



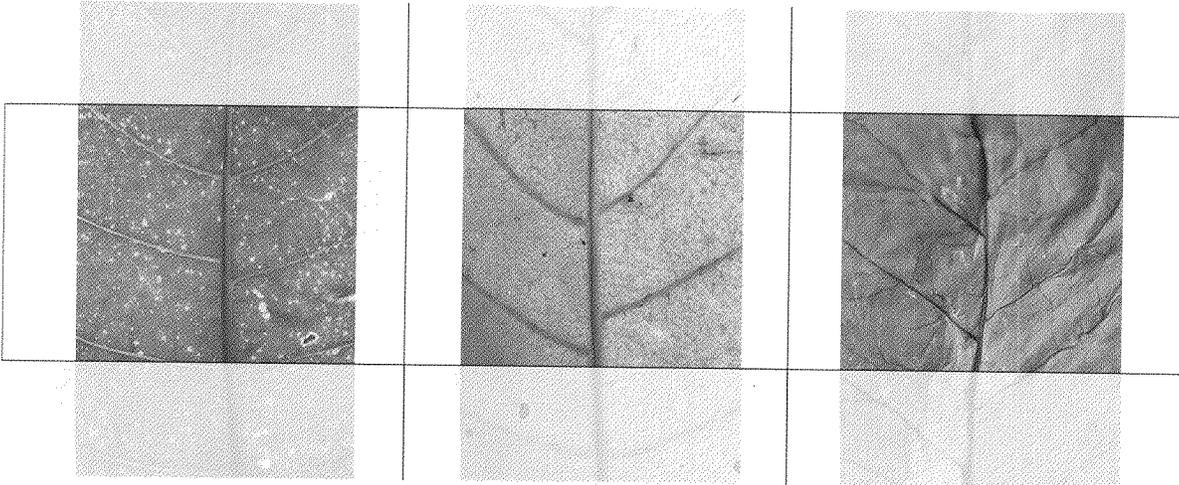
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# STAR SCIENTIFIC, INC

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Washington, DC 20549



## ANNUAL REPORT ON 2008

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# 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 -5 2009

(Mark One)

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

Washington, DC  
110

For the fiscal year ended December 31, 2008

**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.)*

**16 South Market Street, Petersburg, VA 23803**

*(Address of principal executive offices)*

**(804) 861-0681**

*(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 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 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 whether the registrant is a large accelerated filer, a accelerated filer, a non-accelerated filer, or a small reporting company.

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
*(Do not check if a smaller 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, 2008 was approximately \$75,731,280. 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 9, 2009 — 99,847,866 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 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 Pharmaceutical, 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, 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 and related products, market acceptance of our new smokeless tobacco products, competition from companies with greater resources than us, our decision not to join the Master Settlement Agreement, and our dependence on key employees and on our strategic relationships with Brown & Williamson Tobacco Corporation in light of its combination with R.J. Reynolds Tobacco Company, Inc., and the impact of potential litigation, if initiated against or by individual states that have adopted the Master Settlement Agreement, which could be materially adverse to us.

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 tobacco company with a mission to reduce toxins in tobacco leaf and tobacco smoke. 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 TSNAs;
- the manufacture, sales, marketing and 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 cigarett® pieces and STONEWALL Hard Snuff®;
- the licensing of trademarks for certain of our cigarette brands that we discontinued manufacturing in 2007, consistent with our previously announced plan to transition from the sale of cigarettes to low-TSNA smokeless tobacco products; and
- 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 potentially related products such as neutraceuticals.

#### Our History

In February 1998, Star Tobacco completed a share exchange with Eye Technology, Inc., a publicly held OTC Bulletin Board company based in Minneapolis, Minnesota. Eye Technology was organized as a Delaware corporation in 1985. While Eye Technology became Star Tobacco's parent corporation, control of Eye Technology in effect shifted to the former stockholders of Star Tobacco and the management of Star Tobacco became the management of Eye Technology. By December 30, 1998, the assets and liabilities that comprised the pre-merger business of Eye Technology had been sold or liquidated, and the stockholders of Eye Technology voted to change its name to Star Scientific, Inc. Our primary corporate focus from that time forward has centered on the sales, marketing and development of tobacco products that expose adult tobacco users to lower levels of toxins and, pending the results of future peer-reviewed studies, may be proven to reduce health risks.

Historically our revenues have been generated principally through the sale of discount cigarettes by Star Tobacco. Star Tobacco was incorporated in 1990 and, until 1994, was primarily a contract manufacturer of cigars and cigarettes. In late 1994, Star Tobacco 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, Star Tobacco 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, Star Tobacco shifted its near-term research to technology focused on reducing the carcinogenic TSNAs, particularly the NNNs and NNKs, in the tobacco leaf and tobacco smoke.

#### Our Strategy

Our long-term focus is the research, development and licensing of technology for the production of very low-TSNA tobacco and related products, particularly dissolvable smokeless tobacco products, that expose adult tobacco users to substantially lower levels of toxins as compared to other smoked and smokeless tobacco products. Our overall objective is to ultimately reduce the range of serious health hazards associated with the use of smoked and smokeless tobacco products, both in the form of low-TSNA smokeless tobacco products and related 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, given available technology. Accordingly, we believe we have a corporate responsibility to continue our research and development efforts to manufacture tobacco products with the lowest level of toxins possible, particularly through the development of products containing tobacco cured using our StarCured® tobacco curing process.

To facilitate our long-term strategy to exit the cigarette business as soon as practically possible, we entered into a license agreement with Tantus Tobacco LLC, or Tantus, in 2007 for the exclusive license of our cigarette trademarks Sport®, MainStreet® and GSmoke® to Tantus. We ceased the sale of those brands in 2007 and discontinued our cigarette operations at that time. Additionally, in 2007 we incorporated a new subsidiary, Rock Creek, to pursue the development and regulatory approval of pharmaceutical products designed to treat tobacco addiction and a range of neurological conditions and related products such as neutraceuticals.

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 is now set for a jury trial beginning on May 18, 2009 in the United States District Court for the District of Maryland, or District Court, (ii) the development of ARIVA® and STONEWALL Hard Snuff®, our low-TSNA dissolvable smokeless tobacco products, (iii) the license of low-TSNA products and the technology behind our StarCured® tobacco curing process, and (iv) the initial development efforts of Rock Creek. 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 smokeless tobacco products, develop pharmaceutical products to treat tobacco addiction and a range of neurological conditions and related products, and to pursue licensing arrangements for those products and related technology.

## **Our Technology**

We are the exclusive licensee of our technology for producing low-TSNA tobacco, which is utilized in ARIVA® and STONEWALL Hard Snuff®, our low-TSNA dissolvable smokeless tobacco products. This technology serves as the basis of our initiative to develop pharmaceutical products to treat tobacco addiction and a range of neurological conditions and potentially related products such as neutraceuticals, in each case, through our Rock Creek subsidiary.

### *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 the lowest possible levels (with carcinogenic NNKs and NNNs 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.

### *Our Intellectual Property Rights*

Our proprietary technology for producing low-TSNA tobacco has been licensed exclusively from Regent Court Technologies, LLC, or Regent Court, a company in which Jonnie R. Williams, the technology's inventor, our founder, Chief Executive Officer and largest stockholder, 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 inhibitor, or MAO, agents in treating neurological conditions. For additional information related to our proprietary curing process, see “— Our Patents, Trademarks and Licenses.” 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. In the future, we intend, through our Rock Creek subsidiary, acting alone or working with a major pharmaceutical company, to pursue the development of tobacco-based cessation products. We also plan to direct efforts to develop a product designed to help patients who have relapsed after a trial of smoking cessation to prepare for another cessation attempt, particularly if Congress grants jurisdiction over all tobacco products to the U.S. Food and Drug Administration, or FDA.

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, which has been set for a jury trial in the United States District Court for the District of Maryland beginning on May 18, 2009. A favorable outcome of the RJR litigation is crucial to our further development, implementation and licensing of our proprietary technology for the curing of tobacco, the sales, marketing and development of our very low-TSNA dissolvable smokeless tobacco products and our development of a pharmaceutical product to treat tobacco related dependence and related products such as neutraceuticals. Accordingly, we have dedicated substantial time and resources to defend and enforce our proprietary rights with respect to these patents at issue in our lawsuit against RJR. For additional information related to our lawsuit against RJR, see “Item 3. Legal Proceedings.”

## **Our Products**

### *Smokeless Tobacco Products*

Over the past seven 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 Scientific Advisory Board and other independent scientific, medical and public health advisors who 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.

ARIVA® and STONEWALL Hard Snuff® are currently marketed nationwide through tobacco distributors and wholesalers. In addition, we have introduced ARIVA® and STONEWALL Hard Snuff® through direct arrangements with several national retail chains, including Walgreen’s and RiteAid drug stores, and through other national distributors experienced with consumer products. In 2007, we introduced two new blends of STONEWALL Hard Snuff®, “Natural” and “Java” in addition to the original “Wintergreen” blend. We also introduced a “Java” blend of ARIVA® in 2008.

Our domestic sales of ARIVA® and STONEWALL Hard Snuff® have been de minimis to date and we did not have any international sales in 2008. 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 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources.”

#### *Tobacco-based Pharmaceutical Products*

In 2007, we incorporated a new subsidiary, Rock Creek, to pursue a range of pharmaceutical products that have a botanical, tobacco-based component. Through Rock Creek, we intend to pursue the development of 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 related products such as neutraceuticals. 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.

Following the incorporation of Rock Creek, a search was undertaken for a Clinical/Medical Director who would oversee our subsidiary’s anticipated clinical trials and new drug development efforts. On February 28, 2008, we announced that Curtis Wright, MD, MPH had joined our company as Senior Vice President, Medical/Clinical Director of Rock Creek. 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.

In late 2008 Rock Creek completed a study with 49 cigarette smokers to assess the effectiveness of STONEWALL Hard Snuff® in relieving cigarette withdrawal symptoms as compared to a conventional over-the-counter, or OTC, nicotine replacement product used in connection with nicotine replacement therapy or NRT, which study also incorporated placebos of each product. Both the NRT and the STONEWALL Hard

Snuff® products were statistically effective in reducing cigarette withdrawal symptoms. Based on the results of this study, we are moving forward to formulate a botanical-based product under conditions that comply with FDA Good Manufacturing Practices, or GMP, for drug products and, thereafter, plan to conduct a study to determine the bioequivalence of the proposed botanical-based product against similar products used in connection with NRT. Depending upon results of the bioequivalence study, we plan to seek FDA approval of a botanical-based NRT cessation product for use by adult tobacco users who smoke and/or use smokeless tobacco products. Through Rock Creek, we also are continuing to explore the development of other pharmaceutical products with clinical claims, as well as a “relapse prevention product” to assist smokers during nicotine withdrawal, with the goal of higher “quit” rates for long term smokers who have failed in their treatments with conventional NRT smoking cessation products and related products.

### *Discount Cigarettes*

Until June 2007, when we exited the cigarette business, the majority of our revenues were derived from the sale of discount cigarettes. However, since 2000, our discount cigarette business had experienced a significant decline in sales, partly due to intensified pricing competition from wholesalers selling deeply discounted, foreign-manufactured cigarettes. In May 2007, we entered into an agreement with Tantus for the exclusive license of 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, consistent with our previously announced goal to exit from the cigarette business as soon as practically possible. Although we retain the right to manufacture and sell other branded cigarettes, we plan to continue to focus our efforts on the sale of our low-TSNA dissolvable smokeless tobacco products, as opposed to cigarettes. Accordingly, we accounted for our cigarette operations as “discontinued operations” in our consolidated financial statements beginning with the second quarter of 2007. See our consolidated financial statements included in Item 15 of this Report for further information on our discontinued operations and results of operations.

### **Our Research and Development**

In the mid-1990’s, we commenced research and development activities based on newly conceived technology for the processing of tobacco that substantially prevents the formation of TSNA’s in cured tobacco. Our research and development activities have focused on: (i) perfecting and testing methods for processing very low-TSNA tobacco; (ii) developing products that incorporate our specially processed tobacco, including products for the smoked and smokeless tobacco markets; (iii) establishing and expanding our patent portfolio; and (iv) developing relationships with tobacco farmers, as well as the tobacco industry, with the intent to commercialize our processes through licensing and royalty arrangements, among other vehicles, to generate revenue. 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. Through our license agreement with Regent Court, we have exclusive rights to 12 U.S. patents, other foreign patents and pending patent applications relating to the process of producing very low-TSNA tobacco as well as products developed using this technology. For additional information related to our intellectual property, see “— Our Patents, Trademarks and Licenses.”

Beginning in 2003 we deferred the initiation and continuation of certain research projects by Star Scientific because of the lack of working capital and have not convened a meeting of our Scientific Advisory Board since that time. Prior to the suspension of these initiatives, our research and development efforts were directed at assessing the impact that products with reduced toxin levels may have on the range of serious health hazards linked with the use of conventional smoked and smokeless tobacco products, as well as encouraging scientists in the U.S. and Europe to pursue TSNA-related research. While we have deferred our research efforts, we designed several additional scientific studies to determine, among other things, whether a reduction in TSNA’s can be equated with a reduction in health risk, to assess biomarker differences that can be equated to levels of various toxins in smoked versus smokeless tobacco, and to measure the impact of the decline in TSNA exposure in low-TSNA smokeless tobacco compared to traditional cigarette products. Subject

to the availability of sufficient working capital, we hope to initiate these studies through independent laboratories and universities beginning in 2009. We expended approximately \$0.3 million in 2008 in product development initiatives aimed at improving our low-TSNA smokeless tobacco products and expect to continue to expend similar amounts on this effort in 2009. See our consolidated financial statements included in Item 15 of this Report for further information on our discontinued operations and results of operations.

Since 2007, we also have been exploring the development of a range 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, in each case, through Rock Creek. In 2008, through Rock Creek, we completed an initial study to determine the ability of STONEWALL Hard snuff® to relieve cigarette withdrawal symptoms compared to a conventional OTC nicotine replacement product. Based on the results of this study, we are moving forward to formulate a GMP botanical-based product and, thereafter plan to conduct a study to determine the bioequivalence of the proposed botanical-based product against similar nicotine replacement products. Depending upon results of the bioequivalence study, we plan to seek FDA review for a botanical-based NRT cessation product for use by adult tobacco users who smoke and/or use smokeless tobacco products. We are also continuing to explore the development of other pharmaceutical products with clinical claims, as well as a "relapse prevention product" to assist smokers during nicotine withdrawal and related products such as neutraceuticals.

Our ability to resume and continue these research efforts, including advancement of the research and development activities of 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. 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 of this Report for further information on our working capital constraints and results of operations.

## **Our Prior Research and 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.

### *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's. The Advance® cigarette reduced additional toxic smoke constituents through a unique activated carbon/acetate filter. Advance® also differed from conventional premium cigarette brands because it provided adult tobacco consumers with enhanced health warnings beyond those required by the Surgeon General on the back of the package, and "onserts" that contained comparative content information and additional health-related information. In 2001, Brown & Williamson Tobacco Corporation, or B&W, initiated a test market of a version of the Advance® cigarette in Indianapolis, Indiana and expanded the test market to Phoenix, Arizona in 2004. Following the combination of B&W and RJR in 2004, the test market was discontinued. See "— Our Relationship with B&W."

### *Prior Development of CigRx™ and Tobacco-Flavored Chewing Gum Containing Tobacco Extract*

In 1997, we submitted a cigarette product called CigRx™ to the FDA as a pharmaceutical product. CigRx™ 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 under the direction of Professor William Barr, Director of the Center for Drug Studies. The study, involving male and female subjects, used a cross-over methodology designed to test in vivo elimination or reduction of TSNA's following the smoking of CigRx™ cigarettes as

compared to the subjects' normally used cigarettes. These test cigarettes were made entirely from flue-cured Virginia tobacco with no added flavorings. The average total TSNA levels in the tobacco used in CigRx™ at the time of testing was about 100 parts per billion, as compared to TSNA Levels of more than 3,000 parts per billion in the most popular cigarette brands. As measured by the current Federal Trade Commission, or FTC, method, the CigRx™ cigarettes used in the study delivered substantially less carbon monoxide to the subjects (4.8 milligrams versus 12.2 milligrams) and about half as much tar (7.0 milligrams versus 14.0 milligrams) as compared to the average carbon monoxide and tar delivery levels from the best selling full-flavored cigarettes. The study contrasted our CigRx™ product with conventional brands in terms of breath levels of carbon monoxide, blood levels of nicotine and urinary levels of TSNA. With regard to the CigRx™ product, blood nicotine levels were somewhat higher and carbon monoxide was substantially lower. The subjects' urinary levels of TSNA (as measured by NNAL) were analyzed by the American Health Foundation. The average levels of NNAL and its metabolite after nine days on the CigRx™ product 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. We secured an additional Investigational New Drug Application, or IND, from the FDA for this product. While the initial results of the IND protocol testing of the gum product were positive, we determined that further testing as well as the preparation and submission of required marketing applications to the FDA for that product or for the CigRx™ product 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. Thereafter, we focused our efforts on the development of our low-TSNA tobacco products, including the Advance® cigarette, Stonewall® moist and dry snuff, and the ARIVA® and STONEWALL Hard Snuff® dissolvable smokeless tobacco products. 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 neutraceuticals.

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

Our sales and marketing activities are lead by Mr. Jonnie R. Williams, 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. On a day-to-day basis the General Manager of Star Tobacco supervises a staff of sales managers who currently are focused on our dissolvable smokeless tobacco products. It has been our strategy to rely in large part on the sale of our dissolvable hard tobacco brands to distributors who, in turn, promote our hard tobacco products to retail customers. We provide our distributors with point-of-sale materials such as posters, pole signs, display racks and counter top and floor displays and other marketing materials for use by their direct sales forces and for distribution to their retail customers. We also work to facilitate the direct placement and sale of our products at the retail level through cooperative arrangements with sales personnel employed by our customers. Under these arrangements, our customers' sales representatives receive a commission based on the level of retail sales of our products within their territory. In September 2008, we retained Roger Grogman, the former vice-president of marketing for McLane Company, Inc. on an exclusive basis to assist in marketing our unique dissolvable smokeless tobacco products to adult tobacco consumers.

We sell our smokeless tobacco products through approximately 116 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.

## **Our Availability of Raw Materials and Manufacturing Capabilities**

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 electronic 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 continue to own 37 StarCured® barns, and we believe that these barns will be sufficient to provide us with an adequate supply of StarCured® tobacco for our low-TSNA dissolvable smokeless tobacco products, and for other needs.

In 2002, we installed 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. We plan to move these manufacturing operations to a larger immediately adjacent facility, which we lease from the Mecklenburg County Industrial Development Authority by August 2009. 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 to 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.

## **Our Competition**

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, B&W. UST, Inc., or UST, has been the dominant manufacturer in the smokeless segment of the market, which market also includes companies such as Conwood Company, LLC, or Conwood, a wholly owned subsidiary of RAI, and Swedish Match AB, or Swedish Match. In 2008 Altria Group, Inc., or Altria, Philip Morris’s parent company also expanded its role in the smokeless tobacco market through the acquisition of UST. Recently, there has been increased competition between the smoked and smokeless tobacco markets as companies have begun to market smokeless tobacco as a less toxic alternative to smoked tobacco, and 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 claims to have reduced levels of carcinogens. UST also has been test marketing a pouch-style smokeless tobacco product, which it claims has low levels of TSNA. 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. With the recent introduction of smokeless tobacco products by Philip Morris and RJR, our sales of Stonewall Hard Snuff® will also face competition from these tobacco manufacturers.

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 and enforcing the patents for the technology used to produce such products, to which we are the exclusive licensee, 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.

In the past we competed with the major cigarette manufactures in the sale of our discount cigarette products. As a result of our licensing the trademarks for our cigarette brands to Tantus and the decision to cease manufacturing any cigarette products in favor of the sale of our low-TSNA smokeless tobacco products, we are no longer competing directly with the manufactures of smoked tobacco products in that segment of the tobacco market.

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. Accordingly, such products may compete with ARIVA® and STONEWALL Hard Snuff® in the "When You Can't Smoke"® market. There are also non-tobacco cigarettes produced with fillers such as lettuce and herbs. 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.

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 Relationship with B&W**

Beginning in October 1999, we entered into a series of agreements with B&W for, among other things, the purchase of low-TSNA StarCured® tobacco, the licensing of other low-TSNA tobacco and the development of low-TSNA cigarettes and smokeless tobacco products. Under the agreements, B&W purchased very low-TSNA StarCured® tobacco from us or our participating StarCured® farmers during each growing season from the period 1999 through 2003, and we jointly developed the first low-TSNA cigarette "Advance®." In January 2000, we also entered into two agreements under which B&W manufactured cigarettes for us and supplied us with leaf tobacco for use in our tobacco products. B&W ceased manufacturing cigarettes for us as of December 31, 2002, and ceased supplying tobacco to us in the first half of 2003.

In April 2001, we entered into a series of restated agreements with B&W, whereby B&W agreed 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 \$11.0 million as of December 31, 2008. Pursuant to these agreements, we also had a trade payable balance to B&W that was paid in full as of August 2007. In April 2001 we also entered into agreements with B&W that permitted B&W to test market our low-TSNA Advance® cigarette as well as a hard tobacco smokeless product utilizing our technology, the latter of which we refer to as the Hard Tobacco Agreement.

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 the new operating entity established as a result of this business combination had assumed all of the rights and obligations under the April 2001 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, and found that B&W had attempted to assign the April 2001 agreements to the new RJR/B&W operating entity but that we had not consented to the assignment. 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. We have been advised by B&W Holdings that the tobacco and cigarette division of B&W has been combined with the operations of RJR. Following the B&W/RJR combination, the test market of the Advance® cigarette was discontinued and in December 2004 RJR (as the purported successor to B&W) advised us that the hard tobacco test market was not successful and that the Hard Tobacco Agreement was terminated as of that date.

## **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 45 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 latest expiration date of a U.S. patent subject to the License Agreement is 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.

In late December 2008 and early January 2009, RJR filed requests with the Patent and Trademark Office to reexamine the two patents that are the subject of our patent infringement litigation against RJR. On February 12, 2009, the Patent and Trademark Office granted the reexamination request as to one of the patents and on March 5, 2009 granted the other request. The reexamination process will proceed in due course, and

we believe that this process will likely last at least two years. During the process the Patent and Trademark Office will undertake a review of the patentability of the subject matter of the patents in view of the prior art cited in RJR's requests.

*Patents and Proprietary Rights*

We believe that our patent portfolio establishes us as a world leader in curing technology that consistently produces very low-TSNA tobacco. Under the License 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 TSNAs 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. 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 (Reissued as RE 38,123 E)	10/24/2000	Tobacco Products Having Reduced Nitrosamine Content	06/28/2016
U.S. Patent No. 6,202,649	03/20/2001	Method of Preventing Nitrosamine Formation by Treating Tobacco in Controlled Environment	12/02/2016
U.S. Patent No. 6,311,695 B1	11/06/2001	Method of Treating Tobacco With High Frequency Energy to Prevent Nitrosamine Formation	06/28/2016
U.S. Patent No. 6,338,348 B1	01/15/2002	Method of Treating Tobacco With Microwave Energy to Prevent Nitrosamine Formation	06/28/2016
U.S. Patent No. 6,350,479 B1	02/26/2002	Method of Administering Alcohol Extracts of Tobacco	06/04/2019
U.S. Patent No. 6,425,401	07/30/2002	Method of Preventing Nitrosamine Formation By Treating Tobacco in Controlled Environment	12/02/2016
U.S. Patent No. 6,569,470 B2	05/27/2003	Method of Administering Alcohol Extracts of Tobacco	06/04/2019
U.S. Patent No. 6,668,839 B2	12/30/2003	Smokeless Tobacco Products Made from Powdered Tobacco	05/06/2021
U.S. Patent No. 6,834,654	12/28/2004	Smokeless Tobacco Product Made from Compressed Powdered Tobacco	05/01/2021
U.S. Patent No. 6,929,811 B2	8/16/2005	Method of Modulating Monoamine Oxidase (MAO) Activity Using Tobacco Alkaloids	06/04/2019

## **Government Regulation**

### *Overview*

The manufacture and sale of cigarettes and other tobacco products are subject to extensive federal and state governmental regulation in the United States and by comparable authorities in many foreign countries. The manufacture and sale of tobacco products is regulated by the Tax and Trade Bureau, or TTB, under authority of the Department of the Treasury, and the Internal Revenue Code of 1986, as amended (26 U.S.C. § 5701 et seq.) and we have been granted a manufacturing license from the TTB for the manufacture of smokeless tobacco products at our facilities in Chase City, Virginia. Also, the FTC regulates the warnings on tobacco product labels and the advertising of tobacco products under the Federal Cigarette Labeling and Advertising Act (15 U.S.C. §§ 1331-1341) and the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. §§ 4401-4408). In accordance with these statutes, we have submitted plans for the labeling and advertising of our tobacco products that have been approved by the FTC in its role as the agency responsible for implementing these statutes. Many states also require manufacturers of tobacco products to obtain a cigarette license or a tobacco product license in order to sell tobacco products. Where required, we have obtained the necessary state licenses to permit us 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.

Multiple bills have been introduced in both the United States Congress and in several state legislatures during the past five years which, if enacted, would have significantly changed the United States tobacco industry. Some of these federal bills contained provisions which would provide substantial federal government funds for smoking cessation programs and products, as well as incentives that require tobacco companies and others to produce less toxic or reduced-risk tobacco products under specific standards. Most recently, bills providing the FDA with regulatory oversight over all tobacco products were introduced in both the U.S. Senate and the House of Representatives in 2007 (S.625 and H.R. 1108). Following committee hearings on both bills, the House of Representatives in 2008 passed its version of the bill by a two-thirds' majority vote of 326 to 102, but the Senate failed to vote on its version of the bill before the end of the 110<sup>th</sup> Congress. Both the House and Senate bills would have given FDA authority to impose product standards relating to, among other things, nicotine yields and smoke constituents. This legislation also would have restricted marketing and imposed larger warning labels on tobacco products. On March 4, 2009, the House Energy & Commerce Committee conducted a mark-up of the 2009 version of HR 1108, which in the current Congressional session is known as HR 1256. Representative Steven Buyer (R- IN) introduced an alternative bill during mark-up (HR 1261) as an amendment to HR 1261. Rep. Buyer's bill focused principally on the role that harm reduction can play in tobacco regulation. That amendment failed, but HR 1256 was passed by the Committee by a vote of 39-13 and, accordingly, the bill will be introduced to the entire House of Representatives for a vote. The Senate has not yet introduced an FDA tobacco regulation bill. We believe that consideration of legislation to regulate all tobacco products under the FDA will be a priority for the 111<sup>th</sup> Congress. We are unable to predict what effect, if any, these provisions, if enacted, would have on our low-TSNA tobacco curing technology or on the sale of smoking cessation products. However, because we were the first tobacco company to support comprehensive and equitable jurisdiction within the FDA of all products containing tobacco and given our continued focus on products with low TSNAs, we believe the enactment of any bill that requires manufacturers to reduce or disclose levels of TSNAs in tobacco or tobacco smoke in a meaningful manner would be beneficial to us.

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 2008. 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 2009.

#### *FDA Regulation*

On March 21, 2000, in *FDA v. Brown & Williamson Tobacco Corporation*, 529 U.S. 120 (2000), the United States Supreme Court held that Congress has not given the FDA authority to regulate tobacco products as customarily marketed. Given the decision by the Supreme Court, it is unclear whether Congress will act to grant authority to the FDA over tobacco products, although legislation that would create such authority has been introduced in each session of Congress over the past several years and it is expected that similar legislation will be introduced early this year in the 111<sup>th</sup> Congress. However, we believe that in the future, reasoned FDA regulation of all tobacco products would better enable us to compete in our current target markets. In furtherance of this belief, we have publicly stated since 1999 our position in favor of reasoned FDA regulation of all tobacco products.

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, nutraceuticals or drug products depending upon their chemical composition, intended use and claims. Under existing authority, the production and marketing of pharmaceutical products being developed by our Rock Creek subsidiary or that may be developed in the future, as well as related research and development activities for such pharmaceutical products, are subject to FDA regulation for safety, efficiency and quality.

The FDA has regulatory authority over drug products under the Federal Food Drug and Cosmetic Act (21 U.S.C. § 301 et seq.) and such products may not be marketed or sold in the United States unless and until the FDA approves a New Drug Application, or NDA. Prior to our submitting an NDA for a pharmaceutical product, we would be required to submit an Investigational New Drug Application with the FDA to undertake initial clinical trials that would be used to support any such NDA. The FDA approval process requires a company to prove the safety and efficacy of a drug product to the satisfaction of the FDA. FDA approval generally takes several years and is an expensive process because an NDA must be supported by detailed and comprehensive scientific and human clinical data. Also, it is possible that the FDA may not approve an NDA even after a company has expended significant time, effort and resources, if the agency determines that the product at issue is not safe and efficacious for its intended use. Products developed by us through Rock Creek, including any botanical tobacco-based products, may be classified as pharmaceutical products and, in that case, will need to be submitted to the FDA for approval prior to such products 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.

### *Federal Trade Commission*

The requirements for health warnings on cigarettes are governed by the Federal Cigarette Labeling and Advertising Act. Similar requirements are imposed on smokeless tobacco products under the Comprehensive Smokeless Tobacco Health Education Act of 1986. Both acts impose labeling and advertising requirements on the manufacturers, packagers and importers of cigarettes and smokeless tobacco products and require any company wishing to sell such products within the United States to submit a plan to the FTC explaining how it will comply with the warning label display requirements. We have submitted labeling plans for cigarette and smokeless products to the FTC in accordance with these acts and we will be required to do so before introducing any new tobacco products. Additionally, prior to the initiation of the test marketing of Advance® in October 2000, we met with the FTC staff and shared our enhanced warning labels for Advance®. In 2001, we shared the enhanced warning labels for Stonewall® moist snuff and ARIVA® hard tobacco prior to the market introduction of these products.

### *Tax and Trade Bureau*

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. Our tobacco products are subject to tax under such regulations. Smokeless tobacco in the form of snuff had been subject to federal tax at a rate of \$0.585 per pound, which will be increased to \$1.51 per pound on or about April 1, 2009. 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 facilities. Our TTB license requires that we adhere to strict regulations regarding the manufacturing and transportation of our tobacco products.

### *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 North Dakota tax smokeless products at a rate of 12 cents per ounce and 60 cents per ounce, respectively, while the states of North Carolina and Oregon impose an excise tax of 3% and 65% of wholesale price, 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 were 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, 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.

In May 2007, we entered into a license agreement with Tantus for the exclusive licensing of our trademarks Sport®, MainStreet® and GSmoke® and we ceased manufacturing cigarettes in June 2007. Given the discontinuation of our cigarette operations in June 2007 and the focus on our smokeless tobacco products we do not anticipate having MSA escrow obligations in the future.

Most of the Settling States enacted statutes that require non-participating manufacturers to certify that they are in full compliance with the escrow requirements of the MSA as a condition to being permitted to sell

cigarette products in those jurisdictions. Following the discontinuation of our cigarette operations, we withdrew the certifications for cigarette sales that we previously had obtained in all applicable Settling States.

*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, 101 of the 168 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.

### **Our Employees and Consultants**

As of December 31, 2008, we employed 42 full-time employees as compared to 39 employees as of December 31, 2007.

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 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](http://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](http://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, D.C. 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 six years and we expect operating expenses to continue to be greater than operating revenues in the foreseeable future.***

We have incurred operating losses for six consecutive fiscal years beginning with the year ended December 31, 2003. Our net losses were approximately \$(12.3) million for the year ended December 31, 2006, \$(41.5) million for the year ended December 31, 2007 and \$(18.3) million for the year ended December 31, 2008. Our accumulated deficit as of December 31, 2008 was approximately \$(119.6) 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 on the sale of low-TSNA dissolvable smokeless tobacco products and the licensing of the related technology, as opposed to cigarettes. Accordingly, we have accounted for our cigarette operations as “discontinued operations” in our consolidated financial statements beginning with the second of 2007.

Our future profitability will depend on our ability to generate and sustain increased revenue levels in future periods. This will largely be dependent on the distribution and consumer acceptance of our low-TSNA smokeless tobacco products as well as the continued development of our low-TSNA smokeless tobacco products, independently and through alliances with other tobacco manufacturers, and our ability to begin generating significant revenues through royalties from the our patented tobacco curing process or from the development of drug products by Rock Creek, which has had no revenue to date. These efforts may be more costly than we expect, and we may not be able to increase our revenue enough to offset our higher operating expenses associated with these initiatives especially given the loss of revenues from the discontinuation of our discount cigarette business. Additionally, our ability to generate revenues through royalty payments from the licensing of our low-TSNA technology will also be dependent upon the successful completion of our ongoing patent infringement lawsuit against RJR, which is uncertain at this time.

***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 the way of private placements of our common stock and the cash exercise of related warrants. Since January 1, 2009, through the exercise of an aggregate of 1,308,789 options and 6,279,001 warrants for our common stock, in each case for cash, our company received proceeds of approximately \$14.0 million. See “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources.” However, absent the successful completion of our ongoing patent infringement lawsuit against RJR, the exercise of outstanding options and warrants, a substantial improvement in revenues and/or royalties from the license of our low-TSNA technology, we believe that it will be necessary to pursue additional sources of funds during the second quarter of 2010. 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.

***Current levels of market volatility are unprecedented.***

The capital and credit markets have been experiencing volatility and disruption for more than 12 months reaching unprecedented levels. 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 current levels of market disruption and volatility continue or worsen, 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 exploiting our licensed tobacco curing technology and low-TSNA smokeless tobacco products, and our development of 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. A jury trial in this case is set to begin on May 18, 2009. In late December 2008 and January 2009, RJR filed requests with the Patent and Trademark Office to reexamine the two patents that are the subject of our patent infringement litigation against RJR. On February 12, 2009, the Patent and Trademark Office granted the reexamination request as to one of the patents and, on March 5, 2009 it granted the other request. The reexamination process will proceed in due course, and we believe that this process will likely last at least two years. During the process the Patent and Trademark Office will undertake a review of the patentability of the subject matter of the patents in view of the prior art cited in RJR's requests. If we are not successful in the RJR case or in the reexamination process at the Patent and Trademark Office, we may not be able to enforce or license the two patents for producing low-TSNA tobacco that are at issue in these proceedings, which will have a material adverse affect on our operations and future development of our products.

We do not know whether we will obtain the patent protection we seek, or that the protection we do obtain will be found valid and enforceable, if challenged. We also do not know whether we will be able to develop additional patentable proprietary technologies. 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. Our future growth is also heavily dependent upon increased consumer acceptance of our low-TSNA smokeless tobacco products, as well as on increased demand to license the 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 and our 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 our ability to derive revenue from the licensing of our low-TSNA technology, have been de minimis. Beginning in September 2001, we introduced three new smokeless tobacco products, Stonewall® moist and dry snuffs and ARIVA® hard tobacco cigarett® pieces. In the second quarter of 2003, we began a commercial test market of a new, non-fermented spit-free® “hard tobacco” product for moist snuff users, called STONEWALL Hard Snuff®. Given our company’s decision to focus on dissolvable smokeless tobacco products, we discontinued manufacturing Stonewall® moist snuff and are not actively marketing Stonewall dry snuff.

Additionally, our success 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 distribution channels for our very low-TSNA smokeless tobacco products. If our significant retail customers or independent distributors were to reduce the quantity of any of our products they sell or 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.

To date, sales of our dissolvable smokeless products have been slower than expected. We believe this is due in part to the lack of consumer awareness of ARIVA® and STONEWALL Hard Snuff® and the lack of sufficient capital to increase consumer awareness and acceptance of those products. It is not certain whether 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 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 ARIVA® and STONEWALL Hard Snuff® to adult tobacco users will also 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 low-TSNA smokeless tobacco products to adults as alternatives to cigarettes and other smokeless products, or to generate revenue through the license of the

related technology to which we are the exclusive licensee, we will not have sufficient sales volumes to support our operations.

***The tobacco industry is highly competitive, 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 alternative products 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. 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, spitless 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 manufacturers have introduced products that claim to have reduced levels of carcinogens. In 2008 Altria, Philip Morris's parent company expanded its role in the smokeless tobacco market through its acquisition of UST. Also, in 2008 RJR announced its entry into the area of dissolvable smokeless tobacco products and began test marketing three dissolvable smokeless tobacco products in January 2009 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.

***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, particularly as alternatives 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 currently continue to maintain 37 StarCured® tobacco curing barns, which we believe to be sufficient to meet our need for low-TSNA StarCured® tobacco in the immediate future. However, 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 do not have long-term contracts with any of our retail customers or independent distributors, and a loss or material reduction in their business with us could result in reduced sales of our products.***

Our success 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 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 9, 2009, we had outstanding options granted to directors, employees and consultants to purchase approximately 6,075,011 shares of our common stock, with a weighted-average exercise price of \$1.93 per share, of which options for 5,945,011 shares were exercisable at March 9, 2009. We also have outstanding warrants, which are currently exercisable into 13,776,445 shares of our common stock, with a weighted-average exercise price of \$2.39 per share. The issuance of these shares will cause dilution which may adversely affect the market price of our common stock. If we issue additional shares of our common stock for sale in future financings, our stockholders would experience further dilution.

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

On July 30, 2004, RJR and B&W, the second and third largest cigarette manufacturers, completed the combination of their United States tobacco businesses to create a new publicly traded holding company, Reynolds American Inc. Prior to this combination, we had been party to multiple substantial commercial relationships with B&W for a number of years, including licensing and royalty agreements relating to the purchase of StarCured® tobacco and other low-TSNA tobacco and the financing of our StarCured® tobacco curing barns.

Additionally, we are currently involved in significant patent infringement litigation with RJR with respect to certain of our patents related to the production of low-TSNA tobacco. During the pending patent litigation described above, RJR took the position that the new operating entity resulting from the combination of RJR and B&W assumed all of the rights and obligations under the agreements that we previously entered into with B&W, and moved to dismiss our patent infringement case on this basis. The District Court denied RJR's motion to dismiss, and found that B&W had attempted to assign these agreements to Reynolds American Inc. without our consent. 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 on the claims asserted in the present litigation.

Pursuant to our April 2001 agreement with B&W, as amended by letter agreements dated December 4, 2002 and August 14, 2003, B&W loaned us \$29 million to fund our purchase of StarCured® tobacco curing barns. B&W also agreed to a 96-month repayment schedule consisting of equal consecutive monthly installments beginning on January 3, 2006. The B&W debt is secured by tobacco leaf inventory and our remaining tobacco curing barns. Once the outstanding loan balance is reduced to \$10 million, the collateral, except for our guarantees, will be released. The loan balance was approximately \$11.1 million as of December 31, 2008. Previously, B&W granted us a number of concessions under our agreements, including deferring interest and principal payments, consenting to our incurrence of additional indebtedness and agreeing to modify the Hard Tobacco Agreement to allow us to pursue similar licensing arrangements with third parties. RJR's failure to grant us similar concessions in the future 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, under the agreements entered into with B&W. 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 are dependent on the domestic tobacco business.***

All of our revenues are now derived from sales of our low-TSNA smokeless tobacco products. The market for smokeless products is much smaller than the market for smoked tobacco products, and all of our revenue from smokeless tobacco product sales to date has been derived from sales in the United States, except for de minimis amounts of ARIVA® sold in Bermuda, Turkey and Norway, which were discontinued prior to 2007. Accordingly, we do not currently have access to foreign markets to offset the impact of the declining U.S. tobacco market.

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

In 1996, the FDA promulgated regulations governing the sale and advertising of tobacco products. These regulations were designed primarily to discourage the sale to and consumption by, adolescents and children. The authority of the FDA to promulgate such regulations was challenged in the federal courts. On March 21, 2000, the United States Supreme Court held that the Congress has not given the FDA authority to regulate tobacco products as customarily marketed. Since the decision by the Supreme Court did not preclude Congress from granting the FDA authority to regulate tobacco products, it is unclear whether Congress will act to grant such authority to the FDA in the future. However, legislation that would create such authority has been introduced regularly in Congress since the Supreme Court's decision. Most recently, bills providing the FDA with regulatory oversight over all tobacco products were introduced in both the U.S. Senate and the House of Representatives in 2007 (S.625 and H.R. 1108). Following committee hearings on both bills, the House of Representatives in 2008 passed its version of the bill by a two-thirds' majority vote of 326 to 102, but the Senate failed to vote on its version of the bill before the end of the 110<sup>th</sup> Congress. Both the House and Senate bills would have given FDA authority to impose product standards relating to, among other things, nicotine yields and smoke constituents. This legislation also would have restricted marketing and imposed larger warning labels on tobacco products. On March 4, 2009, the House Energy & Commerce Committee conducted a mark-up of the 2009 version of HR 1108, which in the current Congressional session is known as HR 1256. Representative Steven Buyer (R-IN) introduced an alternative bill during mark-up (HR 1261) as an amendment to HR 1261. Rep. Buyer's bill focused principally on the role that harm reduction can play in tobacco regulation. That amendment failed, but HR 1256 was passed by the Committee by a vote of 39-13 and, accordingly, the bill will be introduced to the entire House of Representatives for a vote. The Senate has not yet introduced an FDA tobacco regulation bill. We believe that consideration of legislation to regulate all tobacco products under the FDA will be a priority for the 111<sup>th</sup> Congress. The tobacco industry is also subject to a wide range of laws regarding the marketing, sale and taxation (both federal and state) of tobacco products. In addition, there have been increased restrictions imposed on the use of tobacco products at the local, state

and federal government levels. These developments generally receive widespread media attention and have proliferated in recent years. Further, additional restrictions on smoked tobacco products could also lead to increased consumer use of smokeless tobacco products, which could in turn lead to further restrictions and scrutiny by regulators of smokeless tobacco products, which could have material and adverse effects on our sales volumes, operating income and cash flows.

We have a license from the TTB to manufacture smokeless tobacco products. While we have discontinued our discount cigarette operations subsequent to our entering into a license agreement with Tantus for the exclusive license of our trademarks Sport®, MainStreet® and GSmoke®, we are not precluded from re-entering the discount cigarette market, although we would need to obtain a new license for any such manufacturing. To the extent that we are unable to maintain our current license or to obtain any additional licenses required by the TTB, this could materially and adversely affect our operations.

In October 2004, federal legislation was enacted which eliminated the federal tobacco quota system and price support system through an industry funded buyout of tobacco growers and quota holders. Pursuant to the legislation, manufacturers of tobacco products have been assessed \$10.1 billion over a ten-year period to compensate tobacco growers and quota holders for the elimination of their quota rights. Under the buyout legislation 96% of the assessments are made against cigarette sales and 4% against the sales of other tobacco products. Accordingly, the impact of the buyout legislation is less significant in relation to the sale of smokeless tobacco products than for cigarettes. However, if sales of our smokeless tobacco products increase substantially, we would have increased obligations under the buyout legislation.

***The tobacco industry is subject to substantial and increasing federal, state and local excise taxes.***

The federal excise tax on smokeless tobacco products is substantially lower (\$0.585 per pound) than the excise tax for cigarettes, but smokeless tobacco products are subject to substantial and increasing excise taxes. On April 1, 2009 the federal excise tax for snuff will increase to \$1.51 per pound. Also, it is possible that increased use of smokeless tobacco products could result in more stringent regulation. A number of states have recently considered increases in state excise taxes on smoked and smokeless tobacco products, and while one state has no excise tax on smokeless tobacco products, that state could choose to institute an excise tax and states that currently have an excise tax could choose to increase their tax rate. Further, state excise tax rates vary considerably. For example, the states of Alabama and North Dakota tax smokeless products at a rate of 12 cents per ounce and 60 cents per ounce, respectively, while the states of North Carolina and Oregon impose an excise tax of 3% and 65% of wholesale cost, respectively. New or increased excise taxes may result in declines in sales volume for the industry generally, and our low-TSNA smokeless tobacco products in particular. This result 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, the Settling States entered into the MSA to resolve litigation that had been instituted against the major cigarette manufacturers. We were 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, we were 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, 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 by the Settling States the amount of any judgment or settlement could exceed the amount that has been deposited into escrow.

In May 2007, we entered into a license agreement with Tantus for the exclusive license of the trademarks used to market our discount cigarettes and in June 2007, we ceased the manufacture and sale of our discount

cigarettes. Under the terms of the license agreement with Tantus, we have the ability to manufacture and sell other branded cigarettes and any future cigarette sales would be subject to MSA escrow obligations. We deposited into our MSA escrow accounts approximately \$0.4 million during 2008 to cover the sale of cigarettes in the Settling States for the year ended December 31, 2007. Since the sale of smokeless tobacco products are not subject to the MSA escrow obligations, we do not anticipate having any material MSA escrow obligations in the future given the discontinuance of our cigarette operations in June 2007 and our focus on the sale of our smokeless tobacco products.

***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, we received notification from the Commonwealth of Virginia that the Commissioner of Taxation had rejected our request with respect to a sales and use tax assessment and that the sales and use tax assessment plus penalties and interest together, as of October 7, 2004, totaled approximately \$988,000. We continue to challenge this assessment and have filed a request for reconsideration with the Commissioner of Taxation, and are prepared to take judicial action if the result of the administrative action is unfavorable. The filing of the request for reconsideration stays any collection of the tax assessment, although interest continues to accrue. While we are optimistic that our request for reconsideration will be accepted based on prior rulings in similar cases, if the assessment is not reversed, we will be required to pay the tax, penalties and interest due.

***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. In addition, beginning in 2001, we embarked on the test market and distribution of new smokeless tobacco products. If, in the future, we are involved in any actions related to our smokeless tobacco products, we will not have insurance coverage for damages relating to such claims, which could have a material and 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. There can be no assurance that we can overcome the challenge of scaling up our processing and production operations or that our personnel, systems, procedures and controls will be adequate to support our future operations. Any failure

to implement and improve our operational, financial and management systems or to attract, integrate, motivate and retain additional employees required by future growth, if any, 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 upon 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 that we have suffered over the past six years that 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 9, 2009, our directors and executive officers and their affiliates, own an aggregate of approximately 24.9% of our outstanding common stock. As a result, these persons acting together may have the ability to control 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 \$5.33 to \$0.67 during 2007 and 2008. 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;
- announcements of new products, technological innovations, contracts, acquisitions, financings, corporate partnerships or joint ventures by us or our competitors;
- our success in developing a pharmaceutical product to treat tobacco-related dependence;
- negative regulatory action or regulatory approval with respect to our products or our competitors' products; and
- market conditions for the tobacco industry in general.

The stock market has, from time to time, and in particular over the last 12 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 August 24, 2007, 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 4450(a)(5), because the bid price per share of the our common stock closed below \$1.00 per share for 30 consecutive business days. However, on October 15, 2007, the NASDAQ Global Market notified us that since the minimum closing bid price of our common stock had been at \$1.00 per share or greater for ten consecutive trading days, we had regained compliance with the minimum bid price requirement set forth in Marketplace Rule 4450(a)(5). We have been in compliance with the minimum bid price rule since that date and this rule has been temporarily suspended by NASDAQ. However, if we are unable to continue to meet the NASDAQ listing requirements, there is a possibility that we could again face delisting from the NASDAQ Global Market, which could have a negative effect on the market price of our common stock.

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

Beginning in 2003 we deferred the initiation and continuation of certain research projects by Star Scientific because of the lack of working capital and have not convened a meeting of our Scientific Advisory Board since that time. Prior to the suspension of these initiatives, our research and development efforts were directed at assessing the impact that products with reduced toxin levels may have on the range of serious health hazards linked with the use of conventional smoked and smokeless tobacco products, as well as encouraging scientists in the U.S. and Europe to pursue TSNA-related research. We also designed but have not initiated several additional scientific studies to determine, among other things, whether a reduction in TSNAs can be equated with a reduction in health risk, to assess biomarker differences that can be equated to levels of various toxins in smoked versus smokeless tobacco, and to measure the impact of the decline in TSNA exposure in low-TSNA smokeless tobacco compared to traditional cigarette products.

Since 2007, we have been exploring the development of a range 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 through Rock Creek. In 2008, we completed an initial a study with 49 cigarette smokers to determine the ability of STONEWALL Hard Snuff® to relieve cigarette withdrawal symptoms compared to a conventional OTC nicotine replacement product. Based on the results of this study, we plan to move forward to formulate a GMP botanical-based product and, thereafter to conduct a study to determine the bioequivalence of the proposed botanical-based product against similar nicotine replacement products. Depending upon the results of the bioequivalence study, we plan to seek FDA review for a botanical-based NRT cessation product for use by adult tobacco users who smoke and/or use smokeless tobacco products. We are also continuing to explore the development of other pharmaceutical products with clinical claims, as well as a "relapse prevention product" to assist smokers during nicotine withdrawal and related products.

However, given our working capital constraints, our ability to resume the research and development efforts of Star Scientific and to advance Rock Creek's research and development efforts will depend on our ability to obtain funding, which we may not be able to obtain at reasonable terms, if at all. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources." Our ability to proceed with the initiatives will also largely depend upon the successful outcome of our ongoing patent litigation with RJR. Our inability to renew these initiatives and initiate new research and development efforts could result in a failure to develop new products or to improve our current 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 approvals, and for potentially related products such as nutraceuticals .*

We plan to continue to make significant investments in new product development projects. Also, we intend to pursue the development of a pharmaceutical products designed to treat tobacco-related dependence and other neurological conditions and potentially related products such as nutraceuticals through our Rock Creek subsidiary. These initiatives are subject to high levels of risk, uncertainties and contingencies, including the challenges inherent in new product development and regulatory approvals for any new pharmaceutical products that we develop. Products derived from tobacco are subject to multiple, overlapping federal and state regulations. Such products could be classified as tobacco products, nutraceuticals or drug products depending on their chemical composition, intended use and claims.

We incorporated Rock Creek in June 2007 to pursue a range of pharmaceutical products, including products that have a botanical, tobacco-based component and related products such as nutraceuticals. However, Rock Creek does not have any pharmaceutical products cleared or approved for commercialization, or any current sources of revenue. The future success of our Rock Creek business will depend on our ability to obtain regulatory clearance or approval to market our products, create product sales, successfully introduce new products, establish our sales force and distribution network, and our access to additional working capital to finance our development initiatives, all of which we may be unable to realize.

Even if we develop a 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 Investigational New Drug Application and obtaining a premarket approval after filing a New Drug Application. 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.

#### **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, 2008.

#### **ITEM 2. PROPERTIES**

We own approximately 3.5 acres of real estate in Petersburg, Virginia, or the Petersburg Property, and currently occupy one of the two buildings located on the property; a 6,000 square-foot single-story office building that houses our executive, marketing, sales and administrative offices. We moved to this facility from leased offices in Chester, Virginia in March 2007. Our lease at the Chester facility was terminated at that time.

The Petersburg Property also has a 50,000 square foot, four-story building that we utilized for manufacturing cigarettes until we discontinued our cigarette operation in June 2007. The factory building has been idle since that time. We anticipate continuing to occupy the office building at the Petersburg Property for

our executive, marketing, sales and administrative offices for the foreseeable future. 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. 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.

We lease a portion of one building and all of an adjacent building in Chase City, Virginia. The first property has approximately seven acres of land and houses an approximately 100,000 square foot building. We currently lease a portion of this building for our ARIVA® and STONEWALL Hard Snuff® manufacturing operations and plan to relocate these manufacturing operations to the second adjacent facility in Chase City, Virginia by August 2009. The second property has approximately nine acres of land and houses a facility with approximately 91,000 square feet of space that can accommodate our manufacturing operations and an expanded testing facility and also has approximately 9,000 square feet of office space. We lease the facility located on the second property from the Mecklenburg County Industrial Development Authority. We have approximately four years remaining on the initial ten-year portion of the lease for this facility, which is then subject to renegotiation as to 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 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 TSNA's 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. We filed a Motion for Summary Judgment on Claim Construction and Definiteness, and RJR filed six Motions for Summary Judgment asserting various defenses. Pursuant to an Order dated September 15, 2003, the District Court appointed a Special Master to prepare Reports and Recommendations, or R&Rs, for the District Court on our Motion for Summary Judgment and five of RJR's six Motions for Summary Judgment. The Special Master issued R&Rs on all six of the Summary Judgment Motions and on March 31, 2004, the District Court issued final rulings on five of the six Summary Judgment Motions that had been reviewed by the Special Master. In its March 31, 2004 rulings, 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 Motion for Summary Judgment seeking to limit our damages claim, which had not been reviewed by the Special Master. On June 24, 2004, the District Court issued a final order adopting without modification the Special Master's last R&R which recommended that the District Court deny the final RJR Summary Judgment Motion.

On August 17, 2004, we were informed that 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. These orders set an initial trial date of January 24, 2005, permitted additional discovery of certain defenses raised by RJR and the filing of two additional Motions for Summary Judgment. Subsequently,

the District Court ordered that it would bifurcate RJR's defense of inequitable conduct before the patent office and would have that defense 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 issue a ruling 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. Briefing on these motions was completed on March 11, 2005.

On January 19, 2007, the District Court granted RJR's Motions for Summary Judgment in part and denied these motions in part. On its 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. In its January 2007 ruling, the District Court indicated that it would issue its ruling on RJR's inequitable conduct defense by the end of February. The District Court ultimately issued its decision on the inequitable conduct defense on June 26, 2007. In its ruling the 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. Oral argument before a three-judge panel of the Court of Appeals was held on March 7, 2008.

On August 25, 2008, the Court of Appeals issued a unanimous opinion in our favor. In its unanimous ruling, the Court of Appeals reversed 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. On September 8, 2008, RJR filed a petition for rehearing or rehearing en banc with the Court of Appeals. The Court of Appeals on October 22, 2008 issued an order denying RJR's petition and, on October 29, 2008, a mandate formally terminating the proceedings in the Court of Appeals was filed. As a result, the District Court regained jurisdiction over the case to conduct further proceedings on our infringement complaint. On January 16, 2009, RJR filed a Petition for Certiorari with the United States Supreme Court, or Supreme Court, seeking to have the Supreme Court review the unanimous decision issued by the Court of Appeals. The Supreme Court on March 9, 2009, issued an order denying RJR's Petition for Certiorari. Following remand to the District Court, we and RJR filed a number of motions seeking to limit the evidence that may be introduced at trial. Also, despite the District Court's statement in its December 3, 2008 First Case Management Order that new summary judgment motions "are not encouraged," RJR filed four additional Summary Judgment Motions. RJR has also filed a motion to continue the trial based on the pending reexamination proceedings in the Patent and Trademark Office. Those motions, along with other previously filed motions, are currently pending.

In November 2008 the District Court, following remand from the Court of Appeals, scheduled a jury trial lasting between two and three weeks for the period April 20, 2009 through May 29, 2009. The District Court, at a recent conference with counsel, has set May 18, 2009 as the date for the start of the jury trial.

In July 2007, RJR filed a motion for a bill of cost and also filed a motion requesting the District Court to determine that this is an "exceptional" case under 35 USC § 285 and award attorneys' fees to RJR under that provision and/or under 28 USC § 1927. Following the decision by the Circuit Court of Appeals, RJR, on November 13, 2008, filed a notice with the District Court withdrawing these motions and an order denying RJR's motions without prejudice was issued by the District Court on February 5, 2009. On December 31, 2008 and January 2, 2009 RJR filed requests with the United States Patent and Trademark Office to reexamine the two patents that are the subject of our patent infringement litigation against RJR. In February and March, the Patent and Trademark Office granted the reexamination requests. The reexamination process will proceed in due course, and we believe that this process will likely last at least two years. During the process the Patent and Trademark Office will undertake a review of the patentability of the subject matter of the patents in view of the prior art cited in RJR's requests.

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 and a percentage of the resulting payments we actually receive 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 are 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 expect that the IRS will prepare a closing agreement that will confirm that our company's tax returns for the years 2001 through 2004 were correct as filed and that it will close its open examination for the tax years in question. 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 our Company 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, we 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 us and that the sales and use tax assessment plus penalties and interest together, as of October 7, 2004, totaled approximately \$988,000. We continue to challenge this assessment and filed a request for reconsideration with the Commissioner of Taxation, and are prepared to file a judicial action if the administrative action is not favorable. The filing of the request for reconsideration stays any collection of the tax assessment, although interest continues to accrue. While we are optimistic that the request for reconsideration will be accepted based on prior rulings in similar cases, if the assessment is not reversed we will be required to pay the tax, penalties and interest due.

We are also currently involved, as we are from time to time, in legal proceedings that arise in the ordinary course of our business, which we are vigorously defending or pursuing. Except as set forth above, there is no other litigation pending that could materially harm our results of operations and financial condition.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

On November 14, 2008, we held the annual meeting of our company’s stockholders. The matters voted upon at the meeting and the corresponding results are set forth below.

1. The election of seven directors to hold office until the next meeting of stockholders and until their respective successors have been elected or appointed:

<u>Nominee</u>	<u>For</u>	<u>Withhold</u>
Dr. Christopher C. Chapman . . . . .	82,469,085	668,057
Neil L. Chayet . . . . .	82,466,885	600,257
Marc D. Oken . . . . .	82,572,320	584,822
Paul L. Perito . . . . .	81,345,206	1,811,936
Leo S. Tonkin . . . . .	82,466,667	690,275
Alan Weichselbaum . . . . .	82,555,620	601,522
Jonnie R. Williams . . . . .	81,329,957	1,827,185

2. The approval of the 2008 Incentive Award Plan

<u>For</u>	<u>Against</u>	<u>Abstain</u>
53,303,451	3,655,312	312,912

3. Ratification of the appointment of Cherry, Bekaert, & Holland, L.L.P. as independent auditors to audit our Company’s 2008 financial statements for the year ended December 31, 2008.

<u>For</u>	<u>Against</u>	<u>Abstain</u>
82,588,879	195,615	372,648

**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, or Common Stock, is traded on the NASDAQ Global Market under the symbol “STSI.” Set forth below are the high and low sales prices for each full quarterly period during 2007 and 2008, as reported by NASDAQ. From time to time, during the periods indicated, trading activity in the Common Stock was infrequent. As of March 9, 2009, there were approximately 675 registered holders of Common Stock.

<u>Quarter</u>	<u>2008</u>		<u>2007</u>	
	<u>High</u>	<u>Low</u>	<u>High</u>	<u>Low</u>
First . . . . .	\$2.09	\$0.74	\$5.33	\$0.75
Second . . . . .	2.05	1.19	1.23	0.71
Third . . . . .	4.19	1.06	1.05	0.74
Fourth . . . . .	4.20	1.40	1.45	0.67

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

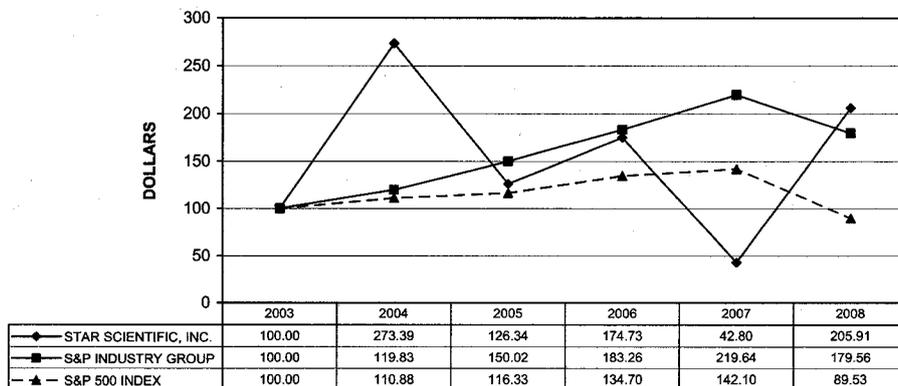
The following table provides certain information as of December 31, 2008, with respect to our equity compensation plans under which Common Stock is authorized for issuance:

<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 .....	7,480,000	\$2.33	3,818,500
Equity Compensation Plans Not Approved by Shareholders(1) .....	<u>145,000</u>	\$1.00	<u>—</u>
Total .....	<u>7,625,200</u>	\$2.38	<u>3,818,500</u>

- (1) Non-qualified options to purchase shares of Common Stock at an exercise price of \$1.00 granted to a consultant on June 1, 2000 pursuant to an individual option agreement. These options were fully vested on the date of grant and were fully exercised prior to the expiration date of March 1, 2009. We have also granted warrants to purchase shares of Common Stock to two consultants. Specifically, on December 20, 2000, we issued 210,526 warrants to purchase shares of Common Stock at an exercise price of \$2.375 to a consultant. These warrants fully vested on the date of issuance and expire on December 20, 2010. We also issued 200,000 warrants to purchase shares of Common Stock at an exercise price of \$2.02 on March 20, 2002 to another consultant. These warrants were fully exercised in 2008 through a cashless exercise provision in the warrants that resulted in the issuance of 81,488 shares of Common Stock to the consultant and the cancellation of the warrant.

**Five-year financial performance graph: 2004-2008**

**COMPARISON OF 5-YEAR CUMULATIVE TOTAL RETURN  
AMONG STAR SCIENTIFIC, INC.,  
S&P 500 INDEX AND S&P GROUP INDEX**



ASSUMES \$100 REINVESTED ON DEC. 31, 2002  
ASSUMES DIVIDENDS REINVESTED  
FISCAL YEAR ENDING DEC. 31, 2008

**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					
	2003	2004	2005	2006	2007	2008
Star Scientific, Inc.	100.00	273.39	126.34	174.73	42.80	205.91
S&P Tobacco Group	100.00	119.83	150.02	183.26	219.64	179.56
S&P Composite	100.00	110.88	116.33	134.70	142.10	89.53

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.
- UST, 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

In 2008, we granted our directors, or the Purchaser Class, and members of management options to purchase Common Stock as described in our Quarterly Reports on Form 10-Q filed during 2008 or during the fourth quarter of 2008 as described below. All options described below were granted under our company's 1998 Stock Option Plan, our company's 2000 Equity Incentive Plan or our company's 2008 Incentive Award Plan. On October 11, 2008, 50,000 options for shares of Common Stock with an exercise price of \$3.00 were granted to one member of the Purchaser Class and on November 20, 2008, 50,000 options for shares of common stock with an exercise price of \$1.86 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, 2008, 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 of this Report.

	Years Ended December 31,				
	2008	2007	2006	2005	2004
	(In thousands, except per share data)				
Statement of Operations Data:					
Net sales . . . . .	\$ 451	\$ 482	\$ 391	\$ 181	\$ 236
Cost of goods sold (excludes federal excise tax) . .	2,116	2,067	1,791	2,949	3,841
Gross margin (loss) . . . . .	(1,672)	(1,604)	(1,404)	(2,771)	(3,609)
Loss from continuing operations before income taxes . . . . .	(20,564)	(40,882)	(13,790)	(24,836)	(21,809)
Discontinued operations income(loss) . . . . .	—	(451)	1,505	(225)	5,221
Net income (loss) . . . . .	(18,339)	(41,458)	(12,285)	(25,062)	(16,576)
Basic and diluted income (loss) per share:					
Continuing operations . . . . .	\$ (0.20)	\$ (0.51)	\$ (0.18)	\$ (0.34)	\$ (0.33)
Discontinued operations . . . . .	\$ —	\$ (0.01)	\$ 0.02	\$ —	\$ 0.07
Total basic and diluted income (loss) per share . . .	\$ (0.20)	\$ (0.52)	\$ (0.16)	\$ (0.34)	\$ (0.26)
Weighted average shares outstanding . . . . .	89,844	80,395	77,836	73,096	62,137

	Years Ended December 31,				
	2008	2007	2006	2005	2004
	(In thousands, except per share data)				
Balance Sheet Data:					
Cash and cash equivalents . . . . .	\$ 6,473	\$ 8,881	\$ 4,297	7,703	\$ —
Property and equipment . . . . .	1,668	1,986	9,515	15,182	18,877
MSA escrow funds . . . . .	365	4	38,329	33,396	27,024
Discontinued operations assets . . . . .	—	—	6,041	4,814	9,441
Total assets . . . . .	12,252	14,827	60,937	69,517	60,305
Long-term obligations . . . . .	9,499	11,111	14,975	34,227	31,637
Discontinued operations liabilities . . . . .	—	—	1,443	1,277	5,058
Stockholders' equity (deficit) . . . . .	(498)	(1,988)	38,909	23,330	9,049

## 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 included in Item 15 of this Report. 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 tobacco company with a mission to reduce toxins in tobacco leaf and tobacco smoke. 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;
- the manufacture, sales, marketing and 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 cigarett® pieces and STONEWALL Hard Snuff®;
- the licensing of trademarks for certain of our cigarette brands that we discontinued manufacturing in 2007, consistent with our previously announced plan to transition from the sale of cigarettes to low-TSNA smokeless tobacco products; and
- 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 potentially related products such as neutraceuticals.

Our long-term focus is the research, development and licensing of technology for the production of very low-TSNA tobacco and related products, particularly dissolvable smokeless tobacco products, that expose adult tobacco users to substantially lower levels of toxins as compared to other smoked and smokeless tobacco products. Our overall objective is to ultimately reduce the range of serious health hazards associated with the use of smoked and smokeless tobacco products, both in the form of low-TSNA smokeless tobacco products and related pharmaceutical products.

We currently are focusing our efforts on the manufacture and sale of ARIVA® and STONEWALL Hard Snuff®, our dissolvable low-TSNA smokeless tobacco products, as opposed to cigarettes, consistent with our previously announced plan to exit the cigarette business as soon as practically possible. In furtherance of this plan, in May 2007, we entered into a license agreement with Tantus for the exclusive license of certain of our discount cigarette trademarks. We ceased the sale of those brands in June 2007 and discontinued our cigarette operations at that time.

Additionally, in 2007 we incorporated a new subsidiary, Rock Creek, to pursue the development and regulatory approval of pharmaceutical products to treat smokeless tobacco addiction and a range of neurological conditions and potentially related products such as neutraceuticals. 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 our ability to resume and continue these research efforts, including advancement of the research and development activities of 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, which is now set for a jury trial beginning on May 18, 2009 in the United States District Court for the District of Maryland.

In the period from 1999 through 2003, we purchased or arranged for the purchase of very low-TSNA flue-cured tobacco cured by farmers using the StarCured® tobacco curing process for resale to B&W. We suspended the purchase and sale of such low-TSNA flue-cured tobacco in 2004 after B&W indicated it would not make further purchases from us. 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 continue to own 37 StarCured® barns that will be used to ensure we have an adequate supply of StarCured® tobacco for our low-TSNA dissolvable smokeless tobacco products, and for other needs.

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 license of low-TSNA products and the technology behind, our StarCured® tobacco curing process, and the initial development efforts of Rock Creek. 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 related 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 and, given the typical long lead time for federal approval of any pharmaceutical products, we do not expect that Rock Creek will generate any revenues for the foreseeable future, but rather that Rock Creek will focus on the research and development aspects of a range of pharmaceuticals, including tobacco-based drug products and related products, assuming sufficient capital can be generated to support such activities. Our future prospects are dependent on the distribution and consumer acceptance of our low-TSNA dissolvable smokeless tobacco products. They also depend on our continued development of new low-TSNA smokeless tobacco, independently and through alliances with other tobacco manufacturers, and, in particular, 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 such products will substantially be dependant upon the successful completion of our ongoing patent infringement lawsuit against RJR.

We experienced revenue of approximately \$0.5 million for 2008 and an operating loss from continuing operations of approximately \$(18.3) million. Overall, the net loss during 2008 was \$(18.3) million. The recurring losses generated by operations continue to impose significant demands on our company's liquidity. As of December 31, 2008, we had approximately \$5.9 million of working capital of which approximately \$6.5 million was cash and cash equivalents. Since January 1, 2009, through the exercise of an aggregate of 1,308,789 options and 6,279,001 warrants for our common stock, in each case for cash, our company received proceeds of approximately \$14.0 million. However, absent the successful completion of our ongoing patent infringement lawsuit against RJR, the exercise of outstanding warrants and options for cash or a substantial improvement in revenues and/or royalties from smokeless tobacco products, we believe that it will be necessary to pursue additional sources of funds during the second quarter of 2010. 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 unchanged at \$0.5 million in 2008 compared to 2007. STONEWALL Hard Snuff® represents a majority of our hard 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. Our working capital constraints over the last several years have limited both our direct marketing of smokeless products and our research and development efforts, which if successful, would likely contribute to consumer acceptance of our smokeless tobacco products.

*Development of Tobacco-based Pharmaceutical Products.* In June 2007, we incorporated our wholly owned subsidiary Rock Creek through which we intend to pursue a range of pharmaceutical products, including products that have a botanical, tobacco-based component, 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 related products such as neutraceuticals. 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. In late 2008 Rock Creek completed a study with 49 cigarette smokers to determine the effectiveness of STONEWALL Hard Snuff® in relieving cigarette withdrawal symptoms as compared to a conventional over-the-counter nicotine replacement product used in connection with nicotine replacement therapy which study also incorporated placebos of each product. Based on the results of this study, we are moving forward to formulate botanical-based products under conditions that comply with GMPs for drug products and, thereafter, plan to conduct a study to determine the bioequivalence of the proposed botanical-based product against similar products used in connection with NRT. Depending upon results of the bioequivalence study, we plan to seek FDA approval of a botanical-based NRT cessation product for use by adult tobacco users who smoke and/or use smokeless tobacco products. Through Rock Creek we also are continuing to explore the development of other pharmaceutical products with clinical claims, as well as a “relapse prevention product” to assist smokers during nicotine withdrawal, with the goal of higher “quit” rates for long term smokers who have failed in their treatments with conventional NRT smoking cessation products and related products such as neutraceuticals

*Discount Cigarettes.* Since 2000, our discount cigarette business experienced a significant decline in sales, partly due to intensified pricing competition from wholesalers selling deeply discounted foreign manufactured cigarettes. 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. 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. Accordingly, we have accounted for our cigarette operations as “discontinued operations” in our consolidated financial statements beginning with the second quarter of 2007.

*Licensing.* We have an exclusive, worldwide license from Regent Court under 12 U.S. patents and 45 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 electronic 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. We continue to pursue means of collecting royalties with respect to this curing technology and through our patent infringement lawsuit against RJR, which has been set for a jury trial beginning on May 18, 2009, in the United States District Court for the District of Maryland. We expect that any royalties arising from the license of our curing technology would be substantially dependent on the successful completion of our patent litigation against the combined RJR and B&W operating entity. 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.

*Impact of the MSA and Other Legislation Relating to Cigarettes and Smokeless Tobacco Products.* In May 2007, we entered into a license agreement with Tantus for the exclusive license of our trademarks Sport®, MainStreet® and GSmoke® and we ceased the manufacturing cigarettes in June 2007. Our sale of smokeless tobacco products are not subject to the MSA escrow obligations. Following the discontinuation of our cigarette operations in June 2007, we withdrew our certifications for cigarette sales that most of the Settling States had required as part of the MSA requirements. Given the discontinuation of our cigarette operations, the withdrawal of the certifications for cigarette sales and the focus on our smokeless tobacco products, we do not anticipate having material MSA escrow obligations in the future.

Beyond restrictions on cigarette sales, the tobacco industry remains subject to significant state and federal regulation. For example, a number of states have recently sought to impose limits on flavors that could be used for smoked, as well as smokeless tobacco products. Additionally, in 2008 and 2009 bills providing the FDA with regulatory oversight over all tobacco products were introduced in the 110<sup>th</sup> and 111<sup>th</sup> Congress,

respectively. These as well as other current and future state and federal regulations could have a significant impact on our future prospects and results of operations, see “Item 1. Business — Government Regulation.”

The Department of Agriculture, which is responsible for structuring the payment program to tobacco growers under the tobacco quota buyout program, issued regulations in February 2005 relating to the assessment of the buyout cost pursuant to the Fair and Equitable Tobacco Reform Act of 2004. Assessments under the regulations are made quarterly based on the prior quarter’s taxable amount of cigarettes and other tobacco products removed from bond. 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 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 July 2007, our payment obligations under the FSC/CTI were negligible in 2008 and 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 2009.

### **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 tobacco 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.

#### *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.

#### *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 is

recognized using a “units of production” method of accounting to more closely match depreciation with the period during which such depreciation takes place. Currently the barns are classified as idle equipment, and as such are not depreciated.

#### *MSA Escrow Fund*

Amounts deposited into MSA escrow accounts are required to be held in escrow for 25 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 quarterly payments made in 2007 and 2008 relating to cigarette sales in 2007. These amounts total approximately \$0.4 million.

#### *Sale of Licensing Rights*

In May 2007, we entered into an exclusive seven-year license agreement with Tantus for the license of our company’s 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 has made and will continue to make consecutive monthly payments of \$100,000 per month for twenty-four months beginning in July 2007 and \$3,000 per month thereafter for the duration of the term of the agreement. As of December 31, 2008, our company has an outstanding note receivable balance due from Tantus of \$0.7 million and we have received monthly payments totaling \$1.8 million through December 31, 2008. 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 a \$600,000 payment received on the Effective Date. Given the nature of the license agreement with Tantus, we also classified our company’s cigarette business as a discontinued operation beginning in the second quarter of 2007. Our results of operations, financial position and cash flows are separately reported for all periods presented, as the cigarette operations and cash flows have been eliminated from ongoing operations and we will not have any significant continuing involvement in these operations.

#### **Year Ended December 31, 2008 Compared to Year Ended December 31, 2007**

Please refer to “Item 6. 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 \$0.7 million in 2008, reflecting only a de minimis increase from 2007 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 unchanged at \$0.5 million in 2008 substantially consistent with 2007 levels. The wholesale price per 20-piece pack for our smokeless tobacco products remained unchanged from 2004 until January 1, 2009, at which time we raised prices \$0.10 per pack.

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 2008, overall gross margin loss (net revenue less costs of goods sold and federal excise taxes) increased to \$(1.7) million compared to \$(1.6) million in 2007. The negative gross margin for dissolvable tobacco was due primarily to the underutilization of manufacturing and packaging equipment. The estimated excess cost was \$1.8 million and \$1.7 million for 2008 and 2007, 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 in 2008 remain the property of our company, and we receive interest on these deposits.

#### *Total Operating Expenses*

Total operating expenses increased approximately \$3.7 million, or 24.0%, to \$19.2 million for 2008 from \$15.5 million in 2007. The increase was due to additional Marketing and Distribution expenses of \$0.7 million, General and Administrative expenses of \$2.7 million and Research and Development expenses of \$0.2 million

- *Marketing and Distribution Expenses.* Marketing and distribution expenses for our dissolvable tobacco products were \$3.5 million in 2008, an increase of approximately \$0.7 million from approximately \$2.8 million in 2007, which reflects increased expenses for trade-related promotions of \$0.3 million and sales personnel of \$0.6 million related to individuals who were reassigned from cigarette sales when that business was discontinued during 2007, partially offset by a reduction in promotional programs directed to consumers of \$0.2 million.
- *General and Administrative Expenses.* General and administrative expenses were approximately \$15.2 million in 2008, an increase of approximately \$2.6 million from approximately \$12.6 million in 2007. The increase primarily was the result of a \$2.8 million noncash charge for stock-based compensation from the issuance of stock options to senior management in May 2008. Legal expenses increased approximately \$0.3 million, primarily due to expenses related to the appeal of the rulings issued by the District Court in January and June 2007 and, following the reversal of the those decisions, for pretrial preparation of our patent infringement litigation against RJR. Additionally, in 2008, we had increased executive travel costs of \$0.8 million, primarily related to meetings of our Board of Directors and with investors, and reductions in accounting fees of \$0.3 million, director fees of \$0.1 million, office rent of \$0.3 million and other general reductions totaling \$0.5 million in the aggregate.

*Research and Development Expenses.* Beginning in 2003 we deferred the initiation and continuation of certain research projects of Star Scientific because of the lack of working capital and expended de minimis amounts on research in 2008 and 2007. We did expend approximately \$0.3 million in 2008 in product development initiatives aimed at improving our low-TSNA smokeless tobacco products and expect to expend similar amounts in 2009. Also, since 2007, we have been exploring the development of a range 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 and related products through Rock Creek. In 2008, Rock Creek undertook an initial assessment related to the applicability of low-TSNA tobacco for pharmaceutical and related applications. Given our working capital constraints, our ability to resume our research efforts and to

advance the research and development activities will depend on our ability to obtain funding for these initiatives. It will also depend on the results of our ongoing patent litigation with RJR.

- *Interest Income/Expense.* In 2008, interest income was approximately \$0.4 million and interest expense was approximately \$0.7 million for a net interest expense of approximately \$0.3 million as compared to interest income of approximately \$0.8 million and interest expense of approximately \$1.3 million for a net interest expense of approximately \$0.5 million in 2007. The lower interest expense during 2008 reflected reductions in the outstanding balance on our debt due to our payments on the RJR debt and lower interest rates. The lower interest income during 2008 reflected the decreased interest earned from our MSA escrow accounts as a result of the sale in March 2007 of the interest stream and reversionary interest in the amount deposited into escrow for sales of cigarettes through 2006.

*Income Tax Benefit/Expense.* During 2007 and during the nine months ended September 30, 2008, pursuant to Financial Accounting Standards Board, or FASB, Interpretation No. 48, *Accounting for Uncertainties in Income Taxes, an interpretation of FASB Statement No. 109* (FIN 48), 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, that are 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 expect that the IRS will prepare a closing agreement that will confirm that our company's tax returns for the years 2001 through 2004 were correct as filed and that it will close its open examination for the tax years in question. 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.

*Discontinued Operations.* We had no discontinued operations in 2008. We recorded a loss for discontinued operations in 2007 of approximately \$(0.5) million from the discontinuation of our cigarette operations in June 2007 after licensing our trademarked cigarette brands to Tantus in May 2007. Under the licensing agreement with Tantus, Star Tobacco continues to have the ability to manufacture and sell cigarettes; however, we are focusing our efforts on the manufacture and sale of our dissolvable low-TSNA smokeless tobacco products, as opposed to cigarettes. Marketing and distribution expenses totaled approximately \$2.0 million in 2007. In 2007, there was also a write-down of equipment for \$22,583, as well as a loss for the transfer of salesperson promotional funds to Tantus of \$180,041. We recorded a gain on the sale of the licensing rights under the Tantus license agreement in the second quarter of 2007 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 a \$600,000 payment on the date of the agreement. This resulted in a gain on licensing rights from discontinued operations of approximately \$2.4 million which was recognized during 2007.

Beginning on January 1, 2005, there was an increased cost of approximately \$0.50 per carton for the tobacco farmer buyout legislation. The assessment on cigarettes under the buyout legislation is included in discontinued operations. The assessment on our smokeless tobacco products is recorded in continued operations, however, these amounts are de minimis given the level of our smokeless tobacco sales and the fact that 96% of the USDA assessments are based on cigarette sales. In 2007, our cigarette sales totaled \$10.4 million.

*Net Loss.* Our company had a net loss of approximately \$(18.3) million in 2008 compared to approximately \$(41.5) million in 2007. The net loss in 2008 reflects the approximately \$0.6 million gain relating to the assignment of purchase rights to one of our leased facilities in Chase City, Virginia. The net loss in 2007 reflects the impact of the \$(27.0) million loss associated with the sale of the interest stream and reversionary interest in the MSA escrow accounts, and the operating loss of approximately \$(17.1) million, partially offset by the \$3.6 million gain from the sale of approximately 990 tobacco curing barns as well as the loss from discontinued operations of approximately \$(0.5) million.

In 2008, our company had basic and diluted net loss per share of \$(0.20) compared to basic and diluted net loss per share of \$(0.52) in 2007.

### **Year Ended December 31, 2007 Compared to Year Ended December 31, 2006**

Please refer to “Item 6. 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 dissolvable tobacco increased to \$0.7 million in 2007, reflecting an increase of \$0.2 million, or 41.9%, from 2006 gross sales of \$0.5 million. Net Sales (gross sales reduced by sales returns and allowances, cash discount and promotion expenses such as couponing, buy downs and slotting fees) increased to \$0.5 million in 2007, or 23.2%, compared to \$0.4 million in 2006.

*Gross Margin.* In 2007, overall gross margin (net revenue less costs of goods sold and federal excise taxes) loss increased to \$(1.6) million compared to \$(1.4) million in 2006. The negative gross margin for dissolvable tobacco was due primarily to the under utilization of manufacturing and packaging equipment. The estimated excess cost was \$1.7 million and \$1.6 million for 2007 and 2006, respectively.

Historically MSA escrow payments have neither been expensed nor accrued for income statement purposes, but the escrow deposit remained the property of our company on its 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.

#### *Total Operating Expenses*

Total operating expenses increased approximately \$3.1 million, or 25.0%, to \$15.5 million for 2007 from \$12.4 million in 2006. The increase was due to Marketing and Distribution costs of \$2.7 million, and General and Administrative costs of \$1.9 million offset somewhat by a decrease in depreciation expense of \$1.4 million.

- *Marketing and Distribution Expenses.* Marketing and distribution expenses for our dissolvable tobacco products were \$2.8 million in 2007 compared to \$0.1 million for 2006, an increase of \$2.7 million, which reflects increased marketing expenses for advertising and sampling, particularly for the new “Natural” and “Java” blends of STONEWALL Hard Snuff® that were introduced in March and August 2007, respectively. Additionally, the increase in marketing and distribution expenses reflects costs associated with several sales personnel who had been primarily selling cigarettes with a secondary attention on smokeless tobacco products and who were assigned exclusively to smokeless tobacco sales upon execution of the Tantus license agreement. This increase also reflects increased shipping costs associated with our sampling program and the utilization of package shippers rather than full trucks for delivery of smokeless tobacco products. We spent approximately \$1.6 million in 2007 to promote the product to the distribution trade and at retail.
- *General and Administrative Expenses.* General and Administrative expenses totaled approximately \$12.6 million for 2007, which is an increase of approximately \$2.0 million from the approximately \$10.6 million in 2006. In 2007, there were increased legal expenses of approximately \$0.9 million, most of which were associated with the appeal of the rulings issued by the District Court in January 2007 and June 2007 in our ongoing patent infringement litigation against RJR, and other legal costs related to corporate restructuring to pursue the development of tobacco-based pharmaceuticals through a separate subsidiary. Additionally, approximately \$850,000 was paid during 2007 in connection with the appeals process of our litigation with RJR. In 2007, we had increased insurance costs of approximately \$0.4 million, as well as increased executive travel costs of \$0.6 million primarily related to meetings of our Board of Directors and with investors related to our company’s legal and financial matters. These expenses were partially offset by decreased facility costs of approximately \$0.1 million in 2007.

- *Depreciation.* Depreciation expense totaled approximately \$0.1 million in 2007, a decrease of approximately \$1.3 million, compared with approximately \$1.4 for 2006. The higher depreciation expense during 2006 primarily reflects depreciation on our company's curing barns during the third and fourth quarter of 2006. Depreciation was calculated based on a unit of production method. During the first quarter of 2007, approximately 990 tobacco curing barns were sold to farmers participating in our StarCured® tobacco curing program. There was no depreciation for the remaining barns because they were classified as idle equipment for which no depreciation is recorded under GAAP.
- *Research and Development Expenses.* We maintained our spending on research at a minimum level while we continued to concentrate on our patent infringement lawsuit against RJR. Consistent with our efforts to cut costs, we have deferred our research projects since the last half of 2003, and we have not convened a meeting of our Scientific Advisory Board during this period. Presently, our research focus is directed to assessing the impact that products with reduced toxin levels may have on the range of serious health hazards linked with the use of conventional smoked and smokeless tobacco products, and encouraging scientists in the U.S. and Europe to pursue TSNA-related research. While our research work has been deferred as a result of a lack of available working capital, we have designed several additional scientific studies to determine, among other things, whether a reduction in TSNA exposure can be equated with a reduction in health risk; to assess biomarker differences that can be equated to levels of various toxins in smoked versus smokeless tobacco; and to measure the impact of the decline in TSNA exposure in low-TSNA smokeless tobacco compared to traditional cigarette products. However, because of monetary constraints we are not moving forward with these studies at this time. When we initiate these studies, they will be conducted by independent laboratories and universities. We hope to renew research and developmental efforts in 2008, subject to the availability of funds, and to pursue the development of a range of tobacco-based pharmaceutical products through our subsidiary, Rock Creek, which was incorporated in June 2007. The extent of future research and development efforts will depend, in part, on the results of the RJR litigation.
- *Interest Income/Expense.* In 2007, interest income was approximately \$0.8 million and interest expense was approximately \$1.3 million for a net interest expense of approximately \$0.5 million as compared to interest income of approximately \$1.9 million and interest expense of approximately \$2.0 million for a net interest expense of approximately \$0.1 million in 2006. The lower interest income during 2007 was the result of the sale of the interest stream in our MSA escrow accounts offset by interest earned on higher cash balances. In the past, our company received for its own account the current interest on the amounts in escrow. As a result of the sale and assignment of the interest stream and reversionary interest in its MSA escrow accounts in March 2007, we are not receiving any further interest payments on these escrow accounts. The decrease in the interest expense relates directly to the reduction in debt due to repayments of principal totaling approximately \$6.6 million of principal outstanding during 2007. In August 2007 we paid off our accounts payable note to RJR. As of December 31, 2007, we had a principal balance of approximately \$12.7 million on our long-term barn notes payable to RJR.

*Income Tax Benefit/Expense.* Our company incurred an expense of \$125,000 for interest on liabilities for unrecognized tax benefits during 2007. However, the losses during 2007 reduced the tax exposure of the Alternative Minimum Tax. As of January 1, 2007, we recorded a \$2.1 million liability for unrecognized tax benefit as a charge to beginning accumulated deficit and the resulting interest on the unrecognized tax benefit was charged during 2007. During 2006, our company had no income tax expense due to net losses.

*Discontinued Operations.* In 2007, our cigarette sales decreased by approximately 72.2% to \$10.4 million as compared to approximately \$37.4 million in 2006. The decrease in cigarette sales reflected our efforts to continue to operate in very competitive and price-sensitive geographic regions, namely Texas, Florida, Mississippi and Minnesota, and to aggressively limit sales in MSA states in the first five months of the year and our discontinuation of our cigarette operations in June 2007 following the license of our trademarked cigarette brands to Tantus in May 2007. As a result, cigarette shipments in 2007 totaled approximately 39.7 truckloads as compared to approximately 137.5 truckloads in 2006. Under the licensing agreement with Tantus, Star Tobacco continues to have the ability to manufacture and sell cigarettes; however,

we are focusing our efforts on the manufacture and sale of our dissolvable low-TSNA smokeless tobacco products, as opposed to cigarettes.

The average sales price per carton of cigarettes was approximately \$7.57 per carton in 2007, compared to approximately \$7.87 per carton in 2006. The sales price decreased \$0.30 per carton for 2007 from 2006 and reflects, in part, the agreement to sell Tantus inventoried product at a reduced price as part of the license agreement.

Gross profit decreased approximately \$(8.2) million to a loss of approximately \$(0.8) million in 2007 compared to a profit of approximately \$7.4 million during 2006. The decrease was primarily due to lower sales volume (sales for six months compared to a full year) and a lower selling price. The Federal Excise Taxes have remained constant at \$3.90 per carton for both periods.

For discount cigarettes sales during 2007, our company's cost-of-goods sold increased by approximately 8.8% to a blended average of approximately \$2.48 per carton, compared with a blended average cost of approximately \$2.28 per carton in 2006. This increase was primarily attributable to greater volume production and more stable production schedules in 2006.

Beginning on January 1, 2005, there was an increased cost of approximately \$0.50 per carton for the tobacco farmer buyout legislation. In addition to the \$0.50 per carton charge, the USDA in August 2005 assessed our company a charge of \$1.1 million for its portion of the Commodity Credit Corporation loan losses on tobacco and administrative costs. The USDA permitted our company to pay this amount over six quarters in installments of approximately \$190,000 per quarter, but because the USDA assessed this amount in the third quarter of 2005, we expensed the full amount during that quarter. The last payment for this assessment was paid during the fourth quarter of 2006. The special assessment and the ongoing assessment related to cigarettes and are included in discontinued operations. The assessment on our smokeless tobacco products is recorded in continued operations, however, these amounts are de minimis given the level of our smokeless tobacco sales and the fact that 96% of the USDA assessments are based on cigarette sales.

Marketing and Distribution expenses for our cigarette operations totaled approximately \$2.0 million in 2007, a decrease of approximately \$3.9 million, compared with \$5.9 million in 2006. This decrease was primarily due to the termination of thirty-one field sales force staff in the second quarter of 2007. This sales force had been selling cigarettes in Texas and Mississippi and were terminated in connection with the discontinuation of our sale of discount cigarettes in June 2007. In addition we ceased our point of sale product promotions for cigarettes in June 2007.

In 2007, there was also a write-down of equipment for \$22,583, as well as a loss for the transfer of salesperson promotional funds to Tantus of \$180,041 which has been included in discontinued operations.

We recorded a gain on the sale of the licensing rights under the Tantus license agreement in the second quarter of 2007 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 a \$600,000 payment received on the date of the agreement. This resulted in a gain on licensing rights from discontinued operations of approximately \$2.4 million which was recognized during 2007. There was no similar gain from licensing rights in 2006.

The overall loss for discontinued operations in 2007 totaled approximately \$(0.5) million as compared to a gain of approximately \$1.5 million in 2006.

*Net Loss.* Our company had an operating loss from continuing operations of approximately \$(17.1) million in 2007 compared with an operating loss from continuing operations of approximately \$(13.8) million in 2006. The net loss in 2007 was approximately \$(41.5) million compared with a net loss of approximately \$(12.3) million in 2006. The net loss in 2007 reflects the impact of the \$(27.0) million loss associated with the sale of the interest stream and reversionary interest in the MSA escrow accounts, and the operating loss of approximately \$(17.1) million, partially offset by the \$3.6 million gain from the sale of approximately 990 tobacco curing barns as well as the loss from discontinued operations of approximately \$(0.5) million. The results in 2006 reflected the loss from continuing operations of approximately \$(13.7) million, offset by a gain from discontinued operations of approximately \$1.5 million.

In 2007, our company had basic and diluted net loss per share of \$(0.52) compared to basic and diluted net loss per share of \$(0.16) in 2006.

### **Liquidity and Capital Resources**

Our company has been operating at a loss for the past six years. Our future prospects are dependent on the distribution and consumer acceptance of our low-TSNA smokeless tobacco products as well as the continued development of new low-TSNA smokeless tobacco products, independently and through alliances with other tobacco manufacturers. Also, our long-term prospects are 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, the ability to generate revenues through such royalty payments are also dependent upon the successful completion of our ongoing patent infringement lawsuit against RJR. A jury trial in that case has been set to begin on May 18, 2009, in the United States District Court for the District of Maryland.

As of December 31, 2008, we had a working capital surplus of approximately \$5.9 million, which included cash and cash equivalents of approximately \$6.5 million. Anticipated future cash needs during 2009 include:

- additional litigation costs in connection with the pretrial and trial portion of our ongoing patent infringement case against RJR of between \$1.0 and \$2.0 million;
- monthly principal and interest payments of approximately \$180,000 in connection with the repayment of our long-term B&W debt; and
- funding of other aspects of our 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 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 has had no revenues. Given the typical long lead time for federal approval of any pharmaceutical products, we do not expect that Rock Creek will generate any revenues for the foreseeable future, but rather that Rock Creek will focus its efforts on the research and development aspects of a range of pharmaceuticals, including products having a botanical, tobacco-based component and related products, assuming sufficient capital can be generated to support such activities.

Since January 1, 2009, through the exercise of an aggregate of 1,308,789 options and 6,279,001 warrants for our common stock, in each case for cash, our company received proceeds of approximately \$14.0 million. We anticipate that we will have sufficient funds to support our operations through March 2010. However, absent the successful completion of our company's ongoing patent infringement lawsuit against RJR, the exercise of outstanding warrants, or a substantial improvement in revenues and/or royalties from smokeless tobacco products, we believe that it will be necessary to pursue additional sources of funds during the second quarter 2010. 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, if at all.

We expect to continue to pursue opportunities for licensing our smokeless tobacco products and expanding our sales and marketing efforts. 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*

As of December 31, 2008, we had positive working capital of approximately \$5.9 million, approximately \$6.5 million in cash and cash equivalents and approximately \$0.1 million of accounts receivable, compared to

working capital, of approximately \$7.6 million, approximately \$8.9 million of cash and cash equivalents, and approximately \$0.1 million in accounts receivable, as of December 31, 2007.

Our statement of cash flows combines the cash flows generated from discontinued operations with the cash flows from continuing operations within each of the three categories shown below. As a result of the licensing agreement with Tantus, our revenues from cigarette sales ceased after June 2007 and our total revenues have decreased significantly as a result of our exiting the cigarette business. However, we had been losing money on our cigarette sales for the two quarters prior to the Tantus transaction, and we have achieved some cash flow savings from the elimination of our discount cigarette operations. The license agreement with Tantus also provides a stable source of cash flow from our trademarked brands. Pursuant to the license agreement, Tantus made an initial payment of \$600,000 on the agreement date and made monthly payments totaling \$1.8 million through December 2008. Tantus will make consecutive monthly payments of \$100,000 for an additional six months and \$3,000 per month thereafter for the seven-year duration of the term of the agreement. As of December 31, 2008, Tantus has made all payments required by the contract on a timely basis. This transaction was recognized as a sale of licensing rights and was recorded on a discounted cash flow basis in the second quarter of 2007.

*Net Cash From Operating Activities.* In 2008, approximately \$17.8 million of cash was used in operating activities compared to approximately \$14.9 million of cash used in operating activities in 2007.

*Net Cash From Investing Activities.* During 2008, we generated \$0.8 million of cash from investing activities, primarily reflecting proceeds from the Tantus licensing rights receivable. In 2007, there was a total of approximately \$12.6 million of cash generated by investing activities. Of that amount, approximately \$11.6 million was generated by the sale of approximately 990 of our tobacco curing barns and \$1.1 million was generated from the initial and monthly payments from the sale of the licensing rights under the agreement with Tantus. Approximately \$0.1 million was used to purchase hard tobacco equipment which had previously been leased, of which \$0.5 million of the purchase price was released from a deposit being held by the leasing company.

*Net Cash From Financing Activities.* During 2008, we generated net cash of approximately \$14.9 million from financing activities. Of that amount, \$16.5 million was generated by the private placement of our common stock and warrants and \$0.2 million from the exercise of stock options to purchase common shares. This was offset by \$1.7 million for the repayment of our long-term debt with RJR (the remaining entity from the 2004 combination of RJR and B&W) against the principal of our outstanding barn loan. In 2007, approximately \$4.4 million was used in financing activities of which approximately \$6.7 million was used to repay long-term debt while \$2.2 million was generated by the sale of common stock and approximately \$0.1 million was generated by the exercise of stock options to purchase common shares. Of the approximately \$6.7 million used to repay debt, approximately \$2.9 million was paid to RJR against the principal of our outstanding barn debt in connection with the sale of our tobacco curing barns and the release of certain of the tobacco curing barns from a security interest initially granted to B&W. The \$2.9 million principal payment was applied against Note "A" of the original B&W long-term debt and reduced principal payments on that note for approximately forty months beginning April 1, 2007.

*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. Also, we are continuing to seek reimbursement of approximately \$180,000 for certain of our 2007 escrow costs under agreements with distributors that require those customers to cover this cost, if our products sold to them in a non-MSA state is subsequently tax stamped in an MSA state. Given the fact that

we discontinued the sale of cigarette in June 2007 and stopped selling cigarettes at that time, we do not anticipate having any material MSA escrow obligations for 2008 cigarette sales.

#### *Cash Demands on Operations*

In 2008, our company had operating losses from continuing operations that totaled \$(18.3) million.

In addition, in 2008 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 and related products through Rock Creek.

Our inability to improve operations or to raise funds during the second quarter 2010 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 \$11.0 million on our long-term tobacco curing barn loans. 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 secured by any remaining tobacco leaf inventory and our remaining tobacco curing barns. Once the outstanding loan balance is reduced to \$10.0 million, the collateral will be released.

*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 and a percentage of the resulting payments we actually receive in the event that the litigation is resolved in our favor in return for a cap on fee payments during the litigation.

We are preparing for a jury trial in our RJR patent infringement litigation, which is set to begin on May 18, 2009. We anticipate incurring significant expenses in terms of legal fees and costs in connection with the RJR litigation 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.

Since June 2007 we have been focusing our activities on the sale of smokeless tobacco products, as opposed to cigarettes. As a result, we do not anticipate incurring MSA escrow obligations for cigarette sales in 2008 or thereafter.

*Internal Revenue Service Examination.* In 2004, we were notified that our company’s 2001 tax return had been selected for examination by the 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 have been filed for the years ended December 31, 2002 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, that are 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, it is expected that the IRS will prepare a closing agreement that will confirm that our company’s tax returns for the years 2001 through 2004 were correct as filed and that it will close its open examination for the tax years in question. 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 a letter dated October 7, 2004, we received notice 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 us and that the sales and use tax assessment plus penalties and interest together, as of October 7, 2004, totaled approximately \$988,000. We continue to challenge this assessment and have filed a request for reconsideration with the Commissioner of Taxation, and are prepared to file a judicial action if the administrative action is not favorable. The filing of the request for reconsideration stays any collection of the tax assessment, although interest continues to accrue. While we are optimistic that our request for reconsideration will be accepted based on prior rulings in similar cases, if the assessment is not reversed, we will be required to pay the tax, penalties and interest due. We do not believe that it is probable an obligation has been incurred and, as a result, no amounts have been accrued for this cost in the accompanying financial statements.

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

Since January 1, 2009, through the exercise of an aggregate of 1,308,789 options and 6,279,001 warrants for our common stock, in each case for cash, our company received proceeds of approximately \$14.0 million. For a description of the transactions related to the exercise of the warrants see Note 15 to our consolidated financial statements included in Item 15 of this Report. As a result of the warrant exercise transactions, we were required to adjust the exercise price and the number of warrants issued to Manchester Securities Corporation, or Manchester, under a 2004 warrant agreement with Manchester pursuant to which Manchester received warrants for 609,390 shares of our common stock, as previously adjusted. Since the warrant exercise transactions involved the sale of shares of our common stock at an effective price per share below \$3.29 per share, Manchester was entitled to a reduction in the exercise price of the its warrants from \$3.29 per share to approximately \$3.24 per share and to receive approximately 9,201 additional warrants to purchase our common stock.

Also, we expect to continue to pursue opportunities for licensing our company’s smokeless tobacco products and expanding our sales and marketing efforts, particularly if we obtain additional funds that could be devoted to such activity. While we may seek to obtain funds in the future through debt financing, there are significant limitations on our company’s ability to obtain new debt financing, including our agreements with B&W. Moreover, our ability to complete future financings on terms acceptable to us will depend on a number

of factors, including the performance of our company's stock price, results of operations and an improvement in economic conditions. Any future equity financings will be dilutive to our existing shareholders.

Our inability to raise funds during the second quarter 2010 could have a material adverse effect on our ability to meet our working capital needs and continue operations.

### 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, 2008, 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, 2007		
			1-3 Years	3-5 Years	More Than 5 Years
Long-term Debt.....	\$10,976.5	\$1,477.7	\$6,975.7	\$2,523.2	\$ —
Operating Leases.....	1,255.5	125.9	321.2	173.0	635.4
<b>TOTAL.....</b>	<b>\$12,232.0</b>	<b>\$1,603.9</b>	<b>\$7,296.9</b>	<b>\$2,696.2</b>	<b>\$635.4</b>

### Accounting and Reporting Developments

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 13* (SFAS No. 161). SFAS No. 161 establishes, among other things, the disclosure requirements for derivative instruments and for hedging activities. SFAS No. 161 is effective for fiscal years and interim periods beginning after November 15, 2008. The adoption is not expected to have an impact on our consolidated financial statements.

In June 2008, the FASB ratified the consensus reached on EITF Issue No. 07-05, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock*. EITF Issue No. 07-05 clarifies the determination of whether an instrument (or an embedded feature) is indexed to an entity's own stock, which would qualify as a scope exception under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. EITF Issue No. 07-05 is effective for financial statements issued for fiscal years beginning after December 15, 2008. Early adoption for an existing instrument is not permitted. Accordingly, effective on January 1, 2009, we reclassified certain outstanding warrants, at their fair value of \$687,818, to liabilities where they will continue to be measured at their respective fair values with corresponding changes in fair values charged or credited to our income. The applicable warrants expire on March 25, 2009 and if unexercised at that date, such amount will be recorded as income.

On October 10, 2008, the FASB issued FSP FAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active* (FSP FAS 157-3). FSP FAS 157-3 clarifies the application of SFAS 157 in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial instrument when the market for that financial asset is not active. The FSP was effective upon issuance, including prior periods for which financial statements have not been issued. We maintain excess cash in cash type instruments such as certificates of deposits or money market funds, which are defined as cash, and as such would not be covered by FASB 157.

## **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 its exposure to market risk associated with other financial instruments (such as investments and borrowings) and interest rate risk is not material.

Our company's \$11.0 million outstanding debt due to RJR, consisting of long-term loans, bears an interest rate of prime plus 1%. As a result our company is subject to interest rate exposure on those obligations.

## **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. including periods previously reported on by Aidman, Piser & Company, P.A., which was merged into Cherry, Bekaert & Holland, L.L.P. in 2008, Independent Registered Public Accounting Firm, is included elsewhere in this Report as described below in "Item 15. Exhibits, Financial Statement Schedules," and is 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, 2008, 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, 2008, 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 the our internal controls over financial reporting as of December 31, 2008 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, 2008, as stated in their report, which appears on page F-2 of Item 15 of this Report.

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

During 2008 in connection with the evaluation of internal controls described above in paragraph (b) of this Item 9A, we did not identify any areas requiring changes or improvements.

**ITEM 9B. OTHER INFORMATION**

None.

## 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>
Christopher C. Chapman, Jr., M.D.(1)(2)(3) . .	56	Director
Neil L. Chayet(2) . . . . .	70	Director
Marc D. Oken(1) . . . . .	62	Director
Paul L. Perito . . . . .	72	Chairman, President and Chief Operating Officer
Leo S. Tonkin(1)(2)(3) . . . . .	71	Director
Alan Weichselbaum(1) . . . . .	44	Director
Jonnie R. Williams . . . . .	53	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.*, 56, 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 1995-2000. In that capacity, Dr. Chapman had oversight responsibility for the support of new drug applications, clinical studies and device submissions to the United States Food & Drug Administration for approval. From 1992-1994, 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.

*Neil L. Chayet*, 70, has served as a member of our Board of Directors since September 2007. Mr. Chayet is President of Chayet Communications Group, Inc. Mr. Chayet has served as a visiting lecturer and adjunct professor for the Department of Psychiatry at Harvard Medical School, as well as the School of Dental Medicine and School of Veterinary Medicine at Tufts University. From 2002 until 2006, Mr. Chayet served as Chairman of the Massachusetts Mental Health Institute, Inc. He is a former 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 United Nations Conference on Psychotropic Substances and the Single Convention on Narcotic Drugs. Since 1976, Mr. Chayet has hosted a daily radio feature, "Looking at the Law," which is syndicated by CBS, and he frequently lectures on topics related to the intersection of health sciences and the law. Mr. Chayet earned an undergraduate degree from Tufts University in 1960, and a law degree from Harvard Law School in 1963. In April 2007, Mr. Chayet received the Civic Achievement Award from the American Jewish Committee.

*Marc D. Oken*, 62, has served as a member of our Board of Directors since October 2005. Mr. Oken is managing partner of Falfurrias Capital Partners, a private equity firm. In October 2005, Mr. Oken retired as Chief Financial Officer of Bank of America Corporation, a position he held since 2004. Prior to his appointment as Chief Financial Officer, Mr. Oken was Principal Financial Executive, a position he held since

joining the Bank in 1989, As Chief Financial Officer, Mr. Oken was responsible for finance, supply chain management, corporate treasury, corporate investments, corporate workplace, and investor relations. He served as the Transition Executive for the mergers with Fleet Boston Financial Corporation and credit card provider MBNA Corporation. From 1981 to 1983, he was a fellow with the Securities and Exchange Commission, serving as principal advisor to the chief accountant on matters relating to financial service industry accounting and disclosure. Mr. Oken was a partner with PricewaterhouseCoopers and was associated with that firm from 1974 to 1981 and 1983 to 1989. Mr. Oken currently serves as a member of the Board of Directors of Marsh & McLennan Companies, Inc., and Sonoco Products Company and is Chairman of the Board of Directors of Bojangles' Restaurants. Mr. Oken earned an undergraduate degree in business administration in 1968 from Loyola College in Baltimore, Maryland, and a master's degree in business administration in 1973 from the University of West Florida. He is a Vietnam veteran who served as a U.S. Navy aviator from 1968 to 1973.

*Paul L. Perito*, 72, is our company's President and Chief Operating Officer 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 1960-61 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 is the President of the Harvard Law School Association of the District of Columbia, a member of the Executive Committee of the Harvard Law School Association, and Secretary to the Harvard Law School Association. He is Chairman of the Harvard Law School Class of 1964 Reunion and Fund Committees, Co-Chair of the World Alumni Congress 2006-2007, and Class Agent for the Harvard Law School Fund 2006-2007. Also, 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 Chairman of Corporate Risk Advisors.

*Leo S. Tonkin*, 71, 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. 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.

*Alan Weichselbaum*, 44, has served as a member of our Board of Directors since September 2007. In October 2005, Mr. Weichselbaum founded Gimmel Partners, LP, an asset management firm in New York, New York, where he currently serves as Chairman and General Partner. Since 1993, Mr. Weichselbaum has worked with both hedge funds and asset management firms in the area of small-cap equities. After receiving an MBA in finance from New York University in 1990, Mr. Weichselbaum spent three years with Philip Morris Capital Corporation, where he was a Manager of Financial Planning and Analysis. From 1986 to 1989, Mr. Weichselbaum was an audit and tax consultant for the small business division at PricewaterhouseCoopers LLP. Mr. Weichselbaum is a director of Jesup and LaMont Securities Corp. He also is a member of the board and former president of the Young Israel of Lawrence, Cedarhurst, New York, as well as a member of the board of directors of Tony Power, a therapeutic writing center for youth, in New York. Mr. Weichselbaum, a certified public accountant, received an undergraduate degree in accounting with honors from Queens College in 1986.

*Jonnie R. Williams*, 53, has served as our company's Chief Executive Officer 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 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 to assume the primary responsibilities of Director of Product Development and Sales of our company. Mr. Williams, a principal stockholder of our company, is also the inventor of the StarCured<sup>®</sup> tobacco curing process for preventing or significantly retarding the formation of tobacco specific nitrosamines 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 is a principal in Jonnie Williams Venture Capital Corp.

#### **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 . . . . .	49	Vice President of Sales and Marketing
Paul H. Lamb, III. . . . .	75	President of Star Tobacco, Inc.
Park A. Dodd, III. . . . .	56	Chief Financial Officer
Robert E. Pokusa . . . . .	58	General Counsel
Curtis Wright, MD, MPH. . . . .	59	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*, 49, has served as Vice President of Sales and Marketing of our company since November 1999. 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.

*Paul H. Lamb, III*, 75, has served as President of Star Tobacco since 1998 and served in the same capacity from 1990 to 1994. He also has served as a director of Star Tobacco since 1990. He served as a consultant to our company from 1994 until assuming his current position in December 1998. From 1986 to

1990, Mr. Lamb founded and operated Lamb Services, Ltd., an engineering consulting firm, and from 1958 to 1986 he was employed with Brown & Williamson Tobacco Corporation where he held a variety of engineering positions. Mr. Lamb served as a director of the Southside Regional Medical Center in Petersburg, Virginia, for twenty-six years. Mr. Lamb graduated from the Virginia Military Institute with a degree in civil engineering.

*Park A. Dodd, III, 56*, 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. In 2005, Mr. Dodd joined 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.

*Robert E. Pokusa, 58*, 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, 59*, 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, 2008.

#### **Code of Ethics**

We have adopted a Code of Ethics that applies to all of our company's directors, officers (including its 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 have also made the

Code of Ethics available on our company's website at: <http://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. The Audit Committee 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. Oken (Chairman), Chapman, Tonkin and Weichselbaum, 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 Mr. Oken 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 CFO, Paul L Perito, our Chairman, President and COO, Robert E. Pokusa, our General Counsel, David A. 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 (collectively, the "Named Executives"). The following discussion summarizes the compensation awarded to the Named Executives during 2008.

#### *Overview*

Our company's mission has been, and continues to be, 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. 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. However, in May 2007, we licensed three of our company's cigarette trademarks on an exclusive basis in return for licensing fees to be recovered 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®.

We have also sought to develop a sophisticated superstructure for a technology-based, innovative tobacco 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, and the regulation of emerging forms of potentially less hazardous tobacco products including the development of tobacco based pharmaceutical products and related products such as neutraceuticals. 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. We also 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 objectives.

Our mission has been not merely to operate a successful cigarette or smokeless tobacco company, but 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. We also continue to focus on the licensing of our company's low-TSNA 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 several 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. 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. 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 as noted above in the case of Dr. Wright, in each case upon their commencement of service to our company. In May 2008, we did award stock option grants to Jonnie R. Williams, our company's CEO, Paul L. Perito, our company's President and COO, Robert E. Pokusa, our company's General Counsel, Mr. Dodd, our company's CFO, and Sara Troy Machir, our company's Vice President of Communications and Investor Relations, as noted in more detail below.

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. 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, 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 CEO. Our CEO and COO also provide recommendations, as appropriate, regarding

compensation for all executive officers, including themselves. 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 is primarily engaged as a manufacturer of low-TSNA smokeless tobacco products and, in the future, intends to manufacture pharmaceuticals and related products. In the case of our company's COO and General Counsel the Compensation Committee has also 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.

Presently, except with regard to Dr. Wright, with whom our company entered into an employment agreement in 2008 as described below, the Compensation Committee has recommended and the Board of Directors has approved the continuation of salary and benefits for our Named Executives on a month-to-month basis in accordance with employment agreements that have expired or are continuing on a month-to-month basis, without any bonus or stock awards. However, as discussed below, the Compensation Committee anticipates entering into new employment agreements with our Named Executives in 2009, as we believe that such agreements will assist it in attracting and retaining qualified executive officers.

### ***Base Salary***

In 2008, the base salary for each of our company's named executive officers was set in accordance with the terms of contracts that were entered into in years prior to 2008, or entered into in 2008 for Dr. Wright, and which have been continued on a month-to-month basis. 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. It 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 company's wholly owned subsidiary. Under his employment agreement, Dr. Wright is also entitled to a performance bonus in the amount of \$100,000 in the event the FDA does 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, provided he

is employed by our company on the FDA approval date and is not terminated for cause between that date and the date for the scheduled payment of the bonus. The bonuses 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.

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 company's 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***

Our company's executive officers, along with its other employees, are eligible to participate in the award of stock options or restricted stock grants or stock appreciation rights under our company's 1998 Stock Option Plan, its 2000 Equity Incentive 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. In October 2007, Mr. Dodd was granted options to purchase up to 250,000 shares of 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, 80,000 options vested on October 10, 2008 and an additional 80,000 will vest on October 10, 2009. In February 2008, Dr. Wright was granted options to purchase 200,000 shares of 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 an additional 50,000 will vest on each of February 26, 2009 and February 26, 2010. 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 our company. 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.

On May 6, 2008, our Board of Directors, upon recommendation from the Compensation Committee, approved the issuance of options to purchase an aggregate of 1,625,000 shares of Common Stock to Messrs. Williams, Perito, Dodd, Pokusa and Ms. Machir. The amounts granted to each individual were based on an assessment of each individual's level of commitment and contribution to our company's efforts between 2002 and 2008. The options granted were fully vested on the grant date. These grants, with the exception of options issued to Mr. Dodd and Dr. Wright when they joined our company in November 2007 and February 2008, respectively, were intended to further align the interests of these key executives to our company's objectives and as recognition of the fact that no bonuses or equity grants had been issued to key executives since 2003.

#### ***Benefits Plans***

In order to attract and retain individuals who are capable of carrying out and enhancing our company's mission, we have provided certain benefits and perquisites to our company's 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 the CEO, 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 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 have expired and the agreement with Mr. Dean was modified to eliminate any severance payments when his contract was continued on a month-to-month basis after expiration. We did not seek to renew certain terms in these prior agreements as we chose to limit the compensation of our company's executive officers to base salary and benefits only, in light of operating losses that we had been experiencing. While we have not entered into new employment agreements with these executive officers, we believe that such written agreements are in the best interest of our company to attract and retain qualified executive officers. We previously entered into employment agreements with our company's named executive officers that provided for incentive awards and severance payments as additional inducements 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 our company would have difficulty attracting and retaining the type of executive officers that we believe are critical to our company's mission and long-term objectives. Accordingly, we intend to enter into new executive employment agreements with our company's executive officers in 2009. 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 he is entitled to severance payments equal to all salary that would be due under his agreement through the end of its term and all accrued vacation 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 Dr. Wright during the term of his agreement.

Under the employment agreements with Messrs. Dean, Pokusa and Wright, and an option award agreement with Mr. Dodd, 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.

### ***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, 2008. The Compensation Committee has reviewed and discussed the Compensation Discussion and Analysis with management. 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 level of compensation of our company's executive officers is appropriate given their experience, job responsibilities and the diverse management roles that have been assumed by the executive officers. In particular, our company's CEO has responsibility for the overall management of our company's new product development efforts, our low-TSNA smokeless tobacco products, capital raising initiatives and related interactions with investors. Our COO has overall responsibility for all aspects of our litigation, regulatory, and legislative initiatives, including our patent infringement litigation against RJR, and for drug development efforts of Rock Creek as its CEO. The Compensation Committee has also recommended to the Board of Directors that the Compensation Discussion and Analysis be included in this Report.

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

Leo S. Tonkin, Esquire

Neil Chayet, Esquire

## Executive Officer Compensation

The following table summarizes the compensation paid to the Named Executives employed by our company during 2006, 2007 and 2008, 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 . . . . . Chief Executive Officer	2006	1,000,000	—	—	92,346	1,092,346
	2007	1,000,000	—	—	114,246	1,114,246
	2008	1,000,000	—	806,650	52,423(3)	1,859,073
Park A. Dodd, III . . . . . Chief Financial Officer	2006	—	—	—	—	—
	2007	160,000	—	112,500	40,200	312,700
	2008	236,400	1,500	66,630	52,500(4)	357,030
Paul L. Perito . . . . . Chairman, President and Chief Operating Officer	2006	1,000,000	—	—	86,672	1,086,672
	2007	1,000,000	—	—	90,763	1,090,763
	2008	1,000,000	—	832,875	141,662(5)	1,974,437
David M. Dean . . . . . Vice President of Sales and Marketing	2006	295,054	1,500	—	4,881	301,435
	2007	295,054	1,500	—	21,612	318,666
	2008	295,054	1,500	—	42,041(6)	338,595
Robert E. Pokusa . . . . . General Counsel	2006	385,000	1,500	—	16,325	402,825
	2007	385,000	1,500	—	16,248	402,748
	2008	385,000	1,500	299,835	18,781(7)	705,116
Curtis Wright, MD . . . . . Senior Vice President, Medical/Clinical Director, Rock Creek	2006	—	—	—	—	—
	2007	—	—	—	—	—
	2008	236,538	101,500	291,900	8,827(8)	638,765

(1) Represents our company's yearly Holiday bonus of \$1,500 paid to all employees, except the CEO, COO and the signing bonus paid to Curtis Wright.

(2) Amounts represent our company's compensation cost recognized for financial statement reporting purposes for the fiscal year ended December 31, 2006, 2007 and 2008, in accordance with the provisions of

Statement of Financial Accounting Standards No. 123R (FAS 123R), but disregarding forfeitures related to service based vesting conditions. 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 \$29,904 in automobile expenses and \$22,519 in life insurance premiums.
- (4) Includes additional payments to Tatum, LLC of \$300 per day to cover Mr. Dodd's benefits and costs.
- (5) Represents \$60,073 in automobile expenses and \$81,589 in life insurance premiums.
- (6) Represents \$30,296 in automobile expenses and \$11,745 of matching contributions by our company under its 401(k) Plan.
- (7) Represents \$6,787 life and disability insurance premiums and \$11,994 of matching contributions by our company under its 401(k) Plan.
- (8) Represents matching contributions by our company under its 401(k) Plan.

#### Grants of Plan Based Awards During 2008

The equity incentive plan awards described in the following table were granted under our company's 1998 Stock Option Plan or 2000 Equity Incentive Plan in 2008.

<u>Name</u>	<u>Grant Date</u>	<u>Number of Securities Underlying Options (#)(1)</u>	<u>Exercise or Base Price of Option Awards (\$/SH)</u>	<u>Closing Market Price on Date of Grant</u>	<u>Grant Date Fair Value of Stock and Option Awards (\$)</u>
Jonnie R. Williams .....	May 6, 2008	125,000	\$1.89	\$1.72	\$140,350
Jonnie R. Williams .....	May 6, 2008	500,000	\$1.72	\$1.72	\$666,300
Park A. Dodd, III. ....	May 6, 2008	50,000	\$1.72	\$1.72	\$ 66,630
Paul L. Perito .....	May 6, 2008	625,000	\$1.72	\$1.72	\$832,875
David M. Dean .....	—	—	—	—	—
Robert E. Pokusa .....	May 6, 2008	225,000	\$1.72	\$1.72	\$299,835
Curtis Wright, MD. ....	February 26, 2008	200,000(2)	\$1.84	\$1.86	\$291,900

- (1) Unless otherwise noted, all stock options were granted with exercise prices equal to the closing price of a share of Common Stock on the day prior to the date of the grant, vest on that date and expire ten years following the date of grant.
- (2) 100,000 of the shares granted to Dr. Wright vested on March 17, 2008 and 50,000 shares under the grant will vest on each of February 26, 2009 and February 26, 2010.

## Outstanding Equity Awards at Fiscal Year

The following table provides information regarding the stock options held by the Named Executive Officers as of December 31, 2008, including the unexercised and unvested stock option awards. All stock options were fully vested as of December 31, 2008, except for Mr. Dodd's, in which 80,000 will vest in 2009 and Dr. Wright's, in which 50,000 will vest equally in 2009 and 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	125,000 500,000	— —	\$1.89 \$1.72	5/6/13 5/6/18
Park A. Dodd, III	170,000 50,000	80,000 —	\$1.19 \$1.72	10/10/17 5/6/18
Paul L. Perito	1,000,000 625,000	— —	\$1.69 \$1.72	4/27/09 5/6/18
David M. Dean	350,000	—	\$4.00	10/6/10
Robert E. Pokusa	50,000 200,000 225,000	— — —	\$1.47 \$1.12 \$1.72	3/30/11 5/31/12 5/6/18
Curtis Wright, MD	200,000	100,000	\$1.84	2/26/18

## Option Exercises and Stock Vested

None of our Named Executives exercised any stock options during the year ended December 31, 2008. As a result, we have not included a table setting forth such exercises.

## Potential Payments Upon Termination or Change of Control

Except for Mr. Pokusa and Dr. Wright, 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. The employment agreements for the Named Executives are described above under the section titled "Employment and Severance Arrangements". The following chart sets forth the severance Mr. Pokusa and Dr. Wright would be entitled to receive upon certain terminations of employment, assuming the relevant event occurred on December 31, 2008.

<u>Name</u>	<u>Description of Severance</u>	<u>Termination without Cause</u>
Robert E. Pokusa	Salary Continuation	\$192,500
Dr. Curtis Wright, MD	Salary Continuation	\$625,000

## 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 ("Independent Directors"), is granted a stock option to purchase up to 50,000 shares of 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 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.

Messrs. Chapman, Chayet, Oken, Tonkin, and Weichselbaum 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.

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, 2008.

<u>Name and Principal Position</u>	<u>Fees Earned or Paid in Cash (\$)(1)</u>	<u>Option Awards (\$)(2)</u>	<u>Total (\$)</u>
Christopher C. Chapman, MD . . . . .	\$37,000	\$156,735	\$193,735
Neil L. Chayet, Esquire . . . . .	\$50,000	\$155,085	\$205,085
Marc D. Oken . . . . .	\$43,500	\$116,445	\$159,945
Leo S. Tonkin, Esquire . . . . .	\$64,000	\$ 72,420	\$136,420
Alan Weichselbaum . . . . .	\$39,500	\$155,085	\$194,585

- (1) This column represents the amount of compensation earned by each Independent Director during 2008.
- (2) Amounts represent our company's compensation cost recognized for financial statement reporting purposes for the fiscal year ended December 31, 2008, in accordance with the provisions of FAS 123R, but disregarding forfeitures related to service based vesting. 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.

The following represents the number of options granted to each Independent Director in 2008 and the total number of options held as of December 31, 2008.

<u>Name</u>	<u>Options Granted 2008</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>	<u>Total Options</u>
Christopher C. Chapman, M.D. . . . .	50,000	50,000	—	4.03	9/22/18	200,000
Neil L. Chayet, Esquire . . . . .	50,000	50,000	—	3.99	9/7/18	126,200
Marc D. Oken . . . . .	50,000	50,000	—	3.00	10/11/18	200,000
Leo S. Tonkin, Esquire . . . . .	50,000	50,000	—	1.86	11/20/18	475,000
Alan Weichselbaum . . . . .	50,000	50,000	—	3.99	9/7/18	100,000

#### **Compensation Committee Interlocks and Insider Participation**

In 2008, there were no interlocking relationships existing between our company's Board of Directors and the compensation committee of any other company.

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

The following table sets forth as of March 9, 2009 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 9, 2009, there were 99,847,866 shares of our company's common stock outstanding.

<u>Name</u>	<u>Shares Beneficially Owned(1)</u>	<u>Percentage Owned(2)</u>
<b><i>Named Executive Officers</i></b>		
David M. Dean(3) .....	602,842	*
Park A. Dodd(4) .....	220,000	*
Paul L. Perito(5) .....	3,405,000	3.4
Robert E. Pokusa(6) .....	504,199	*
Jonnie R. Williams(7) .....	17,084,119	17.1
Curtis Wright, MD(8) .....	100,000	*
<b><i>Directors Who Are Not Named Executive Officers</i></b>		
Christopher C. Chapman, Jr., M.D.(9) .....	200,000	*
Neil Chayet(10) .....	101,200	*
Marc D. Oken(11) .....	320,000	*
Leo S. Tonkin(12) .....	438,768	*
Alan Weichselbaum(13) .....	75,000	*
All directors and executive officers as a group (12 Persons) .....	24,887,360	24.9
<b><i>Other Beneficial Owners of 5% or More of the Outstanding Common Stock of the Company</i></b>		
Tradewinds Investment Management LP(14) .....	14,259,972	14.3
Iroquois Master Fund Ltd(15) .....	5,561,138	5.4
Kathleen M. O'Donnell as Trustee for Irrevocable Trust #1 FBO(16) .....	5,353,500	5.4

\* 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 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., 16 South Market Street, Petersburg, Virginia 23803.
- (2) The "Percentage Owned" calculations are based on the outstanding shares of Common Stock as of March 9, 2009.
- (3) Includes 251,742 shares held by Mr. Dean, 350,000 shares that Mr. Dean has the right to acquire upon exercise of stock options, and 1,100 shares owned by Mr. Dean's spouse.
- (4) Includes 220,000 shares that Mr. Dodd has the right to acquire upon exercise of stock options.
- (5) Includes 1,731,000 shares held by Mr. Perito, 1,625,000 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. Mr. Perito's address is 7475 Wisconsin Ave., Suite 850, Bethesda, Maryland 20814.

- (6) Includes 29,199 shares held by Mr. Pokusa and 475,000 shares that Mr. Pokusa has the right to acquire upon exercise of stock options. Mr. Pokusa's address is 7475 Wisconsin Ave., Suite 850, Bethesda, Maryland 20814.
- (7) Includes 15,359,119 shares held by Mr. Williams and 625,000 shares that Mr. Williams has the right to acquire upon exercise of stock options. Also includes 1,100,000 shares held by Regent Court of which Mr. Williams's shares voting and investment power.
- (8) Includes 100,000 shares that Dr. Wright has the right to acquire upon exercise of stock options.
- (9) Includes 200,000 shares that Mr. Chapman has the right to acquire upon exercise of stock options.
- (10) Includes 101,200 shares which Mr. Chayet has the right to acquire upon exercise of stock options.
- (11) Includes 120,000 shares held by Mr. Oken and 200,000 shares that Mr. Oken has the right to acquire upon exercise of stock options.
- (12) Includes 13,768 shares held by Mr. Tonkin and 425,000 shares that Mr. Tonkin has the right to acquire upon exercise of stock options.
- (13) Includes 75,000 shares that Mr. Weichselbaum has the right to acquire upon exercise of stock options.
- (14) Based solely on the Schedule 13D filed with the SEC on September 14, 2008. Includes 3,176,452, 3,290,323 and 3,857,528 shares of Common Stock held by Tradewinds Master Fund (BVI) Ltd., Feehan Partners, L.P. and P.V. Partners, L.P., respectively. Also includes an aggregate of 3,870,969 shares of Common Stock issuable upon the exercise of warrants ratably held by each of the before mentioned entities and an aggregate of 64,700 shares of Common Stock held in two individual retirement accounts for the benefit of Scott P. Peters. Robert W. Scannell is a director 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.
- (15) Includes 912,131 shares of common stock held by Iroquois Master Fund, Ltd and 1,000,000 shares of common stock held by Iroquois Capital, LP. Also includes an aggregate of 3,649,007 shares of common stock issuable upon the exercise of warrants ratably held by each of Iroquois Master Fund, Ltd. and Iroquois Capital, LP. The address for these stockholders is c/o Iroquois Master Fund Ltd 641 Lexington Avenue, 26th Floor, New York, New York 10022.
- (16) Includes 3,803,500 shares owned by a trust for the benefit of Francis E. O'Donnell, Jr., M.D., over which Kathleen O'Donnell, as trustee, has sole voting and investment power, and 1,550,000 shares owned by a trust for the benefit of Dr. O'Donnell's children over which Mrs. O'Donnell, as trustee, has sole voting and investment power. Excludes 400,000 shares owned by Hopkins Capital Group II, LLC, 200,000 shares owned by Hopkins Capital Group III, LLC, and 200,000 shares owned by Hopkins Capital Group IV, LLC, each of which is a wholly owned affiliate of Irrevocable Trust #1. The address for these stockholders is c/o Descendants' Trust, 709 The Hamptons, Chesterfield, Missouri 63017.

## Equity Compensation Plan Information

The following table provides certain information as of December 31, 2008, 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 .....	7,480,200	\$2.33	3,818,500
Equity Compensation Plans Not Approved by Shareholders(1) .....	<u>145,000</u>	\$1.00	<u>—</u>
Total .....	<u>7,625,200</u>	\$2.38	<u>3,818,500</u>

- (1) Non-qualified options to purchase shares of Common Stock at an exercise price of \$1.00 granted to a consultant on June 1, 2000 pursuant to an individual option agreement. These options were fully vested on the date of grant and were fully exercised prior to the expiration date of March 1, 2009. We have also granted warrants to purchase shares of Common Stock to two consultants. Specifically, on December 20, 2000, we issued 210,526 warrants to purchase shares of Common Stock at an exercise price of \$2.375 to a consultant. These warrants fully vested on the date of issuance and expire on December 20, 2010. We also issued 200,000 warrants to purchase shares of Common Stock at an exercise price of \$2.02 on March 20, 2002 to another consultant. These warrants were fully exercised in 2008 through a cashless exercise provision in the warrants that resulted in the issuance of 81,488 shares of Common Stock to the consultant and the cancellation of the warrant.

## 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 sublicensees, and 6% on all fees and royalties received by it from unaffiliated sublicensees, 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 Chief Executive Officer, is a principal, 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. William'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. 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 \$1,401,582 in 2008, \$1,294,650 in 2007, \$554,184 in 2006, \$412,060 in 2005, \$501,008 in 2004, and were billed at cost.

Additionally, on March 14, 2008, Mr. Williams executed a letter agreement under which he committed to make available to our company up to \$2.0 million. The agreement ran through March 31, 2009, or until our company received an additional \$2.0 million in capital through an equity investment. On May 12, 2008, our company entered into Securities Purchase Agreements pursuant to which it received proceeds of \$4.0 million in return for the sale of 2,469,135 shares of stock and warrants for an equal number of shares. As a result of this transaction, Mr. Williams' March 14, 2008 letter agreement terminated.

#### **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, Oken, Tonkin and Weichselbaum. 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. successor firm by merger of Aidman, Piser & Company, P.A. in 2008. 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., successor firm by merger to Aidman, Piser & Company, P.A., The Audit Committee has pre-approved audit and tax fees for 2008.

The following is a summary of the fees that our company incurred to Cherry, Bekaert & Holland L.L.P. successor firm by merger to Aidman, Piser & Company, P.A. and Aidman, Piser & Company, P.A. related to the following 2008 and 2007 services:

*Audit Fees:*

Cherry, Bekaert & Holland L.L.P. billed our company \$204,000 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, 2008, the reviews of the interim financial statements included in our company's Forms 10-Q filed during the fiscal year ended December 31, 2008, and other required Securities Act filings.

Aidman Piser, the predecessor company prior to merger with Cherry, Bekaert & Holland L.L.P., billed our company \$381,433 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, 2007, the reviews of the interim financial statements included in our company's Forms 10-Q filed during the fiscal year ended December 31, 2007, and other required Securities Act filings.

*Tax Fees:*

Cherry Bekaert & Holland L.L.P. billed our company \$17,077 for services related to tax compliance (federal and state tax reporting and tax planning) in 2008.

Aidman Piser, the predecessor company prior to merger with Cherry, Bekaert & Holland L.L.P., billed our company \$35,000 for services related to tax compliance (federal and state tax reporting and tax planning) in 2007.

*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>
Report of Independent Registered Public Accounting Firm . . . . .	F-2
Consolidated Balance Sheets as of December 31, 2008 and 2007 . . . . .	F-3
Consolidated Statements of Operations for the years ended December 31, 2008, 2007 and 2006 . . . . .	F-4
Consolidated Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2008, 2007 and 2006 . . . . .	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2008, 2007 and 2006 . . . . .	F-6
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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 \_\_\_\_\_

Jonnie R. Williams  
Chief Executive Officer

Date: March 16, 2009

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>
/s/ Jonnie R. Williams _____ <b>Jonnie R. Williams</b>	Chief Executive Officer and Director (Principal Executive Officer)	March 16, 2009
/s/ Paul L. Perito _____ <b>Paul L. Perito</b>	Chairman of the Board, President and Chief Operating Officer	March 16, 2009
/s/ Park A. Dodd, III _____ <b>Park A. Dodd, III</b>	Chief Financial Officer (Principal Accounting Officer)	March 16, 2009
/s/ Christopher C. Chapman _____ <b>Christopher C. Chapman</b>	Director	March 16, 2009
/s/ Neil L. Chaylet _____ <b>Neil L. Chaylet</b>	Director	March 16, 2009
/s/ Marc D. Oken _____ <b>Marc D. Oken</b>	Director	March 16, 2009
/s/ Alan Weichselbaum _____ <b>Alan Weichselbaum</b>	Director	March 16, 2009
/s/ Leo S. Tonkin _____ <b>Leo S. Tonkin</b>	Director	March 16, 2009

## 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	Fourth 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)
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)

<u>Item</u>	<u>Description</u>
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)
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)

<u>Item</u>	<u>Description</u>
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	Amendment to Executive Employment Agreement dated as of December 19, 2008 between Star Scientific, Inc. and Robert E. Pokusa
10.57	2008 Incentive Award Agreement(24)
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(25)
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 18, 2007
  - (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 Current Report on Form 8-K filed on March 3, 2009

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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, 2008 and 2007, 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, 2008. We also have audited the Company's internal control over financial reporting as of December 31, 2008, 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 2008 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, 2008 and 2007, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2008 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, 2008, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

As discussed in Note 10, the Company changed its method of accounting for uncertain tax positions in 2007 as the result of the adoption of Financial Accounting Standards Board Interpretation No. 48.

/s/ Cherry, Bekaert & Holland, L.L.P.  
Richmond, Virginia  
March 16, 2009

**STAR SCIENTIFIC, INC. AND SUBSIDIARIES**

**CONSOLIDATED BALANCE SHEETS  
DECEMBER 31, 2008 AND 2007**

	2008	2007
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents .....	\$ 6,473,441	\$ 8,881,341
Accounts receivable, trade, net of allowance for doubtful accounts of \$35,560 (2008) and \$46,731 (2007) .....	86,221	104,641
Receivable from sale of licensing rights .....	589,245	1,078,477
Inventories .....	713,236	420,435
Prepaid expenses and other current assets .....	1,252,375	606,189
Total current assets .....	9,114,518	11,091,083
Property and equipment, net .....	1,668,309	1,985,711
Idle equipment .....	299,700	299,700
Intangible assets, net of accumulated amortization .....	673,278	724,472
Receivable from sale of licensing rights, less current maturities (note 3) . . . .	132,116	721,361
MSA escrow funds .....	364,525	4,271
Total assets .....	\$ 12,252,446	\$ 14,826,598
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities:		
Current maturities of long-term debt .....	\$ 1,477,601	\$ 1,611,928
Accounts payable, trade .....	1,128,418	887,444
Accrued expenses .....	595,125	929,011
Due to stockholders .....	50,000	50,000
Total current liabilities .....	3,251,144	3,478,383
Long-term debt, less current maturities .....	9,498,936	11,110,864
Unrecognized tax benefits .....	—	2,225,000
Total liabilities .....	12,750,080	16,814,247
Commitments and contingencies (Notes 10 and 17)		
Stockholders' equity (deficit):		
Common stock(A) .....	9,225	8,149
Preferred stock(B) .....	—	—
Additional paid-in capital .....	119,102,327	99,274,482
Accumulated deficit .....	(119,609,186)	(101,270,280)
Total stockholders' equity (deficit) .....	(497,634)	(1,987,649)
Total liabilities and stockholders' equity (deficit) .....	\$ 12,252,446	\$ 14,826,598

(A) \$.0001 par value, 135,000,000 shares authorized, 92,246,308 and 81,487,715 shares issued and outstanding 2008 and 2007, 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, 2008, 2007 AND 2006**

	<u>2008</u>	<u>2007</u>	<u>2006</u>
Net sales . . . . .	\$ 451,307	\$ 481,650	\$ 390,959
Less:			
Cost of goods sold . . . . .	2,116,224	2,066,630	1,790,933
Excise taxes on products . . . . .	6,173	17,873	4,135
Department of Agriculture tobacco buyout program assessment . . . . .	<u>975</u>	<u>1,090</u>	<u>357</u>
Gross margin loss . . . . .	(1,672,065)	(1,603,943)	(1,404,466)
Operating expenses:			
Marketing and distribution . . . . .	3,538,484	2,834,794	145,887
General and administrative . . . . .	15,231,089	12,571,112	10,630,586
Depreciation . . . . .	121,117	66,018	1,437,776
Research and development . . . . .	<u>316,691</u>	<u>73,108</u>	<u>166,874</u>
Total operating expenses . . . . .	<u>19,207,381</u>	<u>15,545,032</u>	<u>12,381,123</u>
Operating loss from continuing operations . . . . .	(20,879,446)	(17,148,975)	(13,785,589)
Other income (expense):			
Interest income . . . . .	399,688	850,552	1,940,642
Interest expense . . . . .	(741,153)	(1,347,250)	(1,977,315)
Loss on retirement of assets . . . . .	(2,541)	(50,689)	—
Loss on sale of MSA . . . . .	—	(26,982,426)	—
Gain on sale of tobacco curing barns . . . . .	—	3,554,969	—
Other . . . . .	<u>659,546</u>	<u>241,338</u>	<u>32,146</u>
Total other expense . . . . .	315,540	(23,733,506)	(4,527)
Loss from continuing operations before income taxes . . . . .	(20,563,906)	(40,882,481)	(13,790,116)
Income tax benefit (expense) . . . . .	<u>2,225,000</u>	<u>(125,000)</u>	<u>—</u>
Net loss from continuing operations . . . . .	(18,338,906)	(41,007,481)	(13,790,116)
Discontinued operations:			
Gain on sale of licensing rights . . . . .	—	2,354,300	—
Income (loss) from discontinued operations . . . . .	<u>—</u>	<u>(2,805,057)</u>	<u>1,504,741</u>
Total discontinued operations . . . . .	—	(450,757)	1,504,741
Net loss . . . . .	<u><u>\$ (18,338,906)</u></u>	<u><u>\$ (41,458,238)</u></u>	<u><u>\$ (12,285,375)</u></u>
Loss per common share; basic and diluted:			
Continuing operations . . . . .	\$ (0.20)	\$ (0.51)	\$ (0.18)
Discontinued operations . . . . .	<u>\$ —</u>	<u>\$ (0.01)</u>	<u>\$ 0.02</u>
Total basic and diluted . . . . .	<u><u>\$ (0.20)</u></u>	<u><u>\$ (0.52)</u></u>	<u><u>\$ (0.16)</u></u>
Weighted average shares outstanding — basic and diluted . . . . .	89,843,683	80,394,897	77,836,073

See notes to consolidated financial statements.

**STAR SCIENTIFIC, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**  
**YEARS ENDED DECEMBER 31, 2008, 2007 AND 2006**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount			
Balances, January 1, 2006 . . . . .	75,151,415	\$7,515	\$ 85,802,440	\$ (45,426,667)	\$ 40,383,288
Stock-based compensation . . . . .	—	—	689,905	—	689,905
Stock option exercise . . . . .	100,000	10	120,740	—	120,750
Issuance of common stock and warrant exercise . . . . .	4,000,000	400	9,999,600	—	10,000,000
Net loss . . . . .	—	—	—	(12,285,375)	(12,285,375)
Balances, December 31, 2006 . . . .	79,251,415	\$7,925	\$ 96,612,685	\$ (57,712,042)	\$ 38,908,568
Stock-based compensation . . . . .	—	—	380,908	—	380,908
Stock option exercise . . . . .	36,300	4	81,109	—	81,113
Issuance of common stock and warrant exercise . . . . .	2,200,000	220	2,199,780	—	2,200,000
Income tax adjustment resulting from change in accounting principle (Note 10) . . . . .	—	—	—	(2,100,000)	(2,100,000)
Net loss . . . . .	—	—	—	(41,458,238)	(41,458,238)
Balances, December 31, 2007 . . . .	81,487,715	\$8,149	\$ 99,274,482	\$(101,270,280)	\$ (1,987,649)
Stock-based compensation . . . . .	—	—	3,172,581	—	3,172,581
Stock option exercise . . . . .	58,000	6	156,334	—	156,340
Issuance of common stock and warrant exercise . . . . .	10,700,593	1,070	16,498,930	—	16,500,000
Net loss . . . . .	—	—	—	(18,338,906)	(18,338,906)
Balances, December 31, 2008 . . . .	<u>92,246,308</u>	<u>\$9,225</u>	<u>\$119,102,327</u>	<u>\$(119,609,186)</u>	<u>\$ (497,634)</u>

See notes to consolidated financial statements.

**STAR SCIENTIFIC, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**YEARS ENDED DECEMBER 31, 2008, 2007 AND 2006**

	2008	2007	2006
<b>Operating activities:</b>			
Net loss .....	\$(18,338,906)	\$(41,458,238)	\$(12,285,375)
Adjustments to reconcile net loss to net cash flows from operating activities:			
Depreciation and amortization .....	601,819	662,764	2,170,121
Loss on sale of MSA .....	—	26,982,426	—
Gain on sale of curing barns .....	—	(3,554,969)	—
Gain on sale of licensing rights .....	—	(2,354,300)	—
Loss on disposal of property and equipment .....	2,541	45,548	—
Deferred income taxes .....	(2,225,000)	125,000	—
Stock-based compensation expense .....	3,172,581	380,908	689,905
Provision for (recovery of) bad debts .....	(11,171)	(41,731)	(100,000)
Increase (decrease) in cash resulting from changes in:			
Accounts receivable, trade .....	29,591	4,750,547	(2,268,443)
Inventories .....	(292,804)	972,859	1,101,755
Prepaid expenses and other current assets .....	(646,186)	(471,991)	(149,503)
Other assets .....	—	87,305	(19,397)
Accounts payable, trade .....	240,974	(109,345)	37,189
Federal excise taxes payable .....	(345)	(917,840)	291,643
Accrued expenses .....	(333,538)	(1,306)	(133,915)
Net cash flows from operating activities .....	(17,800,444)	(14,902,363)	(10,666,020)
<b>Investing activities:</b>			
Purchases of property and equipment .....	(111,689)	(78,391)	(6,073)
Proceeds from sale of tobacco curing barns .....	—	11,614,100	—
Proceeds from sale of licensing rights .....	1,078,477	1,120,849	—
Purchase of intangible assets .....	(9,656)	(2,715)	(9,054)
Deposits (made) returned on property and equipment .....	(114,419)	(74,950)	—
Net cash flows from investing activities .....	842,713	12,578,892	(15,127)
<b>Financing activities:</b>			
Payments on long-term debt and capital leases .....	\$ (1,746,255)	\$ (6,716,304)	\$ (5,543,147)
Stockholder advances .....	—	—	(69,595)
Proceeds from sale of stock and warrant exercise .....	16,500,000	2,200,000	10,000,000
Proceeds from exercise of options .....	156,340	81,113	120,750
Net cash flows from financing activities .....	14,910,085	(4,435,191)	4,508,008
Deposits to MSA escrow fund .....	(360,254)	(220,911)	(1,061,992)
Proceeds from sale of MSA escrow fund .....	—	11,563,447	—
Net cash flows from MSA activities .....	(360,254)	11,342,536	(1,061,992)
Change in cash and cash equivalents .....	(2,407,900)	4,583,874	(7,235,131)
Cash and cash equivalents, beginning of year .....	8,881,341	4,297,467	11,532,598
Cash and cash equivalents, end of year .....	\$ 6,473,441	\$ 8,881,341	\$ 4,297,467
<b>Supplemental disclosure of cash flow information:</b>			
Cash paid during the year for:			
Interest .....	\$ 831,258	\$ 1,409,824	\$ 1,859,177
Income taxes .....	\$ —	\$ —	\$ —
<b>Supplemental schedule of non-cash investing and financing activities:</b>			
Equipment or vehicle acquired with debt or capital lease .....	\$ —	\$ 122,019	\$ —
Acquisition of equipment with lease deposit .....	\$ —	\$ 500,000	\$ —

See notes to consolidated financial statements.

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

### *Nature of business:*

Star Scientific, Inc. ("Star") and its wholly owned subsidiaries, Star Tobacco, Inc. and Rock Creek Pharmaceutical, Inc. ("Star Tobacco" and "Rock Creek", respectively, and together with Star, the "Company") are technology-oriented tobacco companies with a mission to reduce toxins in tobacco leaf and tobacco smoke. The Company is 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 ("TSNAs");
- the manufacture, sales, marketing and 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 cigarett® pieces and STONEWALL Hard Snuff®;
- the licensing of trademarks for certain of the Company's cigarette brands that it discontinued manufacturing in 2007, consistent with the Company's previously announced plan to transition from the sale of cigarettes to low-TSNA smokeless tobacco products; and
- the planned 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 potentially related products such as neutraceuticals.

### *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 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. In March 2007, the Company entered into an agreement under which it received a payment of approximately \$11.6 million in return for assigning to the purchasers the right, title and interest to interest paid on the 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, the Company wrote off these assets in the second quarter 2007, however the escrow accounts remain in the Company's name and may be used to satisfy portions of any judgments or settlements by the Settling States if filed against the Company for the types of claims asserted against the major tobacco manufacturers and which resulted in the negotiation of the MSA.

To date, the Company has not had any MSA state file suit against it for such claims or to attempt to collect on amounts that have been deposited into escrow. The probability that such suits will be filed in the future is generally unknown, although there will be an incentive for such suits to be filed prior to the time that the funds deposited into escrow are returned to the Company. If such suits are filed, the Company will undertake to assess the viability of such suits and determine what impact such pending litigation would have on the value of the Company's MSA escrow funds or on the Company generally if a demand exceeds the amount of the MSA escrow funds.

*Accounts receivable, trade and allowance for doubtful accounts:*

Accounts receivable are customer obligations due under normal trade terms. The Company sells its products to distributors and retail customers. The Company performs continuing credit evaluations of its customers' financial condition and does not require collateral.

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, 2008 and 2007 was \$35,560 and \$46,731, 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 costs and wasted materials 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. Assets under capital leases are amortized over the lesser of the lease term or estimated useful life, using the units of production method. As of December 31, 2008 no capital leases existed. With regard to the tobacco curing barns, depreciation is recognized using a "units of production" method of accounting to more closely match depreciation with the period in which such assets are used in the third and fourth quarters of each fiscal year. The Company in March 2007 sold approximately 990 of its tobacco curing barns for approximately \$11.6 million. The remaining barns are accounted for as idle equipment as of December 31, 2008.

*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 follows Statement of Financial Accounting Standards No. 123R — Share-based Payments. The statement requires the use of 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 9).

*Revenue Recognition:*

Revenue from the sale of the Company's hard 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.

As required by generally accepted accounting principles of the United States (GAAP), 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.

*Shipping costs:*

Shipping costs are included in marketing and distribution expenses and aggregated \$35,395, \$34,468, and \$23,408, in 2008, 2007 and 2006, respectively.

*Advertising Costs:*

Advertising costs are expensed as incurred and are included in marketing and distribution expenses. For the years ended December 31, 2008, 2007 and 2006, advertising costs were \$199,283, \$98,224, and \$60,341, 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.

*Recent Accounting and Reporting Pronouncements:*

In March 2008, the FASB issued SFAS No. 161, "*Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133*" ("SFAS No. 161"). SFAS No. 161 establishes, among

other things, the disclosure requirements for derivative instruments and for hedging activities. SFAS No. 161 is effective for fiscal years and interim periods beginning after November 15, 2008. The adoption is not expected to have a material impact on the Company's consolidated financial statements.

In June 2008, the FASB ratified the consensus reached on EITF Issue No. 07-05, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock*. EITF Issue No. 07-05 clarifies the determination of whether an instrument (or an embedded feature) is indexed to an entity's own stock, which would qualify as a scope exception under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. EITF Issue No. 07-05 is effective for financial statements issued for fiscal years beginning after December 15, 2008. Early adoption for an existing instrument is not permitted. Accordingly, on January 1, 2009 the Company will reclassify a warrant, at its fair value of \$687,818, as a liability. The applicable warrant expires on March 25, 2009 and if the warrant remains unexercised the amount will be recorded as income.

In October 2008 the FASB issued FSP FAS 157-3, "Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active" (FSP FAS 157-3). FSP FAS 157-3 clarifies the application of SFAS 157 in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial instrument when the market for that financial asset is not active. The FSP was effective upon issuance, including prior periods for which financial statements have not been issued. The Company maintains its excess cash in cash type instruments such as certificates of deposits or money market funds, which are defined as cash, and as such would not be covered by FASB 157.

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

The Company has been operating at a loss for the past six years. The Company's prospects are dependent on the distribution and consumer acceptance of its low-TSNA smokeless tobacco products as well as the continued development of new low-TSNA smokeless tobacco products, independently and through alliances with other tobacco manufacturers. Also, the Company's long-term prospects will be dependent on its ability to begin generating significant revenues through royalties from the patented tobacco curing process to which it is the exclusive licensee. However, the ability to generate revenues through such royalty payments will also be dependent upon the successful completion of the Company's ongoing patent infringement lawsuit against RJ Reynolds Tobacco Company, or RJR. A jury trial in that case has been set to begin on May 18, 2009 in the United States District Court for the District of Maryland.

As of December 31, 2008, the Company had a working capital surplus of approximately \$5.9 million, which included cash of approximately \$6.5 million. Future cash needs during 2009 include:

- additional litigation costs in connection with the pretrial and trial portion of the Company's patent infringement case against RJR of approximately \$1.0-\$2.0 million;
- monthly principal and interest payments of approximately \$180,000 in connection with the repayment of the Company's long term B&W 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. It will require substantially increased sales to reach a breakeven level for these products. Rock Creek has had no revenues or appreciable operating expenses 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 for the foreseeable future, but rather that Rock Creek will focus its efforts on the research and development aspects of a range of tobacco-based pharmaceuticals and related products, assuming sufficient capital can be generated to support such activities.

In or before May 2008, we entered into securities purchase and registration rights agreements (collectively, the "Agreements") with certain accredited investors (each an "Investor" and collectively, the "Investors") for the private placement of shares of our common stock, par value \$0.0001 per share ("Common Stock"), and warrants (the "Warrants") to purchase shares of Common Stock (the "Warrant Shares"), with per share exercises prices of \$2.00 or \$3.00 per share.

Since January 1, 2009, through the exercise of an aggregate of 1,308,789 options and 6,279,001 warrants for the Company's common stock, in each case for cash, the Company received proceeds of approximately \$14.0 million. With the proceeds from the recent exercise of warrants and options, the Company anticipates that it will have sufficient funds to support its operations through March 2010. See Note 15 for a further description of these transactions. However, absent the successful completion of the Company's ongoing patent infringement lawsuit against RJR, or a substantial improvement in revenues and/or royalties from smokeless tobacco products, the Company believes that it will be necessary to pursue additional sources of funds during the second quarter 2010. 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, if at all.

The Company expects to continue to pursue opportunities for licensing its smokeless tobacco products and expanding its sales and marketing efforts. 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.

The Company's long-term success is ultimately dependent upon the successful resolution of its patent infringement lawsuit against RJR (see Note 14) and the return to profitability through its smokeless tobacco products, royalties from the licensing of the Company's low-TSNA patents and products and eventually from the development and sale of drug products and related products by Rock Creek.

### **3. Discontinued operations:**

In May 2007, the Company entered into an exclusive seven-year license agreement with Tantus Tobacco, LLC, or Tantus, for the licensing of the Company's 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 on June 10, 2007 ("Effective Date"). Pursuant to the license agreement, Tantus made an initial payment of \$600,000 on the agreement date and has made and will continue to make consecutive monthly payments of \$100,000 for twenty-four months beginning July 2007 and \$3,000 per month thereafter for the duration of the term of the agreement. As of December 31, 2008, the Company had an outstanding licensing receivable balance due from Tantus of \$0.7 million and the Company received monthly payments totaling \$1.8 million through December 31, 2008. While Star Tobacco continues to have the ability to manufacture and sell cigarettes, as of June 2007, it stopped selling the three licensed brands and is focusing its efforts on the manufacture and sale of dissolvable low-TSNA smokeless tobacco products, as opposed to cigarettes. Although the Company continues to hold legal ownership of the licensed trademarks, the Company has 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 the Company under the license agreement has no significant obligation to provide future services beyond maintenance of the trademarks. Therefore, on the Effective Date, the Company 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 a \$600,000 payment received on the date of the agreement. Given the nature of the license agreement with Tantus, the Company also classified its cigarette business as discontinued operations beginning in the second quarter of 2007 and the results of operations, assets and liabilities associated with the cigarette business are separately reported for all periods presented. The cigarette operations and cash flows have been eliminated from ongoing operations and the Company will not have any significant continuing involvement in these operations.

The following represents a summary of the Company's operating results and the gain on the disposition of the cigarette operations.

	<u>2008</u>	<u>2007</u>	<u>2006</u>
Net sales .....	\$—	\$10,367,727	\$37,354,941
Cost of goods sold .....	—	11,151,822	29,937,761
Gross margin (loss) .....	—	(784,095)	7,417,180
Operating expenses .....	—	2,020,962	5,912,439
Operating income (loss) .....	—	(2,805,057)	1,504,741
Gain on disposition (net of income tax) .....	—	2,354,300	—
Total from discontinued operations .....	<u>\$—</u>	<u>\$ (450,757)</u>	<u>\$ 1,504,741</u>

The Company had no assets or liabilities related to the discontinued operations on its Balance Sheet as of December 31, 2008 and 2007.

#### 4. Inventories:

Inventories consist of the following:

	<u>2008</u>	<u>2007</u>
Raw materials .....	\$146,084	\$ 84,472
Packaging materials .....	434,288	223,823
Finished goods .....	132,864	112,140
	<u>\$713,236</u>	<u>\$420,435</u>

The Company had product manufacturing cost that exceeded its normal capacity cost of approximately \$1.8 million and \$1.7 million for 2008 and 2007, respectively. These costs are included in cost of goods sold in the accompanying consolidated statements of operations.

#### 5. Property and equipment:

Property and equipment consists of the following:

	<u>2008</u>	<u>2007</u>
Land .....	\$ 159,879	\$ 159,879
Buildings .....	352,904	352,904
Leasehold improvements .....	451,217	1,440,197
Machinery and equipment .....	4,511,574	4,320,180
Office and sales equipment .....	833,614	802,860
Total property and equipment .....	6,309,188	7,076,020
Less accumulated depreciation .....	(4,640,880)	(5,090,309)
Property and equipment-net .....	<u>\$ 1,668,309</u>	<u>\$ 1,985,711</u>

During March 2007, the Company sold approximately 990 tobacco curing barns for cash proceeds of approximately \$11.6 million. These sales resulted in a gain of approximately \$3.6 million during 2007. The Company continues to own 37 tobacco curing barns, which will be used in the future to ensure a supply of very-low TSNA tobacco for its smokeless tobacco products. However, the barns are currently not in use and, as such, are classified as idle equipment in the 2008 and 2007 accompanying consolidated balance sheet. In March 2007, in connection with the sale and the release of certain of the tobacco curing barns from a security interest initially granted to B&W, the Company paid RJR (the remaining entity from the 2004 combination of RJR and B&W) approximately \$2.9 million on its long-term debt. That payment was applied against Note "A"

of the original B&W debt and reduced principal payments on that note for approximately forty months beginning April 1, 2007.

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 continues to lease a portion of the Chase City facility for its manufacturing operations while it transitions those operations to an adjacent facility in Chase City that it also leases.

Depreciation expense is included in the consolidated statement of operations for the years ended December 31, 2008, 2007 and 2006, as follows:

	<u>2008</u>	<u>2007</u>	<u>2006</u>
Cost of Goods Sold .....	\$419,853	\$521,504	\$ 570,606
Operating Expenses .....	121,116	66,018	1,437,776
Discontinued operations .....	—	11,461	98,632
Total Depreciation Expense .....	<u>\$540,969</u>	<u>\$598,983</u>	<u>\$2,107,014</u>

**6. Intangible assets:**

Intangible assets consist of the following:

	<u>2008</u>	<u>2007</u>
Patents .....	\$1,034,266	\$1,024,610
Trademarks and other intangibles .....	90,393	90,393
	1,124,659	1,115,003
Less: accumulated amortization .....	<u>(451,381)</u>	<u>(390,531)</u>
	<u>\$ 673,278</u>	<u>\$ 724,472</u>

Amortization expense associated with the intangibles was \$60,850, \$63,781, and \$63,107 in 2008, 2007 and 2006, respectively. An aggregate of \$83,543 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>	
2009 .....	\$ 61,164
2010 .....	61,164
2011 .....	61,164
2012 .....	61,164
2013 .....	61,164
Thereafter .....	<u>283,915</u>
	<u>\$589,735</u>

In the event the Company is unsuccessful in its patent infringement litigation, as discussed in Note 15, recognition of an impairment loss related to certain patents with a carrying value of approximately \$87,032 as of December 31, 2008 may be necessary. The consolidated financial statements do not include any adjustments that might result from this uncertainty.

**7. Long-term debt:**

Long-term debt consists of the following:

	<u>2008</u>	<u>2007</u>
Notes payable due B&W, collateralized by any remaining tobacco leaf inventory and the Company's remaining tobacco curing barns payable in 96 monthly installments of approximately \$134,327 until August 2010 and then \$208,000 until fully paid in December 2013 plus interest at prime plus 1% . . . . .	\$10,976,537	\$12,722,792
Less current maturities . . . . .	<u>(1,477,601)</u>	<u>(1,611,928)</u>
	<u>\$ 9,498,936</u>	<u>\$11,110,864</u>

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

<u>Years Ending December 31,</u>	
2009 . . . . .	\$ 1,477,601
2010 . . . . .	1,980,871
2011 . . . . .	2,497,392
2012 . . . . .	2,497,392
2013 . . . . .	<u>2,523,281</u>
Total notes payable and long term debt . . . . .	<u>\$10,976,537</u>

**8. 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, 2008, 2007 and 2006 are as follows:

	<u>Number</u>	<u>Weighted Average Exercise Price per Share</u>
<b>Warrants</b>		
Warrants outstanding at January 1, 2006 . . . . .	4,613,207	\$ 4.30
Warrants issued during 2006 . . . . .	4,028,754	3.01
Warrants exercised during 2006 . . . . .	(2,000,000)	(4.15)
Warrants expired during 2006 . . . . .	<u>(1,600,000)</u>	<u>(4.63)</u>
Warrants outstanding at December 31, 2006 . . . . .	5,041,961	\$ 3.05
Warrants issued during 2007 . . . . .	2,210,552	1.01
Warrants exercised during 2007 . . . . .	(1,250,000)	(1.00)
Warrants expired during 2007 . . . . .	<u>(750,000)</u>	<u>(2.87)</u>
Warrants outstanding at December 31, 2007 . . . . .	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 . . . . .	<u>—</u>	<u>—</u>
Warrants outstanding at December 31, 2008 . . . . .	<u>15,739,021</u>	<u>\$ 2.06</u>

*Sale of equity securities and exercise of warrants 2006:*

On March 3, 2006, the Company entered into a Securities Purchase and Registration Rights Agreement (the "Agreement") with an existing shareholder (the "Investor") whereby the Company sold to the Investor, for an aggregate purchase price of \$6,000,000, a total of 2,000,000 shares (the "Shares") of the Company's common stock, \$0.0001 par value per share ("Common Stock"), and warrants, at an exercise price of \$3.00 per share, to purchase an additional 2,000,000 shares of Common Stock (the "March 2006 Warrant"), which were set to expire on June 30, 2007. The aggregate purchase price of \$6,000,000 consisted of \$600,000 payable upon execution of the Agreement and \$5,400,000 payable pursuant to a promissory note (the "Note") between the Investor and the Company entered into simultaneously with the Agreement. The Note was full recourse and was secured by a pledge of the Shares, and initially carried no interest. The issuance of the Shares and the March 2006 Warrant were pursuant to the exemption from registration afforded by Section 4(2) of the Securities Act of 1933, and the Company filed a registration statement with respect to the resale of the Shares and the Common Stock issuable upon exercise of the March 2006 Warrant that became effective on July 3, 2006.

On June 15, 2006, the Company modified the payment terms for the Note by extending the final payment date from June 15, 2006 to July 17, 2006, and providing for interest at the Federal Funds rate on the outstanding principal amount from the date the Investor was advised that the Company's Registration Statement relating to the shares and warrant shares became effective. On July 14, 2006, the Company again modified the payment terms for the Note by extending the final payment date from July 17, 2006 to September 18, 2006, and providing for no interest on the outstanding principal amount during this period. The Company modified the terms of this Note in connection with the Investor's decision to exercise certain warrants held by the Investor by July 17, 2006. The Company accounted for this transaction as a modification of the Note pursuant to EITF 01-7, "Creditor's Accounting for a Modification or Exchange of Debt Instruments". On September 27, 2006, the Company received \$1.5 million toward payment of the Note and received the final payment of the balance of the Note of \$1.5 million on October 2, 2006.

*Modification of outstanding warrants:*

On June 15, 2006, the Company amended certain Securities Purchase and Registration Rights Agreements (the "September Purchase Agreements") it had executed with three investors in a September 2005 private placement as well as the Securities Purchase and Registration Rights Agreement it had executed with an investor in a February 2005 private placement (the "February Purchase Agreement" as amended, together with the September Purchase Agreements, the "Purchase Agreements"). In connection with the Purchase Agreements, the Company issued to these four investors warrants, at an exercise price of \$4.00 per share, to purchase an aggregate of 2,900,000 shares of Common Stock with an expiration date of June 15, 2006. The June 15, 2006 amendments to the Purchase Agreements increased the warrant exercise price from \$4.00 to \$4.15 per share and extended the expiration date of the warrants for thirty days from June 15, 2006 to July 15, 2006.

On July 14, 2006, the Company entered into Securities Purchase and Registration Rights Agreements (the "July Purchase Agreements") with the Company's largest institutional investor and one of the Company's largest private investors (collectively, the "Investors"). Pursuant to the terms of the July Purchase Agreements, the Company agreed to reset the exercise price of certain existing warrants held by the Investors, which were due to expire on July 15, 2006, from \$4.15 to \$2.00 per share, and in exchange, the Investors agreed to exercise the warrants in their entirety whereby the Investors purchased 2,000,000 shares of the Common Stock for an aggregate of \$4.0 million. Additionally, pursuant to the July Purchase Agreements, the Company agreed to grant the Investors warrants, at an exercise price of \$3.00 per share, to purchase an additional 2,000,000 shares of Common Stock exercisable within five years of the grant date (the "July Warrants"). These warrants were exercised in full in March 2009.

In connection with Securities Purchase and Registration Rights Agreements dated March 2006 and July 2006, the Company was required to adjust the strike price and the number of warrants issued to Manchester Securities Corporation ("Manchester") under a 2004 warrant agreement for 502,681 shares (the "2004

Warrants”). Pursuant to the terms of the 2004 Warrants, because the Company in the March 2006 Agreement and the July 2006 Purchase Agreements sold shares of Common Stock at an effective price per share below \$4.00 per share, Manchester was entitled to a reduction of the strike price under the 2004 Warrants from \$4.00 per share to approximately \$3.78 per share and to receive an additional grant of 28,754 warrants.

*Sale of equity securities and exercise of warrants 2007:*

On February 27, 2007, the Company and Joseph L. Schwarz, the beneficial holder of warrants issued March 3, 2006 and set to expire on February 28, 2007, to purchase a total of 1.25 million shares of the Company’s common stock, at an exercise price of \$3.00 per share, amended each of the warrants by extending the termination date of the exercise period to June 30, 2007 and increasing the exercise price from \$3.00 per share to \$3.50 per share. A portion of these warrants were exercised under the Schwarz Agreement in June 2007 and the remainder expired.

On June 29, 2007, the Company entered into Securities Purchase and Registration Rights Agreements with Joseph L. Schwarz (the “Schwarz Agreement”), one of the Company’s largest private investors and Joseph Rice, Esquire (the “Rice Agreement” and together with the Schwarz Agreement, the “June 2007 Agreements”).

Pursuant to the Schwarz Agreement, the Company sold to Mr. Schwarz a total of 750,000 shares of the Company’s common stock for an aggregate purchase price of \$750,000. Additionally, the Company reset the per share exercise price of certain existing warrants for 1,250,000 shares of common stock held by Mr. Schwarz or his IRA, which were due to expire on June 30, 2007, from \$3.50 and \$3.00 to \$1.00. In exchange for the re-pricing, Mr. Schwarz exercised the re-priced warrants in their entirety whereby Mr. Schwarz purchased 1,250,000 shares of common stock for an aggregate of \$1,250,000. Further, pursuant to the Schwarz Agreement, the Company granted Mr. Schwarz warrants, at an exercise price of \$1.00 per share, to purchase an additional 2,000,000 shares of common stock exercisable until July 14, 2011. The warrants are callable by the Company if the price of the common stock exceeds \$5.00 per shares as quoted on an approved market for twenty consecutive trading days.

Pursuant to the Rice Agreement, the Company sold to Mr. Rice, for an aggregate purchase price of \$200,000, a total of 200,000 shares of common stock and warrants, at an exercise price of \$1.00 per share, to purchase an additional 200,000 shares of common stock by July 14, 2011. The warrants are also callable by the Company if the price of the common stock exceeds \$5.00 per share as quoted on an approved market for twenty consecutive trading days.

In connection with the June 2007 Agreements, the Company was required to adjust the exercise price and the number of warrants issued to Manchester under a 2004 warrant agreement for 531,435 shares as previously adjusted (the “2004 Warrants”). Under the terms of the 2004 Warrants, since the Company, pursuant to the June 2007 Agreements, sold shares of common stock at an effective price per share below \$3.78 per share, Manchester was entitled to a reduction in the exercise price of the 2004 Warrants from \$3.78 per share to approximately \$3.71 per share and to receive an additional grant of 10,552 warrants.

*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 Company registered the March Shares and Common Stock to be issued upon exercise of the March Warrants for resale by the March Investors under the Securities Act of 1933, as amended (the "Securities Act"), on a Registration Statement on Form S-3, which was declared effective by the SEC on April 14, 2008. The March Securities 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 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.

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 \$3.78 per share, Manchester was entitled to a reduction in the exercise price of the 2004 Warrants from \$3.78 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 grants the May Investors certain registration rights with respect to the Securities. The Company registered the May Shares and Common Stock to be issued upon exercise of the May Warrants for resale by the May Investors under the Securities Act, on a Registration Statement on Form S-3, which was declared effective by the SEC on June 2, 2008. The May Securities 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 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.

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.

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.

*September Exercise of Warrants:*

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.

*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 12,000,000 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, 2008, 2007 and 2006 are as follows:

	<u>Number</u>	<u>Weighted Average Exercise Price per Share</u>	<u>Grant Date Fair Value</u>
<b>Options</b>			
Options outstanding at January 1, 2006* . . . . .	5,069,500	\$ 2.74	
Options forfeited during 2006 . . . . .	—	—	
Options exercised during 2006 . . . . .	(100,000)	(1.21)	
Options issued during 2006 . . . . .	<u>250,000</u>	<u>3.35</u>	\$2.39
Options outstanding at December 31, 2006 . . . . .	5,219,500	\$ 2.11	
Options forfeited during 2007 . . . . .	(125,000)	(3.41)	
Options exercised during 2007 . . . . .	(36,300)	(2.23)	
Options issued during 2007 . . . . .	<u>600,000</u>	<u>1.12</u>	\$0.88
Options outstanding at December 31, 2007 . . . . .	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>	\$1.49
Options outstanding at December 31, 2008 . . . . .	<u><u>7,625,200</u></u>	<u><u>\$ 2.38</u></u>	

\* Non-qualified options to purchase shares of Common Stock at an exercise price of \$1.00 granted to a consultant on June 1, 2000 pursuant to an individual option agreement. These options fully vested on the date of grant and were exercised in full prior to the expiration date of March 1, 2009.

The following table summarizes information for options outstanding and exercisable at December 31, 2008.

Range of Prices	Options Outstanding			Exercisable			
	Number	Weighted Avg. Remaining Life	Weighted Avg. Exercise Price	Aggregate Intrinsic Value	Number	Weighted Avg. Exercise Price	Aggregate Intrinsic Value
\$0.99-2.00 . . .	4,980,000	4.91	\$1.66		4,750,000	\$1.66	
2.01-3.00 . . .	905,200	2.51	2.86		905,200	2.86	
3.01-4.00 . . .	1,075,000	3.53	3.89		1,075,000	3.89	
4.01-5.00 . . .	550,000	5.63	4.76		550,000	4.76	
5.01-6.25 . . .	115,000	5.35	5.16		115,000	5.16	
\$0.99-6.25 . . .	<u>7,625,200</u>	4.51	\$2.38	<u>\$11,782,899</u>	<u>7,395,200</u>	\$2.41	<u>\$11,231,199</u>

A summary of the status of the Company's nonvested stock options as of December 31, 2008, and changes during the year then ended, is presented below.

Nonvested Stock Options	Shares	Weighted Average Grant-Date Fair Value
Nonvested at December 31, 2007 . . . . .	360,000	\$ 0.89
Granted . . . . .	2,075,000	1.46
Vested . . . . .	(2,205,000)	(0.90)
Forfeited . . . . .	—	—
Nonvested at December 31, 2008 . . . . .	<u>230,000</u>	<u>\$ 1.13</u>

As of December 31, 2008, there was \$94,064 of total unrecognized compensation cost related to nonvested share-based compensation arrangements granted under the Plan. That cost is expected to be recognized over a weighted-average period of approximately one year. The intrinsic value of options exercised in the year ended December 31, 2008 was \$36,820.

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

	2008	2007	2006
Expected life of options based on simplified method for employees . . . . .	2.5 - 5 years	5-5.67 years	5 years
Risk free interest rate . . . . .	2.22 - 3.15%	3.52-4.52%	4.55-4.75%
Expected volatility . . . . .	103.4 - 112.0%	100.2-108.0%	86-92%
Expected dividend yield . . . . .	0%	0%	0%

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

	2008	2007	2006
Employee . . . . .	\$2,470,026	\$205,010	\$ —
Non-employee consultants and directors . . . . .	702,555	175,898	689,905
	<u>\$3,172,581</u>	<u>\$380,908</u>	<u>\$689,905</u>

**9. Earnings per share:**

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

	<u>2008</u>	<u>2007</u>	<u>2006</u>
Net loss .....	<u>\$(18,338,906)</u>	<u>\$(41,458,238)</u>	<u>\$(12,285,375)</u>
Denominator for basic earnings per share-weighted average shares .....	89,843,683	80,394,897	77,836,073
Effect of dilutive securities: stock options and warrants outstanding(a) .....	—	—	—
Denominator for diluted earnings per share — weighted average shares adjusted for dilutive securities .....	89,843,683	80,394,897	77,836,073
Loss per common share — basic .....	<u>\$ (0.20)</u>	<u>\$ (0.52)</u>	<u>\$ (0.16)</u>
Loss per common share — diluted .....	<u>\$ (0.20)</u>	<u>\$ (0.52)</u>	<u>\$ (0.16)</u>

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

	<u>2008</u>	<u>2007</u>	<u>2006</u>
Stock options and warrants .....	10,231,213	10,910,713	10,261,461

**10. Income taxes:**

The Company adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainties in Income Taxes, an interpretation of FASB Statement No. 109 (FIN 48)*, on January 1, 2007. As a result, the Company recognized a \$2.1 million liability for alternative minimum tax and interest, which was accounted for as an adjustment to beginning accumulated deficit. The Company's potential liability resulted primarily from timing differences for deductions for amounts paid into 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 and all of 2007, the Company recognized approximately \$120,000 and \$125,000, respectively, of interest expense associated with uncertain tax positions. In 2005, the Company's request for a private letter ruling or PLR, dealing with the tax status of the Company's MSA escrow accounts, was resolved generally in its favor. An amended private letter ruling or amended PLR was issued by the IRS in January 2009. The amended PLR confirmed the Company's deductions taken for MSA escrow payments, which are 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 claimed. Based on the amended PLR, it is expected the IRS will prepare a closing agreement that will confirm the Company's tax returns for the years 2001 through 2004 were correct as filed, and it will close its open examination for the tax years in question without change. 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>2008</u>	<u>2007</u>
Deferred tax assets:		
Net operating loss carry-forwards (portions subject to annual limitation) .....	\$ 39,273,263	\$ 32,599,506
Credit carry-forward .....	501,000	501,000
Stock option compensation .....	1,319,870	—
Differing basis in property and equipment for tax and financial reporting purposes .....	52,312	—
Other .....	30,914	74,294
	<u>\$ 41,177,359</u>	<u>\$ 33,174,800</u>
Deferred tax liabilities:		
Differing basis in property and equipment for tax and financial reporting purposes .....	\$ —	(44,987)
MSA escrow payments taxable in future .....	(136,514)	(1,599)
Brand licensing revenue .....	—	(432,471)
	(136,514)	(479,057)
Valuation Allowance* .....	<u>(41,040,845)</u>	<u>(32,695,743)</u>
	<u>\$ —</u>	<u>\$ —</u>

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

Income tax benefit consists of the following:

	<u>2008</u>	<u>2007</u>	<u>2006</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>2008</u>	<u>2007</u>	<u>2006</u>
Statutory federal rate .....	(34.00)%	(34.00)%	(34.0)%
Permanent items .....	0.44	0.22	0.61
State tax provision, net of federal benefit .....	(3.45)	(3.45)	(3.45)
Valuation allowance .....	<u>37.01</u>	<u>37.23</u>	<u>36.84</u>
	<u>(0.00)%</u>	<u>(0.0)%</u>	<u>(0.0)%</u>

At December 31, 2008, the Company had net operating loss carry-forwards of approximately \$106.3 million, which expire from 2009 through 2027. As a result of previous ownership changes, an aggregate of \$532,000 in Federal loss carry-forwards are limited to \$116,000 annually.

## 11. 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 years ended December 31:

	<u>2008</u>	<u>2007</u>	<u>2006</u>
Business travel — aircraft expense(a) .....	\$1,401,582	\$1,294,650	\$554,184
Legal fees(b) .....	—	\$ —	\$ 5,000

- (a) The Company from time to time during 2006, 2007 and a portion of 2008 has used an aircraft owned by Starwood Industries LLC, a company in which Jonnie R. Williams, Star's CEO and largest shareholder, 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.
- (b) The Company paid legal fees to Paul Hastings, Janofsky & Walker LLP with respect to various legal matters. An executive officer of the Company was until March 31, 2001 senior counsel and a former partner of such firm but received no compensation from the firm for work undertaken on behalf of the Company.

### *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 the Company's largest shareholder, 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 2008, 2007 or 2006.

### *Due (to) from stockholders:*

Due (to) from Stockholders consists of unsecured non-interest bearing advances of \$(50,000) as of December 31, 2008 and December 31, 2007.

### *Officer loan commitment:*

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. The agreement went through March 31, 2009, or until the Company received an additional \$2.0 million in capital through an equity investment. 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"). 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.

## 12. Employee benefit plan:

The Company is the sponsor of a defined contribution retirement plan under Section 401(k) of the Internal Revenue Code. The plan covers all employees who meet certain eligibility and participation

requirements. Participants may contribute up to 15% of their annual compensation. The Company matches these contributions at a rate of \$0.75 for each \$1.00 of employee contribution. The Company made contributions of approximately \$97,726, \$114,008, and \$193,000, in 2008, 2007 and 2006, respectively.

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

*Fair value of financial instruments:*

The estimated fair value of cash and cash equivalents, trade receivables, licensing rights receivable, MSA escrow funds, due from and to stockholders and trade payables approximate the carrying value due to their short-term nature, variable interest rates or interest rates charged at rates at which the Company can currently borrow. In applying the FASB 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 our 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:

2008		2007	
Carrying Amount	Estimated Fair Value	Carrying Amount	Estimated Fair Value
\$10,976,537	\$10,976,537	\$12,722,792	\$12,722,792

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.

During 2008, the Federal Deposit Insurance Corporation, "FDIC" temporarily increased the coverage on substantially all depository accounts to \$250,000 and for certain qualifying and participating non-interest bearing transaction accounts the coverage is unlimited. The increase in coverage is scheduled to expire on December 31, 2009, at which time the amounts insured by the FDIC will return to \$100,000. During 2008 the Company had amounts on deposit which exceed these insured limits and as of December 31, 2008, had \$5.8 million which exceeded these insured limits.

Trade accounts receivable 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.

Receivable from the sale of licensing rights is collectible in monthly installments with the substantial portion of such receivable collected by May 2009. All required payments to date have been timely received. As such, management believes this receivable is fully collectible.

The Company had the following customers who represented in excess of 10% of sales:

	2008		2007		2006	
	Sales	Accounts Receivable	Sales	Accounts Receivable	Sales	Accounts Receivable
Starco Inpex, Inc DBA						
Wholesale Outlet . . . . .	8.7%	13.8%	17.9%	25.6%	18.2%	17.8%
CVS . . . . .	—%	—%	3.3%	21.5%	17.1%	55.3%
Food Lion . . . . .	11.6%	1.2%	—	—	—	—

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

##### *Operating leases:*

The Company leased manufacturing machinery and equipment under non-cancelable operating lease agreements for approximately \$35,000 per month. In July 2007 the Company purchased the equipment according to the lease terms. The Company utilized the \$500,000 security deposit and additional cash to purchase the machinery.

The Company also leases certain of its office, warehouse and manufacturing facilities under non-cancelable operating leases for approximately \$7,210 per month; expiring in 2022.

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, 2008.

<u>Year Ending December 31,</u>	
2009 .....	\$ 125,880
2010 .....	127,478
2011 .....	107,688
2012 .....	86,520
2013 .....	86,520
Thereafter .....	<u>721,000</u>
	<u>\$1,255,456</u>

Rent expense for all operating leases was approximately \$217,183, \$667,438, and \$564,238, for the years ended December 31, 2008, 2007 and 2006, respectively. Rent expense included in discontinued operations for 2006 was \$641,762.

##### *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, 2008, the Company had deposited into escrow a net amount of approximately \$38.7 million for sales of cigarettes in Settling States. The Company's total escrow obligation for 2007 sales (paid in April of 2008) was \$364,525. 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.

Most of the Settling States enacted statutes that require non-participating manufacturers to certify that they are in full compliance with the escrow requirements of the MSA as a condition to being permitted to sell cigarette products in those jurisdictions. Following the discontinuation of the Company's cigarette operations,

the Company withdrew the certifications for its brands that the Company had obtained in all of the applicable Settling States.

### *RJR Litigation*

In May 2001, Star filed a patent infringement action against RJR in the United States District Court for Maryland, Southern Division to enforce Star'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, the Company filed a second patent infringement lawsuit against RJR in the same 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. Star filed a Motion for Summary Judgment on Claim Construction and Definiteness, and RJR filed six Motions for Summary Judgment asserting various defenses. Pursuant to an Order dated September 15, 2003, the Court appointed a Special Master to prepare Reports and Recommendations ("R&Rs") for the Court on Star's Motion for Summary Judgment and five of RJR's six Motions for Summary Judgment. The Special Master issued R&Rs on all six of the Summary Judgment Motions and on March 31, 2004, the Court issued final rulings on five of the six Summary Judgment Motions that had been reviewed by the Special Master. In its March 31, 2004 rulings, the Court adopted without modification the Special Master's R&Rs, which collectively recommended that the Court deny RJR's Summary Judgment Motions, and that Star's Motion for Summary Judgment on claim construction and definiteness be granted in part and denied in part. The Court also issued an order denying RJR's Motion for Summary Judgment seeking to limit Star's damages claim, which had not been reviewed by the Special Master. On June 24, 2004, the Court issued a final order adopting without modification the Special Master's last R&R which recommended that the Court deny the final RJR Summary Judgment Motion.

On August 17, 2004, Star was informed that 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. These orders set an initial trial date of January 24, 2005, permitted additional discovery of certain defenses raised by RJR and the filing of two additional Motions for Summary Judgment. Subsequently, the Court ordered that it would bifurcate RJR's defense of inequitable conduct before the patent office and would have that defense 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 Court advised the parties that it would take the matter under advisement, and expected to issue a ruling 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. Briefing on these motions was completed on March 11, 2005.

On January 19, 2007, the Court granted RJR's Motions for Summary Judgment in part and denied these motions in part. On its Motion for Summary Judgment on the Effective Filing Date of the Patents, the 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 Court granted the motion on the basis that the term "anaerobic condition" was indefinite. The Court ultimately issued its decision on the inequitable conduct defense on June 26, 2007. In its ruling the Court held the two patents unenforceable due to inequitable conduct in their procurement and a final judgment against the Company was docketed on June 27, 2007. The Company immediately filed a notice of appeal as to the rulings issued in January and as to the ruling on the inequitable conduct defense with the United States Court of Appeals for the Federal Circuit. Oral argument before a three judge panel of the Federal Circuit Court of Appeals was held on March 7, 2008.

On August 25, 2008, the United States Court of Appeals for the Federal Circuit ("Court of Appeals") issued a unanimous opinion in the Company's favor. In its unanimous ruling, the Court of Appeals reversed 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 proceeding

on the infringement complaint. On September 8, 2008, RJR filed a petition for rehearing or rehearing en banc with the Court of Appeals. The Court of Appeals on October 22, 2008 issued an order denying RJR's petition and on October 29, 2008, a mandate formally terminating the proceedings in the Court of Appeals was filed. As a result, the District Court regained jurisdiction over the case to conduct further proceedings on the Company's infringement complaint. On January 16, 2009, RJR filed a Petition for Certiorari with the United States Supreme Court (the "Supreme Court") seeking to have the Supreme Court review the unanimous decision issued by the Court of Appeals. The Supreme Court on March 9, 2009, issued an order denying RJR's Petition for Certiorari. Following remand to the District Court, the Company and RJR filed a number of motions seeking to limit the evidence that may be introduced at trial. Also, despite the District Court's statement in its December 3, 2008 First Case Management Order that new summary judgment motions "are not encouraged," RJR filed four additional summary judgment motions. RJR also filed a motion to continue the trial based on the pending reexamination proceedings in the Patent and Trademark Office. Those motions, along with other previously filed motions, are currently pending.

In November 2008 the District Court, following remand from the Court of Appeals, scheduled a jury trial lasting between two and three weeks for the period April 20, 2009 through May 29, 2009. The District Court, at a recent conference with counsel, has set May 18, 2009, as the date for the start of the jury trial.

In July 2007, RJR filed a motion for a bill of cost and also filed a motion requesting the District Court to determine that this is an "exceptional" case under 35 USC § 285 and award attorneys' fees to RJR under that provision and/or under 28 USC § 1927. Following the decision by the Circuit Court of Appeals, RJR, on November 13, 2008, filed a notice with the District Court withdrawing these motions and an order denying RJR's motions without prejudice was issued by the District Court on February 5, 2009. On December 31, 2008 and January 2, 2009 RJR filed requests with the United States Patent and Trademark Office to reexamine the two patents that are the subject of our patent infringement litigation against RJR. In February and March 2009, the Patent and Trademark Office granted the reexamination requests. The reexamination process will proceed in due course, and the Company believes that this process will likely last at least two years. During the process the Patent and Trademark Office will undertake a review of the patentability of the subject matter of the patents in view of the prior art cited in RJR's requests.

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 and a percentage of the resulting payments the Company actually receives in the event that the litigation is resolved in its favor, 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. The Company applied for a correction of the assessment and a total abatement of the tax on the grounds that its barns are exempt from sales and use taxes under the industrial use and processing exemption and/or the agricultural exemption. In a letter dated October 7, 2004, the Company received notification from the Commonwealth of Virginia that an adverse decision had been made by the Commissioner of Taxation with respect to the sales and use tax assessment previously issued to the Company and that the sales and use tax assessment plus penalties and interest together, as of October 7, 2004, totaled approximately \$988,000. The Company continues to challenge this assessment and filed a request for reconsideration with the Commissioner of Taxation, and is prepared to file a judicial action if the administrative action is not favorable. The filing of the request for reconsideration stays any collection of the tax assessment, although interest continues to accrue. While the Company is optimistic that its request for reconsideration will be accepted based on prior rulings in similar cases, if the assessment is not reversed the Company will be required to pay the tax, penalties and interest due. The Company does not believe that it is

probable that an obligation has been incurred and, as a result, no amounts have been accrued for this cost in the accompanying consolidated financial statements.

The Company is also currently involved, as it is from time to time, in legal proceedings that arise in the ordinary course of its business, which the Company is vigorously defending or pursuing. Except as set forth above, there is no other litigation pending that could be expected to materially harm the Company's results of operations and financial condition.

#### *Real Estate Sale*

On December 1, 2008, the Company entered into an agreement to sell the buildings and property in Petersburg, Virginia at which the Company previously manufactured cigarettes. The contract includes typical buyer contingencies relating to the condition and use of the property and for financing. If those contingencies are satisfied, it is expected that a closing on the sale would take place toward the end of the third quarter 2009 or shortly thereafter.

#### **15. Subsequent Events:**

On several occasions during or prior to March 2008, the Company entered into securities purchase and registration rights agreements with certain accredited investors (each an "Investor" and collectively, the "Investors") pursuant to which the Company sold shares of its common stock, par value \$0.0001 per share ("Common Stock"), and warrants (the "Prior Warrants") to purchase an aggregate of 6,279,001 shares of Common Stock. The Prior Warrants had per share exercises prices ranging from \$2.00 to \$3.00 per share.

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 of the 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 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.

Since January 1, 2009, through the exercise of an aggregate of 1,308,789 options and 6,279,001 warrants in each case for cash, the Company received proceeds of \$14.0 million.

As a result of the Recent Transactions, the Company was required to adjust the exercise price and the number of warrants issued to Manchester Securities Corporation ("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 Recent 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 the its warrant from \$3.29 per share to approximately \$3.24 per share and to receive 9,201 additional warrants to purchase Common Stock.

**16. Quarterly results (unaudited):**

The following is a summary of quarterly unaudited results of operations for the years ended December 31, 2008, 2007 and 2006. See also Note 18 regarding restatement of quarterly financial statements filed in 2007.

	<u>March</u>	<u>June</u>	<u>September</u>	<u>December</u>
<b>2008</b>				
Revenues .....	\$ 145,651	\$ 52,176	\$ 136,725	\$ 116,755
Gross profit(loss) .....	(323,717)	(497,288)	(435,514)	(415,546)
Net loss from continuing operations .....	(5,517,578)	(6,387,476)	(4,397,405)	(2,036,447)
Net loss .....	(5,517,578)	(6,387,476)	(4,397,405)	(2,036,447)
EPS — basic and diluted continuing operations .....	\$ (0.07)	\$ (0.07)	\$ (0.05)	\$ (0.01)
EPS — net loss basic and diluted .....	(0.07)	(0.07)	(0.05)	(0.01)
	<u>March</u>	<u>June</u>	<u>September</u>	<u>December</u>
<b>2007</b>				
Revenues .....	\$ 151,136	\$ 196,168	\$ 51,603	\$ 82,742
Gross profit(loss) .....	(321,548)	(494,877)	524,293	(263,225)
Net loss from continuing operations .....	(27,283,667)	(3,991,357)	(4,489,991)	(5,242,472)
Discontinued operations .....	(913,443)	998,765	(471,004)	(65,075)
Net loss .....	(28,197,110)	(2,992,592)	(4,960,995)	(5,307,544)
EPS — basic and diluted continuing operations .....	(0.35)	(0.05)	(0.05)	(0.06)
EPS — basic and diluted discontinued operations .....	(0.01)	0.01	(0.01)	(0.01)
EPS — net loss basic and diluted .....	(0.36)	(0.04)	(0.06)	(0.07)
	<u>March</u>	<u>June</u>	<u>September</u>	<u>December</u>
<b>2006</b>				
Revenues .....	\$ 64,204	\$ 93,815	\$ 116,336	\$ 99,223
Gross profit(loss) .....	(352,805)	(340,855)	(438,070)	291,047
Net loss from continuing operations .....	(4,952,259)	(2,918,448)	(4,199,283)	(3,316,160)
Discontinued operations .....	1,721,013	627,141	598,420	154,198
Net loss .....	(3,231,243)	(2,291,307)	(3,600,863)	(3,161,962)
EPS — basic and diluted continuing operations .....	(0.06)	(0.04)	(0.06)	(0.04)
EPS — basic and diluted discontinued operations .....	0.02	(0.01)	0.01	—
EPS — net loss basic and diluted .....	(0.04)	(0.03)	(0.05)	(0.04)

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

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