

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.

There are also non-tobacco cigarettes produced with fillers such as lettuce and herbs and variations of cigarettes that do not burn tobacco, such as E-cigarettes. Also, there are non-nicotine nutraceuticals that are marketed as assisting to maintain a nicotine free metabolism or to balance metabolism in the absence of nicotine. In addition to the use of consumable products for smoking cessation or reduction purposes, medical practitioners and others have developed a variety of programs intended to assist a person in withdrawing from nicotine dependence. Treatments used include psychological counseling, hypnosis, group therapy and behavior modification techniques.

In August 2010, we introduced, CigRx[®] as a tobacco alternative designed to temporarily reduce the desire to smoke. CigRx[®] is a nutraceutical 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[®] and other non-tobacco products compete with smokeless tobacco products in the "When You Can't Smoke"[®] market, which we believe includes our ARIVA[®] and STONEWALL Hard Snuff[®] tobacco products. Also, to the extent that the FDA approves cessation products for nicotine maintenance, we believe our CigRx[®] product and our dissolvable smokeless tobacco products ARIVA[®] and STONEWALL Hard Snuff[®] would be positioned to compete in this market.

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, that are less toxic than our products, or that would render our products obsolete or non-competitive.

Our Prior Relationship with B&W

Beginning in October 1999, we entered into a series of agreements with B&W including an agreement to finance approximately \$29 million of debt used to support our purchase of StarCured[®] tobacco curing barns. The loan balance on this debt was approximately \$7.5 million as of December 31, 2010. On July 30, 2004, RAI combined the U.S. assets, liabilities and operations of Brown & Williamson Holdings, Inc. (formerly B&W), hereinafter referred to as B&W Holdings, an indirect, wholly owned subsidiary of British American Tobacco p.l.c., with RJR. In our ongoing patent infringement litigation with RJR, RJR took the position that this business combination had assumed all of the rights and obligations under the agreements previously entered into with B&W, and moved to dismiss the patent infringement lawsuit on this basis. The District Court denied RJR's motion to dismiss. In its ruling the District Court did leave open the question of what impact, if any, the combination may have on the future licensing arrangements with RJR, but noted that those considerations did not impact the claims asserted in the patent litigation.

Our Patents, Trademarks and Licenses

License Agreement with Regent Court

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 12 U.S. patents and 51 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 May 6, 2021.

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 sublicensees, and 6% on all fees and royalties received by us from unaffiliated sublicensees, 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 patent enforcement and the defense of any infringement claims asserted against us or our sublicensees. 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. Two of the patents under our license with Regent Court that relate to our method for producing low-TSNA tobacco are the subject of our ongoing lawsuit against RJR. See "Item 3. Legal Proceedings" for further details.

Patents and Proprietary Rights

We believe that our patent portfolio under the License Agreement with Regent Court establishes us as a world leader in curing technology that consistently produces very low-TSNA tobacco. Under the agreement with Regent Court, we have exclusive rights to the issued patents listed below, which are the only United States' patents issued to Regent Court. The patents cover the current technology for substantially preventing the formation of TSNA's in tobacco, as well as patents relating to the production of low-TSNA dissolvable smokeless tobacco products and the use of certain tobacco-based MAO inhibitor agents in treating neurological conditions. We have filed corresponding patent applications in numerous foreign countries, some of which have been granted. Also, in December 2008 we filed a new U.S. 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 TSNA's as measured by prevailing standards. In 2010, Rock Creek filed three patent applications relating to our CigRx[®] product, and a patent application for a relapse prevention product. Rock Creek also has several provisional patent applications pending that we expect to mature into one or more non-provisional patent applications 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.

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.

We are the exclusive licensee to the following United States' patents pursuant to our License Agreement with Regent Court:

<u>Patent Number</u>	<u>Date of Issue</u>	<u>Description</u>	<u>Expiration Date</u>
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	10/24/2000	Tobacco Products Having Reduced Nitrosamine Content	06/28/2016
(Reissued as RE 38,123 E) 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

Government Regulation

Overview

The manufacture and sale of cigarettes and other tobacco products are subject to extensive federal governmental regulation in the United States and by comparable authorities in many foreign countries. In addition to federal statutes and regulations, many states also require manufacturers of tobacco products to obtain a cigarette license or a tobacco product license in order to sell tobacco products. States also regulate the age at which adult consumers may purchase tobacco products and the locations where tobacco products can be sold. Many states over the past few years have placed increased restrictions on the purchase and use of tobacco products.

FDA Regulation

Tobacco products and all products derived from tobacco are subject to multiple, overlapping federal and state regulations. Any products derived from tobacco could be viewed as tobacco products, or drug products depending upon their chemical composition, intended use and claims.

FDA Tobacco Act. The Family Smoking Prevention and Tobacco Control Act, or FDA Tobacco Act, which went into effect on June 22, 2009, provides the FDA with broad authority over all tobacco products through a new division within the FDA (The Center for Tobacco Products). The FDA Tobacco Act grants the Center for

Tobacco Products broad authority over the manufacturing, sale and distribution of tobacco products including expanded control over the introduction of new tobacco products, warnings that must be included on all tobacco products and the manner in which tobacco products may be marketed and sold. Many of the changes specified in the FDA Act will be implemented gradually over a period of several years. Tobacco manufacturers were required to register with the FDA by the end of February 2010 and file annually thereafter. We timely submitted our initial registration and filed our annual registration in December 2010. Under the FDA Tobacco Act new labeling requirements with expanded health warnings, additional warnings and restrictions on advertising of tobacco products were put into place during 2010. In April 2010, we submitted a new labeling plan to the FDA along with new package labeling to comply with those changes in the law and have supplemented those materials since that time. The FDA Tobacco Act permits companies to apply to have products designated as “modified risk tobacco products,” and we filed applications seeking this designation for our Ariva-BDL™ our Stonewall-BDL™ products in 2010 and for a moist snuff product, Stonewall Moist-BDL™ in February, 2011. Those applications are currently pending. Under the FDA Tobacco Act, a manufacturer also may seek to have products that are substantially similar to a product that was marketed and sold prior to February 15, 2007 designated as a “substantially equivalent” tobacco product. Such a designation would allow the continued marketing of these products without the need to file an application with the FDA for a new tobacco product designation. We intend to file applications with the FDA seeking to have certain of our blends for ARIVA® and STONEWALL Hard Snuff® designated as substantially equivalent to our ARIVA® and STONEWALL Hard Snuff® blends that were manufactured and sold prior to February 15, 2007. The FDA Tobacco Act also contains provisions that we believe eventually could be beneficial to us in marketing our very-low TSNA smokeless tobacco products, such as those that would require a listing of various constituents and the publication of ingredients in all tobacco products with notations as to the harmfulness of those ingredients, but under the provisions of the FDA Tobacco Act those types of labeling changes and comparative ingredient information will not be put into place for at least two years from the June 2009 effective date of the legislation. In the interim, the FDA Tobacco Act attempts to level the playing field for all tobacco products by restricting the types of claims and descriptions that can be made with respect to various components in tobacco products, including any claims relating to reduced levels of toxins or reduced risk, unless a product receives a designation as a “modified risk tobacco product.” The FDA Tobacco Act also imposes user fees on tobacco manufactures to cover the cost of the FDA process. Given the low volume of sales of our tobacco products since 2009, the impact of the user fee under the FDA Tobacco Act has not been significant to date. However, if sales of our smokeless tobacco products increase substantially, we would have increased user-fee obligations which could become substantial in the future.

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 IND 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.

Dietary Supplement Act. The Dietary Supplement Health Education Act or 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 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 nutraceutical 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. Our CigRx[®] product was introduced in August 2010 as a dietary supplement that is intended to be a smoking alternative that temporarily reduces the desire to smoke. We believe that we have appropriately marketed CigRx[®] as a nutraceutical and have made claims for the product that are consistent with those for a dietary supplement tobacco alternative. If CigRx[®] was 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 its being sold in the United States.

Institute of Medicine Report and Potential Reduced-Exposure Products. On February 22, 2001, the Institute of Medicine issued a comprehensive report, entitled "Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction," in response to a request from the FDA to assess the scientific basis for potentially reducing the health risks associated with tobacco use. This voluminous report suggested, among other findings, that it is scientifically feasible to design and manufacture a range of Potential Reduced Exposure Products, or PREPs, but that, without appropriate governmental regulation and independent scientific evaluation of PREPs, the public is left without clear information regarding the degree to which these products reduce the risks associated with the use of traditional tobacco products. Since 2001, support for PREPs has been the subject of an ongoing debate concerning whether any tobacco products should be considered less toxic and a viable alternative to traditional tobacco products. Over the last several years, the scientific community has begun to recognize that certain forms of tobacco products, particularly low-TSNA smokeless tobacco products, deliver fewer toxins than smoked tobacco. At the same time, concern has been expressed by certain members of the public health community about the use of smokeless tobacco because of potential "unintended consequences" that may accompany a switch from the most lethal form of tobacco to a less toxic tobacco product. The FDA Tobacco Act specifically allows companies to seek approval of products as "modified risk tobacco products" if they contain substantially less toxins than other products on the market and can be demonstrated to reduce the risk associated with tobacco use.

Federal Trade Commission

Requirements for health warnings on cigarettes have been governed by the Federal Cigarette Labeling and Advertising Act and are currently being transitioned to the FDA under provisions contained in the FDA Tobacco Act. Prior to the passage of the FDA Tobacco Act, warning requirements for smokeless tobacco products were mandated under the Comprehensive Smokeless Tobacco Health Education Act of 1986. Those Acts imposed labeling and advertising requirements on the manufacturers, packagers and importers of cigarettes and smokeless tobacco products and required any company wishing to sell such products within the United States to submit a plan to the FTC explaining how it would comply with the warning label display requirements. We submitted labeling plans for smokeless products to the FTC in accordance with these acts. Under the FDA Tobacco Act labeling plans for smokeless tobacco products are now submitted to the FDA for approval and the type and form of warnings that must be included on packages and labeling for smokeless tobacco products are now governed by the statutory requirements of the FDA Tobacco Act and its implementing regulations. We submitted a labeling plan to the FDA along with new package labeling to comply with the changes in the FDA Tobacco Act in April 2010 and have supplemented those materials since that time. Although the FTC no longer has authority over the labeling for smokeless tobacco products, it does have concurrent jurisdiction with the FDA over advertising claims made for tobacco products as well as jurisdiction over claims made for nutraceuticals and other OTC products. The FTC requires that all claims for such products be adequately substantiated. Violations can result in cease and desist orders and consumer redress, such as refunds, among other things.

Tax and Trade Bureau

Manufacturers and importers of tobacco products are taxed pursuant to regulations promulgated by the Tax and Trade Bureau, or TTB under authority of the Internal Revenue Code of 1986, as amended. Our tobacco products are subject to tax under such regulations. The Federal excise tax rate for smokeless tobacco is \$1.51 per pound. The manufacturing of tobacco products is also subject to regulation by the TTB. We currently have a license from the TTB to manufacture smokeless tobacco products at our Chase City, Virginia facility. Our TTB

license requires that we adhere to strict regulations regarding the manufacturing and transportation of our tobacco products.

Fair and Equitable Tobacco Reform Act

In October 2004, Congress passed the Fair and Equitable Tobacco Reform Act of 2004, or FSC/ETI, which provides for the end of the federal tobacco quota program by means of a \$10 billion buyout of the tobacco quota system that is being financed by assessments on tobacco manufacturers. The buyout is paid for by all tobacco manufacturers over a ten-year period based on each company's percentage of sales. The apportionment of responsibility for payments to quota holders is approximately 96% to cigarette manufacturers, and the remaining 4% is divided among other tobacco product manufacturers, based on market share. Given the low volume of sales of our dissolvable low-TSNA smokeless tobacco products to date, the fact that 96% of the assessment for the tobacco quota payment is directed towards cigarette sales, and the discontinuation of our cigarette operations in June, 2007, our payment obligations under the FSC/CTI were negligible in 2010. Absent a substantial increase in our sales of smokeless tobacco products, we believe that our payment obligations under the FSC/CTI should also be de minimis in 2011.

State and Municipal Laws

The sale of smokeless tobacco is taxed in most jurisdictions. One state has no excise tax on smokeless tobacco and the rates in other states vary significantly from state to state using formulas based on weight or on a percentage of the wholesale price of the product. For example, the states of Alabama and Maine tax smokeless products at a rate of \$0.12 per ounce and \$2.02 per ounce, respectively, while the states of South Carolina and Wisconsin impose an excise tax of 5.0% and 100% of wholesale cost, respectively. In addition, some states permit municipalities to impose an additional sales tax, and many municipalities do so. The state and municipal sales taxes are imposed upon wholesalers and/or retailers but not on manufacturers, and therefore we have no liability for such taxes.

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 as a non-participating manufacturer, 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. On March 14, 2007, we sold the rights, title and interest in and to all income from and reversionary interest in our MSA escrow accounts, including our 2006 MSA escrow deposits made in April 2007. Although we 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 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, if such claims are successfully asserted in litigation against us as a result of our prior sale of cigarettes.

In May 2007, we entered into a license agreement with Tantus for the exclusive licensing of our cigarette trademarks Sport[®], MainStreet[®] and GSmoke[®]. We ceased manufacturing cigarettes in June 2007 and, thereafter, we withdrew the certifications for cigarette sales that we previously had obtained in all applicable Settling States. Given the discontinuation of our cigarette operations in June 2007 we did not have any MSA obligation for cigarette sales in MSA states since 2007 and do not anticipate having MSA escrow obligations in the future.

World Health Organization Global Public Health Advocacy; Framework Convention on Tobacco Control

Members of our management team testified in October 2000, at the World Health Organization, or WHO, public hearings in Geneva, Switzerland on the structure of a Global Framework Convention on Tobacco Control, or FCTC. In that testimony we reiterated our support for reasoned regulation of all tobacco products in the U.S. and worldwide to create a more rational environment in which toxicity reduction rather than marketing creativity

would determine relevant market share. Members of our management team also testified before the WHO Scientific Advisory Committee on Tobacco Product Regulation in February 2001, and reiterated our support for reasoned world-wide tobacco regulation within the FCTC-proposed structure. On February 27, 2005, the FCTC went into effect. Although the U.S. signed the FCTC in May 2004, the White House has not sent the Treaty to the Senate for ratification by the requisite two-thirds majority. The State Department has reported that it is reviewing the FCTC for legal issues, particularly those impacting on "commercial free speech". The U.S. has opposed the blanket advertising prohibitions in the FCTC, although prior to promulgation of the FCTC, nations with commercial free speech protections could have opted out of that provision in the treaty and retained the ability to become a signatory to the FCTC. To date, 172 of the 195 nations that signed the FCTC have ratified this comprehensive document.

UK Royal College of Physicians Statement on Tobacco Regulation and Statement on European Union Policy on Smokeless Tobacco

In December 2002, the British Royal College of Physicians issued a report titled "Protecting Smokers, Saving Lives." In that report, the Royal College of Physicians concluded that "the consumption of non-combustible tobacco is in the order of 10-1,000 times less hazardous than smoking, depending on the product." In February 2003, an independent group of researchers and public health educators issued a report titled: "European Union Policy on Smokeless Tobacco — A Statement in Favor of Evidence-Based Regulation." In this report, the researchers called on the European Union, or EU, to reconsider the ban on smokeless tobacco products applicable to all EU members except Sweden, which received an exemption when it joined the EU in 1992. As stated in the report, the request to lift the ban was made in part because "smokeless tobacco is substantially less harmful than smoking, and evidence from Sweden suggest it is used as a substitute for smoking." In 2002, Swedish Match challenged the validity of the EU's ban on the sale of smokeless tobacco products in all member countries in Great Britain's High Court. The British High Court stayed the proceeding and referred the challenge to the EU's High Court of Justice. Oral arguments were heard in September 2004, during which Swedish Match pointed out that maintaining a prohibition of the sale of snus did not take into account the development of scientific information about the relatively decreased health risks associated with oral tobacco use as compared to data relating to the health risks associated with smoking. In December 2004, the EU High Court ruled that the prohibition, while in need of reformulation by the EU legislature, continues to be valid in principle.

The Tobacco Advisory Group of the UK Royal College of Physicians also issued a report in October 2008, "Ending Tobacco Smoking in Britain: Radical Strategies for Prevention and Harm Reduction in Nicotine Addiction." One of the major premises of the report argues again that harm reduction strategies offer a major opportunity to reduce the prevalence and health impact of smoking. The report identifies "compressed smokeless tobacco" as a harm reduction product.

Product Liability

In the United States, there have been numerous and well-publicized lawsuits against the largest manufacturers of cigarettes and 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. The legal theories underlying such lawsuits are varied, but are generally based on one or more of the following: (i) that manufacturer defendants have deceived consumers about the health risks associated with tobacco product consumption; (ii) such defendants knew or should have known about various harmful ingredients of their products and failed to adequately warn consumers about the potential harmful effects of those ingredients; and (iii) such defendants knew of the addictive attributes of nicotine and have purposefully manipulated their product ingredients so as to enhance the delivery of nicotine.

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;
- have never targeted adolescent or young persons as customers;
- have not advertised our cigarette products to consumers except for point-of-sale materials;
- have conducted research on the chemical or other constituents of our products only in the course of efforts to reduce the delivery of toxins;
- have stated unequivocally that smoking involves a range of serious health risks, is addictive, and that smoked cigarettes products can never be produced in a “safe” fashion;
- did not produce our own brands of cigarettes until the mid-1990s, and our sales volumes were never substantial in relation to the volume generated by the major manufacturers; and
- discontinued our cigarette operations in June 2007, in favor of our very low-TSNA dissolvable smokeless tobacco products.

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. Although to date, no health-related lawsuit has ever been filed against us, a lawsuit based on such claims could have a materially adverse effect upon our company.

Prior to the introduction of CigRx® we obtained product liability insurance for CigRx® as a nutraceutical product. This insurance covers claims arising from product defects or claims arising out of the sale, distribution and marketing of our CigRx® product. There have been no claims asserted with respect to our CigRx® product. 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.

Our Employees and Consultants

As of December 31, 2010, we employed 31 full-time employees, as compared to 39 employees as of December 31, 2009.

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 their 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 upon any written request by a shareholder.

ITEM 1A. RISK FACTORS

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

We have incurred operating losses for eight consecutive fiscal years beginning with the year ended December 31, 2003. Our net losses were approximately \$(18.3) million for the year ended December 31, 2008, \$(22.8) million for the year ended December 31, 2009 and \$(28.3) million for the year ended December 31, 2010. Our accumulated deficit as of December 31, 2010 was approximately \$(170.7) million. Additionally, a majority of our historical operating revenues have been derived from sales of our discount cigarettes. However, in May 2007, we entered into a license agreement with Tantus for the exclusive license of our trademarks MainStreet®, Sport® and GSmoke®, in return for licensing fees during the seven-year term of the license agreement and beyond, if the license is renewed. Although we retain the right to manufacture and sell other branded cigarettes, we discontinued the manufacture and sale of our discount cigarettes in June 2007 and are focusing our efforts in the tobacco area on the sale of low-TSNA dissolvable smokeless tobacco products and the licensing of the related technology, as opposed to cigarettes. In August 2010, we introduced CigRx®, a non-nicotine, non-tobacco nutraceutical, in the Richmond, Virginia area. Sales of CigRx® were de minimis in 2010 and it would take a substantial increase in sales of CigRx® and our dissolvable tobacco products for operating revenues to exceed expenses.

Our future prospects, therefore, are dependent on the expanded distribution and consumer acceptance of our low-TSNA dissolvable smokeless tobacco products as well as CigRx® our ability to support the expansion of the market for these products and the continued development of new low-TSNA smokeless tobacco products, related pharmaceutical products and nutraceuticals, independently and through alliances with other tobacco manufacturers or pharmaceutical companies. Our future results of operations are also dependent on our ability to begin generating significant revenues through royalties from the patented tobacco curing process to which we are the exclusive licensee. However, our ability to generate revenues through sales of our smokeless tobacco products and the licensing of related products will substantially be dependent on the successful completion of our ongoing patent infringement lawsuit against RJR.

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 the cash exercise of related warrants and stock options. In 2010 our company received proceeds of approximately \$27.8 million through private placements and we obtained an additional \$11.0 million in private placement transactions subsequent to December 31, 2010. See note 15 to our consolidated financial statements included in "Item 15. Exhibits, Financial Statement Schedules" for further details of the latter transaction. 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 2012. Additionally, although options or warrants are currently or in the future may be in-the-money, there can be no assurances that holders of these derivatives will exercise these securities.

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 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.

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 2010. 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.

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 technologies contained in our products, and on successfully defending our patents and other intellectual property against third-party challenges. In particular, our success in commercially marketing our licensed tobacco curing technology and low-TSNA smokeless tobacco products, and our development of tobacco-based pharmaceutical products to treat tobacco-related dependence and related products, depends in large part on our ability to protect the patents related to our low-TSNA technology for which we are the exclusive licensee, to obtain further patent protection for this technology in the United States and other jurisdictions, and to operate without infringing upon the patents and proprietary rights of others. We have incurred, and expect to continue to incur, substantial costs in obtaining patents and, if necessary, defending our proprietary rights. In particular, we have been prosecuting patent infringement claims against RJR in the United States District Court for the District of Maryland with respect to two patents used in our low-TSNA tobacco technology. Following remand from an earlier appeal to the Federal Circuit Court of Appeals, the case was 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. We appealed the jury verdict to the Federal Circuit Court of Appeals in December 2010 and the case was argued before a three-judge panel of the Federal Circuit on January 11, 2011. We are currently awaiting a decision on the appeal. 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. The future prosecution of the new complaint will be dependent on our achieving a reversal of the jury verdict of invalidity in our initial RJR action, which is uncertain at this time.

Also, since 2008 Rock Creek has developed several processes and product formulations relating to our non-nicotine nutraceutical (CigRx[®]), a relapse prevention product and a compound (RCP006) that may be useful in maintaining a healthy metabolism. In 2010, Rock Creek filed three patent applications relating to our CigRx[®] product, and a patent application for a relapse prevention product. Further, there are several provisional patent applications pending that we expect to mature into one or more non-provisional patent applications 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. We believe this technology will be important for our business going forward, however, there can be no assurances that we will be able to mature these provisional patent applications into non-provisional applications or that any related non-provisional patent applications will be granted.

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 patent or other intellectual property rights, or may design around our proprietary technologies.

U.S. patents and patent applications may also be subject to interference proceedings and U.S. patents may be subject to reexamination proceedings in the U.S. Patent and Trademark Office. 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, which 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.

Our growth strategy anticipates that we will create new products and distribution channels and expand existing distribution channels for our low-TSNA smokeless tobacco products, for CigRx® and for other products developed by Rock Creek. Our future growth is also heavily dependent upon increased consumer acceptance of our low-TSNA smokeless tobacco products, CigRx® and other non-nicotine nutraceuticals and pharmaceutical products, as well as on increased demand to license our related technology. If we are unable to effectively manage these initiatives, our business, financial condition, results of operations and cash flows would be adversely affected.

Our long-term growth strategy includes an increased focus on the sales and marketing of our low-TSNA smokeless tobacco products ARIVA® and STONEWALL Hard Snuff®, our dietary supplement CigRx® and the introduction of other non-nicotine nutraceuticals and tobacco-based pharmaceuticals as well as the receipt of royalty fees for the licensing of our patented technology for producing low-TSNA tobacco. However, to date sales of our smokeless tobacco products and CigRx®, as well as our ability to derive revenue from the licensing of our low-TSNA technology, have been de minimis.

Additionally, our success will be dependent on our ability to develop other non-nicotine products that may be helpful to consumers in maintaining a healthy metabolism, as well as tobacco-based 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, including tobacco-based drug products, in addition to the development of non-nicotine nutraceutical products. Assuming that we are successful in introducing such products into the market, the success of those products and the success of our low-TSNA smokeless tobacco products and CigRx® 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 our significant retail customers or independent distributors were to reduce the quantity of any of our smokeless tobacco 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 CigRx® or our low-TSNA smokeless tobacco products will be accepted by the market in sufficient volume to support our operations. Adult tobacco users may decide not to purchase our products due to taste or other preferences, including a preference for our competitor's products or because of the extensive health warnings contained on the packaging for our tobacco 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, that are less toxic than our products, or that would render our products obsolete or non-competitive.

Further, an inability to successfully increase consumer awareness of and demand for our very low-TSNA smokeless tobacco products would negatively affect our ability to license our patented technology for producing

low-TSNA tobacco. This accordingly would materially diminish our ability to derive royalty fees from the license of this technology. If we are unable to license our patented technology for producing low-TSNA tobacco, our financial condition and results of operations could be adversely affected.

Our efforts to successfully market CigRx[®] and ARIVA[®] and STONEWALL Hard Snuff[®] also will require the expenditure of substantial funds that we will need to obtain from external financing, the availability of which cannot be assured, and ultimately these products may not be accepted in the national marketplace. If we are not successful in our efforts to offer CigRx[®] or our low-TSNA smokeless tobacco products to adults as alternatives to cigarettes and other smokeless products, to generate revenue through the license of the related technology to which we are the exclusive licensee or to introduce new nutraceutical and pharmaceutical products, we will not have sufficient sales volumes to support our operations.

We are subject to increased regulation relating to our tobacco products as a result of the FDA assuming jurisdiction over all tobacco products under the FDA Tobacco Act.

The FDA Tobacco Act, which went into effect on June 22, 2009, provides a new division within the FDA (The Center for Tobacco Products) with broad authority over the manufacturing, sale and distribution of tobacco products including expanded control over the introduction of new tobacco products, warnings that must be included on all tobacco products and the manner in which tobacco products may be marketed and sold. Many of the changes specified in the FDA Act will be implemented gradually over a period of several years. We have sought to comply with these requirements by registering with the FDA as a tobacco manufacturer and taking other steps to comply with the FDA Tobacco Act requirements with respect to the manufacture, sale and marketing of our low-TSNA smokeless tobacco products. Also, in 2010 we filed applications seeking to have variants of our ARIVA[®] and STONEWALL Hard Snuff[®] products (Ariva-BDL[™] and Stonewall-BDL[™]) approved as “modified risk products”. We filed a similar application for a Stonewall Moist-BDL[™] product in February, 2011. Those applications are pending. If we are not successful in meeting the requirements of the FDA Tobacco Act with respect to our current low-TSNA smokeless tobacco products, or obtaining approval to market any new tobacco products, our effort to expand the distribution and sales of our low-TSNA smokeless tobacco products or other tobacco products could be adversely affected which could have an adverse effect on our results of operations, financial position and cash flows.

The tobacco industry as well as the market for non-nicotine tobacco alternatives are highly competitive, we may not be able to effectively compete in these markets and our competitors may develop technology for the production of low-TSNA tobacco that does not infringe on the technology to which we are the exclusive licensee, or they may develop technology for low-TSNA tobacco or other cigarette alternatives that could make our technology obsolete.

Virtually all flue-cured tobacco grown in the United States since 2001 has been cured in a manner to reduce the levels of TSNA's. If our competitors produce low-TSNA tobacco that does not infringe on the technology to which we are the exclusive licensee, or develop other tobacco products with less toxins that can compete with our very low-TSNA products, this could adversely affect our operating income and cash flows.

The tobacco industry is highly competitive. STONEWALL Hard Snuff[®] competes with major manufacturers of smokeless tobacco products and ARIVA[®] competes with traditional cigarette manufacturers because ARIVA[®] is positioned as an alternative to cigarettes in situations where adult cigarette users cannot or choose not to smoke. Those companies generally have substantially greater financial and operating resources than we do. Also, these companies have a more established presence in the smokeless tobacco industry than we do. Certain of the major cigarette makers are marketing alternative cigarette products. For example, Philip Morris has developed an alternative cigarette called Accord in which the tobacco is heated rather than burned. RJR has developed an alternative cigarette called Eclipse in which the tobacco is primarily heated, with only a small amount of tobacco burned. Vector Tobacco Inc. developed a cigarette offered in several packings with declining levels of nicotine, called Quest. Further, in 2006 and 2007, both Philip Morris and RJR introduced into test market smokeless tobacco pouch products designed to provide alternatives to cigarettes that utilize their primary brand names (Marlboro Snus and Camel Snus, respectively), and other smokeless tobacco manufactures have

introduced products that claim to have reduced levels of carcinogens. In 2009 Altria, Philip Morris's parent company expanded its role in the smokeless tobacco market through its acquisition of UST. Also, in 2009 RJR introduced into test market three dissolvable smokeless tobacco products that compete directly with our ARIVA® and STONEWALL Hard Snuff® low-TSNA dissolvable smokeless tobacco products. If these initiatives are successful or if our competitors develop new technology for low-TSNA tobacco for use in smokeless tobacco products, we will be subject to increased competition for market share and our current technology for the production of low-TSNA tobacco could become obsolete.

CigRx® may compete with both FDA approved smoking cessation products and nutraceutical tobacco alternatives. 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 and are marketed by the leading pharmaceutical companies as alternatives to cigarettes. Also there are other tobacco alternatives, such as E-cigarettes, and non-nicotine nutraceuticals that are marketed as assisting to maintain a nicotine free metabolism or to balance metabolism in the absence of nicotine. Many companies marketing smoking cessation products or related nutraceutical alternatives have substantially greater financial and operating resources than we do. To the extent competitors in these markets are able to develop products that are accepted as tobacco alternatives, the sale of our low-TSNA smokeless tobacco products could be adversely affected, which could have a material adverse effect on our results of operations, financial position and cash flows.

We may not be successful in introducing and marketing our non-nicotine, non-tobacco CigRx® product.

We introduced into test market in August 2010 CigRx®, a non-nicotine nutraceutical product that is intended to temporarily reduce the desire to smoke. Currently CigRx® is being sold through an interactive website, an infomercial and, to a limited extent, through direct retail sales. Our success in marketing CigRx® will be dependent on consumer acceptance of this product and our ability to have the product sold to consumers principally through our website and through infomercials. If we are not able to attract interest in the product at the consumer level, expand on the distribution channels for CigRx® or compete with other companies marketing alternatives to tobacco products our financial condition and results of operations could be adversely affected.

Sales of tobacco products have been declining, which could have a material adverse effect on our revenues and cash flows.

The overall U.S. market for cigarettes has generally been declining in terms of volume of sales, as a result of restrictions on advertising and promotions; funding of smoking prevention campaigns; increases in regulation and excise taxes; a decline in the social acceptability of smoking, and other factors, and sales are expected to continue to decline. While the sales of smokeless tobacco products have been increasing over the last several years, the smokeless tobacco market is substantially smaller than the cigarette market. Prior to our exit from the discount cigarette business, we experienced a similar decline in sales of our discount cigarette products, and this downward trend may adversely impact our ability to sell and market our low-TSNA smokeless tobacco products or CigRx® as an alternative to cigarettes. This could have a material adverse effect on our results of operations, financial position and cash flows.

We may face delays in obtaining very low-TSNA tobacco or other raw materials to adequately manufacture our products.

As a result of the discontinuation of our business relationship with B&W, and the ongoing burden and expense of the pending patent infringement litigation with RJR, during 2007 we sold approximately 990 tobacco curing barns used for the production of our low-TSNA StarCured® tobacco. We sold our remaining 37 StarCured® tobacco curing barns in December 2009 to growers who had previously participated in the StarCured® program. While we currently do not own any StarCured® barns, we have a significant amount of StarCured® tobacco in inventory and access to StarCured® tobacco through growers who previously participated in our StarCured® tobacco curing program. However, given the sale of our remaining barns, we cannot be assured that we will have sufficient availability to curing barns to meet future demand for our low-TSNA tobacco, particularly if the sales volumes of our very low-TSNA smokeless tobacco products substantially

increase over a short period of time. Further, in the event that we are unable to obtain adequate amounts of StarCured® tobacco and other raw materials to meet product demands, our customers may seek to fulfill their supply needs by purchasing competing brands, which in turn would reduce our market share and ability to successfully commercialize our very low-TSNA smokeless tobacco products. This could have a material adverse effect on our results of operations, financial position and cash flows.

We may face disruptions relating to the manufacture and sale of CigRx® based on the fact that we have arranged for third parties to manufacture and distribute CigRx®.

In order to facilitate the launch of CigRx® and limit capital expenditures, we have outsourced the manufacturing, storage, order processing and delivery of CigRx® through contracts and arrangements with a number of third-party suppliers. We anticipate that the arrangements that have been put in place with these various entities should be sufficient to meet our manufacturing and distribution needs for CigRx® for the foreseeable future. However, these contractors may 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 CigRx®, which may be difficult to obtain in a timely and cost effective manner, or at all. Also, if sales volumes for CigRx® increase substantially over a short period of time, our current contractors may have difficulty meeting our manufacturing and supply demands. In the event we are not able to obtain adequate amounts of CigRx® 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 CigRx®, which could have a material adverse effect on our results of operations, financial position and cash flows.

Our research & development efforts may not result in commercially viable products and may continue to 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 lessen reliance on and the impact of the use of all forms of tobacco, reduce the range of serious health hazards associated with the use of smoked and smokeless tobacco and more generally assist consumers in maintaining a health metabolism. We have pursued these objectives through the production of very low-TSNA tobacco and the development of dissolvable smokeless tobacco products. Also, through Rock Creek we have pursued the development of our non-nicotine, non-tobacco nutraceutical CigRx® and ongoing research and development efforts directed to botanical based products for the treatment of tobacco dependence, products that would utilize certain MAO agents in tobacco to treat a range of neurological conditions, including Alzheimer's disease, Parkinson's disease, schizophrenia and depression as well as non-nicotine nutraceuticals. 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 are subject to risks inherent in new product development initiatives, particularly with respect to our goal of developing pharmaceutical products to treat tobacco-related dependence and other neurological conditions, which are subject to FDA regulation and approval, and for related products such as nutraceuticals.

Our future success is substantially dependent upon implementation of our business strategy related to our new product initiatives. Since 2007, through our Rock Creek subsidiary, we have been exploring the development of botanical-based products for the treatment of tobacco dependence, as well as products that would utilize certain MAO agents in tobacco to treat a range of neurological conditions, including Alzheimer's disease, Parkinson's disease, schizophrenia and depression. Rock Creek also has been involved in pursuing the development of a non-nicotine nutraceutical product that was introduced in 2010 under the name CigRx® and other nutraceuticals that could be used to support a healthy metabolism. 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 nutraceuticals. Since the passage of the FDA Tobacco Act, all tobacco products are now regulated under the FDA Tobacco Act. They are also, subject to multiple, overlapping federal and state regulations and products derived from tobacco could be classified as tobacco products or drug products depending on their chemical composition, intended use and claims.

Additionally, the Dietary Supplement Health Education Act, 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. DSHEA does not require prior approval by the FDA for the introduction of dietary supplements into the market, but does require that the nutraceutical products being developed by our Rock Creek subsidiary 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 nutraceuticals and other OTC products.

In marketing CigRx®, we will have to comply with the requirements of DSHEA, which could impact the time required to fully commercialize this product. 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 future success of our pharmaceutical, and to a more limited extent, our nutraceutical, 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 nutraceuticals 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 a 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.

We do not have long-term contracts with any of our retail customers or independent distributors selling our low-TSNA smokeless tobacco products and a loss or material reduction in their business with us could result in reduced sales of our products.

Our success in marketing our low-TSNA smokeless tobacco products is dependent upon the willingness and ability of retail customers to market and sell our products to consumers, as well as our success in developing new channels for our low-TSNA smokeless tobacco products. If any of our significant retail customers or independent distributors were to reduce the quantity of the products we sell, or to stop selling our products, or if we are unable to open new distribution channels for our products, our financial condition and results of operations could be adversely affected.

Our retail customers and independent 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 retail customers 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 customers 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 CigRx® and our low-TSNA smokeless tobacco products.

All of our revenues are currently derived from domestic sales of CigRx® and our low-TSNA smokeless tobacco products. The overall market for tobacco products in the U.S. has been declining on a year-to-year basis for the last several years, even as the market for smokeless tobacco products has been growing. Because CigRx® and our low-TSNA smokeless tobacco products are being marketed only in the U.S., we do not currently have access to any foreign markets, which access could help offset the impact of declining sales of tobacco products in the U.S.

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

We may be exposed to product recalls and adverse public relations if our nutraceuticals products or our low-TSNA smokeless tobacco 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.

The tobacco industry is subject to substantial and increasing regulation and taxes with respect to the sale and marketing of its products.

The FDA Tobacco Act provides The Center for Tobacco Products, a new division within the FDA, with broad authority over the manufacturing, sale and distribution of tobacco products including expanded control over the introduction of new tobacco products, warnings that must be included on all tobacco products and the manner in which tobacco products may be marketed and sold. The FDA Tobacco Act also provides for the establishment of a Scientific Advisory Committee that, among other initiatives, has been designated to undertake an analysis of dissolvable tobacco products and to provide a report on such products within two years from the date on which this committee was first convened. As currently implemented, we do not believe the FDA Tobacco Act presents a material risk to our business activities, but there is no assurance that the current legislation as implemented by the FDA will not limit or delay our future initiatives or that difficulties and/or delays in obtaining approvals from the FDA will not have an adverse impact on our ability to market our low-TSNA smokeless tobacco products and the applications that we have filed to have variants of our existing products designated as “modified risk tobacco products”.

We have a license from the TTB to manufacture smokeless tobacco products. To the extent that we are unable to maintain our current TTB license or to obtain any additional licenses required by the TTB, this could materially and adversely affect our operations. Also, we are subject to assessments based on our sales volume to cover a portion of the fund established in 2004 to compensate growers and quota holders at the time that the U.S. Congress eliminated the federal tobacco quota system and price support system. While the impact of this legislation is less significant in relation to the sale of smokeless tobacco products than for cigarettes, if sales of our smokeless tobacco products increase substantially, we would have increased obligations during the ten-year period in which the buyout program is in effect.

The federal excise tax on smokeless tobacco products is substantially lower than the excise tax for cigarettes, but smokeless tobacco products are subject to substantial and increasing excise taxes. The current federal excise tax for snuff is \$1.51 per pound. It is possible that increased use of smokeless tobacco products could result in more stringent regulation and higher taxes. Recently a number of states have considered increases in state excise taxes on smoked and smokeless tobacco products. At the state level the rate of tax on smokeless tobacco varies significantly. For example, one state imposes no tax on smokeless tobacco products while another state imposes a tax of \$2.02 per ounce. New or increased excise taxes or restrictions on the use of tobacco products may result in declines in sales volume for the industry generally, and our low-TSNA smokeless tobacco products in particular, which could adversely affect our operating income and cash flows.

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 from and reversionary interest in the funds deposited into the MSA escrow accounts 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. However, 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 have many potentially dilutive derivative securities outstanding and the issuance of these securities as well as the future sales of our common stock would have a dilutive effect on current stockholders.

At March 15, 2011, we had outstanding options granted to directors, employees and consultants to purchase approximately 8,620,200 shares of our common stock, with a weighted-average exercise price of \$2.31 per share, of which options for 8,220,200 shares were exercisable at March 15, 2011. We also have outstanding warrants, which are currently exercisable into 35,897,255 shares of our common stock, with a weighted-average exercise price of \$1.75 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 in connection with future financings, our stockholders would experience further dilution.

The combination transaction between RJR and B&W may negatively impact us.

Under our prior agreements with B&W, B&W loaned us \$29 million to fund our purchase of StarCured[®] tobacco curing barns. The balance on this loan was approximately \$7.5 million as of December 31, 2010. Previously, B&W granted us a number of concessions under our loan agreement, including deferring interest and principal payments and consenting to our incurrence of additional indebtedness. In 2004 B&W and RJR completed a combination of their United States tobacco business through a new entity Reynolds American, Inc.

We are currently involved in a significant patent infringement litigation with RJR, which, in effect, is the successor of the RJR and B&W combination. Although our current loan is unsecured, RJR's failure to grant us concessions under our loan could have a number of adverse consequences, including restricting our pursuit of business opportunities with third parties, limiting our ability to raise funds through debt financing and requiring payment of our obligations in circumstances where we may not have sufficient funds available to do so. Since the combination of B&W and RJR, we have had no operational relationship with RJR and given our ongoing patent litigation against RJR, we do not anticipate that we would have the same type of cooperative relationship with RJR as we had with B&W, or that RJR would be inclined to grant concessions similar to those that we received from B&W.

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 intend to timely pursue this matter through all available means. The sales and use tax assessment plus penalties and interest together, as of December 31, 2010, totaled \$1.5 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.

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 believe that the risk of being named a defendant in such a lawsuit is relatively low, we may be named as a defendant in the future 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. 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 we previously maintained did not cover health-related claims such as those that have been made against the major manufacturers of tobacco products. We currently do not have and do not believe that such insurance coverage for health-related claims can be obtained. If, in the future, we are named as a defendant in any actions related to our 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. We may also face lawsuits relating to our dietary supplement CigRx®, although CigRx® is not a tobacco product and does not contain nicotine. Prior to the introduction of CigRx®, we obtained product liability insurance for CigRx® as a nutraceutical product. This insurance covers claims arising from product defects or claims arising out of the sale, distribution and marketing of our CigRx® product. There have been no claims asserted with respect to the manufacturer, sale or use of our CigRx® product 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.

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. Our ability to successfully manage such volume also will be dependent on our ability to scale up our tobacco processing and production operations. Also, if we are successful in marketing our CigRx® dietary supplement we will have to maintain sufficient capacity for the contract manufacturing of the product and for its sales and distribution through third-party contractors. 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 CigRx®. 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 and adverse effect on our business and prospects, financial condition and results of operations.

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.

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 eight 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.

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 15, 2011, our directors and executive officers and their affiliates, own an aggregate of approximately 10.6% 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.

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 \$0.51 to \$3.84 for the period January 1, 2010 to March 15, 2011. We receive only limited attention from securities analysts and may experience an imbalance between supply and demand for our common stock resulting from low 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:

- developments related to our patents or other proprietary rights, including developments in our litigation against RJR;
- developments in our efforts to market smokeless tobacco products;
- our success in marketing, CigRx®, our non-nicotine, non-tobacco smoking alternative designed to temporarily reduce the desire to smoke, related nutraceuticals designed to assist in maintaining a healthy metabolism, a pharmaceutical product to treat tobacco-related dependence and related pharmaceutical 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 for the tobacco, pharmaceutical and dietary supplement industries in general.

The stock market has, from time to time, and in particular over the last 24 months, 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.

On November 5, 2009, we received a NASDAQ Staff Deficiency Letter, indicating that we were not in compliance with the minimum bid price requirement for continued listing set forth in NASDAQ Marketplace Rule 5450(a)(1), because the bid price per share of the our common stock closed below \$1.00 per share for 30 consecutive business days. On March 16, 2010, we announced that we had received a notice from NASDAQ confirming that we were once again in compliance with the minimum bid price requirement and we have remained complaint with this requirement since that time.

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, 2010.

ITEM 2. PROPERTIES

Until February 2010 we occupied approximately 6,000 square feet of office space in Petersburg, Virginia that housed our executive, marketing and administrative offices. In October 2009, we sold our Petersburg property and entered into a leaseback of the office space. As of February 2010 we began leasing approximately 2,500 square feet of office space for our executive, marketing and administrative offices in Glen Allen, Virginia, which is located in the Richmond, Virginia metropolitan area. We terminated the leaseback for the Petersburg property in February, 2010, once we completed our transition to the property in Glen Allen.

Until July 2007, our executive, administrative, legal and scientific offices were located in a 5,600 square foot leased office space in Bethesda, Maryland. We terminated that lease in July 2007 and entered into a lease for a smaller amount of office space in Bethesda. We also have been utilizing space in a nearby location 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 U.S. 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 consisting of approximately 3,200 square feet of office space.

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 accommodates our manufacturing operations, an expanded testing facility and office space. We have approximately one year remaining on the initial ten-year portion of the lease for this facility, which is then subject to renegotiation of the lease payments for the additional ten years of the lease. We also have an option to buy the property at any time during the lease.

We believe our manufacturing facilities and other facilities will be sufficient to allow us to respond to the demand for our smokeless tobacco 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). The new patent is a continuation of the '649 Patent, and on August 27, 2002 the two suits were consolidated.

In April 2003, the parties filed dispositive Motions for Summary Judgment. After appointment of a Special Master to prepare Reports and Recommendations, or R&Rs, for the District Court on six of the Summary Judgment Motions, the District Court adopted without modification the Special Master's R&Rs, which collectively recommended that the District Court deny RJR's Summary Judgment Motions, and that our Motion for Summary Judgment on claim construction and definiteness be granted in part and denied in part. The District Court also issued an order denying RJR's other Motion for Summary Judgment seeking to limit our damages claim.

On August 17, 2004, the case was transferred from Judge Alexander Williams to Judge Marvin J. Garbis. Judge Garbis over the next several months issued a series of orders concerning various aspects of the case and ordered that the RJR's defense of inequitable conduct before the patent office be bifurcated from the remaining issues and tried before Judge Garbis beginning on January 31, 2005. That portion of the case was tried during the period January 31, 2005 to February 8, 2005. At the conclusion of the bench trial, the District Court advised the parties that it would take the matter under advisement, and expected to rule on this portion of the case at the same time that it ruled on the two additional Summary Judgment Motions that were filed by RJR on January 25, 2005. On January 19, 2007, the District Court granted RJR's Motions for Summary Judgment in part and denied these motions in part. On RJR's Motion for Summary Judgment on the Effective Filing Date of the patents, the District Court established September 15, 1999 as the effective filing date, but denied RJR Summary Judgment of Invalidity with regard to the patents-in-suit. On RJR's Motion for Summary Judgment on Indefiniteness, the District Court granted the motion on the basis that the term "anaerobic condition" was indefinite. On June 26, 2007 the District Court issued its ruling on RJR's inequitable conduct defense. In its ruling the District Court held the two patents unenforceable due to inequitable conduct in their procurement and a final judgment against our company was docketed on June 27, 2007. We immediately filed a notice of appeal as to the rulings issued in January 2007 and as to the ruling on the inequitable conduct defense with the United States Court of Appeals for the Federal Circuit, or Court of Appeals.

Following briefing and oral argument, the Court of Appeals on August 25, 2008 issued a unanimous opinion reversing the rulings by the District Court that had found the patents at issue in the RJR litigation invalid because of inequitable conduct during the prosecution of the patents and because the patents were indefinite. As part of its opinion, the Court of Appeals ordered that the case be remanded to the District Court for further proceedings on the infringement complaint. Following remand from the Court of Appeals, the case was 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. RJR filed its brief on August 2, 2010 and our reply was filed on September 20, 2010. Oral argument on the appeal was held before a three-judge Panel of the Federal Circuit Court of Appeals on January 11, 2011. We are currently awaiting a decision from the Federal Circuit Court of Appeals on the appeal.

On November 30, 2009, RJR filed a motion for a bill of cost 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 the 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. Any potential award of attorneys' fees should be eliminated if the Court of Appeals for the Federal Circuit overturns the jury verdict in the District Court or if the claims at issue in the reexamination proceeding in the U.S. Patent and Trademark Office are determined to be valid, and any award of costs should also be eliminated if the Federal Circuit overturns the jury verdict in favor of RJR. Because the likelihood of an unfavorable ruling on the fee motion and bill of cost is not determinable at this time and the amount of any potential assessment cannot be reasonably estimated, no amounts have been accrued for these items in the accompanying condensed consolidated financial statements.

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 action against RJR. The future prosecution of the new complaint will be dependent on our achieving a reversal of the jury verdict of invalidity in our initial RJR action.

On December 31, 2008 and January 2, 2009, RJR filed requests in the U.S. Patent and Trademark Office to reexamine the two patents that are the subject of the patent infringement litigations described above. In February and March 2009, the Patent and Trademark Office granted the reexamination requests, agreeing to review the patentability of the subject matter claims 4, 12 and 20 of the '649 patent and claim 41 of the '401 patent. On March 10, 2011, the Patent and Trademark Office confirmed the validity of each of the claims of the '649 and '401 patents that were under reexamination and closed each of the reexamination proceedings.

We entered into fee arrangements with counsel in several litigation and related matters under which certain costs related to the litigation are being advanced by counsel on our company's behalf. Given the contingent nature and the fact that a probability assessment of liability cannot be made at this time, no accrual has been made for this contingent liability. We have paid or accrued all existing obligations. Also, as part of our fee arrangements in certain of these matters, we have agreed to pay counsel a percentage of any damage awards, a percentage of the resulting payments we actually receive or a result fee in the event that the litigation is resolved in our favor, in return for a cap on fee payments during the litigation.

Internal Revenue Service Examination

In 2004, we were notified that our company's 2001 tax return had been selected for examination by the Internal Revenue Service, or IRS. In the course of its conduct of this examination, the IRS expanded the scope of the examination to include all of our company's returns that had been filed for the years ended December 31, 2002 through 2004. In 2005, our request for a private letter ruling, or PLR, which related to the years under IRS examination, was resolved generally in our favor and an amended private letter ruling, or Amended PLR, was

issued by the IRS in January 2009. The Amended PLR confirmed that our company's deductions taken for MSA escrow payments, which were the subject of the IRS ongoing audit for tax years 2001 through 2004 and a pending tax appeal, were fully deductible and appropriate in the years taken. Based on the Amended PLR, we entered into a closing agreement with the IRS which confirmed the deductions taken for those years and, thereafter, the IRS confirmed that our company's tax returns for the years 2001 through 2004 were correct as filed. As a result of the notification by the IRS in the Amended PLR, we reversed our position of recording this income tax expense as of December 31, 2008, which resulted in a \$2.2 million income tax benefit.

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. We disagree with the ruling by the Commissioner and intend to timely pursue this matter through all available means. The sales and use tax assessment plus penalties and interest together, as of December 31, 2010, totaled \$1.5 million. Interest will continue to accrue during our company's continued pursuit of a resolution of this matter.

Except as set forth above, there are no other litigation matters pending that could be expected to materially harm our results of operations and financial condition.

ITEM 4. (RESERVED AND REMOVED)

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 "CIGX" (formerly "STSI"). On March 15, 2011, the closing price of our common stock as reported on the NASDAQ Global Market was \$2.94. Set forth below are the high and low sales prices for each full quarterly period during 2010 and 2009, as reported by NASDAQ. From time to time, during the periods indicated, trading activity in our common stock was infrequent. As of March 15, 2011, there were approximately 630 registered holders of our common stock.

Quarter	2010		2009	
	High	Low	High	Low
First	\$3.00	\$0.66	\$4.75	\$2.11
Second	3.05	1.07	5.89	0.84
Third	2.32	1.40	1.15	0.84
Fourth	2.12	1.64	1.02	0.51

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.

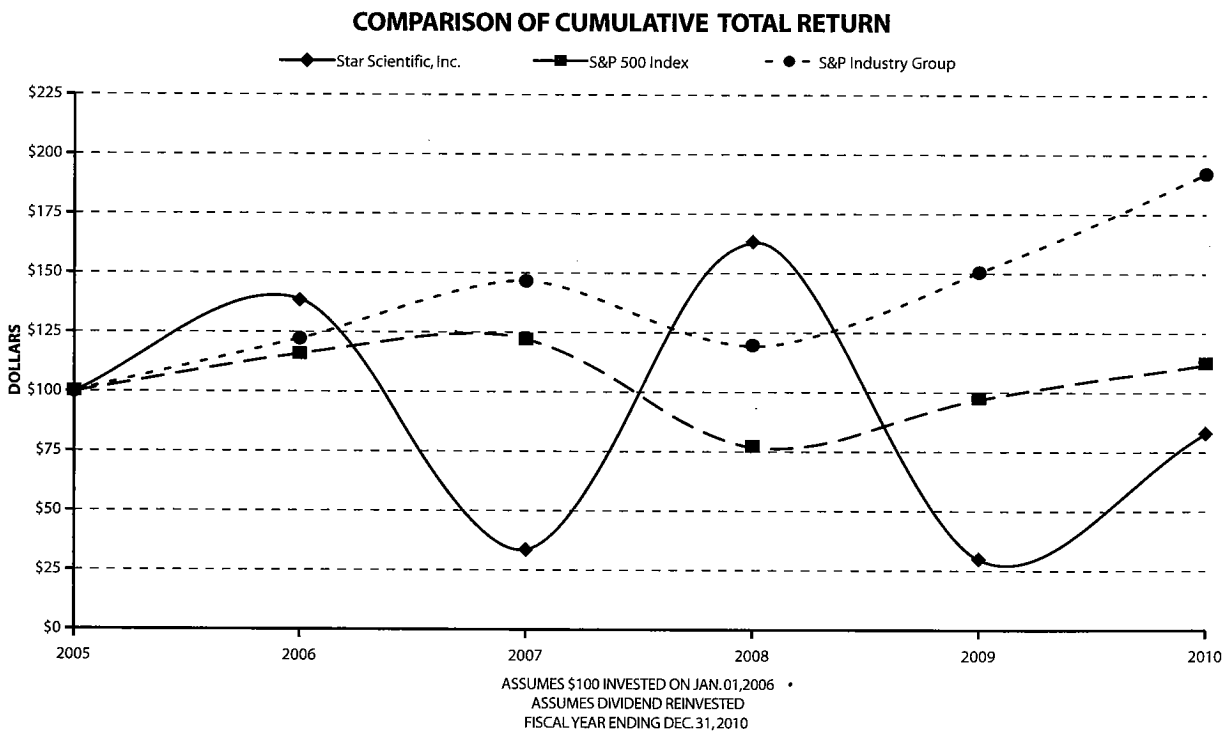
Securities Authorized for Issuance Under Equity Compensation Plan

The following table provides certain information as of December 31, 2010, with respect to our equity compensation plans under which our common stock is authorized for issuance:

<u>Plan Category</u>	<u>Number of Shares to be Issued Upon Exercise of Outstanding Options and Rights(1)</u>	<u>Weighted-Average Exercise Price of Outstanding Options and Rights</u>	<u>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding Column (a))</u>
	(a)	(b)	(c)
Equity Compensation Plans Approved by Shareholders	7,716,200	\$2.31	2,684,000

- (1) We have also granted warrants to purchase shares of our common stock to consultants. Specifically, on December 20, 2000, we issued 210,526 warrants to purchase shares of our common stock at an exercise price of \$2.375 to a consultant. These warrants fully vested on the date of issuance and expired on December 20, 2010.

Five-year financial performance graph: 2006-2010



Comparison of five-year cumulative return among Star Scientific, the S&P Tobacco Industry Group, and the S&P Composite

COMPANY / INDEX / MARKET	FISCAL YEAR ENDING					
	2005	2006	2007	2008	2009	2010
Star Scientific, Inc.	100.00	138.50	33.87	162.98	29.79	82.98
S&P Tobacco Group	100.00	115.79	122.16	76.96	97.33	111.99
S&P Composite	100.00	122.16	146.41	119.69	150.34	191.98

The current composition of S&P Industry Group 30203010 — Tobacco — is as follows:

ALTRIA GROUP, INC.
 PHILIP MORRIS INTERNATIONAL, INC.
 LORILLARD, INC.
 REYNOLDS AMERICAN, INC.

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.

Option Grants and Stock Awards

In 2010, 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 2010 or during the fourth quarter of 2010 from our company’s 2008 Incentive Award Plan. On October 22, 2010, the Board of Directors elected Burton J. Haynes, Esquire as an Independent Director. Upon his election to the Board, Mr. Haynes was awarded a stock option grant in the amount of 50,000 option shares. Those options have a strike price of \$2.03 per share and aggregate stock compensation of \$86 thousand, which will be recognized in the financial statements over the two year vesting period of the options. On November 20, 2010, 50,000 options for shares of our common stock with an exercise price of \$1.75 were granted to one member of the Purchaser Class.

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, 2010, 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,				
	2010	2009	2008	2007	2006
	(In thousands, except per share data)				
Statement of Operations Data:					
Net sales	\$ 848	\$ 708	\$ 451	\$ 482	\$ 391
Cost of goods sold (excludes federal excise tax)	2,172	2,612	2,116	2,067	1,791
Gross margin (loss)	(1,337)	(1,920)	(1,672)	(1,604)	(1,404)
Loss from continuing operations before income taxes	(28,281)	(22,800)	(20,564)	(40,882)	(13,790)
Discontinued operations income(loss)	—	—	—	(451)	1,505
Net income (loss)	(28,281)	(22,800)	(18,339)	(41,458)	(12,285)
Basic and diluted income (loss) per share:					
Continuing operations	\$ (0.24)	\$ (0.22)	\$ (0.20)	\$ (0.51)	\$ (0.18)
Discontinued operations	—	—	\$ —	\$ (0.01)	\$ 0.02
Total basic and diluted income (loss) per share	\$ (0.24)	\$ (0.22)	\$ (0.20)	\$ (0.52)	\$ (0.16)
Weighted average shares outstanding	118,384	101,907	89,844	80,395	77,836
	(In thousands, except per share data)				
Balance Sheet Data:					
Cash and cash equivalents	\$ 13,192	\$ 12,360	\$ 6,473	\$ 8,881	\$ 4,297
Property and equipment	2,169	1,057	1,668	1,986	9,515
MSA escrow funds	368	365	365	4	38,329
Discontinued operations assets	—	—	—	—	6,041
Total assets	20,285	15,234	12,252	14,827	60,937
Long-term obligations	5,049	7,518	9,499	11,111	14,975
Discontinued operations liabilities	—	—	—	—	1,443
Stockholders' equity (deficit)	\$ 10,659	\$ 2,288	\$ (498)	\$ (1,988)	\$ 38,909

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 reduce the harm associated with the use of tobacco at every level. We are primarily engaged in:

- the development, implementation and licensing of our proprietary technology for the curing of tobacco so as to substantially prevent the formation of carcinogenic toxins present in tobacco and tobacco smoke, primarily the tobacco-specific nitrosamines, or TSNA's;
- the manufacture, sales, marketing and/or development of very low-TSNA dissolvable smokeless tobacco products that carry enhanced warnings beyond those required by the Surgeon General, including ARIVA® compressed powdered tobacco cigarette pieces and STONEWALL Hard Snuff® and "modified risk tobacco products" as defined in the Family Smoking Prevention and Tobacco Control Act of 2009, or the FDA Tobacco Act;
- the development of pharmaceutical products, particularly products that have a botanical, tobacco-based component, that are designed to treat tobacco dependence and a range of neurological conditions, including Alzheimer's disease, Parkinson's disease, schizophrenia and depression; and
- the manufacture, sale, marketing and development of non-nicotine nutraceutical products designed to assist individuals who are seeking a smoking alternative as well as related non-nicotine products that are designed to assist consumers in maintaining a healthy metabolism.

Since the 1990s, we have sought to develop processes and products that significantly reduce the levels of toxins, principally TSNA's, in tobacco compared to traditional smoked and smokeless tobacco products. Given our long-term focus on reducing the levels of toxins in tobacco and the harm associated with tobacco use, we believe we are uniquely positioned to pursue a range of very-low TSNA smokeless tobacco products as "modified risk tobacco products" under the FDA Tobacco Act. We also believe that we are positioned to utilize our technology to produce a range of non-nicotine nutraceuticals and tobacco-based pharmaceuticals furthering our mission to reduce the harm associated with tobacco use at every level.

We currently are focusing our efforts on the manufacture and sale of CigRx®, our new dietary supplement launched in test market during August 2010, and ARIVA® and STONEWALL Hard Snuff®, our dissolvable low-TSNA smokeless tobacco products. CigRx®, a non-nicotine, non-tobacco dietary supplement manufactured and sold through our Rock Creek Pharmaceutical subsidiary, is designed to temporarily reduce the desire to smoke. Rock Creek also continues to pursue the development of botanical based products for the treatment of tobacco dependence, as well as products that would utilize certain MAO agents in tobacco to treat a range of neurological conditions, including Alzheimer's disease, Parkinson's disease, schizophrenia and depression and other non-nicotine nutraceutical products that may be helpful to consumers in maintaining a health metabolism. Our significant experience with the proprietary technology related to the development of tobacco products with reduced levels of toxins also has positioned us to seek the approval of a variant of our very-low TSNA smokeless tobacco products as "modified risk tobacco products" by the FDA under the FDA Tobacco Act. In the past we deferred the initiation and continuation of certain research projects because of the lack of working capital. Our success in promoting the sale of our low-TSNA dissolvable smokeless tobacco products and CigRx® as well as our ability to resume our prior research activities and continue the research efforts by Rock Creek will in large part depend on our working capital constraints, ability to procure funding for these initiatives, and the successful outcome of our ongoing patent infringement litigation with RJR.

Over the last several years, we have expended significant time and resources on our ongoing patent infringement litigation with RJR, the development of ARIVA® and STONEWALL Hard Snuff®, our low-TSNA dissolvable smokeless tobacco products, the licensing of low-TSNA products and the technology behind, our StarCured® tobacco curing process, and the development efforts of Rock Creek, particularly with respect to our CigRx® dietary supplement. Our future success will largely depend on the successful results of these initiatives. While product licensing royalties and smokeless tobacco sales have been de minimis to date, we intend to continue our efforts to develop and sell smokeless tobacco products, develop pharmaceutical products to treat tobacco addiction and a range of neurological conditions and the development of related non-nicotine nutraceutical products, and to pursue licensing arrangements for those products and related technology.

Prospects for Our Operations

The recurring losses generated primarily by our smokeless tobacco business continue to impose significant demands on our liquidity. Product licensing royalties and smokeless tobacco sales have been de minimis to date. We introduced CigRx® into test market in August 2010 as a non-nicotine, non-tobacco nutraceutical product that temporarily reduces the desire to smoke. Sales of CigRx® have also been de minimis to date. Rock Creek also is pursuing the development of other non-nicotine nutraceutical products, as well as pharmaceutical products that would utilize certain MAO agents in tobacco to treat a range of neurological conditions, including Alzheimer's disease, Parkinson's disease, schizophrenia and depression. Given the typical long lead time for federal approval of pharmaceutical products, we do not expect that Rock Creek will generate any revenues for the foreseeable future from the sale of pharmaceutical products. Rather, we expect that Rock Creek, in addition to the manufacturer and sale of CigRx®, will focus in the near time on the development of other non-nicotine nutraceutical products and, on a longer-term basis, on the research and development aspects of a range of pharmaceuticals, including tobacco-based drug products.

Our future prospects are also dependent on the distribution and consumer acceptance of our low-TSNA dissolvable smokeless tobacco products, our ability to support the expansion of the market for these products and our continued development of new low-TSNA smokeless tobacco products, such as the "modified risk tobacco products" for which applications are currently pending before the FDA, independently and through alliances with other tobacco manufacturers and pharmaceutical companies. Our future results of operations are also dependent on our ability to begin generating significant revenues through royalties from the patented tobacco curing process to which we are the exclusive licensee. However, our ability to generate revenues through sales of our smokeless tobacco products as well as the licensing of such products and the technology related to our patented curing process will substantially be dependent upon the successful completion of the ongoing patent infringement lawsuit against RJR.

We experienced revenue of approximately \$0.8 million for 2010 and an operating loss from continuing operations of approximately \$(28.3) million. The recurring losses generated by operations continue to impose significant demands on our company's liquidity. As of December 31, 2010, we had approximately \$12.6 million of working capital, of which approximately \$13.2 million was cash and cash equivalents. Between January 1, 2010 and March 15, 2010, our company received proceeds of approximately \$13.8 million and on November 4, 2010 we received proceeds of \$14.0 million, all from the sale of common stock in private placements. Subsequent to December 31, 2010, we received proceeds of \$11.0 million through the sale of common stock and the exercise of a warrant in private placements. See Note 15 to our Consolidated Financial Statements included in "Item 15, Exhibits, Financial Statement Schedules". 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 2012. However, depending upon market conditions and the price of the common stock, we may decide to seek additional funds before that date.

Smokeless Tobacco. Net Sales were \$0.8 million in 2010 compared to \$0.7 million in 2009. STONEWALL Hard Snuff® represents a majority of our dissolvable tobacco sales. We continue to work to increase the distribution and consumer acceptance of low-TSNA smokeless tobacco products as well as the improvement of our existing very low-TSNA products, and the development of other smokeless tobacco products, independently and through alliances with other tobacco manufacturers. While our working capital constraints over the last several years have limited both our direct marketing of smokeless products and our research and development efforts, we introduced in the first quarter of 2010 three additional blends of our Ariva® low-TSNA smokeless tobacco product and a new packaging format (10-piece sleeves) for ARIVA®.

"Modified risk tobacco products". In 2009 and 2010 we developed Ariva-BDL™ and Stonewall-BDL™, as variants of our ARIVA® and STONEWALL Hard Snuff® smokeless tobacco products that have significantly lower levels of carcinogenic TSNA's as well as other toxins compared to conventional tobacco products and which are at levels comparable to those found in nicotine replacement therapy products. In February, 2010, we submitted an application to the FDA for the approval of Ariva-BDL™ as the first modified risk tobacco product under the FDA Tobacco Act and we filed a similar application for Stonewall-BDL™ in June 2010. In February

2011, we filed a third application with the FDA related to a moist snuff product, Stonewall Moist-BDL™, also requesting its designation as a “modified risk tobacco product”.

Introduction of CigRx® and Development of Tobacco-based Pharmaceutical Products and other Nutraceuticals. In 2009, Rock Creek developed a non-nicotine, non-tobacco nutraceutical that is intended to temporarily reduce the desire to smoke. This product, CigRx®, was introduced in August 2010 in the Richmond, Virginia area. We have been working jointly with InVentiv Health to develop awareness for the CigRx® product through an outreach program involving visits to physicians and other health care professionals and through direct advertising at the consumer level. In late February 2011, we began testing CigRx® on a national basis through expanded infomercials and radio spots. Through Rock Creek we are exploring the development of other related nutraceutical products that may assist in stabilizing metabolism, pharmaceutical products with clinical claims, a “relapse prevention product” to assist smokers during nicotine withdrawal, with the goal of higher quit rates, as well as pharmaceutical products, including products for the treatment of tobacco dependence, and a range of neurological conditions, including Alzheimer’s disease, Parkinson’s disease, schizophrenia and depression.

Discount Cigarettes. Until June 2007 we manufactured and sold a line of discount cigarette products. In May 2007, we entered into an exclusive license agreement with Tantus for our cigarette trademarks MainStreet®, Sport® and GSmoke® in return for licensing fees during the seven-year term of the license agreement and beyond, if the license is renewed. As part of the license agreement, we stopped selling cigarettes under the MainStreet®, Sport® and GSmoke® brands in June 2007 and discontinued our cigarette operations at that time. Although we retain the right to manufacture and sell other cigarette brands, we are focusing our efforts on the sale of low-TSNA dissolvable smokeless tobacco products, as opposed to cigarettes, consistent with our expressed intention to transition from the sale of cigarette products to our low-TSNA smokeless tobacco products.

Licensing. We have an exclusive, worldwide license from Regent Court under 12 U.S. patents and 51 foreign patents as well as additional patents pending in the U.S. and foreign countries relating to methods to substantially prevent the formation of TSNA in tobacco, including the StarCured® tobacco curing process and the production of very low-TSNA tobacco products. The StarCured® tobacco curing process involves the control of certain conditions in tobacco curing barns, and in certain applications, the use of microwave and/or electron beam technology. The StarCured® process substantially prevents the formation in the tobacco leaf of the carcinogenic TSNA, which are widely believed by medical and scientific experts to be among the most abundant and powerful cancer-causing toxins present in tobacco and in tobacco smoke. Two of the patents under our license with Regent Court that relate to our method for producing low-TSNA tobacco are the subject of our ongoing lawsuit against RJR. See “Item 3 Legal Proceedings” for further details.

We continue to pursue means of collecting royalties for our curing technology through licensing arrangements and through our patent infringement lawsuit against RJR. Any royalties arising from the license of our curing technology will be dependent on the successful completion of our patent litigation against RJR. While licensing of our exclusive patent rights is a major potential source of additional revenue for us, full realization of this potential also will depend on our ability to successfully defend and enforce our patent rights.

Federal and State Legislation Relating to Cigarettes and Smokeless Tobacco Products. On June 22, 2009, President Barack Obama signed into law the FDA Tobacco Act, which provides a new division within the FDA (The Center for Tobacco Products) broad authority over the way tobacco products are manufactured and sold, including requiring expanded warnings on all tobacco products and imposing restrictions on the manner in which tobacco products may be marketed. The FDA Tobacco Act permits companies to apply to have products designated as “modified risk tobacco products” and in February 2010 we filed an application to have our Ariva-BDL™ product designated as a modified risk tobacco product because of the lower levels of toxins (principally the carcinogenic TSNA) in this product. We filed a similar application for a Stonewall-BDL™ product in June 2010 and an application for a third product Stonewall Moist-BDL™ in February 2011. The FDA Tobacco Act also contains provisions that eventually could be beneficial to us in marketing our very-low TSNA smokeless tobacco products, such as those that would require a listing of various constituent elements and the publication of ingredients in all tobacco products with notations as to the harmfulness of those ingredients, but under the provisions of the FDA Tobacco Act those types of labeling changes and comparative ingredient information will

not be put into place for at least two years. In the interim, the FDA Tobacco Act restricts the types of claims and descriptions that can be made with respect to various components in tobacco products, including any claims relating to reduced levels of toxins or reduced risk, absent receiving a designation of a product as a "modified risk tobacco product."

Manufacturers and importers of tobacco products are taxed pursuant to regulations promulgated by the TTB under authority of the Internal Revenue Code of 1986, as amended, and we have a license from the TTB to manufacture smokeless tobacco products at our Chase City, Virginia facility. In addition, states and local jurisdictions impose additional taxes on tobacco products and regulate the manner in which such products are sold. In recent years there have been increased taxes and restrictions imposed on the use of tobacco products at the local and state levels, including efforts to impose limits on flavors that could be used for smoked, as well as smokeless tobacco products. These as well as other current and future state and federal statutes and regulations could have a significant impact on our future prospects and results of operations, see "Item 1. Business — Government Regulation."

Impact of the Tobacco Master Settlement Agreement, or MSA. In November 1998, 46 states and the District of Columbia, or the Settling States, entered into the MSA, to resolve litigation that had been instituted against the major tobacco manufacturers. Manufacturers who did not join the MSA were required to satisfy escrow requirements for any cigarette sales in the MSA states. We did not join the MSA and we were required to satisfy escrow obligations for cigarette sales in the MSA states until we exited from the cigarette business in May 2007. Given the discontinuation of our cigarette operations, we do not anticipate having material MSA escrow obligations in the future.

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.

Revenue Recognition

Revenue is recognized when products are shipped to customers and title passes. We also record appropriate provisions for rebates and discounts and credits for returns. These amounts are estimated due to the variability in credits (as a result of promotional programs in the field), allowances for collectability, and allowances for product which may be returned by customers after a sale is completed. In order to quantify these estimates, we make quarterly estimates in these areas based on the available quarterly information and historical experience. Revenue for our dietary supplement that is shipped to our direct buying consumers is recognized upon shipment of the product from our third-party fulfillment vendor. The dietary supplement product is shipped once our company has received confirmation of a valid credit card charge, which is the only payment option offered to consumers of the dietary supplement at this time.

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.

Cost of Goods Sold

Cost of Goods Sold consists of the direct and indirect costs to produce and distribute our products. Inventory related costs include materials, inbound freight, production costs, inventory obsolescence and shrinkage. In

addition to the aforementioned costs, the cost for our dietary supplement product, CigRx[®], includes fulfillment partner fees, credit card processing fees, and costs of consumer support.

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. With regard to the tobacco curing barns, depreciation had been recognized using a "units of production" method of accounting to more closely match depreciation with the period during which such depreciation takes place. As of December 2009 we sold our remaining 37 curing barns.

MSA Escrow Fund

Amounts deposited into MSA escrow accounts are required to be held in escrow for twenty-five years and had been reported as a non-current asset in our company's consolidated financial statements, given the restrictions placed on the use of these funds. In March 2007, we sold the rights, title and interest in and to all income from and reversionary interest in our MSA escrow accounts, including our 2006 MSA escrow deposits made in April 2007 for total cash proceeds of approximately \$11.6 million in return for assigning to the purchasers the right to interest paid on our company's escrow fund and to any releases of the escrow principal for any overpayments, or, if these funds are not used to satisfy judgments or settlements by the Settling States, releases of the principal on a rolling basis after twenty-five years. As a result of the sale of all rights to the interest stream and reversionary interest in the MSA escrow funds, we wrote off the value of the MSA escrow accounts in March 2007, at the time of the transaction. We have maintained separate MSA accounts for payments made in 2007 and 2008 relating to cigarette sales in 2007. The amounts held in escrow for 2007 sales total approximately \$0.4 million. We discontinued any sale of cigarette products in 2007. As a result, we have not incurred MSA escrow obligations for the sale of cigarette products after 2007 and do not expect having any MSA escrow obligations in the future.

Commitment and Contingency Accounting

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

Sale of Licensing Rights

In May 2007, we entered into an exclusive seven-year license agreement with Tantus for our company's cigarette trademarks Sport[®], MainStreet[®] and GSmoke[®] and the sale of an amount of Star Tobacco's inventoried cases of cigarettes bearing these trademarks. The licensing rights became effective in June 2007, or the Effective Date. Pursuant to the license agreement, Tantus made an initial payment of \$600,000 on the agreement date and made monthly payments of \$100,000 per month until July 2009. Since that time it has been making payments of \$3,000 per month which will continue through the remaining five years of the agreement. As of December 31, 2010, our company has an outstanding note receivable balance due from Tantus of \$0.1 million and we have received payments totaling \$3.1 million through December 31, 2010. While we continue to have the ability to manufacture and sell cigarettes, we discontinued our cigarette operations in June 2007, and are focusing our efforts on the manufacture and sale of our dissolvable low-TSNA smokeless tobacco products. Although we continue to hold legal ownership of the licensed trademarks, we have accounted for this licensing agreement as a

sale since the agreement is non-cancellable, has established a fixed fee for the rights to the trademarks and our company under the license agreement has no significant obligation to provide future services beyond maintenance of the trademarks. Therefore, on the Effective Date, we recorded a gain on the sale of the licensing rights based on the present value of the total proceeds to be received of approximately \$2.9 million using a discount rate of 9.25% net of the \$600,000 payment received on the Effective Date.

Year Ended December 31, 2010 Compared to Year Ended December 31, 2009

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.

Sales. Gross sales were \$1.0 million in 2010, reflecting a \$0.1 million increase from 2009 gross sales. Dissolvable tobacco products sales year-over-year were approximately the same, but were augmented by the sales of CigRx[®] following its introduction in August 2010. Net Sales (gross sales reduced by sales returns and allowances, cash discount and promotion expenses such as coupons, buy downs and slotting fees) were \$0.8 million in 2010 compared to \$0.7 million for 2009, with the increase primarily related to our reduction of dissolvable tobacco promotion expenses and price increases that were partially offset by a decrease in sales volume of approximately 26%. Prices on our dissolvable tobacco products were raised \$0.10 per pack on January 1, 2009 and \$0.50 per pack on December 1, 2009.

We believe that the acceptance of dissolvable tobacco is adversely impacted by a number of factors, including, among others: (i) lack of consumer familiarity with the products; (ii) the fact that dissolvable tobacco requires a change in habit by smokers, i.e. using a smokeless product rather than a smoked product; (iii) dissolvable tobacco requires Federally mandated smokeless warning labels that may be unfamiliar to and/or misunderstood by cigarette smokers; (iv) the need to develop brand name recognition with consumers; and (v) difficulty in obtaining capital required for large-scale consumer education and marketing directed to adult tobacco users.

Prior to the introduction of CigRx[®] Rock Creek had no source of revenue. CigRx[®] was initially launched in the Richmond, Virginia area. In late February 2011, we began testing CigRx[®] on a national basis through expanded infomercials and radio spots.

Gross Margin. In 2010, overall gross margin loss (net revenue less costs of goods sold and federal excise taxes) decreased to \$(1.3) million compared to \$(1.9) million in 2009, a \$0.6 million improvement. Both the dissolvable tobacco products and CigRx[®] had negative gross margins in 2010. The negative gross margin for dissolvable tobacco decreased by \$0.7 million in 2010 primarily due to the reduction in force implemented in December 2009. CigRx[®] had a gross margin loss of \$0.1 million in 2010. The consolidated gross loss was due primarily to the underutilization of manufacturing and packaging equipment.

Total Operating Expenses

Total operating expenses increased approximately \$6.1 million, or 28.6%, to \$26.9 million in 2010 from \$20.8 million in 2009. This included increases in marketing and distribution expenses of \$0.2 million general and administrative expenses of \$5.3 million, and research and development expenses of \$1.2 million. These increases were partially offset by the fact that there were no severance costs in 2010 compared to \$0.6 million in 2009

- *Marketing and Distribution Expenses.* Marketing and distribution expenses for our dissolvable tobacco products were \$1.3 million in 2010, a decrease of approximately \$1.3 million from approximately \$2.6 million in 2009, which reflected decreased expenses of \$0.5 million attributable to our reduction of sales personnel, reductions for in store promotional materials of \$0.3 million, sales personnel travel and tradeshow attendance of \$0.3 million and a reduction in general brand advertising of \$0.2 million. Marketing and advertising costs related to the CigRx[®] launch totaled \$1.5 million and offset the reductions related to our dissolvable tobacco products.
- *General and Administrative Expenses.* General and administrative expenses were approximately \$21.1 million in 2010, an increase of approximately \$5.3 million from approximately \$15.8 million in 2009. Legal expenses were reduced by \$3.9 million due to the fact that in 2009 was incurred cost of

approximately \$3.8 million in connection with the trial of our patent infringement case against RJR. This reduction was more than offset by the increased non-cash stock based compensation charge of \$8.2 million related to the issuance of stock options to senior management, employees, directors and a consultant in April 2010. In addition we had increased costs for consulting fees related to raw material sourcing, executive travel and other consulting related to the CigRx[®] launch of \$0.9 million.

- *Research and Development Expenses.* We expended substantially more on research in 2010 (approximately \$3.0 million) compared to our expenditures in 2009 (approximately \$1.8 million). Of this amount, we spent approximately \$0.2 million on product development for our modified risk versions of our dissolvable tobacco products and approximately \$2.8 million for development of our CigRx[®] product and for other costs related to Rock Creek's pharmaceutical and nutraceutical development efforts.
- *Restructuring.* During the quarter ending December 31, 2009, we restructured and reduced our tobacco sales force and certain general and administrative personnel in response to the slower than expected sales of our dissolvable tobacco products. As part of the restructuring effort, we limited the day-to-day activities of our sales force and are focusing our company's marketing efforts on store level support and consumer marketing in Virginia and contiguous states, with the intent of gaining more extensive market penetration and product acceptance in those areas. Our company's restructuring efforts were announced on December 3, 2009 and separation dates for effected employees occurred on various dates through January 31, 2010. The restructuring charge of \$0.6 million in our accompanying consolidated financial statements for the year ended December 31, 2009 reflects severance in the form of salary and benefit continuation payments for periods of up to twelve months for employees affected by the restructuring effort as of the close of business on December 31, 2009. There were no restructuring charges in 2010.

Interest Income/Expense. In 2010, interest income was approximately \$0.1 million and interest expense was approximately \$0.4 million for a net interest expense of approximately \$0.3 million as compared to interest income of approximately \$0.2 million and interest expense of approximately \$0.4 million for a net interest expense of approximately \$0.2 million in 2009. The lower interest income during 2010 reflected the decreased interest earned on available cash balances in 2010.

Income Tax Benefit/Expense. Due to a history of recurring operating losses we had no income tax expense or benefit to be recognized for the year ended December 31, 2010. In order to recognize the deferred tax asset, our company must generate sufficient taxable income. The valuation allowance is regularly reviewed for adequacy.

Net Loss. Our company had a net loss of approximately \$(28.3) million in 2010 compared to approximately \$(22.8) million in 2009. The net loss in 2010 reflected the increased cost related to the non-cash stock based compensation charge of approximately \$8.2 million and increased research cost (approximately \$1.2 million), partially offset by the reduction of legal expenses in 2010 of approximately \$3.8 million.

In 2010, our company had basic and diluted net loss per share of \$(0.24) compared to basic and diluted net loss per share of \$(0.22) in 2009.

Year Ended December 31, 2009 Compared to Year Ended December 31, 2008

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.

Sales. Gross sales of our dissolvable tobacco products were \$0.9 million in 2009, reflecting a \$0.1 increase from 2008 gross sales. Net Sales (gross sales reduced by sales returns and allowances, cash discount and promotion expenses such as coupons, buy downs and slotting fees) were \$0.7 million in 2009 compared to \$0.5 million for 2008 primarily due to our reduction of promotion expenses and price increases. Volume sales were essentially flat between years. We raised prices \$0.10 per pack on January 1, 2009 and \$0.50 per pack on December 1, 2009.

We believe that the acceptance of dissolvable tobacco is adversely impacted by a number of factors, including, among others: (i) lack of consumer familiarity with the products; (ii) the fact that dissolvable tobacco requires a change in habit by smokers, i.e. using a smokeless product rather than a smoked product;

(iii) dissolvable tobacco requires Federally mandated smokeless warning labels that may be unfamiliar to and/or misunderstood by cigarette smokers; (iv) the need to develop brand name recognition with consumers; and (v) difficulty in obtaining capital required for large-scale consumer education and marketing directed to adult tobacco users.

Gross Margin. In 2009, overall gross margin loss (net revenue less costs of goods sold and federal excise taxes) increased to \$(1.9) million compared to \$(1.7) million in 2008. The negative gross margin for dissolvable tobacco was due primarily to the underutilization of manufacturing and packaging equipment. The estimated excess cost was \$1.4 million and \$1.8 million for 2009 and 2008, respectively.

Historically MSA escrow payments have neither been expensed nor accrued for income statement purposes, but the escrow deposits remained the property of our company on our balance sheet. In March 2007, we assigned our company's rights to the interest earned on the MSA deposits and to any releases of principal in return for a payment of approximately \$11.6 million, and we wrote off the value of the MSA escrow deposits at that time. In 2008 we deposited approximately \$0.4 million in escrow for cigarette sales for the year ended December 31, 2007. Amounts deposited into escrow for 2007 sales or for adjustments after 2007 for prior year sales remain the property of our company and we receive interest on these deposits. We discontinued any sales of cigarette products in 2007 and, as a result, we have not incurred MSA escrow obligations for the sale of cigarette products after 2007.

Total Operating Expenses

Total operating expenses increased approximately \$1.6 million, or 8.3%, to \$20.8 million for 2009 from \$19.2 million in 2008. The increase was due to an increase in general and administrative expenses of \$0.4 million, research and development expenses of \$1.5 million, and severance costs related to our tobacco operation reduction in force of \$0.6 million, partially offset by reduced marketing and distribution expenses of \$0.9 million.

- *Marketing and Distribution Expenses.* Marketing and distribution expenses for our dissolvable tobacco products were \$2.6 million in 2009, a decrease of approximately \$0.9 million from approximately \$3.5 million in 2008, which reflects decreased expenses for consumer promotions of \$0.2 million and promotional consultants of \$0.7 million and reduced trade show attendance cost of \$0.2 million partially offset by a one-time compensation expense of \$0.1 million related to stock grants from our 2008 Incentive Award program and \$0.1 million for marketing consulting.
- *General and Administrative Expenses.* General and administrative expenses were approximately \$15.8 million in 2009, an increase of approximately \$0.4 million from approximately \$15.4 million in 2008. The 2009 expenses included \$3.8 million in costs incurred in connection with was stock based funds the trial of our patent infringement case against RJR in May and June 2009. The cost in 2008 included a non-cash stock based compensation charge of \$2.8 million related to the issuance of stock options to senior management in May 2008. In 2009, we had decreased executive travel costs of \$0.3 million and a decrease of \$0.1 million in directors and officer's insurance premiums.
- *Research and Development Expenses.* We expended substantially more on research in 2009 (approximately \$1.8 million) compared to our expenditures in 2008 (approximately \$0.3 million). Of this amount, we spent approximately \$0.4 million on product development for our new blends and formula improvements of our dissolvable tobacco products and approximately \$1.4 million for development of our non-nicotine nutraceutical and for other costs related to Rock Creek's nutraceutical and pharmaceutical development efforts.
- *Restructuring.* During the quarter ending December 31, 2009, we restructured and reduced our tobacco sales force and certain general and administrative personnel in response to the slower than expected sales of our dissolvable tobacco products. As part of the restructuring effort, we limited the day-to-day activities of our sales force and are focusing our company's marketing efforts on store level support and consumer marketing in Virginia and contiguous states, with the intent of gaining more extensive market penetration and product acceptance in those areas. Our company's restructuring efforts were announced

on December 3, 2009 and separation dates for effected employees occurred on various dates through January 31, 2010. The restructuring charge of \$0.6 million in our accompanying consolidated financial statements for the year ended December 31, 2009 reflects severance in the form of salary and benefit continuation payments for periods of up to twelve months for employees affected by the restructuring effort as of the close of business on December 31, 2009.

Interest Income/Expense. In 2009, interest income was approximately \$0.2 million and interest expense was approximately \$0.4 million for a net interest expense of approximately \$0.2 million as compared to interest income of approximately \$0.4 million and interest expense of approximately \$0.7 million for a net interest expense of approximately \$0.3 million in 2008. The lower interest expense, during 2009 reflected reductions in the outstanding balance on our RJR debt and lower interest rates. The lower interest income during 2009 reflected the decreased interest earned on available balances in 2009.

Income Tax Benefit/Expense. During 2007 and during the nine months ended September 30, 2008, pursuant to Generally Accepted Accounting Standards we recorded an expense of \$2.2 million for the uncertainties of our company's returns under examination for the years 2001 through 2004. In 2005, our request for a private letter ruling which related to the years under IRS examination was resolved generally in our favor and an amended private letter ruling was issued by the IRS in January 2009. The Amended PLR confirmed that our company's deductions taken for MSA escrow payments, which were the subject of the IRS ongoing audit for tax years 2001 through 2004 and a pending tax appeal, were fully deductible and appropriate in the years in which they were taken. Based on the Amended PLR, we entered into a closing agreement with the IRS which confirmed the deductions taken for those years and, thereafter, the IRS confirmed that our company's tax returns for the years 2001 through 2004 were correct as filed. As a result of the notification by the IRS in the Amended PLR, we reversed our position of recording this income tax expense as of December 31, 2008, which resulted in a \$2.2 million income tax benefit. Due to the operating loss we had no income tax expense or benefit to be recognized for 2009.

Net Loss. Our company had a net loss of approximately \$(22.8) million in 2009 compared to approximately \$(18.3) million in 2008. The net loss in 2009 reflects the increased cost related to the trial of the RJR patent infringement case (approximately \$3.8 million), increased research cost (approximately \$1.5 million) and a \$0.1 million loss on the sale of our remaining tobacco curing barns, offset, in part, by a gain of approximately \$0.2 million relating to the sale of our Petersburg real estate. The net loss in 2008 reflects the impact of the \$0.6 million gain related to the assignment of purchase rights to one of our leased facilities in Chase City, Virginia.

In 2009, our company had basic and diluted net loss per share of \$(0.22) compared to basic and diluted net loss per share of \$(0.20) in 2008.

Liquidity and Capital Resources

Our company has been operating at a loss for the past eight years. Our prospects will depend on our ability to generate and sustain increased revenue levels in future periods, which will largely be dependent on the distribution and consumer acceptance of our company's new CigRx® product, a non-nicotine, non-tobacco nutraceutical developed by our Rock Creek subsidiary to temporarily decrease the desire to smoke and introduced in Richmond, Virginia in August 2010. Our future prospects also will be dependent on increased distribution and consumer acceptance of our company's low-TSNA smokeless tobacco products, as well as our ability to begin generating significant revenues through royalties from the patented tobacco curing process for which we are the exclusive licensee. CigRx® is Rock Creek's first product introduction and Rock Creek had no revenue stream prior to the introduction of CigRx® and little revenue from CigRx® in 2010. In late February 2011, we began testing CigRx® on a national basis through expanded infomercials and radio spots. Our prospects also will be dependent on Rock Creek's ability to develop additional pharmaceutical and non-nicotine nutraceutical products and the approval by the FDA of our applications to market variations of our ARIVA® and STONEWALL Hard Snuff® smokeless tobacco products as well our Stonewall Moist-BDL™ low TSNA smokeless tobacco product as "modified risk tobacco products" under the FDA Tobacco Act. The ability to generate revenues through royalty payments will be dependent on the success of our company's ongoing patent infringement lawsuit against RJR which has been pending since 2001. In that litigation, following a jury trial that

took place between May 18, 2009 and June 16, 2009, 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. That decision has been appealed to the United States Court of Appeals for the Federal Circuit and oral argument before a three-judge panel of the Court was held on January 11, 2011. We are currently awaiting a ruling on the appeal from the Federal Circuit Court of Appeals. On May 29, 2009 we filed a new complaint against RJR for patent infringement during the period beginning 2003 and continuing to the filing date of the new complaint. The new case has been stayed pending the outcome of the appeal to the Federal Circuit and the prosecution of the new complaint will be dependent on our achieving a reversal of the jury verdict of invalidity in the initial RJR action.

As of December 31, 2010, we had a working capital surplus of approximately \$12.6 million, which included cash of approximately \$13.2 million. Future cash needs during 2011 include:

- litigation costs in connection with the RJR patent infringement trial of approximately \$1.4 million;
- monthly principal and interest payments of approximately \$245 thousand in connection with the repayment of our company's long-term debt; and
- funding of other aspects of our company's current operations in light of continued operating losses.

We expect to continue to incur losses in connection with the sale of our smokeless tobacco products for the foreseeable future. While net sales of smokeless tobacco have been increasing year over year, substantially increased sales will be required to reach a breakeven level for these products. Rock Creek had no revenues prior to the introduction of CigRx® in August 2010. We expect that Rock Creek will be deriving revenues from the sales of CigRx® on a going forward basis as it expands distribution of CigRx®, but we have had only limited revenue from the sale of CigRx® to date.

Given the typical long lead time for federal approval of any pharmaceutical products, we do not expect that Rock Creek will generate any revenues from the sale of pharmaceutical products, as opposed to nutraceuticals, for the foreseeable future. Rather, Rock Creek will focus its future development efforts on the research and development aspects of a range of pharmaceuticals, including products having a botanical, tobacco-based component and related nutraceuticals products that may assist in stabilizing metabolism, assuming sufficient capital can be generated to support such activities.

During the period January 1, 2010 through March 15, 2010, we received proceeds of approximately \$13.8 million through the sale of 11,727,120 shares of our common stock, new warrants to purchase up to 6,323,727 shares of our common stock and the repricing and immediate exercise into cash of warrants exercisable into 5,402,393 shares of our common stock. On November 5, 2010, our company received proceeds of \$14.0 million through the sale of 7,615,435 shares of our common stock and new warrants to purchase up to 7,615,435 shares of our common stock. Subsequent to December 31, 2010, we received proceeds of \$11.0 million through the sale of 4,856,730 shares of our common stock and new warrants to purchase up to 4,856,730 shares of our common stock as well as the immediate exercise for cash of warrants to purchase 2,000,000 shares of our common stock in exchange for a new warrant to purchase 2,000,000 shares of our common stock. See note 15 to our consolidated financial statements included in "Item 15. Exhibits, Financial Statement Schedules" and our current reports on Form 8-K, filed with the SEC on March 5, 2010, March 15, 2010, November 9, 2010 and March 4, 2011, for a further description of these transactions. 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 2012, but that it will be necessary to pursue additional sources of funds during the first quarter 2012. Depending upon market conditions and the price of our common stock, we may decide to seek additional funds before that time. There can be no assurance that we will be successful in obtaining such funding at commercially reasonable terms.

We expect to continue to pursue opportunities for licensing our low-TSNA smokeless tobacco products, expanding the sales and marketing efforts for those products and for our non-nicotine nutraceutical product, CigRx®, and continuing the work of Rock Creek in developing other pharmaceutical and nutraceutical products. While we may seek to obtain funds in the future through debt financing, there are significant limitations on our

ability to obtain new debt financing, including our agreements with B&W. 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. In 2010, approximately \$23.7 million of cash was used in operating activities compared to approximately \$19.0 million of cash used in operating activities in 2009. The increase is due primarily to higher development expenses associated with our non-nicotine nutraceutical product and the pay down of expenses incurred in connection with the 2009 jury trial in our patent litigation against RJR.

Net Cash From Investing Activities. During 2010, we expended \$1.3 million of cash primarily for the CigRx® packaging equipment line installed at our manufacturing vendor. In 2009, we generated \$1.4 million of cash from primarily the sale of our remaining 37 tobacco curing barns, the sale of our Petersburg, Virginia factory and office and proceeds from Tantus licensing rights receivable.

Net Cash From Financing Activities. During 2010, we generated net cash of approximately \$25.8 million. Approximately \$27.8 million was generated from common stock sales to accredited investors in private placement transactions and was partially offset by \$2.0 million in the repayment of our long term debt with RJR. In 2009, we generated net cash of approximately \$23.5 million from financing activities. Approximately \$25.0 million was generated by the exercise of common stock options, warrants and the private placement of common stock and warrants, and was partially offset by \$1.5 million in the repayment of our long term debt with RJR.

Net Cash Used in MSA Escrow Payments. In March 2007, we assigned all of our rights to the interest stream and any reversionary interest in the MSA escrow accounts that we deposited for cigarette sales through 2006. While the escrow accounts will remain in our company's name and be available to satisfy judgments or settlements by the Settling States for twenty-five years after deposit, we no longer receive the interest generated by those MSA escrow accounts and have no right to receive a release of the funds after twenty-five years, to the extent the funds are not used to satisfy judgments or settlements by the Settling States. In 2008, we deposited approximately \$0.4 million into escrow for sale of cigarettes in the Settling States in 2007. We will continue to receive the interest earned on the approximately \$0.4 million deposited into escrow for 2007 cigarette sales. Given the fact that we discontinued the manufacturing of cigarette in June 2007 and stopped selling cigarettes at that time, we did not have any MSA escrow obligations for cigarette sales in 2008 and 2009. In 2010 we deposited \$3 thousand into escrow for sales the 2006 and 2007 in the State of Tennessee, based on an audit of cigarette sales for those years. We do not anticipate having any material MSA obligation for cigarette sales in 2011.

Cash Demands on Operations

In 2010, our company had operating losses from continuing operations that totaled \$(28.3) million.

In addition, in 2009 we spent a significant amount of money in connection with the development and protection of our intellectual property portfolio, principally in connection with our patent infringement litigation against RJR. We recognize that in order to protect and defend our intellectual property, additional capital will need to be spent in connection with our ongoing patent litigation matters. Also, we will need to budget for expenditures of funds in connection with the anticipated development efforts in regard to tobacco-based pharmaceuticals, non-nicotine, non-tobacco nutraceuticals and related products through Rock Creek.

Our inability to improve operations or to raise funds during the next twelve months could have a material adverse effect on our ability to meet our working capital needs and continue operations.

Contingent Liabilities and Cash Demands

B&W Agreements. Under the Restated Master Agreement with B&W, as amended by letter agreements dated December 4, 2002 and August 14, 2003, we currently owe approximately \$7.5 million on our long-term tobacco curing barn loan. Interest began to accrue on this debt at prime plus 1% as of January 1, 2006, and payment of principal and interest is due in 96 monthly payments that began on January 1, 2006. The debt is unsecured.

Litigation Costs. We have entered into fee arrangements with counsel in several litigation and related matters under which certain costs related to the litigation are being advanced by counsel on our behalf. Given the contingent nature and the fact that a probability assessment of liability cannot be made at this time, no accrual has been made for this contingent liability.

We have paid or accrued all existing obligations. Also, as part of our fee arrangements in certain of these matters, we have agreed to pay counsel a percentage of any damage award, a percentage of the resulting payments we actually receive in the event that the litigation is resolved in our favor or a result fee in return for a cap on fee payments during the litigation.

We anticipate incurring significant expenses in terms of legal fees and costs in connection with our litigation against RJR for the foreseeable future.

In the past, we have maintained product liability insurance only with respect to claims that tobacco products manufactured by or for us contain 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 and as a result are self-insured for this risk. The product liability insurance that we 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 such insurance currently can be obtained. We have never been named as a defendant in any legal proceedings involving claims arising out of the sale, distribution, manufacture, development, advertising, marketing or claimed health effects relating to the use of our tobacco products. While we may be named as a defendant in the future, we believe we have conducted our business in a manner which decreases the risk of liability in a lawsuit relating to product liability because we have:

- attempted to consistently present to the public the most current information regarding the health effects of long-term smoking and tobacco use;
- always acknowledged the addictive nature of nicotine;
- stated unequivocally that smoking involves a range of serious health risks, is addictive and that smoked cigarettes products can never be produced in a "safe" fashion; and
- ceased selling cigarettes in June 2007 in favor of our very low-TSNA dissolvable smokeless tobacco products.

Prior to the introduction of CigRx[®] we obtained product liability insurance for CigRx[®] as a nutraceutical product. This insurance covers claims arising from product defects or claims arising out of the sale, distribution and marketing of our CigRx[®] product. There have been no claims asserted with respect to the manufacturer, sale or use of our CigRx[®] product 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.

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. We disagree with the ruling by the Commissioner and intend to timely pursue this matter through all available means. The sales and use tax assessment plus penalties and interest together, as of December 31, 2010, totaled \$1.5 million. Interest will continue to accrue on this amount during our pursuit of a final resolution of this matter.

Recent Transactions and Potential for Additional Financing

On February 28, 2011, we entered into a securities purchase and registration rights agreement, or the February 28 Agreement, with an accredited investor who previously held warrants exercisable into 2,000,000 shares of our common stock for \$1.00 per share. Pursuant to the February 28 Agreement, in order to induce the investor to immediately exercise these warrants, we agreed to grant the investor new warrants with an exercise price of \$2.00 per share exercisable into 2,000,000 shares of our common stock in exchange for the investor's immediate and full exercise of his previously held warrants into 2,000,000 shares of our common stock, which resulted in gross proceeds to our company of \$2.0 million. We refer to the before mentioned private placement as the "February 28 Private Placement." The warrants purchased in the February 28 Private Placement are exercisable immediately into an aggregate of 2,000,000 shares of our common stock and expire on February 28, 2016. Additionally, the February 28 Agreement grants the investor certain customary resale registration rights with respect to the shares of common stock underlying the warrants purchased in the February 28 Private Placement.

On March 4, 2011, we entered into a securities purchase and registration rights agreement, or the March 4 Agreement, with certain accredited investors, including Jonnie R. Williams, or Chief Executive Officer, for the purchase of 4,856,730 shares of our common stock for \$1.84 per share and new warrants to purchase up to 4,856,730 shares of our common stock with an exercise price \$2.00 per share, which resulted in proceeds to our company of \$9.0 million. We refer to the before mentioned private placement as the "March 4 Private Placement." In addition to purchasing his respective shares of common stock for \$1.84 per share, Mr. Williams also paid our company \$0.125 per warrant purchased in the March 4 Private Placement. The warrants purchased in the March 4 Private Placement are first exercisable on September 4, 2011 and expire on September 4, 2016. Additionally, the March 4 Agreement granted the investors certain customary resale registration rights with respect to the shares of common stock and the shares of common stock underlying the warrants purchased in the March 4 Private Placement. Mr. Williams' participation in the March 4 Private Placement transaction was approved by our company's Audit Committee on March 4, 2011.

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. Our 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.

See note 15 to our consolidated financial statements included in "Item 15. Exhibits, Financial Statement Schedules" of this Report and our report on Form 8-K, filed with the SEC on March 4, 2011, for a further description of these transactions.

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, 2010, our company's contractual cash obligations, with initial or remaining terms in excess of one year, were as follows (in thousands):

	TOTAL	Less Than 1 Year	Amount of Commitment (\$) Expired By Year Ended December 31, 2010		
			1-3 Years	3-5 Years	More than 5 Years
Long-term Debt	\$7,567	\$2,518	\$5,049	\$ —	\$ —
Operating Leases	\$1,195	\$ 150	\$ 394	\$266	\$385
TOTAL	\$8,762	\$2,668	\$5,443	\$266	\$385

Our company had purchase commitments as of December 31, 2010 totaling \$1.1 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.

Our company's \$7.5 million outstanding debt due to RJR, consisting of a long-term loan, bears an interest rate of prime plus 1%. As a result, our company is subject to interest rate exposure on this obligation.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements and notes thereto and the Report of Cherry, Bekaert & Holland, L.L.P. 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, 2010, 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 controls over financial reporting are evaluated on an ongoing basis by personnel in our organization. The overall goals of these various evaluation activities are to monitor our disclosure and internal controls 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 controls, or whether we had identified any acts of fraud involving personnel who have a significant role in the our internal controls. 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 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, 2010, 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, 2010 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 & Holland L.L.P., an independent registered public accounting firm, has audited the effectiveness of our internal control over financial reporting as of December 31, 2010, 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 2010, in connection with the evaluation of internal controls described above in paragraph (b) of this Item 9A, we identified areas requiring changes or improvements. New controls related to the CigRx® production, inventories, sales and collection were implemented based on the outsourcing of all production, product fulfillment and direct sales to consumers. We are performing reconciliations for all product movement and obtaining verification documents of delivery of raw materials and packaging shipped to our contract manufacturer. Physical inventories are occurring monthly with internal audits of quantities on hand periodically.

ITEM 9B. OTHER INFORMATION

Following approval by our Board of Directors, upon recommendation of the Compensation Committee, on March 14, 2011, our company entered into an executive employment agreement with Jonnie R. Williams, our company's Chief Executive Officer, a third amended and restated executive employment agreement with Paul L.

Perito, our company's President and Chief Operating Officer, and an amended and restated executive employment agreement with Curtis Wright, IV, MD, MPH, the Senior Vice President, Medical/Clinical Director of Rock Creek. We refer to the before mentioned employment agreements as the "Williams Employment Agreement," "Perito Employment Agreement" and the "Wright Employment Agreement," respectively.

The Williams Employment Agreement

Under the Williams Employment Agreement, Mr. Williams will be provided an annual base salary payable in cash in such amounts as approved by our Board of Directors, upon the recommendation of the Compensation Committee, which initially will be \$1,000,000, Mr. Williams' base salary for each of the years ended December 31, 2010, 2009 and 2008, and which base salary will be subject to further adjustment from time-to-time in the good faith discretion of our Board of Directors. Mr. Williams also will be eligible to receive discretionary bonuses under the Williams Employment Agreement upon our company's achievement of certain performance goals established by the Compensation Committee and approved by our Board of Directors. The Williams Employment Agreement further provides that Mr. Williams will be awarded performance based options to purchase 4,900,000 shares of our common stock under our company's 2008 Incentive Award Plan. These options will vest in such amounts and upon the achievement of the performance goals set forth on Schedule 2.3 to the Williams Employment Agreement, provided that such performance goals and vesting schedule is approved by our company's stockholders. The options are for a 10-year term from March 14, 2011 and have an exercise price of \$2.95 per share. The estimated maximum value of the options, as determined by the Black Scholes valuation method, is \$12.3 million, and we expect to record a substantial portion of the related compensation expense in our company's consolidated financial statements for the year ending December 31, 2011 with the remainder recorded in our company's consolidated financial statements for the year ending December 31, 2012. The Williams Employment Agreement is effective immediately and will expire on December 31, 2012, absent an extension thereof following the non-binding discussions regarding an extension that are mutually agreed to commence in September 2012 as provided therein.

In addition, the Williams Employment Agreement will entitle Mr. Williams to paid vacation and other bonuses and benefits in accordance with our company's plans and arrangements, on the same basis as other employees of our company, as well as reimbursement of general business and travel expenses.

In the event the Mr. Williams' employment is terminated without "Cause" or Mr. Williams resigns his employment for "Good Reason" (as such terms are defined in the Williams Employment Agreement), Mr. Williams will be entitled to all salary, benefits, bonuses and other compensation that would be due thereunder through the end of the term thereof had our company not terminated Mr. Williams' employment or had Mr. Williams not so resigned.

The Perito Employment Agreement

Under the Perito Employment Agreement, Mr. Perito will be provided an annual base salary payable in cash in such amounts as approved by our Board of Directors, upon the recommendation of the Compensation Committee, which initially will be \$1,000,000, Mr. Perito's base salary for each of the years ended December 31, 2010, 2009 and 2008, and which base salary will be subject to further adjustment from time-to-time in the good faith discretion of our Board of Directors. Mr. Perito also will be eligible to receive discretionary bonuses under the Perito Employment Agreement upon our company's achievement of certain performance goals established by the Compensation Committee and approved by our Board of Directors. The Perito Employment Agreement further provides that Mr. Perito will be awarded performance based options to purchase 4,000,000 shares of our common stock under our company's 2008 Incentive Award Plan. These options will vest in such amounts and upon the achievement of the performance goals set forth on Schedule 2.3 to the Perito Employment Agreement, provided that such performance goals and vesting schedule is approved by our company's stockholders. The options are for a 10-year term from March 14, 2011 and have an exercise price of \$2.95 per share. The estimated maximum value of the options, as determined by the Black Scholes valuation method, is \$10.0 million, and we expect to record a substantial portion of the related compensation expense in our company's consolidated financial statements for the year ending December 31, 2011 with the remainder recorded in our company's consolidated financial statements for the year ending December 31, 2012. The Perito Employment Agreement is

effective immediately and will expire on December 31, 2012, absent an extension thereof following the non-binding discussions regarding an extension that are mutually agreed to commence in September 2012 as provided therein.

In addition, the Perito Employment Agreement will entitle Mr. Perito to paid vacation and other bonuses and benefits in accordance with our company's plans and arrangements, on the same basis as other employees of our company, as well as reimbursement of general business and travel expenses and professional education expenses and fees.

In the event the Mr. Perito's employment is terminated without "Cause" or Mr. Perito resigns his employment for "Good Reason" (as such terms are defined in the Perito Employment Agreement), Mr. Perito will be entitled to all salary, benefits, bonuses and other compensation that would be due thereunder through the end of the term thereof had our company not terminated Mr. Perito's employment or had Mr. Perito not so resigned.

The Wright Employment Agreement

Under the Wright Employment Agreement, Dr. Wright will be provided an annual base salary of \$330,000 payable in cash. The Wright Employment Agreement further provides that Dr. Wright will be awarded performance based options to purchase 300,000 shares of our common stock under our company's 2008 Incentive Award Plan. These options will vest ratably on an annual basis subject to the achievement of certain performance goals set forth in Section 2(b)(iii) of the Wright Employment Agreement. The options are for a 10-year term from March 14, 2011 and have an exercise price of \$2.95 per share. The estimated maximum value of the options, as determined by the Black Scholes valuation method, is \$0.7 million and we will record the related compensation expense in our company's consolidated financial statements for the years ending December 31, 2011, 2012 and 2013. The Wright Employment Agreement is effective beginning on March 14, 2011 and will expire on March 14, 2014. The Wright Employment Agreement provides our company on option to renew the Wright Employment Agreement for successive 12-month terms by providing Dr. Wright notice of such an extension at least 30 days prior to the expiration of the then applicable term. Absent such an extension, following expiration on March 14, 2014, the Wright Employment Agreement will continue on a month-to-month basis upon mutual agreement of the parties thereto.

In addition, the Wright Employment Agreement will entitle Dr. Wright to paid vacation and other bonuses and benefits in accordance with our company's plans and arrangements, on the same basis as other employees of our company, as well as reimbursement of general business and travel expenses and professional education expenses and fees.

In the event the Dr. Wright's employment is terminated without "Cause" or Dr. Wright resigns his employment for "Good Reason" (as such terms are defined in the Wright Employment Agreement), Dr. Wright will be entitled to all salary, benefits, bonuses and other compensation that would be due thereunder through the end of the term thereof had our company not terminated Dr. Wright's employment or had Dr. Wright not so resigned.

The foregoing summary is qualified in its entirety by reference to the full text of each of the Williams Employment Agreement, Perito Employment Agreement and Wright Employment Agreement, copies of which are attached as Exhibits 10.78, 10.79 and 10.80 respectively, to this Annual Report on Form 10-K and are incorporated by reference into this Item 9B.

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:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Burton J. Haynes(1)	63	Director
Christopher C. Chapman, Jr., M.D.(1)(2)(3) ...	58	Director
Neil L. Chayet(2)	72	Director
Mario Mirabelli(1)(3)	71	Director
Paul L. Perito	74	Chairman, President and Chief Operating Officer
Leo S. Tonkin(1)(2)(3)	73	Director
Jonnie R. Williams, Sr	55	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., 58, 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 and is also a member of the Board of Directors of Biovest International, Inc. and Acentia Biopharmaceuticals, Inc. 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 in connection with our company's increased efforts to expand the acceptance of our very-low TSNA smokeless tobacco products as a viable alternative to more toxic forms of tobacco and at the time that our company was seeking to establish a pharmaceutical subsidiary that would focus on tobacco-based products, including FDA approved cessation products. 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, lead our Board of Directors to conclude that he could provide valuable assistance in connection with the development of both our low-TSNA smokeless tobacco products and the anticipated activities of a new subsidiary that would focus on tobacco-based 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, 72, 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 specializes in building "deep coalitions" to address difficult public policy issues, including those related to health care, addiction and mental health services, energy 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 faculties of the Tufts University School of Dental Medicine and the Tufts University Cummings School of Veterinary

Medicine, and serves as a member of the Board of the Tisch College of Citizenship and Public Service at Tufts. He is President of the Harvard Law School Association of Massachusetts. Mr. Chayet also serves as a member of the Advisory Council of MassINC, the Board of Mass.

Humanities, and the Board of Associates of the Whitehead Institute for Biomedical Research. He previously served as the 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 was 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 Lawtm," which is syndicated by CBS, and he frequently lectures on topics related to the intersection of health sciences and the law. He also serves as acting Executive Director of GEO (Geothermal Exchange Organization), 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.

Burton J. Haynes, 63, 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. Haynes 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 Masters 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. Haynes 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 in Maryland, where he taught courses in accounting and tax law.

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 as a tobacco manufacturer and in connection with our ongoing efforts relating to the development and marketing of pharmaceutical and nutraceutical products.

Mario V. Mirabelli, 71, has served as a member of our Board of Directors since July 2010. Mr. Mirabelli was a partner and presently serves in an Of Counsel capacity to the Washington D.C. law firm Patton Boggs LLP. Prior to joining Patton Boggs, he served as Managing Partner of the Washington, DC office of Shea & Gould for fourteen years from 1977 to 1991 and later as a partner at Baker Hostetler from 1991 to 2001, where

he represented domestic and international clients on federal securities law and corporate and transactional matters, including privatization, corporate formation and mergers and acquisitions. Prior to entering private practice, Mr. Mirabelli served as a trial attorney with the Securities and Exchange Commission in the Office of Administrative Proceedings and Investigations within the Division of Corporate Finance, and with the Federal Trade Commission in the Bureau of Deceptive Practices. Mr. Mirabelli has served as a director of RNA Pharmacy Solutions of Dallas, TX, a pharmaceutical management software company, since 2009. Mr. Mirabelli is President of the John R. Mott Scholarship Foundation, Inc. Mr. Mirabelli formerly served as a director of Atlantic Bank of New York, Guest Services Inc. of Fairfax, VA, as a member of The Metropolitan Washington Airport Authority Advisory Board, and as a director and the Treasurer of the National Italian American Foundation. Mr. Mirabelli received his undergraduate degree from Georgetown University in 1961 and his law degree from the American University, Washington College of Law in 1964. He is a member of the District of Columbia bar.

Mr. Mirabelli was nominated to serve on our Board of Directors based on his extensive experience in representing start-up companies and other corporate clients on a range of corporate law issues including federal securities law and transactional matters, corporate formation, organization and maintenance issues, and matters relating to mergers and acquisitions. Mr. Mirabelli's extensive corporate experience combined with his public sector work were viewed by the Board as providing the type of experience in both business and corporate legal matters that would be beneficial to our company, particularly as we seek to expand into new products and continue to be an innovative force in the area of tobacco harm reduction.

Paul L. Perito, 74, 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 the past 15 years. In June 2010, Mr. Perito was elected First Vice President of the Harvard Law School Association for a two-year term and will assume the role of President of that association in June 2014 for a further 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 is Chair of the Harvard Law School 45th 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, a former member of the Board of Georgetown Visitation Preparatory School in Washington, DC, and Co-Chair Emeritus of Treliant Risk Advisors, LLC.

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 mission to act as a catalyst for change in the highly regulated tobacco industry, our emerging intellectual property portfolio and our focus on the health aspects of tobacco use, 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. In light of the significant legal 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 a variety of tobacco-based pharmaceutical products, non-nicotine nutraceuticals and related products and the expanded focus of our company in seeking to reduce the harm related to tobacco use at every level, Mr. Perito's expertise has become more essential to our company's business strategy.

Leo S. Tonkin, 73, has served as a member of our Board of Directors since November 1998. He established the Washington Workshops Foundation in 1967, and has served as Founding Director since that time. Since 1999, he also has served as President and Director of Travel Seminars, Inc. He served as a member of the White House Conference on Youth in 1971, Special Assistant to the Chairman of the U.S. House of Representatives Select Committee on Crime, Legal Consultant to the U.S. House of Representatives Higher Education Subcommittee, Minority Counsel to the U.S. House of Representatives Select Committee on Government Research and Executive Director of the Commissioners' Council on Higher Education in Washington, DC. He has served as Chairman of the Board of Trustees of St. Thomas Aquinas College and as a Board member of Southeastern University and Immaculata College. He is a vice president of the London, England Federation of Youth Clubs and is an advisor to the Retinitis Pigmentosa Foundation in California. He was awarded the 1973 George Washington Americanism Award of the Valley Forge Freedoms Foundation, presented by President Gerald L. Ford in a 1974 White House ceremony. Mr. Tonkin is a graduate of Johns Hopkins University and received his law degree from Harvard Law School. He holds an honorary Doctor of Pedagogy degree from St. Thomas Aquinas College and the State University of New York.

Prior to joining our Board of Directors, Mr. Tonkin had extensive business and legislative experience. He was elected to our Board of Directors at a time when our company first announced its intention to act as a catalyst for change in the tobacco industry, particularly in dealing in the way that tobacco had traditionally been grown and cured. Mr. Tonkin's business and legislative background were viewed by our Board of Directors as providing the type of expertise that would be of assistance to our company as we sought to further our corporate mission to reduce the harm associated with tobacco use at every level, given the highly regulated nature of the tobacco industry and Mr. Tonkin's familiarity with regulated industries and the legislative and regulatory processes impacting on our industry, particularly as they relate to preventing youth access to tobacco products.

Jonnie R. Williams, Sr., 55, 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[®] tobacco curing process for preventing or significantly retarding the formation of TSNAs in tobacco and tobacco smoke. 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® tobacco curing process, as a significant contributor to our company's product development initiatives relating to our very-low TSNA products and our new product initiatives 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 reducing the harm related to tobacco use at all levels.

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."

<u>Name</u>	<u>Age</u>	<u>Position</u>
David M. Dean	51	President of Star Tobacco, Inc.
Park A. Dodd, III	58	Chief Financial Officer
Robert E. Pokusa	60	General Counsel
Curtis Wright, MD, MPH	61	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, 51, 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, 58, 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-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, 60, 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, Perito 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, 61, 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, 2010.

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

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, Mirabelli and Tonkin, 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 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 include Jonnie R. Williams, 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, David M. Dean, our Vice President of Sales and Marketing and Dr. Curtis Wright our Senior Vice President, Medical/Clinical Director of our pharmaceutical subsidiary, Rock Creek. We collectively refer to these executive officers as the "Named Executives." The following discussion summarizes the compensation awarded to the Named Executives during 2010.

Overview

Our company's mission has been, and continues to be, to reduce the harm associated with the use of tobacco at every level. In fulfilling that mission we have sought to reduce the range of serious health hazards associated with the use of smoked and smokeless tobacco products by reducing the toxins in the tobacco leaf; offering less toxic alternatives to traditional tobacco products; demonstrating the viability of our less toxic tobacco technology; and sublicensing that technology to the tobacco industry. Also, since 2007, we have been pursuing the development of related pharmaceutical products that are designed to treat tobacco dependence and a range of neurological conditions including a non-nicotine, non-tobacco nutraceutical product that is designed to temporarily reduce the urge to smoke and related products that may assist in maintaining a balanced metabolism.

That mission has been a principal driver in decisions regarding the determination of total compensation for our senior executives, as well as the compensation for members of our Board of Directors and consultants who have been retained to assist our company in these long-term objectives. As part of this mission, we have sought to affect a major shift in the way tobacco is grown and cured, as well as in the use of tobacco products generally.

In its structure and functioning, our company's goal has been to act as a disruptive force in the tobacco industry, and to challenge many of what we believe are preconceived assumptions that have governed the manufacture and sale of tobacco products over a number of decades. As we worked to achieve these objectives, we initially utilized our company's existing cigarette business as a platform to provide a base of financial support for our intellectual property, licensing and development initiatives, and as a demonstration vehicle for the manufacture and sale of a range of low-TSNA tobacco products and related pharmaceutical and non-nicotine nutraceuticals. However, in May 2007, we licensed three of our company's cigarette trademarks on an exclusive basis in return for licensing fees to be received over the term of the license agreement and, in June, 2007, we ceased manufacturing any cigarette products. Currently, we are focusing our tobacco operations on the sale of our company's dissolvable low-TSNA smokeless tobacco products, ARIVA[®] and STONEWALL Hard Snuff[®]. Also, we are pursuing approval from the FDA of two related products, Ariva-BDL[™] and Stonewall-BDL[™] that have levels of the carcinogenic TSNA comparable to those found in nicotine replacement therapy products as well as a Stonewall Moist-BDL[™] as "modified risk tobacco products" under the FDA Tobacco Act. Consistent with our goals and objectives, in 2007 we also incorporated our pharmaceutical subsidiary, Rock Creek, to pursue the development of botanical based products for the treatment of tobacco dependence, pharmaceutical products that would utilize certain MAO agents in tobacco to treat a range of neurological conditions, including Alzheimer's disease, Parkinson's disease, schizophrenia and depression, a non-nicotine, non-tobacco nutraceutical product to temporarily reduce the urge to smoke and related nutraceuticals that may assist in maintaining a balanced metabolism.

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 health impact of tobacco, the regulation of emerging forms of potentially less hazardous tobacco products and the development of tobacco based pharmaceutical products and related products such as non-nicotine nutraceuticals. 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 the tobacco industry. At the same time, our company 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 involved in the regulation of tobacco products, and be in a position to enlist other individuals as employees and consultants to assist in those initiatives. 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 set out to be a force for change in the tobacco industry, 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.

Our mission over the years has been to challenge and transform the constructs relating to cigarettes and tobacco use generally. In this respect, our long-term focus has been, and continues to be, the research, development, and sale of products, particularly very low-TSNA smokeless tobacco products that expose adult tobacco users to lower levels of toxins, non-nicotine, non-tobacco dietary supplements that provide viable alternatives to tobacco products, tobacco-based pharmaceutical products for the treatment of tobacco dependence and other diseases as well as related non-nicotine nutraceuticals designed to maintain a healthy metabolism and the licensing of our company's low-TSNA technology and other technology.

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 eight years our company has experienced operating losses on an annual basis, and, accordingly, prior to 2008, we had chosen to limit compensation of our executive officers to base salary and benefits. As a result, we have not utilized an incentive-based compensation structure as a means of determining levels of compensation 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 have been paid to executive officers since 2002.

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 have been limited to base salary and benefits and have not been tied to additional compensation for meeting specific performance objectives. Based on those consideration 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.

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 the Named Executives' continued contribution towards our company's goals and objections, 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. 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 as part of new employment agreements entered into with these Named Executives. The stock option awards for Messrs. Perito and Williams are subject to shareholder review and approval. See "Item 9B. Other Information."

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 objective to act as a catalyst for significant change in the tobacco industry and to reduce the harm associated with tobacco at every level. 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 licensee, the success of our ongoing patent litigation against RJR, our success in introducing new low-TSNA smokeless tobacco products to the market, non-nicotine nutraceuticals and tobacco based pharmaceuticals through Rock Creek and our success in generating increased awareness of the differences in toxicity among various forms of tobacco products.

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 after undertaking an analysis of appropriate levels of compensation for the 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 its 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. 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 as a force for change in the tobacco industry, we have not used benchmarks from the tobacco industry in setting compensation levels for our company's most senior executives, since the unique nature of our business does not easily lend itself to comparisons with tobacco industry indices. Instead, the Compensation Committee has informally considered general market information for similar senior level executives in setting base compensation. Given our decision in recent years to limit compensation to base salary and benefits, our company's focus has been on 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 prior to August 2010 generated income solely from the sale of tobacco products, and since 2007 exclusively low-TSNA smokeless tobacco products and in August introduced a non-nicotine, non-tobacco nutraceutical (CigRx[®]) that is being manufactured and sold by Rock Creek. In addition to Rock Creek's sale of CigRx[®], we intend in the future to manufacture other nutraceuticals and pharmaceuticals through Rock Creek. Accordingly, going forward 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 CEO 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 its 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 2010, except with regard to Dr. Wright with whom our company entered into an employment agreement in 2008 and for Park Dodd with whom we entered into a contract in 2010, the Compensation Committee recommended and the Board of Directors approved the continuation of salary and benefits for our Named Executives on a month-to-month basis in accordance with employment agreements that had expired or are continuing on a month-to-month basis, without any provisions for bonus or stock awards. Given the losses

suffered by our company in 2010 and the adverse jury verdict in our RJR patent litigation in 2009 for which an appeal is pending in the Federal Circuit Court of Appeals, management did not recommend any form of cash bonuses for 2010 and the Compensation Committee and the Board concurred in that recommendation. However, our Compensation Committee continues to believe that entering into employment agreements with our executive officers that have terms that extend beyond a month-to-month basis assists us in attracting and retaining qualified executive officers. Accordingly, on March 14, 2011 our Board of Directors, upon recommendation of the Compensation Committee, approved new employment agreements for Messrs. Perito and Williams and Dr. Wright. See "Item 9B. Other Information."

Base Salary

In 2010, the base salary for each of our Named Executives was set in accordance with the terms of contracts that were entered into in years prior to 2008 and which have been continued on a month-to-month basis, or entered into in 2008 for Dr. Wright and in 2010 for Park Dodd. 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 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, our wholly owned subsidiary. Under his employment agreement, Dr. Wright would have been entitled to a performance bonus in the amount of \$100,000 in the event the FDA did not impose a clinical hold on the initiation of a Phase 1 Clinical study for a tobacco-based drug product or any other pharmaceutical for the treatment of smoking or smokeless tobacco cessation within eighteen months from the date of his employment agreement. The bonus provision in Dr. Wright's agreement expired in August 2009. The bonus and performance bonus provision were provided as an inducement for Dr. Wright to leave his then current employment situation and assume the role as Medical/Clinical Director of our newly incorporated subsidiary. 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, management has agreed that, to the extent a cash bonus or stock award is made to our CEO or COO, it would recommend 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. In October 2007, Mr. Dodd was granted options to purchase up to 250,000 shares of our common stock in connection with his appointment to the position of CFO, Treasurer and Assistant Secretary of our company. Of the 250,000 stock options granted, 90,000 options vested on October 10, 2007 and 80,000 options vested on October 10, 2008 and on October 10, 2009 respectively. In February 2008, Dr. Wright was granted options to purchase 200,000 shares of our common stock in connection with his appointment to the position of Senior Vice President, Medical/Clinical Director of Rock Creek. Of the 200,000 stock options granted, 100,000 options vested on Dr. Wright's first day of employment and 50,000 options vested on February 26, 2009 and February 26, 2010 respectively. These levels of option grants are similar in level to grants made to other executive officers of our company upon their commencement of employment with us. Neither of the discretionary equity incentive awards was granted based on the achievement of performance goals, but rather to provide incentives for future performance, as an additional incentive to have these individuals accept positions with our company and to align the interests of these individuals with the interests of our shareholders.

In April 2010, our Board of Directors, based on the recommendation of the Compensation Committee, awarded a total of 3,590,000 stock options, respectively, to several of our executive officers, other employees, one consultant and our Independent Board members. 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. On March 14, 2011 our Board of Directors, upon recommendation of the Compensation Committee, approved additional of stock option awards to Messrs. Perito and Williams and Dr. Wright as part of the terms of employment agreements entered into with these executive officers on that date. See "Item 9B. Other Information."

At December 31, 2010, there were 7,716,200 options issued and outstanding with a weighted average exercise price of \$2.31 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 with Messrs. Williams and Perito that had contained severance provisions expired prior to 2010 and, as a result, those provisions were not in effect in 2010. 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 to his base salary payments and benefits. We did not seek to renew certain terms in these prior agreements as we chose to limit the compensation of our executive officers to base salary and benefits only, in light of operating losses that we had been experiencing. We believe that such written agreements are in the best interest of our company to retain our current executive officers and 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. In 2010, except in the case of the Executive Employment Agreement we entered into with Park Dodd, our CFO, in January 2010 at the time he transitioned fully from Tatum Partners, LLC, we did not enter into any new employment agreements with our executive officers. On March 14, 2011 we entered into new employment agreements with Messrs. Perito and Williams and an amended and restated employment agreement with Dr. Wright. See "Item 9B. Other Information." We intend to enter into new executive employment agreements with our executive officers in the future although we have deferred entering into any additional agreements at this time. When we are in a position to enter into new contracts with our other executives 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.

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. In December 2008, Mr. Pokusa's employment agreement was modified to ensure that the severance payments complied with the requirements of Section 409A of the Internal Revenue Code.

Under the terms of Dr. Wright's employment agreement in effect during 2010, he was entitled to severance payments equal to all salary that would have been due under his agreement through the end of its term and all accrued vacation in the event the agreement was terminated without cause or for "Good Reason", as defined in the agreement. Any severance payments would have been made at the same time and in the same manner as salary payments paid to Dr. Wright during the term of his agreement. Dr. Wright's employment agreement in effect during 2010 was due to expire on March 17, 2011 and, on March 14, 2011, our company entered into an amended and restated employment agreement with Dr. Wright that extends the term of his prior agreement for three years beginning on March 14, 2011. The amended and restated employment agreement contains severance provisions identical to those in his initial employment agreement. See "Item 9B. Other Information." 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. Under the prior agreement with Mr. Dodd through Tatum Partners LLC he was not entitled to any severance payments in the event of the termination of his employment. The employment agreement entered into with Messrs. Perito and Williams on March 14, 2011 contain severance provisions identical to those contained in the executive employment agreements with Messrs. Perito and Williams that expired prior to 2010. See "Item 9B. Other Information."

Under the employment agreements with Messrs. Dean, Dodd, Pokusa and Wright, these executive officers 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 executive officers 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. The employment agreements entered into with Messrs. Perito and Williams on March 14, 2011 contain similar noncompetition and confidentiality covenants. See "Item 9B. Other Information."

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.

Compensation Committee Report

The Compensation Committee held four meetings during fiscal year ended December 31, 2010. Given the continued losses suffered by our company, the Compensation Committee in September 2010 undertook an interim review of compensation levels for our company's Named Executives. Based on our company's progress in 2010 in meeting certain goals relating to our smokeless tobacco products and the research and development activities of our company's Rock Creek subsidiary, including the introduction of a non-nicotine, non-tobacco dietary supplement, the Compensation Committee, at that time, determined that the current compensation levels were appropriate. The Compensation Committee subsequently undertook a further review of compensation issues and has reviewed and discussed with management the Compensation Discussion and Analysis for the year ended December 31, 2010. 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 Annual Report on Form 10-K for the year ended December 31, 2010. Additionally, based on such review, the related discussions and such other matters deemed relevant and appropriate by the Compensation Committee, the Compensation Committee 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. Given the continued losses suffered by our company, the Compensation Committee will undertake a further review of compensation levels for the Company's Named Executives in mid-2011.

Christopher C. Chapman, M.D. (Chairman)

Leo S. Tonkin, Esquire

Neil L. Chayet, 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 the 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 2008, 2009 and 2010, for services rendered in all capacities to our company and its subsidiaries.

SUMMARY COMPENSATION TABLE

<u>Name and Principal Position</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Bonus (\$)(1)</u>	<u>Options (\$)(2)</u>	<u>All Other Compensation (\$)</u>	<u>Total(\$)</u>
Jonnie R. Williams, Sr. Chief Executive Officer	2008	1,000,000	—	806,650	52,423	1,859,073
	2009	1,000,000	—	—	80,582	1,080,582
	2010	1,000,000	—	2,858,625	95,158(3)	3,953,783
Park A. Dodd, III Chief Financial Officer	2008	236,400	1,500	66,630	52,500	357,030
	2009	202,350	1,500	—	54,930	258,780
	2010	221,483	1,500	114,345	5,342(8)	342,670
Paul L. Perito Chairman, President and Chief Operating Officer	2008	1,000,000	—	832,875	141,662	1,974,537
	2009	1,000,000	—	—	152,694	1,152,694
	2010	1,000,000	—	2,858,625	236,833(4)	4,095,458
David M. Dean Vice President of Sales and Marketing	2008	295,054	1,500	—	42,041	338,595
	2009	295,054	1,500	—	37,159	333,713
	2010	295,054	1,500	—	36,055(5)	332,610
Robert E. Pokusa General Counsel	2008	385,000	1,500	299,835	18,781	705,116
	2009	385,000	1,500	—	18,937	405,437
	2010	385,000	1,500	—	17,815(6)	404,315
Curtis Wright, MD Senior Vice President, Medical/Clinical Director, Rock Creek	2008	236,538	101,500	292,000	8,827	638,865
	2009	300,000	1,500	—	10,987	312,487
	2010	300,000	1,500	457,380	10,904(7)	769,784

- (1) Represents our company's yearly Holiday bonus of \$1,500 paid to all employees, except the CEO, COO and with respect to Dr. Wright, the \$100,000 signing bonus paid in 2008.
- (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 this Report.
- (3) Represents \$41,889 in automobile expenses, \$33,779 in life insurance premiums and \$19,490 in club memberships.
- (4) Represents \$38,286 in automobile expenses, \$186,956 in life and disability insurance premiums and \$11,591 in club memberships.
- (5) Represents \$25,842 in automobile expenses and \$10,213 of matching contributions by our company under our 401(k) Plan.
- (6) Represents \$6,265 in life and disability insurance premiums and \$11,550 of matching contributions by our company under our 401(k) Plan.
- (7) Represents matching contributions by our company under our 401(k) Plan.

Grants of Plan Based Awards During 2010

On April 5, 2010, our Board of Directors, based on the recommendation of the Compensation Committee, awarded a total of 3,590,000 stock options to several employees, executive officers, one consultant and our Independent Board members. All grants were fully vested on the grant date.

The table below summarizes information relating to the grants to our Named Executives in 2010.

<u>Name</u>	<u>Number of Securities Underlying Unexercised Options</u>	<u>Option Exercise Price</u>	<u>Option Expiration Date</u>
Jonnie R. Williams, Sr.	1,250,000	\$2.72	4/5/2020
Park A. Dodd, III	50,000	\$2.72	4/5/2020
Paul L. Perito	1,250,000	\$2.72	4/5/2020
Curtis Wright M.D.	200,000	\$2.72	4/5/2020

As of December 31, 2010, our company did not have any long term incentive compensation awards for cash or equity that were subject to future vesting and we have not provided incentives in the form of stock awards for our Named Executives. However, on March 14, 2010, we entered into new employment agreements with each of Messrs. Williams and Perito and Dr. Wright each of which granted stock options that are subject to vesting based upon the achievement of certain performance goals. See "Item 9B. Other Information." All grants in 2010 were in the form of stock options that vested on the date of the grant. Therefore, the value of the options awarded represent the aggregate grant date fair value, which is included in the executive compensation table above. For the assumptions used in calculating the value of this award, see note 10 to our consolidated financial statements included in "Item 15. Exhibits, Financial Statement Schedules" of this Report.

Outstanding Equity Awards at Fiscal Year

The following table provides information regarding the stock options held by the Named Executives as of December 31, 2010. All stock options were fully vested and exercisable as of December 31, 2010.

<u>Name</u>	<u>Number of Securities Underlying Unexercised Options (#) Exercisable</u>	<u>Number of Securities Underlying Unexercised Options (#) Unexercisable</u>	<u>Option Exercise Price (\$)</u>	<u>Option Expiration Date</u>
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
Park A. Dodd, III	250,000	—	\$1.19	10/10/17
	50,000	—	\$1.72	5/6/18
	50,000	—	\$2.72	4/5/20
Paul L. Perito	625,000	—	\$1.72	5/6/18
	1,250,000	—	\$2.72	4/5/20
	50,000	—	\$1.47	3/30/11
Robert E. Pokusa	200,000	—	\$1.12	5/31/12
	225,000	—	\$1.72	5/6/18
	200,000	—	\$1.84	2/26/18
Curtis Wright, MD	200,000	—	\$2.72	4/5/20
	200,000	—	\$2.72	4/5/20

Option Exercises and Stock Vested

There were no stock options exercised during 2010.

Potential Payments Upon Termination or Change of Control

Except for Mr. Pokusa, Dr. Wright and Mr. Dodd, none of the Named Executives are entitled to severance upon a termination of employment or any severance or benefits in connection with a change of control of our company or any of its affiliates under agreements that were in effect as of December 31, 2010. The employment

agreements for the Named Executives are described above under “—Employment and Severance Arrangements”. The following chart sets forth the severance Mr. Pokusa, Dr. Wright and Mr. Dodd would be entitled to receive upon certain terminations of employment, assuming the relevant event occurred on December 31, 2010.

<u>Name</u>	<u>Description of Severance</u>	<u>Termination without Cause</u>
Robert E. Pokusa(1)	Salary Continuation	\$192,500
Dr. Curtis Wright, MD(1)	Salary Continuation	\$ 64,166
Park A. Dodd, III(1)	Salary Continuation	\$100,000

- (1) Messrs. Pokusa, Wright and Dodd 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, 2010, 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 and initial and anniversary 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 act as a disruptive force in the tobacco industry, 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 in the past, and beginning in 2011 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, Haynes, Mirabelli, and Tonkin have been designated as 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, 2010.

<u>Name</u>	<u>Fees Earned or Paid in Cash (\$thousand)(1)</u>	<u>Option Awards (\$)(2)</u>	<u>All Other Compensation</u>	<u>Total (\$)</u>
Burton J. Haynes	\$ 8,000	\$ 88,380	—	\$ 19,038
Christopher C. Chapman, MD	66,000	257,308	—	323,308
Neil L. Chayet, Esquire(3)	44,000	242,123	\$60,000	346,123
Mario V. Mirabelli	24,000	90,945	—	42,936
Leo S. Tonkin, Esquire	69,500	245,423	—	314,923
Alan Weichselbaum(4)	31,500	242,123	—	273,623

- (1) This column represents the amount of compensation earned by each Independent Director during 2010 in the form of director fees.
- (2) Amounts represent our company's aggregate compensation cost. All options vested on the date of the grant except for the options granted Messrs. Mirabelli and Haynes, which vest over a two-year period. For the assumptions used in calculating the value of this award, see Note 10 to our consolidated financial statements included in Item 15 of this Report. The amounts set forth in this column reflect our company's accounting expense for these awards and do not correspond to the actual value that may be realized by the Independent Director receiving the award.
- (3) Mr. Chayet received an additional \$60,000 under a consulting contract approved by our Board of Directors in March 2010. See note 10 of to our consolidated financial statements included in "Item 15. Exhibits, Financial Statement Schedules" of this Report for further details.
- (3) Mr. Weichselbaum did not stand for re-election to the Board at the annual meeting held on December 10, 2010.

The following represents the number of options granted to each Independent Director in 2010 and the total number of options held by each Independent Director as of December 31, 2010.

<u>Name</u>	<u>Options Granted 2010</u>	<u>2010 Vested Options</u>	<u>Option Exercise Price (\$)</u>	<u>Option Expiration Date</u>	<u>Total Options outstanding as of December 31, 2010</u>
Burton J. Haynes, Esquire	50,000	—	2.03	10/22/20	50,000
Christopher C. Chapman, M.D.	50,000(2)	50,000	2.03	9/22/20	375,000
	75,000	75,000	2.72	4/5/20	
Neil L. Chayet, Esquire	50,000(2)	50,000	1.67	9/7/20	286,200
	75,000	75,000	2.72	4/5/20	
Mario V. Mirabelli, Esquire	50,000	—	2.08	10/11/20	50,000
Leo S. Tonkin, Esquire	50,000(2)	50,000	1.75	11/20/20	550,000
	75,000	75,000	2.72	4/5/20	
Alan Weichselbaum(1)	50,000	50,000	1.67	9/7/20	275,000
	75,000(2)	75,000	2.72	4/5/20	

- (1) Mr. Weichselbaum did not stand for re-election to the Board at the annual meeting held on December 10, 2010.
- (2) On April 5, 2010 the Board of Directors upon recommendation from the Compensation Committee awarded a one-time stock option to the Independent Directors noted above.

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 2010 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 March 15, 2011 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 March 15, 2011, there were 134,026,053 shares of our company's common stock outstanding.

<u>Name</u>	<u>Shares Beneficially Owned (1)</u>	<u>Percentage Owned (2)</u>
<i>Named Executive Officers</i>		
David M. Dean(3)	602,842	*
Park A. Dodd, III(4)	360,000	*
Paul L. Perito(5)	3,855,000	2.8
Robert E. Pokusa(6)	476,199	*
Jonnie R. Williams, Sr.(7)	20,224,029	14.6
Curtis Wright, MD(8)	400,000	*
<i>Directors Who Are Not Named Executive Officers</i>		
Christopher C. Chapman, Jr., M.D.(9)	375,000	*
Neil Chayet(10)	290,200	*
Burton J. Haynes(11)	44,700	*
Mario V. Mirabelli(12)	109,000	*
Leo S. Tonkin(13)	500,000	*
All Directors and Named Executive Officers (11 Persons)	27,236,970	19.0
<i>Other Beneficial Owners of 5% or More of the Outstanding Common Stock of the Company</i>		
Tradewinds Investment Management, LP(14)	20,327,489	14.6

* Denotes less than 1% beneficial ownership.

- (1) 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, Glen Allen, Virginia 23060.
- (2) The "Percentage Owned" calculations are based on the outstanding shares of our common stock as of March 15, 2011.
- (3) Includes 251,742 shares held by Mr. Dean, 1,100 shares owned by Mr. Dean's spouse and 350,000 shares that Mr. Dean has the right to acquire upon exercise of stock options.
- (4) Includes 350,000 shares that Mr. Dodd has the right to acquire upon exercise of stock options and 10,000 shares held by Mr. Dodd.
- (5) 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, 1,875,000 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 1,199 shares held by Mr. Pokusa and 475,000 shares that Mr. Pokusa has the right to acquire upon exercise of stock options.

- (7) Includes 11,891,907 shares held by Mr. Williams, 3,088,761 shares that Mr. Williams has the right to acquire upon exercise of warrants, 1,875,000 shares that Mr. Williams has the right to acquire upon exercise of stock options and 2,268,361 held by his children or in trust for his children, of which he disclaims beneficial interest. Also includes 1,100,000 shares held by Regent Court of which Mr. William's shares voting and investment power.
- (8) Includes 400,000 shares that Dr. Wright has the right to acquire upon exercise of stock options.
- (9) Includes 375,000 shares that Mr. Chapman has the right to acquire upon exercise of stock options.
- (10) 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 286,200 shares that Mr. Chayet has the right to acquire upon exercise of stock options.
- (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 and 24,700 shares held by Mr. Haynes in an individual retirement account.
- (12) Includes 74,000 shares held by Mr. Mirabelli in an individual retirement account, 20,000 shares owned by Mr. Mirabelli individually, and 15,000 shares held jointly between Mr. Mirabelli and his spouse.
- (13) Includes 500,000 shares that Mr. Tonkin has the right to acquire upon exercise of stock options.
- (14) Based on reported filings and representation from Tradewinds Management and other filings, includes 14,789,854 shares for which Tradewinds Master Fund (BVI) Ltd., Feehan Partners, L.P. and P.V. Partners, L.P. share voting and dispositive power. Also includes 5,537,635 warrants that are currently exercisable, expiring on September 14, 2013 and November 5, 2015. 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

Equity Compensation Plan Information

The following table provides certain information as of December 31, 2010, with respect to our equity compensation plans under which our common stock is authorized for issuance:

<u>Plan Category</u>	<u>Number of Shares to be Issued Upon Exercise of Outstanding Options and Rights</u>	<u>Weighted-Average Exercise Price of Outstanding Options and Rights</u>	<u>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding Column a)</u>
	(a)	(b)	(c)
Equity Compensation Plans Approved by Shareholders	7,716,200	\$2.31	2,684,000

- (1) We have granted warrants to purchase shares of our common stock to two consultants. Specifically, on December 20, 2000, we issued 210,526 warrants to purchase shares of our common stock at an exercise price of \$2.375 to a consultant. These warrants fully vested on the date of issuance and expired on December 20, 2010.

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, 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 TSNAs, 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 it and any affiliated sub-licensees, and 6% on all fees and royalties received by it 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. Twelve 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.

Starwood Industries, LLC, or Starwood, a company in which Mr. Williams, our CEO, and Dr. Francis O'Donnell, who at the time was one of our largest shareholders, each held a fifty percent interest, for several years owned an aircraft that was used by our company from time to time. We had an agreement with Starwood to pay a contracted rate per hour for the use of the aircraft. This agreement did not provide for an adjustment based on the increased cost of fuel. During the year ended December 31, 2007, and the three months ended March 31, 2008, fuel costs exceeded the standard rate set forth in the agreement and, accordingly, Starwood requested a fuel surcharge applicable to our company's use of the aircraft, a practice common in the aircraft industry. Given Mr. Williams's relationship with Starwood, any payment to Starwood by our company constitutes a related party transaction that must be pre-approved by our company's Audit Committee. On May 6, 2008, our company's Audit Committee approved a \$529,672 payment to Starwood in satisfaction of the fuel surcharge related to our company's use of the aircraft during this period.

In 2008 the aircraft owned by Starwood was sold and Starwood Aviation, Inc., or Starwood Aviation, a company wholly owned by Mr. Williams, purchased another aircraft. Effective September 1, 2008, we entered into an agreement for our company's use of the aircraft owned by Starwood Aviation. Under this agreement, we have 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 is used beyond the monthly fixed cost, we are 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, Starwood Aviation or Messrs. Williams and O'Donnell as predecessors-in-interest to the aircrafts with respect to related expenses were \$1,654,000 in 2010, \$1,560,000 in 2009, \$1,401,582 in 2008, and were billed at cost.

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 \$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 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 our company's related party transaction policy, Mr. Williams' intention to purchase shares and warrant exercisable into shares of our common stock was considered and approved by the Audit Committee of our Board of Directors on March 4, 2011. See note 15 to our consolidated financial statements included in "Item 15. Exhibits, Financial Statement Schedules" of this Report for details of this transaction.

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 our company and in communicating to the public health community and others information regarding Rock Creek's products and mission. The agreement runs for a period of one year from March 15, 2010, is terminable by either party without cause on fifteen days written notice and may be extended thereafter at our company's discretion for one month periods. Under the agreement, Mr. Chayet acts as an independent contractor and receives a consulting fee of \$6,000 per month and reimbursement for reasonable business expenses. Given Mr. Chayet's status as a Director of our company, the consideration of the consulting agreement and its potential impact on Mr. Chayet's status as an Independent Director was considered by our company's Audit Committee as a related party transaction in accordance with our 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.

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 material relationship with our company (directly or as a partner, shareholder or officer of an organization that has a relationship with us).

Our Board of Directors, in applying the above-referenced standards, has affirmatively determined that our current independent directors are: Messrs. Chapman, Chayet, Tonkin, Haynes and Mirabelli. 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 "material relationship" with us 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 & Holland L.L.P. in 2010. 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. Services approved by the Audit Committee chairperson are

communicated to the full 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 & Holland L.L.P.:

Audit Fees:

Cherry, Bekaert & Holland L.L.P. billed our company \$235 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, 2010, the reviews of the interim financial statements included in our company's Forms 10-Q filed during the fiscal year ended December 31, 2010, and other required Securities Act filings.

Cherry, Bekaert & Holland L.L.P., billed our company \$189 thousand for professional services for the audits of our company's annual consolidated financial statements, management's assessment of the effectiveness of internal control over financial reporting and the effectiveness of internal control over financial reporting for the year ended December 31, 2009, the reviews of the interim financial statements included in our company's Forms 10-Q filed during the fiscal year ended December 31, 2009, and other required Securities Act filings.

Tax Fees:

Cherry Bekaert & Holland L.L.P. billed our company \$32 thousand for services related to tax Compliance (federal and state tax reporting, tax planning and tax consulting services in connection with analysis of impact on net operating loss carryovers due to changes in Company ownership) in 2010.

Cherry, Bekaert & Holland L.L.P., billed our company \$72 thousand for services related to tax compliance (federal and state tax reporting and tax planning) in 2009.

All Other Fees:

None.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of this Report.

1. Consolidated Financial Statements

	<u>Page</u>
Index to Consolidated Financial Statements	F-1
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2010 and 2009	F-3
Consolidated Statements of Operations for the years ended December 31, 2010, 2009 and 2008	F-4
Consolidated Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2010, 2009 and 2008	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2010, 2009 and 2008	F-6
Notes to Consolidated Financial Statements	F-7

2. Financial Statements Schedules

None.

(b) Exhibits.

An index to exhibits has been filed as part of this Report beginning on page E-1 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

Date: March 16, 2011

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<p><u>/s/ Jonnie R. Williams, Sr.</u> Jonnie R. Williams, Sr.</p>	<p>Chief Executive Officer and Director (Principal Executive Officer)</p>	<p>March 16, 2011</p>
<p><u>/s/ Paul L. Perito</u> Paul L. Perito</p>	<p>Chairman of the Board, President and Chief Operating Officer</p>	<p>March 16, 2011</p>
<p><u>/s/ Park A. Dodd, III</u> Park A. Dodd, III</p>	<p>Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)</p>	<p>March 16, 2011</p>
<p><u>/s/ Christopher C. Chapman</u> Christopher C. Chapman</p>	<p>Director</p>	<p>March 16, 2011</p>
<p><u>/s/ Neil L. Chayet</u> Neil L. Chayet</p>	<p>Director</p>	<p>March 16, 2011</p>
<p><u>/s/ Burton J. Haynes</u> Burton J. Haynes</p>	<p>Director</p>	<p>March 16, 2011</p>
<p><u>/s/ Mario V. Mirabelli</u> Mario V. Mirabelli</p>	<p>Director</p>	<p>March 16, 2011</p>
<p><u>/s/ Leo S. Tonkin</u> Leo S. Tonkin</p>	<p>Director</p>	<p>March 16, 2011</p>

INDEX TO EXHIBITS

<u>Item</u>	<u>Description</u>
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 in St. Paul, Minnesota, dated December 30, 1998(1)
3.1	Sixth Amended and Restated Certificate of Incorporation of Star Scientific, Inc.(2)
3.2	Amended and Restated Bylaws of Star Scientific, Inc.(3)
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(4)
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(5)
10.3	1998 Stock Option Plan, as amended(6)
10.4	2000 Equity Incentive Plan, as amended(7)
10.5	Qualified Stock Option Agreement dated as of April 27, 1999 between Star Scientific, Inc. and Paul L. Perito(8)
10.6	Lease and Purchase Option Contract between Star Scientific, Inc. and the Industrial Development Authority of the Town of Chase City, Virginia, dated March 10, 2000(6)
10.7	Form of Director Indemnification Agreement(6)
10.8	Form of Officer Indemnification Agreement(6)
10.9	Executive Employment Agreement between Star Scientific, Inc. and David M. Dean, dated October 6, 2000(7)
10.10	Restated Loan Agreement between Star Scientific, Inc., Star Tobacco and Pharmaceuticals, Inc. and Brown & Williamson Tobacco Corporation, dated August 21, 2000(9)
10.11	Restated Security Agreement between Star Scientific, Inc. and Brown & Williamson Tobacco Corporation, dated August 21, 2000(9)
10.12	Security Agreement between Star Tobacco and Pharmaceuticals, Inc. and Brown & Williamson Tobacco Corporation, dated August 21, 2000(9)
10.13	Guaranty Agreement between Star Scientific, Inc. and Brown & Williamson Tobacco Corporation, dated August 21, 2000(9)
10.14	Guarantee Agreement between Star Tobacco and Pharmaceuticals, Inc. and Brown & Williamson Tobacco Corporation, dated August 21, 2000(9)
10.15	Amended and Restated Executive Employment Agreement dated as of March 15, 2001 between Star Scientific, Inc. and Christopher G. Miller(7)
10.16	Executive Employment Agreement dated as of March 30, 2001 between Star Scientific, Inc. and Robert E. Pokusa(7)
10.17	Restated Master Agreement, dated April 25, 2001, by and between Star Scientific, Inc. and Brown & Williamson Tobacco Corporation(10)
10.18	First Amendment to Restated Loan Agreement dated April 25, 2001, among Star Scientific, Inc., Star Tobacco & Pharmaceuticals, Inc. and Brown & Williamson Tobacco Corporation(10)
10.19	Trademark License and Royalty Agreement, dated April 25, 2001, between Star Scientific, Inc. and Brown & Williamson Tobacco Corporation(10)
10.20	Other Low TSNA Tobacco Royalty Agreement, dated April 25, 2001 by and between Star Scientific, Inc. and Brown & Williamson Tobacco Corporation(10)
10.21	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(10)

<u>Item</u>	<u>Description</u>
10.22	Exclusive License Agreement dated as of March 16, 2001 by and among Regent Court Technologies and Star Scientific, Inc.(11)
10.23	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(11)
10.24	Amendment No. 1 dated April 5, 2001 to Exclusive License Agreement by and among Regent Court Technologies and Star Scientific, Inc.(11)
10.25	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(12)
10.26	Convertible Debenture, dated March 25, 2004, issued by Star Scientific, Inc. to Manchester Securities Corp. Debenture was amended and then converted(13)
10.27	Warrant, dated March 25, 2004, issued by Star Scientific, Inc. to Manchester Securities Corp.(13)
10.28	Securities Purchase Agreement, dated March 25, 2004, between Star Scientific, Inc. and Manchester Securities Corp.(13)
10.29	Registration Rights Agreement, dated March 25, 2004, between Star Scientific, Inc. and Manchester Securities Corp.(13)
10.30	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(13)
10.31	Executive Employment Agreement, dated December 30, 2005 between Star Scientific, Inc. and Jonnie R. Williams(14)
10.32	Second Amended and Restated Employment Agreement, dated December 30, 2005 between Star Scientific, Inc. and Paul L. Perito(14)
10.33	Securities Purchase and Registration Rights Agreement, dated as of March 3, 2006, between Star Scientific, Inc. and Joseph L. Schwarz(15)
10.34	Common Stock Purchase Warrant, dated as of March 3, 2006, issued by Star Scientific, Inc. to Joseph L. Schwarz(15)
10.35	Securities Purchase and Registration Rights Agreement, dated July 14, 2006, by and between Star Scientific, Inc. and Iroquois Capital(16)
10.36	Common Stock Purchase Warrant, dated July 14, 2006, issued by Star Scientific, Inc. to Iroquois Capital(16)
10.37	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(16)
10.38	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(16)
10.39	First Amendment to Executive Employment Agreement, dated December 15, 2006 between Star Scientific, Inc. and Jonnie R. Williams(3)
10.40	First Amendment to Second Amended Executive Employment Agreement, dated December 15, 2006 between Star Scientific, Inc. and Paul L. Perito(3)
10.41	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.(17)
10.42	Second Amendment to Second Amended Executive Employment Agreement, dated March 23, 2007 between Star Scientific, Inc. and Paul L. Perito(18)
10.43	License Agreement, dated May 10, 2007 between Star Tobacco, Inc., Star Scientific, Inc. and Tantus Tobacco, LLC (19)
10.44	Securities Purchase and Registration Rights Agreement, dated June 29, 2007, by and between Star Scientific, Inc. and Joseph L. Schwarz(20)
10.45	Common Stock Purchase Warrant dated June 29, 2007, issued by Star Scientific, Inc. to Pershing LLC, FBO Joseph L. Schwarz Roth IRA(20)

<u>Item</u>	<u>Description</u>
10.46	Common Stock Purchase Warrant dated June 29, 2007 issued by Star Scientific, Inc. to Joseph L. Schwarz(20)
10.47	Securities Purchase and Registration Rights Agreement, dated June 29, 2007 by and between Star Scientific, Inc. and Joseph Rice(20)
10.48	Common Stock Purchase Warrant dated June 29, 2007 issued by Star Scientific, Inc. to Joseph Rice(20)
10.49	Agreement dated October 10, 2007 by and between Christopher G. Miller and Star Scientific, Inc.(21)
10.50	Agreement dated October 10, 2007 by and between Park A. Dodd, III and Star Scientific, Inc.(21)
10.51	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(22)
10.52	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(22)
10.53	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(23)
10.54	Letter Agreement with Jonnie R. Williams, dated March 14, 2008(23)
10.55	Executive Employment Agreement dated February 26, 2008 between Star Scientific, Inc. and Curtis Wright, M.D. MPH(22)
10.56	2008 Incentive Award Agreement(24)
10.57	Amendment to Executive Employment Agreement dated as of December 19, 2008 between Star Scientific, Inc. and Robert E. Pokusa(25)
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 (26)
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 (27)
10.60	Executive Employment Agreement dated January 1, 2010 between Star Scientific, Inc. and Park A. Dodd, III(28)
10.61	Securities Purchase and Registration Rights Agreement, dated March 5, 2010, by and between Star Scientific, Inc. and the several Investors party thereto. (29)
10.62	Amended Warrant, dated March 5, 2010, by and between Star Scientific, Inc. and Iroquois Master Fund Ltd. (29)
10.63	Amended Warrant, dated March 5, 2010, by and between Star Scientific, Inc. and Iroquois Capital, LP. (29)
10.64	Securities Purchase and Registration Rights Agreement, dated March 9, 2010, by and between Star Scientific, Inc. and the several Investors party thereto.(30)
10.65	Amended Warrant No. 1, dated March 9, 2010, by and between Star Scientific, Inc. and Tradewinds Master Fund (BVI), Ltd.(30)
10.66	Amended Warrant No. 2, dated March 9, 2010, by and between Star Scientific, Inc. and Tradewinds Master Fund (BVI), Ltd.(30)
10.67	Amended Warrant No. 1, dated March 9, 2010, by and between Star Scientific, Inc. and Feehan Partners, L.P.(30)
10.68	Amended Warrant No. 2, dated March 9, 2010, by and between Star Scientific, Inc. and Feehan Partners, L.P.(30)
10.69	Amended Warrant No. 1, dated March 9, 2010, by and between Star Scientific, Inc. and PV Partners, L.P.(30)
10.70	Amended Warrant No. 2, dated March 9, 2010, by and between Star Scientific, Inc. and PV Partners, L.P.(30)
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.(30)
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.(30)

<u>Item</u>	<u>Description</u>
10.73	Amended Securities Purchase and Registration Rights Agreement, dated March 12, 2010, by and between Star Scientific, Inc. and the Investor party thereto.(30)
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.(30)
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.(31)
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.(32)
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.(32)
10.78	Executive Employment Agreement, dated March 14, 2011, between Star Scientific, Inc. and Jonnie R. Williams.
10.79	Third Amended and Restated Executive Employment Agreement, dated March 14, 2011, between Star Scientific, Inc. and Paul L. Perito.
10.80	Amended and Restated Executive Employment Agreement, dated March 14, 2011, between Star Scientific, Inc. and Curits Wright, IV, MD, MPH.
14.1	Corporate Code of Business Conduct and Corporate Ethics, dated March 2004 (13)
21.1	Subsidiaries of the Company
23.1	Consent of Cherry, Bekaert & Holland, L.L.P.
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

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- (1) Incorporated by reference to Current Report on Form 8-K filed on March 3, 1999
 - (2) Incorporated by reference to Current Report on Form 8-K filed on December 1, 2010
 - (3) Incorporated by reference to Current Report on Form 8-K filed on December 21, 2006
 - (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 Definitive Proxy Statement on Schedule 14A filed on October 14, 2008
- (25) Incorporated by reference to Annual Report on Form 10-K for the year ended December 31, 2008
- (26) Incorporated by reference to Current Report on Form 8-K filed on March 3, 2009
- (27) Incorporated by reference to Current Report on Form 8-K filed on September 25, 2009
- (28) Incorporated by reference to Current Report on Form 8-K filed on January 28, 2010
- (29) Incorporated by reference to Current Report on Form 8-K filed on March 5, 2010
- (30) Incorporated by reference to Annual Report on Form 10-K for the year ended December 31, 2009
- (31) Incorporated by reference to Registration Statement on Form S-3 filed on December 10, 2010
- (32) Incorporated by reference to Current Report on Form 8-K filed on March 4, 2011

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INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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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, 2010 and 2009, 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, 2010. We also have audited the Company's internal control over financial reporting as of December 31, 2010, 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 2010 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, 2010 and 2009, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2010 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, 2010, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

/s/ Cherry, Bekaert & Holland, L.L.P.
Richmond, Virginia
March 16, 2011

STAR SCIENTIFIC, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2010 AND 2009
(\$ and shares in thousands except per share data)

	2010	2009
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 13,193	\$ 12,360
Accounts receivable, trade, net of allowance for doubtful accounts of \$48 (2010) and \$ 36 (2009)	52	59
Receivable from sale of licensing rights	27	25
Inventories	3,419	230
Prepaid expenses and other current assets	350	404
Total current assets	17,041	13,078
Property and equipment, net	2,169	1,057
Intangible assets, net of accumulated amortization	627	626
Receivable from sale of licensing rights, less current maturities (note 3)	80	108
MSA escrow funds	368	365
Total assets	\$ 20,285	\$ 15,234
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Current maturities of long-term debt	\$ 2,518	\$ 1,981
Accounts payable, trade	1,585	2,419
Accrued expenses	424	978
Due to stockholders	50	50
Total current liabilities	4,577	5,428
Long-term debt, less current maturities	5,049	7,518
Total liabilities	9,626	12,946
Commitments and contingencies (Notes 10 and 13)	—	—
Stockholders' equity (deficit):		
Common stock (A)	13	11
Additional paid-in capital	181,336	144,686
Accumulated deficit	(170,690)	(142,409)
Total stockholders' equity (deficit)	10,659	2,288
Total liabilities and stockholders' equity (deficit)	\$ 20,285	\$ 15,234

(A) \$.0001 par value, 187,500,000 shares authorized; 127,119,322 and 107,676,768 shares issued and outstanding 2010 and 2009, 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.

STAR SCIENTIFIC, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
YEARS ENDED DECEMBER 31, 2010, 2009 AND 2008
(\$ and share in thousands except per share data)

	<u>2010</u>	<u>2009</u>	<u>2008</u>
Net sales	\$ 848	\$ 708	\$ 451
Less:			
Cost of goods sold	2,172	2,612	2,116
Excise taxes on products	12	15	6
Department of Agriculture tobacco buyout program assessment	1	1	1
Gross margin loss	(1,337)	(1,920)	(1,672)
Operating expenses:			
Marketing and distribution	2,760	2,584	3,538
General and administrative	21,084	15,820	15,352
Research and development	3,033	1,798	317
Restructuring	—	639	—
Total operating expenses	26,877	20,841	19,207
Operating loss from continuing operations	(28,214)	(22,761)	(20,879)
Other income (expense):			
Interest income	73	202	400
Interest expense	(383)	(439)	(741)
Gain(loss) on retirement of assets	240	251	(4)
Gain(loss) on sale of tobacco curing barns	—	(100)	—
Derivative expense	—	(67)	—
Other	3	114	660
Total other expense	(67)	(39)	315
Loss from continuing operations before income taxes	(28,281)	(22,800)	(20,564)
Income tax benefit (expense)	—	—	2,225
Net loss	<u>\$ (28,281)</u>	<u>\$ (22,800)</u>	<u>\$ (18,339)</u>
Loss per common share; basic and diluted:	<u>\$ (0.24)</u>	<u>\$ (0.22)</u>	<u>\$ (0.20)</u>
Weighted average shares outstanding — basic and diluted	<u>118,384</u>	<u>101,907</u>	<u>89,844</u>

See notes to consolidated financial statements.

STAR SCIENTIFIC, INC. AND SUBSIDIARIES

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
YEARS ENDED DECEMBER 31, 2010, 2009 AND 2008
(\$ and shares in thousands except per share data)**

	<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Accumulated Deficit</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>			
Balances, January 1, 2008	81,488	\$ 8	\$ 99,274	\$(101,270)	\$ (1,988)
Stock-based compensation	—	—	3,173	—	3,173
Stock option exercise	58	—	156	—	156
Issuance of common stock and warrant exercise	10,700	1	16,499	—	16,500
Net loss	—	—	—	(18,339)	(18,339)
Balances, December 31, 2008	92,246	\$ 9	\$119,102	\$(119,609)	\$ (498)
Stock-based compensation	186	—	498	—	498
Stock option exercise	2,597	1	4,933	—	4,934
Issuance of common stock and warrant exercise	12,648	1	20,840	—	20,841
Derivative liability adjustment resulting from adoption of new accounting policy (Note 2)	—	—	(687)	—	(687)
Net loss	—	—	—	(22,800)	(22,800)
Balances, December 31, 2009	107,677	\$11	\$144,686	\$(142,409)	\$ 2,288
Stock-based compensation	100	—	8,823	—	8,823
Issuance of common stock and warrant exercise	19,342	2	27,827	—	27,829
Net loss	—	—	—	(28,281)	(28,281)
Balances, December 31, 2010	<u>127,119</u>	<u>\$13</u>	<u>\$181,336</u>	<u>\$(170,690)</u>	<u>\$ 10,659</u>

See notes to consolidated financial statements.

STAR SCIENTIFIC, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2010, 2009 AND 2008
(\$ in thousands except per share data)

	<u>2010</u>	<u>2009</u>	<u>2008</u>
Operating activities:			
Net loss	\$(28,281)	\$(22,800)	\$(18,339)
Adjustments to reconcile net loss to net cash flows from operating activities:			
Depreciation and amortization	312	315	602
Loss (Gain) on sale of curing barns	—	100	—
Loss (Gain) on disposal of property and equipment	—	(251)	3
Deferred income taxes	—	—	(2,225)
Stock-based compensation expense	8,823	498	3,173
Provision for (recovery of) bad debts	41	(30)	(11)
Provision for inventory writeoff	59	414	—
Derivative expense	—	67	—
Increase (decrease) in cash resulting from changes in:			
Accounts receivable, trade	(36)	58	30
Inventories	(3,248)	69	(293)
Prepaid expenses and other current assets	54	848	(646)
Accounts payable, trade	(834)	1,290	241
Accrued expenses	(554)	383	(335)
Net cash flows from operating activities	<u>(23,664)</u>	<u>(19,039)</u>	<u>(17,800)</u>
Investing activities:			
Purchases of property and equipment	(990)	(22)	(112)
Proceeds from sale of tobacco curing barns	—	200	—
Proceeds from sale of real estate	—	630	—
Proceeds from sale of licensing rights	25	589	1078
Purchase of intangible assets	(65)	(14)	(10)
Deposits (made) returned on property and equipment	(307)	—	(114)
Net cash flows from investing activities	<u>(1,337)</u>	<u>1,383</u>	<u>842</u>
Financing activities:			
Payments on long-term debt and capital leases	(1,994)	(1,478)	(1,746)
Proceeds from sale of stock and warrant exercise	27,831	20,087	16,500
Proceeds from exercise of options	—	4,934	156
Net cash flows from financing activities	<u>25,837</u>	<u>23,543</u>	<u>14,910</u>
Deposits to MSA escrow fund	(3)	—	(360)
Change in cash and cash equivalents	833	5,887	(2,408)
Cash and cash equivalents, beginning of year	12,360	6,473	8,881
Cash and cash equivalents, end of year	<u>\$ 13,193</u>	<u>\$ 12,360</u>	<u>\$ 6,473</u>
Supplemental disclosure of cash flow information:			
Cash paid during the year for:			
Interest paid	<u>\$ 370</u>	<u>\$ 404</u>	<u>\$ 831</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 6	<u>\$ 63</u>	<u>\$ —</u>	<u>\$ —</u>

See notes to consolidated financial statements.

STAR SCIENTIFIC, INC. AND SUBSIDIARIES
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 reduce the harm associated with the use of tobacco at every level. The Company is primarily engaged in:

- the development, implementation and licensing of proprietary technology for the curing of tobacco so as to substantially prevent the formation of carcinogenic toxins present in tobacco and tobacco smoke, primarily the tobacco-specific nitrosamines, or TSNAs;
- the manufacture, sales, marketing and/or development of very low-TSNA dissolvable smokeless tobacco products that carry enhanced warnings beyond those required by the Surgeon General, including ARIVA® compressed powdered tobacco cigarette pieces and STONEWALL Hard Snuff® and “modified risk tobacco products” as defined in the Family Smoking Prevention and Tobacco Control Act of 2009, or the FDA Tobacco Act;
- the development of pharmaceutical products, particularly products that have a botanical, tobacco-based component, that are designed to treat tobacco dependence and a range of neurological conditions, including Alzheimer’s disease, Parkinson’s disease, schizophrenia and depression; and
- the manufacture, sales, marketing and development of non-nicotine nutraceutical products designed to assist individuals who are seeking a smoking alternative as well as related non-nicotine products that may be helpful to consumers in maintaining a healthy metabolism.

Principles of consolidation:

The accompanying consolidated financial statements include the accounts of Star Scientific and its wholly owned subsidiaries, Star Tobacco and Rock Creek. 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.

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 13 for contingency discussion.

Accounts receivable, trade and allowance for doubtful accounts:

Accounts receivable are customer obligations due under normal trade terms. The Company sells its tobacco products to distributors and retail customers. The Company performs continuing credit evaluations of its customers’ financial condition and does not require collateral. The Company’s nutraceutical product, CigRx®, is sold directly to consumers and through credit card transactions that are approved prior to shipment.

Management reviews accounts receivable on a monthly basis to determine if any receivables will potentially be uncollectible. Any accounts receivable balances that are determined to be uncollectible are included in the allowance for doubtful accounts. The allowance for doubtful accounts contains a general accrual for remaining possible bad debts. The allowance for doubtful accounts at December 31, 2010 and 2009 was \$48 and \$36 thousands, respectively. Based on the information available, management believes the allowance is adequate. However, actual write-offs might exceed the recorded allowance.

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 idle facility expense, freight, handling and wasted materials costs as current period charges. The allocation of fixed production overhead to the costs of conversion is based on the normal capacity of the production facilities.

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, machinery and equipment and thirty-nine years for buildings and improvements. The Company had 37 barns accounted for as idle equipment until their sale in December 2009 for \$200 thousand. The Company currently does not own any curing barns.

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 17 years for patents and licensing costs and 5 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 periodically evaluated for impairment.

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 or equity instruments (warrants and options).

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 from the sale of the Company's tobacco products is recognized net of cash discounts, sales returns and allowances and sales incentives (such as coupons, slotting fees and other buy down promotions). Federal Excise Taxes are included in net sales and account receivable billed to customers. Revenue for our dietary supplement that is shipped directly to our direct buying consumers is recognized upon shipment of the product from our third party fulfillment vendor. The dietary supplement product is 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 supplement at this time.

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 our products. Inventory related costs include materials, inbound freight, production costs, inventory obsolescence and shrinkage. In addition to the aforementioned, the costs for our dietary supplement product, CigRx™, include fulfillment partner fees, credit card processing fees, and costs of consumer support.

Shipping costs:

Shipping costs for our tobacco products are included in marketing and distribution expenses, since we do not charge for freight to our wholesale and distributor customers. Shipping costs for our tobacco products aggregated \$39, \$38, and \$35 thousand, in 2010, 2009 and 2008, respectively. Shipping cost to consumers purchasing our CigRx® product are included in the cost of the product price since we charge consumers shipping and handling fees. Shipping costs for CigRx® to wholesaler and distribution customers will be charged to marketing and distribution since we will not charge a separate fee shipping.

Advertising Costs:

Advertising costs are expensed as incurred and are included in marketing and distribution expenses. Advertising costs for the years 2010, 2009 and 2008, were \$556, \$123, and \$199 thousand, 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.

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 more likely than not to become a direct liability then the Company will record the liability in the financial statements. If not, we 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 other standard setting bodies that may have an impact on our accounting and reporting. We believe that such recently issued accounting pronouncements and other authoritative guidance for which the effective date is in the future either will not have an impact on our accounting or reporting or that such impact will not be material to our 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 eight years. The Company's prospects will depend on its ability to generate and sustain increased revenue levels in future periods. This will largely be dependent on the distribution and consumer acceptance of the Company's new CigRx[®] product, a non-nicotine, non-tobacco nutraceutical developed by its Rock Creek Pharmaceutical subsidiary to temporarily decrease the desire to smoke introduced in Richmond, Virginia in August 2010. It also will be dependent on increased distribution and consumer acceptance of its low-TSNA smokeless tobacco products, as well as its ability to begin generating significant revenues through royalties from the patented tobacco curing process for which it is the exclusive licensee. CigRx[®] is Rock Creek's first product introduction and Rock Creek had no revenue stream prior to the introduction of CigRx[®] and little revenue from CigRx[®] in 2010. In late February 2011, the Company began testing CigRx[®] on a national basis through expanded infomercials and radio spots. The Company's prospects also will be dependant on Rock Creek's ability to develop additional pharmaceutical and non-nicotine nutraceutical products and the approval by the Food and Drug Administration, ("FDA"), of Star Tobacco's applications to market variations of its Ariva[®] and Stonewall Hard Snuff[®] smokeless tobacco products as well as a Stonewall Moist-BDL[™] product as "modified risk tobacco products". The ability to generate revenues through royalty payments will be dependent upon the success of the Company's ongoing patent infringement lawsuit against R J Reynolds Tobacco ("RJR") which has been pending since 2001. In that litigation, following a jury trial that took place between May 18, 2009 and June 16, 2009, 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. That decision has been appealed to the United States Court of Appeals for the Federal Circuit and oral argument before a three-judge panel of the Court was held on January 11, 2011. The Company is currently awaiting a ruling on the appeal from the Federal Circuit Court of Appeals. On May 29, 2009 the Company filed a new complaint against RJR for patent infringement during the period beginning 2003 and continuing to the filing date of the new complaint. The new case has been stayed pending the outcome of the appeal to the Federal Circuit and the prosecution of the new complaint will be dependant on the Company achieving a reversal of the jury verdict of invalidity in the initial RJR action.

As of December 31, 2010, the Company had a working capital surplus of approximately \$12.6 million, which included cash of approximately \$13.2 million. Future cash needs during 2011 include:

- litigation costs in connection with the RJR patent infringement trial of approximately \$1.4 million thousand;
- monthly principal and interest payments of approximately \$245 thousand in connection with the repayment of the Company's long-term debt; and
- funding of other aspects of the Company's current operations in light of continued operating losses.

The Company expects to continue to incur losses in connection with the sale of its smokeless tobacco products for the foreseeable future. While net sales of smokeless tobacco have been increasing year over year, substantially increased sales will be required to reach a breakeven level for these products. Rock Creek had no revenues prior to the introduction of CigRx[®] in August 2010. It is expected that Rock Creek will be deriving revenues from the sales of CigRx[®] on a going forward basis as it expands distribution of CigRx[®], but the Company has had only limited revenue from the sale of CigRx[®] to date.

Given the typical long lead time for federal approval of any pharmaceutical products, the Company does not expect that Rock Creek will generate any revenues from the sale of pharmaceutical products, as opposed to nutraceuticals, for the foreseeable future. Rather, Rock Creek will focus its future development efforts on the research and development aspects of a range of pharmaceuticals, including products having a botanical, tobacco-based component and related nutraceuticals products that may assist in stabilizing metabolism, assuming sufficient capital can be generated to support such activities.

During the period January 1, 2010 through March 15, 2010, the Company received proceeds of approximately \$13.8 million through the sale of 11,727 thousand shares of common stock and a combination of new warrants for an aggregate of 6,324 thousand shares and the repricing of 5,403 thousand shares of previously issued warrants. On November 5, 2010, the Company received proceeds of \$14 million through the sale of 7,615 thousand shares of common stock and 7,615 thousand in new warrants. See note 7 for a further description of these transactions. Subsequent to December 31, 2010 the Company received proceeds of \$11.0 million through the sale of 4,856 thousand shares of common stock, the exercise of 2,000 thousand warrants and the issuance of 6,856 thousand in new warrants. See Note 15 for a further description of this transaction. Absent the exercise of outstanding warrants and options for cash or a substantial improvement in revenues and/or royalties, the Company believes that it has sufficient funding to support its operations into the first quarter of 2012, but that it will be necessary to pursue additional sources of funds during the first quarter 2012. 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.

The Company expects to continue to pursue opportunities for licensing its low-TSNA smokeless tobacco products, expanding the sales and marketing efforts for those products, and its non-nicotine nutraceutical product, CigRx[®] that was introduced in August 2010 in the Richmond, Virginia area and continuing the work of Rock Creek in developing other pharmaceutical and nutraceutical. While the Company may seek to obtain funds in the future through debt financing, there are significant limitations on the ability to obtain new debt financing, including the agreements with B&W. Moreover, the ability to raise future financings on acceptable terms (including through the exercise of outstanding warrants) will depend on a number of factors, including the performance of the Company stock price and its operational performance. Any equity financing will be dilutive to the Company's existing shareholders.

3. Inventories:

Inventories consist of the following:

<u>\$ Thousands</u>	<u>2010</u>	<u>2009</u>
Raw materials	\$1,636	\$ 119
Packaging materials	1,911	446
Work-in-process	91	
Finished goods	<u>300</u>	<u>80</u>
Total inventories	3,938	\$ 645
Less obsolescence and overstock reserve	<u>(519)</u>	<u>(415)</u>
Net inventories	<u>\$3,419</u>	<u>\$ 230</u>

The Company had product manufacturing cost that exceeded its normal capacity cost of approximately \$1.8 million and \$1.4 million for 2010 and 2009, respectively. These costs are included in cost of goods sold in the accompanying consolidated statements of operations.

4. Property and equipment:

Property and equipment consists of the following:

<u>\$ Thousands</u>	<u>2010</u>	<u>2009</u>
Leasehold improvements	\$ 553	\$ 451
Machinery and equipment	5,107	4,529
Vehicles	85	—
Office and sales equipment	674	838
Construction in Progress	571	—
Total property and equipment	6,990	5,818
Less accumulated depreciation	(4,821)	(4,761)
Property and equipment-net	<u>\$ 2,169</u>	<u>\$ 1,057</u>

In 2000 the Company entered into a ten-year lease of a building and land in Chase City, Virginia that has been used for the Company's tobacco receiving and manufacturing operations. The lease contained a provision that granted the Company an option to purchase the leased premises. In November 2008, the Company assigned its option rights under the lease to a third party that, in turn, exercised the rights under the option in December 2008. As a result of the transaction, the Company received a net payment of approximately \$0.6 million on January 6, 2009. The Company later transitioned the manufacturing operation that had been carried on in that facility to an adjacent facility in Chase City that it also leases.

On October 30, 2009, the Company sold a 3.5 acre parcel of land in Petersburg, Virginia along with improvements consisting of the factory that until May 2007 was used for the manufacturing of its cigarette products and the adjacent 6,000 square feet office building that formerly housed its executive, marketing, sales and administrative offices, for gross proceeds of \$630 thousand. The Company entered into a leaseback of the office building for up to two years with a 15 day notice clause to exit the building and lease. The Company terminated the lease in April 2010, after it completed the transition to leased space in Glen Allen, VA. The Company recorded a gain on the sale of the property, plant and equipment of approximately \$245 thousand in the fourth quarter 2009 to reflect the difference between the carrying value of the Petersburg property and buildings and the sales price.

Depreciation expense is included in the consolidated statement of operations for the years ended December 31, 2010, 2009 and 2008, as follows:

<u>\$ thousands</u>	<u>2010</u>	<u>2009</u>	<u>2008</u>
Cost of Goods Sold	\$156	\$163	\$420
Operating Expenses	91	90	121
Total Depreciation Expense	<u>\$247</u>	<u>\$253</u>	<u>\$541</u>

5. Intangible assets:

Intangible assets consist of the following:

<u>\$ thousands</u>	<u>2010</u>	<u>2009</u>
Patents	\$1,114	\$1,049
Trademarks and other intangibles	90	90
	1,204	1,139
Less: Accumulated Amortization	(577)	(513)
	<u>\$ 627</u>	<u>\$ 626</u>

Amortization expense associated with the intangibles was \$66, \$62 and \$61 thousand in 2010, 2009 and 2008, respectively. An aggregate of \$84 thousand in trademarks have indefinite lives and are therefore not amortized. Expected future amortization of intangibles with finite lives is as follows:

<u>Years ending December 31,</u>	<u>\$ thousands</u>
2011	\$ 62
2012	62
2013	62
2014	62
2015	62
Thereafter	<u>233</u>
	<u>\$543</u>

In the event the Company is unsuccessful in its patent infringement litigation, as discussed in Note 13, recognition of an impairment loss related to certain patents with a carrying value of approximately \$71 thousand as of December 31, 2010 may be necessary. The consolidated financial statements do not include any adjustments that might result from this uncertainty.

6. Long-term debt:

Long-term debt consists of the following as of December 31, 2010:

	<u>\$ thousands</u>
Notes payable to RJR in monthly principal installments of \$134 thousand until August 2010 and \$208 thousand thereafter until fully paid in December 2013, plus interest at prime plus 1% (4.25% at December 31, 2010)	\$ 7,518
Vehicle note payable in monthly installments of \$1.7 thousands including interest at 1.9% annually for 36 months ending April 2013	<u>49</u>
Total long-term debt	7,567
Less current maturities	<u>(2,518)</u>
Long term portion of debt	<u>\$ 5,049</u>

The future maturities of long-term debt without regard to potential royalty offsets are as follows:

<u>Twelve months ending December 31,</u>	<u>\$ thousands</u>
2011	\$2,518
2012	2,519
2013	<u>2,530</u>
Total notes payable and long term debt	<u>\$7,567</u>

7. Stockholders' equity:

Warrants:

The Company grants common stock warrants in connection with direct equity shares purchases 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, 2010, 2009 and 2008 are as follows:

	Number	Weighted Average Exercise Price Per Share
Warrants		
Warrants outstanding at January 1, 2008	5,252,513	\$ 2.20
Warrants issued during 2008	10,686,508	2.01
Warrants exercised during 2008	(200,000)	(2.02)
Warrants expired during 2008	—	—
Warrants outstanding at December 31, 2009	15,739,021	\$ 2.06
Warrants issued during 2009	9,320,460	2.43
Warrants exercised during 2009	(7,647,592)	(2.07)
Warrants expired during 2009	(100,000)	(4.49)
Warrants outstanding at December 31, 2009	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	<u>31,040,525</u>	<u>\$ 1.65</u>

Sale of equity securities and exercise of warrants 2008

March 2008 Private Placements:

On March 13, 2008 and March 14, 2008, the Company entered into Securities Purchase and Registration Rights Agreements (the “March Agreements”) with selected accredited investors (the “March Investors”), to sell 4,838,711 shares of its common stock, par value \$0.0001 per share (“Common Stock”), at \$1.55 per share and 3,311,259 shares of its Common Stock at \$1.51 per share, respectively (collectively, the “March Shares”), and warrants to purchase an aggregate of 8,149,970 shares of Common Stock at an exercise price of \$2.00 per share (the “March Warrants” and together with the March Shares, the “March Securities”), which resulted in gross proceeds to the Company of \$12.5 million (the “March Offering”). The March Warrants were first exercisable in September 2008, six months after the closing of the March Offering, and expire five years after the date that the March Warrants were first exercisable. The March Warrants are also callable by the Company if the price of the Common Stock exceeds \$6.00 per share as quoted on an approved market for 20 consecutive trading days. Additionally, the March Agreements granted the March Investors certain registration rights with respect to the March Securities. The March 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. In March 2009 holders of March warrants for 4,311,259 shares exercised these warrants in full at a reduced price per share.

In connection with the March 2008 Agreements, the Company was required to adjust the exercise price and the number of warrants issued to Manchester under a 2004 warrant agreement with Manchester for 541,987 shares as previously and subsequently adjusted (the “2004 Warrants”). Under the terms of the 2004 Warrants, since the Company, pursuant to the March 2008 Agreements, sold shares of Common Stock at an effective price per share below \$3.71 per share, Manchester was entitled to a reduction in the exercise price of the 2004 Warrants from \$3.71 per share to approximately \$3.38 per share and to receive 52,647 additional warrants to purchase Common Stock.

May 2008 Private Placements:

On May 12, 2008, the Company entered into a Securities Purchase Agreement and Registration Rights Agreement (the “May Agreement”) with certain accredited investors (the “May Investors”), to sell 2,469,135

shares of its Common Stock at \$1.62 per share (collectively, the "May Shares") and warrants to purchase an aggregate of 2,469,135 shares of Common Stock at an exercise price of \$2.00 per share (the "May Warrants" and together with the May Shares, the "May Securities"), in return for gross proceeds to the Company of \$4.0 million (the "May Offering"). The May Warrants were first exercisable in November 2008, six months after the closing of the May Offering and expire five years after the date that the May Warrants were first exercisable. The May Warrants are also callable by the Company if the price of the Common Stock exceeds \$6.00 per share as quoted on an approved market for twenty consecutive trading days. Additionally, the May Agreement granted the May Investors certain registration rights with respect to the Securities. The May 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.

In connection with the May 2008 agreements, the Company was required to further adjust the exercise price and the number of warrants issued to Manchester under the 2004 warrant agreement with Manchester for 594,634 shares as previously adjusted. Under the terms of the 2004 Warrants, since the Company, pursuant to the May 2008 Agreements, sold shares of Common Stock at an effective price per share below \$3.38 per share, Manchester was entitled to a reduction in the exercise price of the 2004 Warrants from \$3.38 per share to approximately \$3.29 per share and to receive 14,756 additional warrants to purchase Common Stock.

Additionally, on March 14, 2008, Jonnie R. Williams, the Company's largest shareholder and Chief Executive Officer, executed a letter agreement under which he committed to make available to the Company up to \$2.0 million until the earlier of March 31, 2009, and the date the Company received an additional \$2.0 million in capital through an equity investment. Because the Company received over \$2.0 million in proceeds from the May Offering, the March 14, 2008 agreement with Mr. Williams is no longer in effect in accordance with its terms.

On September 25, 2008, the holder of a warrant for 200,000 shares of Common Stock exercised the warrant in its entirety. The warrant holder elected to exercise the warrant utilizing the warrant's net share settlement provision and was issued 81,488 shares of Common Stock based on a price of \$3.41 per share of Common Stock, the average closing price of the Common Stock over a 30 day period ending three calendar days prior to the date of exercise, in accordance with that provision.

Sale of equity securities and exercise of warrants 2009:

On February 20 and 25, 2009, the Company reduced the exercise price of 1,967,742 Prior Warrants to \$1.25 in exchange for the immediate and full exercise thereof by the Investors holding such Prior Warrants (collectively, the "February Transactions"). The February Transactions resulted in gross proceeds to the Company of approximately \$2.5 million.

On March 2, 2009, the Company entered into a securities purchase and registration rights agreement with certain prior Investors whereby the Company: (i) reduced the exercise price of 1,000,000 Prior Warrants with an exercise price of \$3.00 per share to \$2.50 in exchange for the immediate and full exercise thereof by the Investors holding such Prior Warrants and provided such Investors with warrants having an exercise price of \$3.50 per share for the same number of warrant shares of Common Stock as their respective Prior Warrants and (ii) provided Investors holding 3,311,259 Prior Warrants with an exercise price of \$2.00 per share with warrants having an exercise price of \$3.50 per share for the same number of shares of Common Stock as their respective Prior Warrants in exchange for the immediate and full exercise of such Investors' Prior Warrants (collectively, the "March Transaction" and together with the February Transactions, the "Recent Transactions"). The warrants issued in the March Transaction are exercisable immediately into an aggregate of 4,311,259 shares of Common Stock and expire on March 2, 2014 and are callable by the Company beginning on September 2, 2009 if the price of the Common Stock exceeds \$10.00 per share as quoted on an approved market for twenty consecutive trading days. The March Transaction resulted in gross proceeds to the Company of approximately \$9.1 million. The Recent Transactions were made only to accredited investors, as such term is defined in Rule 501 of Regulation D promulgated under the Securities Act of 1933, as amended (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.

As a result of the warrant exercise transactions, the Company was required to adjust the exercise price and the number of warrants issued to Manchester, under a 2004 warrant agreement with Manchester pursuant to which Manchester received warrants for 609,390 shares of common stock, as previously adjusted. Since the warrant exercise transactions involved the sale of shares of common stock at an effective price per share below \$3.29 per share, Manchester was entitled to a reduction in the exercise price of its warrants from \$3.29 per share to approximately \$3.24 per share and to receive approximately 9,201 additional warrants to purchase common stock.

On March 23, 2009 Manchester fully exercised its warrant for 618,591 shares, at the stated exercise price of \$3.24 per share, providing the Company approximately \$2.1 million of additional capital.

On March 30, April 30 and May 4, 2009, the holder of a warrant for 1,103,960 shares exercised on 250,000 warrant shares on each of the respective dates, for an aggregate of 750,000 warrant shares at a price of \$2.00 per share for proceeds of \$1.5 million.

On September 22, 2009, the Company entered into a securities purchase and registration rights agreement with an accredited investor ("The Investor"), to sell 5,000,000 of its common stock at \$1.00 per share and warrants to purchase an aggregate of 5,000,000 shares of common stock at an exercise price of \$1.50 per share (the "September Transaction" and the "September Warrants"). The September Warrants are first exercisable on February 22, 2010 and expire five years after the date that the September Warrants are first exercisable. The September Warrants are also 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. Additionally, the agreement grants The Investor certain registration rights with respect to the Securities. The September transaction resulted in gross proceeds to the Company of \$5.0 million. The Offering was made only to an accredited investor 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

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 grant 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 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 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 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, are 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 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 Securities sold to the Investors have not been registered under the Securities Act of 1933, as amended (the "Securities Act"), or any state securities laws, and may not be offered or sold in the United States in the absence of an effective registration statement or exemption from the registration requirements. 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 thousand shares of Common Stock at \$1.80 per share and warrants to purchase an aggregate of 7,615 thousand 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 are 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.

See Note 15 for securities sold, warrants and options issued subsequent to December 31, 2010.

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 14,000,000 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, 2010, 2009 and 2008 are as follows:

	<u>Number</u>	<u>Weighted Average Exercise Price Per Share</u>	<u>Grant Date Fair Value</u>
Options			
Options outstanding at January 1, 2008	5,658,200	\$ 2.56	
Options forfeited during 2008	(50,000)	(3.58)	
Options exercised during 2008	(58,000)	(2.70)	
Options issued during 2008	<u>2,075,000</u>	<u>1.94</u>	
Options outstanding at December 31, 2008	7,625,200	\$ 2.38	\$ 1.49
Options forfeited during 2009	(681,400)	4.34	
Options exercised during 2009*	(2,638,600)	1.92	
Options issued during 2009	<u>250,000</u>	<u>0.93</u>	
Options outstanding at December 31, 2009	4,555,200	\$ 2.28	\$ 0.77
Options forfeited during 2010	(729,000)	(3.97)	
Options exercised during 2010	—	—	
Options issued during 2010	<u>3,890,000</u>	<u>2.65</u>	
Options outstanding at December 31, 2010	<u>7,716,200</u>	<u>2.31</u>	\$ 1.74

* Includes 75,000 share options exercised as non cash, resulting in 33,268 shares issued.

The following table summarizes information for options outstanding and exercisable at December 31, 2010.

<u>Range of Prices</u>	<u>Options Outstanding</u>			<u>Exercisable</u>			
	<u>Number</u>	<u>Weighted Avg. Remaining Life Years</u>	<u>Weighted Avg. Exercise Price</u>	<u>Aggregate Intrinsic Value</u>	<u>Number</u>	<u>Weighted Avg. Exercise Price</u>	<u>Aggregate Intrinsic Value</u>
\$ 0.70-2.00	3,100,000	6.70	1.51	\$1,370	3,100,000	1.51	\$1,370
2.01-3.00	4,091,200	8.83	2.70	—	3,991,200	2.71	—
3.01-4.00	350,000	4.87	3.67	—	350,000	3.67	—
4.01-4.95	<u>175,000</u>	4.82	4.69	—	<u>175,000</u>	4.69	—
\$ 0.70-4.95	<u>7,716,200</u>	7.70	2.31	—	<u>7,616,200</u>	2.31	\$ —

A summary of the status of the Company's nonvested stock options as of December 31, 2010, and changes during the year then ended, is presented below.

<u>Nonvested Stock Options</u>	<u>Shares</u>	<u>Weighted Average Grant-Date Fair Value</u>
Nonvested at December 31, 2009	50,000	\$ 1.46
Granted	100,000	1.74
Vested	(50,000)	(1.46)
Forfeited	—	—
Nonvested at December 31, 2010	<u>100,000</u>	<u>\$ 1.74</u>

As of December 31, 2010, there was approximately \$149 thousand of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plans. That cost will be recognized over the next two years. There were no options exercised in the year ended December 31, 2010.

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:

	<u>2010</u>	<u>2009</u>	<u>2008</u>
Expected life of options based on simplified method for employees	2 -5 years	2 -5 years	2.5 -5 years
Risk free interest rate	1.15 - 2.75%	0.93 - 2.47%	2.22 -3.15%
Expected volatility	122.85 - 125.79%	121.2 - 138.33%	103.4 - 112.0%
Expected dividend yield	0%	0%	0%

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

<u>\$ thousands</u>	<u>2010</u>	<u>2009</u>	<u>2008</u>
Employee	\$8,320	\$ 75	\$2,470
Non-employee consultants and directors	229	250	703
	<u>\$8,549</u>	<u>\$325</u>	<u>\$3,173</u>

In 2009 the Company issued 186,000 shares of common shares with a fair value of \$117 thousand. These shares were issued from the Company's 2008 Incentive Award Plan.

The Company issued options for an aggregate of 604,000 shares of common stock to several employees subsequent to December 31, 2010 that vested as of the date of the grant and, as part of employment agreements entered into on March 14, 2011, issued stock option whose vesting is contingent on the satisfaction of retention or performance criteria and, in some cases, on shareholder approval of the option grants. See Note 15, "Subsequent Events" for more details.

8. Earnings per share:

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

<u>\$ and shares in thousands except per share data</u>	<u>2010</u>	<u>2009</u>	<u>2008</u>
Net loss	<u>\$ (28,281)</u>	<u>\$ (22,744)</u>	<u>\$ (18,339)</u>
Denominator for basic earnings per share-weighted average shares	118,384	101,907	89,844
Effect of dilutive securities: stock options and warrants outstanding (a)	—	—	—
Denominator for diluted earnings per share—weighted average shares adjusted for dilutive securities	118,384	101,907	89,844
Loss per common share—basic	<u>\$ (0.24)</u>	<u>\$ (0.22)</u>	<u>\$ (0.20)</u>
Loss per common share—diluted	<u>\$ (0.24)</u>	<u>\$ (0.22)</u>	<u>\$ (0.20)</u>

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

	<u>2010</u>	<u>2009</u>	<u>2008</u>
Stock options and warrants	38,756,725	21,867,089	10,231,213

9. Income taxes:

In 2007, the Company recognized a \$2.1 million liability for alternative minimum tax and interest. The Company's potential liability resulted primarily from timing differences for deductions for amounts paid to the Company's MSA escrow accounts. The Company recognized interest related to the liability for uncertain tax positions in income tax expense. During the first three fiscal quarters of 2008, the Company recognized

approximately \$120 thousand, of interest expense associated with uncertain tax positions. In 2005, the Company's request for a private letter ruling, or PLR, which related to the years under IRS examination, was resolved generally in its favor and an amended private letter ruling, or Amended PLR, was issued by the IRS in January 2009. The Amended PLR confirmed that the Company's deductions taken for MSA escrow payments, which were the subject of the IRS ongoing audit for tax years 2001 through 2004 and a pending tax appeal, were fully deductible and appropriate in the years taken. Based on the Amended PLR, the Company entered into a closing agreement with the IRS which confirmed the deductions taken for those years and, thereafter, the IRS confirmed that the Company's tax returns for the years 2001 through 2004 were correct as filed. As a result of the notification by the IRS in the Amended PLR, the Company derecognized its position of recording this income tax expense as of December 31, 2008, which resulted in a \$2.2 million income tax benefit.

Net deferred tax assets and liabilities consist of the following:

<u>\$ thousand</u>	<u>2010</u>	<u>2009</u>
Deferred tax assets:		
Net operating loss carry-forwards (portions subject to annual limitation)	\$ 54,853	\$ 47,778
Credit carry-forward	477	501
Stock option compensation	4,639	1,442
Differing basis in property and equipment for tax and financial reporting purposes	(38)	17
Inventory Reserve	194	—
Other	82	20
	<u>60,207</u>	<u>49,758</u>
Deferred tax liabilities:		
MSA escrow payments taxable in future	(138)	(137)
Valuation Allowance*	(60,069)	(49,621)
	<u>\$ —</u>	<u>\$ —</u>

* Based on the information available, management believes the allowance is appropriate.

Income tax benefit consists of the following:

	<u>2010</u>	<u>2009</u>	<u>2008</u>
Current:			
Federal	\$—	\$—	\$—
State	—	—	—
Deferred benefit	—	—	—
	<u>\$—</u>	<u>\$—</u>	<u>\$—</u>

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:

	<u>2010</u>	<u>2009</u>	<u>2008</u>
Statutory federal rate	(34.00)%	(34.00)%	(34.0)%
Permanent items	(0.33)	0.57	0.44
State tax provision, net of federal benefit	(3.45)	(3.45)	(3.45)
Valuation allowance	37.78	36.88	37.01
	<u>(0.00)%</u>	<u>(0.0)%</u>	<u>(0.0)%</u>

At December 31, 2010, the Company had net operating loss carry-forwards of approximately \$148 million, which expire from 2010 through 2030. As a result of previous ownership changes, an aggregate of \$532 thousand in Federal loss carry-forwards are limited to \$116 thousand annually.

10. Related party transactions:

Related party activity:

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

<u>\$ thousands</u>	<u>2010</u>	<u>2009</u>	<u>2008</u>
Business travel — aircraft expense	\$1,654	\$1,560	\$1,402

The Company from time to time during a portion of 2008 used an aircraft owned by Starwood Industries LLC, a company in which Jonnie R. Williams, Star's CEO and one of its largest shareholders, is a principal. In 2008 the aircraft owned by Starwood Industries LLC was sold and another aircraft that is owned by Starwood Aviation, Inc. ("Starwood Aviation"), a company wholly owned by Mr. Williams, was purchased. Effective September 1, 2008, the Company entered into an agreement for the use of the aircraft owned by Starwood Aviation. The 2008 agreement with Starwood Aviator 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 largest 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 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 2010, 2009 or 2008.

Due (to) from stockholders:

Due (to) from Stockholders consists of unsecured non-interest bearing advances of \$(50) thousand as of December 31, 2010 and December 31, 2009.

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. 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 4th. See Note 15, "Subsequent Events" for details of the transaction.

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 for the company and in communicating to the public health community and others information regarding Rock Creek's products and mission. The agreement runs for a period of one year from March 15, 2010, is terminable by either party without cause on fifteen days written notice and may be extended thereafter by the company at its discretion for one month periods. Under the agreement, Mr Chayet acts as an independent contractor and receives a consulting fee of \$6,000 per month and reimbursement for reasonable business expenses. Given Mr. Chayet's status as a Director of our company, 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.

11. 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 \$0.75 for each \$1.00 of employee contribution.

The Company made contributions of approximately \$83, \$103, and \$98 thousand, in 2010, 2009 and 2008, respectively.

12. 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. In applying the accounting standards for fair value determination the Company has modified its approach taking into account what the Company would have to pay someone to take over its debt obligations. The Company believes that it could pay someone the carrying value of the debt based on the current market conditions for obtaining credit. Considerable judgment is required in developing estimates of fair value; therefore, the estimates presented herein are not necessarily indicative of the amounts that the Company would realize in a current market exchange.

The estimated fair value of long-term debt is summarized as follows (\$ thousand):

2010		2009	
Carrying Amount	Estimated Fair Value	Carrying Amount	Estimated Fair Value
\$7,567	\$7,567	\$9,499	\$9,499

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 depository accounts. During 2010 the Company had amounts on deposit which exceed these insured limits and as of December 31, 2010, had \$10.2 million which exceeded these insured limits.

Trade accounts receivable for the Company's smokeless tobacco products result from sales of tobacco products to various customers throughout the United States. Credit is extended to customers after an evaluation for credit worthiness; however, the Company does not require collateral or other security from customers.

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, 2010. All required payments to date have been timely received. As such, management believes this receivable is fully collectible.

In 2010 the Company had no customers who accounted for more than 10% of sales or accounts receivable, however in the prior years the Company had the following customers who represented in excess of 10% of sales or accounts receivable.

	2009		2008	
	Sales	Accounts Receivable	Sales	Accounts Receivable
McLane Company, Inc.	10.21%	3.50%	—	—
Starco Inpex, Inc DBA Wholesale Outlet	6.44%	10.56%	8.7%	13.8%
Food Lion	7.62%	21.94%	11.6%	1.2%

13. Commitments, contingencies, and other matters:

Operating leases:

The Company also leases certain of its office, warehouse and manufacturing facilities under non-cancelable operating leases for approximately \$7 thousand per month; expiring in 2022. The Company leases office space for its Rock Creek subsidiary in Gloucester, Massachusetts for approximately \$3 thousand per month, maintains space for Star Scientific and Rock Creek in the Washington, DC area at a cost of approximately \$7 thousand per month and began leasing office space in February 2010 in Glen Allen, Virginia for its corporate functions and the tobacco marketing and administrative activities of Star Tobacco 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, 2010.

Year ending December 31,	\$ thousand
2011	\$ 150
2012	130
2013	131
2014	133
2015	133
Thereafter	518
	<u>\$1,195</u>

Rent expense for all operating leases was approximately \$258, \$124, and \$217 thousand, for the years ended December 31, 2010, 2009 and 2008, 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, 2010, the Company had deposited into escrow a net amount of approximately \$368 million 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 with Tantus for the exclusive licensing of its trademarks Sport®, MainStreet® and GSmoke® and ceased manufacturing cigarettes in June 2007. Given the discontinuation of the Company's cigarette operations in June 2007, and the focus on the sale of smokeless tobacco products, the Company does not anticipate having any material MSA escrow obligations in the future.

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 the 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 cured tobacco. On July 30, 2002, the Company 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). On August 27, 2002 the two suits were consolidated.

In April 2003, the parties filed dispositive Motions for Summary Judgment. After appointment of a Special Master to prepare Reports and Recommendations, or R&Rs, for the District Court on six of the Summary Judgment Motions, the District Court adopted without modification the Special Master's R&Rs, which collectively recommended that the District Court deny RJR's Summary Judgment Motions, and that the Motion for Summary Judgment on claim construction and definiteness be granted in part and denied in part. The District Court also issued an order denying RJR's other Motion for Summary Judgment seeking to limit the Company's damages claim.

On August 17, 2004, the case was transferred from Judge Alexander Williams to Judge Marvin J. Garbis. Judge Garbis over the next several months issued a series of orders concerning various aspects of the case and ordered that RJR's defense of inequitable conduct before the patent office be bifurcated from the remaining issues and tried before Judge Garbis beginning on January 31, 2005. That portion of the case was tried during the period January 31, 2005 to February 8, 2005. At the conclusion of the bench trial, the District Court advised the parties that it would take the matter under advisement, and expected to rule on this portion of the case at the same time that it ruled on two additional Summary Judgment Motions that were filed by RJR on January 25, 2005. On January 19, 2007, the District Court granted RJR's Motions for Summary Judgment in part and denied these motions in part. On RJR's Motion for Summary Judgment on the Effective Filing Date of the patents, the District Court held that September 15, 1999 was the effective filing date, but denied RJR Summary Judgment of Invalidity with regard to the patents-in-suit. On RJR's Motion for Summary Judgment on Indefiniteness, the District Court granted the motion on the basis that the term "anaerobic condition" was indefinite. On June 26, 2007 the District Court issued its ruling on RJR's inequitable conduct defense. In its ruling the District Court held the two patents unenforceable due to inequitable conduct in their procurement and a final judgment against our company was docketed on June 27, 2007. The Company immediately filed a notice of appeal as to the rulings issued in January 2007 and as to the ruling on the inequitable conduct defense with the United States Court of Appeals for the Federal Circuit, or Court of Appeals.

After full briefing by both parties and oral argument on March 7, 2008, the Court of Appeals on August 25, 2008 issued a unanimous opinion reversing the rulings by the District Court that had found the patents at issue in the RJR litigation invalid because of inequitable conduct during the prosecution of the patents and because the patents were indefinite. In October 2008 the case was remanded to the District Court. Following remand from the Court of Appeals, the case was 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. RJR filed its brief on August 2, 2010 and the Company's reply was filed on September 20, 2010. Oral argument on the appeal was held before a three-judge Panel of the Federal Circuit Court of Appeals on January 11, 2011. The Company is currently awaiting a decision from the Federal Circuit Court of Appeals on the appeal.

On November 30, 2009, RJR filed a motion for a bill of cost for \$442 thousand. RJR also filed a motion requesting the District Court to determine that this is an "exceptional" case under 35 USC § 285 and award attorneys' fees of approximately \$35 million under that provision and/or under 28 USC § 1927 on the basis that attorneys' fees were unreasonably multiplied during the litigation. As part of the 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 a renewed petition for a bill of cost that RJR filed on December 30, 2009. Any potential award of attorneys' fees should be eliminated if the Court of Appeals for the Federal Circuit overturns the jury verdict in the District Court or if the claims at issue in the reexamination proceeding in the U.S. Patent and Trademark Office are determined to be valid, and any award of costs should also be eliminated if the Federal Circuit overturns the jury verdict in favor of RJR. Because the likelihood of an unfavorable ruling on the fee motion and bill of cost and the amount of any potential assessment cannot be reasonably estimated, no amounts have been accrued for these items in the accompanying consolidated financial statements.

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 action against RJR. The future prosecution of the new complaint will be dependant on our achieving a reversal of the jury verdict of invalidity in the initial RJR action.

On December 31, 2008 and January 2, 2009, RJR filed requests in the U.S. Patent and Trademark Office to reexamine the two patents that are the subject of the patent infringement litigations described above. In February and March 2009, the Patent and Trademark Office granted the reexamination requests, agreeing to review the patentability of the subject matter claims 4, 12 and 20 of the '649 patent and claim 41 of the '401 patent. On March 10, 2011, the Patent and Trademark Office confirmed the validity of each of the claims of the '649 and '401 patents that were under reexamination and closed each of the reexamination proceedings.

The Company has entered into fee arrangements with counsel in several litigation and related matters under which certain costs related to the litigation are being advanced by counsel on the Company's behalf. Given the contingent nature and the fact that a probability assessment of liability cannot be made at this time, no accrual has been made for this contingent liability. The Company has paid or accrued all existing obligations. Also, as part of its fee arrangements in certain of these matters, the Company has agreed to pay counsel a percentage of any damage award, a percentage of the resulting payments the Company actually receives in the event that the litigation is resolved in its favor or a result fee, in return for a cap on fee payments during the litigation.

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. This Company applied for a correction of the assessment and a total abatement of the tax on the grounds that the 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 Company's request for reconsideration of the state's sales and use tax assessment with respect to our 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. The Company disagrees with the ruling by the Commissioner and intends to timely pursue this matter through all available means. The sales and

use tax assessment plus penalties and interest together, as of December 31, 2010, totaled \$1.5 million. Interest will continue to accrue during the Company's continued pursuit of a resolution of this matter.

Except as set forth above, there are no other litigation matters pending that could be expected to materially harm the Company's results of operations and financial condition.

14. Restructure Charge

During the quarter ending December 31, 2009 the Company restructured and reduced its tobacco sales force and certain general and administrative personnel in response to the slower than expected sales of its dissolvable tobacco products. As part of the restructuring effort, the Company has limited the day-to-day activity of its sales force and is focusing its marketing efforts on store level support and consumer marketing in Virginia and contiguous states, with the intent of gaining more extensive market penetration and product acceptance in those areas. Notice of the Company's restructuring effort was announced on December 3, 2009 and separation dates for effected employees occurred on various dates through January 31, 2010. The restructuring charge in the accompanying consolidated financial statements reflects severance in the form of salary continuation and benefit continuation payments for periods up to twelve months for those employees who accepted the voluntary termination as part of the restructuring effort prior to December 31, 2009.

15. Subsequent Events:

Stock options issued

On January 31, 2011 the Company's 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. The Black Scholes value charged to the first quarter operating expense amounted to \$779 thousand.

On March 14, 2011 the Company's Board of Directors, on recommendation of the Compensation Committee, approved the issuance of additional stock option awards to three off the Company's Named Executives as part of the terms of employment agreements entered into with these executives on the same date. Two of the option grants require shareholder approval.

Corporate Funding

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 ("Common Stock"), at an exercise price of \$1.00 per share (the "Prior Warrant").

Pursuant to the February 28 Agreement, in order to induce the Warrant Holder to immediately exercise the Prior Warrant, the Company agreed to grant the Warrant Holder a new warrant with an exercise price of \$2.00 per share for the same amount of shares of Common Stock as the Prior Warrant (the "New Warrant") in exchange for the Warrant Holder's immediate and full exercise of the Prior Warrant whereby the Warrant Holder purchased 2,000,000 shares of Common Stock. The February 28 Agreement resulted in gross proceeds to the Company of \$2.0 million. The New Warrant is exercisable immediately into an aggregate of 2,000,000 shares of Common Stock and expires on February 28, 2016. Additionally, the February 28 Agreement grants the Warrant Holder certain customary resale registration rights with respect to the shares Common Stock underlying the New Warrant.

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"), including Jonnie R. Williams, a member of the Company's Board of Directors and the Company's Chief Executive Officer, to sell 4,856,730 shares of Common Stock (the "March 4 Shares"), at \$1.84 per share 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"). In addition to purchasing his respective shares of Common Stock for \$1.84 per share, Mr. Williams also paid the Company \$0.125 per Warrant purchased in the March 4 Offering. The March 4 Offering resulted in gross proceeds to the Company of \$9.0 million. The Warrants are first exercisable on September 4, 2011 and expire on September 4, 2016. Additionally, the March 4 Agreement granted the March 4 Investors certain customary resale registration rights with respect to the March 4 Shares and shares of Common Stock underlying the Warrants. Mr. Williams's participation in the March 4 transaction was approved by the Company's Audit Committee on March 4, 2011.

Employment agreements and performance stock options

Following approval by the Board of Directors, upon recommendation of the Compensation Committee, on March 14, 2011, the Company entered into an executive employment agreement with Jonnie R. Williams, the Company's Chief Executive Officer, a third amended and restated executive employment agreement with Paul L. Perito, the Company's President and Chief Operating Officer, and an amended and restated executive employment agreement with Curtis Wright, IV, MD, MPH, the Senior Vice President, Medical/Clinical Director of Rock Creek Pharmaceuticals, Inc., the company's wholly owned subsidiary. The before mentioned employment agreements are referred to as the "Williams Employment Agreement," "Perito Employment Agreement" and the "Wright Employment Agreement," respectively.

The Williams Employment Agreement

Under the Williams Employment Agreement, Mr. Williams will be provided an annual base salary payable in cash in such amounts as approved by the Company's Board of Directors, upon the recommendation of the Compensation Committee, which initially will be the same base salary of \$1,000,000 that Mr. Williams has been receiving and which will be subject to further adjustment from time-to-time in the good faith discretion of the Board of Directors. Mr. Williams also will be eligible to receive discretionary bonuses under the Williams Employment Agreement upon the Company's achievement of certain performance goals established by the Compensation Committee and approved by the Board of Directors. The Williams Employment Agreement further provides that Mr. Williams will be awarded performance based options to purchase 4,900,000 shares of common stock under the Company's 2008 Incentive Award Plan. These options will vest in such amounts and upon the achievement of the performance goals set forth on Schedule 2.3 to the Williams Employment Agreement, provided that such performance goals and vesting schedule is approved by the Company's stockholders. The options are for a 10-year term from March 14, 2011 and have an exercise price of \$2.95 per share. The estimated maximum value of the options, as determined by the Black Scholes valuation method, is \$12.3 million. The Company expects that substantially all of this amount would be recorded in the Company's financial statements for the 2011 fiscal year ending December 31, 2011 with the remainder in fiscal year 2012. The Williams Employment Agreement is effective immediately and will expire on December 31, 2012, absent an extension thereof following the non-binding discussions regarding an extension that are mutually agreed to commence in September 2012 as provided therein.

In addition, the Williams Employment Agreement will entitle Mr. Williams to paid vacation and other bonuses and benefits in accordance with the Company's plans and arrangements, on the same basis as other employees of the Company, as well as reimbursement of general business and travel expenses.

In the event the Mr. Williams' employment is terminated without "Cause" or Mr. Williams resigns his employment for "Good Reason" (as such terms are defined in the Williams Employment Agreement), Mr. Williams will be entitled to all salary, benefits, bonuses and other compensation that would be due thereunder through the end of the term of thereof had the Company not terminated Mr. Williams' employment or had Mr. Williams not so resigned.

The Perito Employment Agreement

Under the Perito Employment Agreement, Mr. Perito will be provided an annual base salary payable in cash in such amounts as approved by the Company's Board of Directors, upon the recommendation of the Compensation Committee, which initially will be the same base salary of \$1,000,000 that Mr. Williams has been receiving and which will be subject to further adjustment from time-to-time in the good faith discretion of the Board of Directors. Mr. Perito also will be eligible to receive discretionary bonuses under the Perito Employment Agreement upon the Company's achievement of certain performance goals established by the Compensation Committee and approved by the Board of Directors. The Perito Employment Agreement further provides that Mr. Perito will be awarded performance based options to purchase 4,000,000 shares of common stock under the Company's 2008 Incentive Award Plan. These options will vest in such amounts and upon the achievement of the performance goals set forth on Schedule 2.3 to the Perito Employment Agreement, provided that such performance goals and vesting schedule is approved by the Company's stockholders. The options are for a

10-year term from March 14, 2011 and have an exercise price of \$2.95 per share. The estimated maximum value of the options, as determined by the Black Scholes valuation method, is \$10.0 million. The Company expects that substantially all of this amount would be recorded in the Company's financial statements for the 2011 fiscal year ending December 31, 2011 with the remainder in fiscal year 2012. The Perito Employment Agreement is effective immediately and will expire on December 31, 2012, absent an extension thereof following the non-binding discussions regarding an extension that are mutually agreed to commence in September 2012 as provided therein.

In addition, the Perito Employment Agreement will entitle Mr. Perito to paid vacation and other bonuses and benefits in accordance with the Company's plans and arrangements, on the same basis as other employees of the Company, as well as reimbursement of general business and travel expenses and professional education expenses and fees.

In the event the Mr. Perito's employment is terminated without "Cause" or Mr. Perito resigns his employment for "Good Reason" (as such terms are defined in the Perito Employment Agreement), Mr. Perito will be entitled to all salary, benefits, bonuses and other compensation that would be due thereunder through the end of the term of thereof had the Company not terminated Mr. Perito's employment or had Mr. Perito not so resigned.

The Wright Employment Agreement

Under the Wright Employment Agreement, Dr. Wright will be provided an annual base salary of \$330,000 payable in cash. The Wright Employment Agreement further provides that Dr. Wright will be awarded performance based options to purchase 300,000 shares of common stock under the Company's 2008 Incentive Award Plan. These options will vest ratably on an annual basis subject to the achievement certain performance goals set forth in Section 2(b)(iii) of the Wight Employment Agreement. The options are for a 10-year term from March 14, 2011 and have an exercise price of \$2.95 per share. The estimated maximum value of the options, as determined by the Black Scholes valuation method, is \$0.7 million which will be recorded in the Company's financial statements during the fiscal period 2011 thru 2013. The Wright Employment Agreement is effective beginning on March 14, 2011 and will expire on March 14, 2014. The Wright Employment Agreement provides the Company an option to renew the Wright Employment Agreement for successive 12 month terms by providing Dr. Wright notice of such an extension at least 30 days prior to the expiration of the then applicable term. Absent such an extension, following expiration on March 14, 2014, the Wright Employment Agreement will continue on a month-to-month basis upon mutual agreement of the parties thereto.

In addition, the Wright Employment Agreement will entitle Dr. Wright to paid vacation and other bonuses and benefits in accordance with the Company's plans and arrangements, on the same basis as other employees of the Company, as well as reimbursement of general business and travel expenses and professional education expenses and fees.

In the event the Dr. Wright's employment is terminated without "Cause" or Dr. Wright resigns his employment for "Good Reason" (as such terms are defined in the Wright Employment Agreement), Dr. Wright will be entitled to all salary, benefits, bonuses and other compensation that would be due thereunder through the end of the term of thereof had the Company not terminated Dr. Wright's employment or had Dr. Wright not so resigned.

The foregoing summary is qualified in its entirety by reference to the full text of each of the Williams Employment Agreement, Perito Employment Agreement and Wright Employment Agreement, copies of which are attached as Exhibits 10.78, 10.79 and 10.80 respectively, to this Annual Report on Form 10-K.

16. Quarterly results (unaudited):

The following is a summary of quarterly unaudited results of operations for the years ended December 31, 2010, 2009 and 2008.

<u>\$ thousands except per share data</u>	<u>March</u>	<u>June</u>	<u>September</u>	<u>December</u>
2010				
Revenues	\$ 149	\$ 335	\$ 211	\$ 153
Gross profit(loss)	(322)	(414)	(197)	(364)
Net loss	(4,925)	(13,501)	(4,823)	(4,952)
EPS — net loss basic and diluted	(0.04)	(0.11)	(0.04)	(0.04)
	<u>March</u>	<u>June</u>	<u>September</u>	<u>December</u>
2009				
Revenues	\$ 148	\$ 238	\$ 232	\$ 90
Gross profit(loss)	(292)	(589)	(400)	(639)
Net loss	(5,231)	(7,026)	(4,902)	(5,562)
EPS — net loss basic and diluted	(0.06)	(0.07)	(0.05)	(0.05)
	<u>March</u>	<u>June</u>	<u>September</u>	<u>December</u>
2008				
Revenues	\$ 146	\$ 52	\$ 137	\$ 117
Gross profit(loss)	(324)	(497)	(436)	(416)
Net loss	(5,517)	(6,387)	(4,397)	(2,036)
EPS — net loss basic and diluted	(0.07)	(0.07)	(0.05)	(0.01)

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

17. Segment Information

The Company's operating subsidiaries manufacture, distribute and sell two lines of consumer products, dissolvable tobacco and dietary supplements. These products constitute the Company's reportable segments.

Star Scientific's chief operating decision maker reviews the income from the operating companies to evaluate segment performance and allocate resources. The income from the Company's operating segments excludes general corporate expenses and amortization of intangibles. Interest and other debt expense, net, and provision for income taxes are centrally managed at the corporate level and, accordingly, such items are not presented by segment since they are excluded from the measure of segment profitability reviewed by the Company's chief operating decision maker.

	<u>2010</u>	<u>2009</u>	<u>2008</u>
	\$ thousands		
Revenues:			
Dissolvable tobacco	\$ 785	\$ 708	\$ 451
Dietary supplement	63	—	—
Total revenue	<u>848</u>	<u>708</u>	<u>451</u>
Operating losses:			
Dissolvable tobacco	(3,401)	(6,462)	(6,499)
Dietary supplement	(5,928)	(2,270)	—
Depreciation and amortization	(311)	(315)	(602)
Corporate expenses	(18,574)	(13,714)	(13,778)
Operating losses	<u>(28,214)</u>	<u>(22,761)</u>	<u>(20,879)</u>
Interest (expense) income-net	(311)	(237)	(342)
Miscellaneous (expense) income-net	244	198	657
Income tax benefit	—	—	2,225
Net losses	<u>\$(28,281)</u>	<u>\$(22,800)</u>	<u>\$(18,339)</u>

The following table provides allocation of assets by segment.

	<u>December 31,</u> <u>2010</u>	<u>December 31,</u> <u>2009</u>
	\$ thousands	
Net assets:		
Dissolvable tobacco	\$ 2,039	\$ 1,756
Dietary supplement	4,451	27
Corporate—includes \$12,693 and \$12,314 in cash, respectively	<u>13,795</u>	<u>13,451</u>
Total net assets	<u>\$20,285</u>	<u>\$15,234</u>

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Marketing Offices**

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Manufacturing Facilities**

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Star Scientific, Inc.

Board of Directors

Paul L. Perito, Esquire, *Chairman*
Jonnie R. Williams
Christopher C. Chapman, MD
Neil L. Chayet, Esquire
Burton J. Haynes, Esquire
Mario V. Mirabelli, Esquire
Richard L. Sharp

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*
Sara Troy Machir – *Vice President of Communications
and Investor Relations*

Star Tobacco, Inc.

Board of Directors

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David M. Dean
Paul H. Lamb, III

Officers

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Park A. Dodd, III – *Secretary & Treasurer*
Sheldon L. Bogaz – *Vice President of Trade Operations*

Rock Creek Pharmaceuticals, Inc.

Board of Directors

Paul L. Perito, Esquire
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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