

US OFFICE PRODUCTS

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)

ANNUAL REPORT UNDER SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 1999

TRANSITION REPORT UNDER SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 0-15324

STAR SCIENTIFIC, INC.

(Exact Name of Registrant as Specified in its charter)

DELAWARE

(State of incorporation)

52-1402131

(IRS Employer Identification No.)

801 LIBERTY WAY

CHESTER, VA 23836

(Address of Principal Executive Offices)

(804) 530-0535

(Registrant's telephone number, including area code)

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

COMMON STOCK, \$.01 PAR VALUE

(Title of Class)

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

Indicate by check mark 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 of information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. []

The aggregate market value of the Registrant's voting stock held by non-affiliates of the Registrant as of March 14, 2000 is approximately \$78,000,000. Shares of voting stock held by each executive officer and director and by each person who owns 5% or more of the any 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 of each class of common equity as of March 14, 2000: 58,749,201 shares of Common Stock.

DOCUMENTS INCORPORATED BY REFERENCE: (To the Extent Indicated Herein)

Note on Forward-Looking Statements

CERTAIN STATEMENTS IN THIS ANNUAL REPORT ON FORM 10-K, UNDER THE SECTIONS MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS, BUSINESS AND

ELSEWHERE RELATE TO FUTURE EVENTS AND EXPECTATIONS AND AS SUCH CONSTITUTE FORWARD-LOOKING STATEMENTS, WITHIN THE MEANING OF THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995. THE WORDS BELIEVES, ANTICIPATES, PLANS, EXPECTS, AND SIMILAR EXPRESSIONS IN THIS REPORT ARE INTENDED TO IDENTIFY FORWARD-LOOKING STATEMENTS. SUCH FORWARD-LOOKING STATEMENTS INVOLVE KNOWN AND UNKNOWN RISKS, UNCERTAINTIES, AND OTHER FACTORS WHICH MAY CAUSE THE ACTUAL RESULTS, PERFORMANCE OR ACHIEVEMENTS OF THE COMPANY TO BE MATERIALLY DIFFERENT FROM ANY FUTURE RESULTS, PERFORMANCE OR ACHIEVEMENTS EXPRESSED OR IMPLIED BY SUCH FORWARD-LOOKING STATEMENTS AND TO VARY SIGNIFICANTLY FROM REPORTING PERIOD TO REPORTING PERIOD. SUCH FACTORS INCLUDE, AMONG OTHERS, THOSE LISTED IN FACTORS THAT MAY AFFECT FUTURE RESULTS UNDER **ITEM 1 BELOW AND OTHER FACTORS DETAILED FROM TIME TO TIME IN THE COMPANY'S OTHER FILINGS WITH THE SECURITIES AND EXCHANGE COMMISSION.**

PART I

Item 1. Business

GENERAL

We are engaged in: (1) the development of proprietary scientific technology for the curing of tobacco so as to prevent, retard or significantly reduce the formation of carcinogenic toxins present in tobacco and tobacco smoke, primarily, the tobacco specific nitrosamines (TSNAs); (2) the development of less harmful smoked tobacco products utilizing tobacco with very low levels of TSNAs (measured in parts per billion) which has been cured using the Company's proprietary StarCure(TM) process; (3) the manufacture and sale of discount cigarettes, with activated charcoal filters; (4) the research and development of tobacco cessation products; and (5) the development of smokeless tobacco products utilizing tobacco with very low levels of TSNAs (measured in parts per billion) which has been cured using the Company's proprietary StarCure(TM) process.

Star Scientific Inc.'s (Star or the Company) central focus is the reduction of the range of serious health hazards associated with the use of tobacco products. Accordingly, Star's primary corporate mission is to demonstrate the commercial viability of less harmful tobacco products and to encourage other tobacco manufacturers to utilize and/or license Star's proprietary curing technology. (When used in this Report, Star Scientific, Inc. and its wholly-owned subsidiary, Star Tobacco & Pharmaceuticals, Inc. are sometimes individually and/or collectively referred to as Star or the Company.)

The Company has an exclusive worldwide license under patents and patents pending relating to methods to prevent the formation of TSNAs in tobacco. Certain TSNAs are generally regarded by cancer researchers as the most abundant and potent carcinogens in tobacco and tobacco smoke.

The Company has pioneered the development of an economically feasible curing (StarCure(TM)) process for preventing the formation of virtually all of the carcinogenic TSNAs in tobacco. This, in turn, reduces these carcinogens in secondhand smoke. Star's non-chemical StarCure(TM) curing process does not affect the taste, color or nicotine content of tobacco.

Today, the Company's revenue generation is principally through its wholly-owned subsidiary, Star Tobacco & Pharmaceuticals, Inc. (ST&P). ST&P's predecessor, a closely held private company, was organized in 1990 and, until 1994, primarily was engaged in the business of manufacturing cigars and cigarettes for others as a contract manufacturer. By late 1994, ST&P had commenced development and commercialization of its own brands of discount cigarettes using primarily Virginia flue-cured tobacco and competed principally on the basis of price. At about that same time, ST&P commenced a program of research and development relating to a range of potentially less harmful tobacco products and tobacco cessation products wherein ST&P secured certain Investigatory New Drug applications (INDs) from the U. S. Food and Drug Administration (FDA) to commence human clinical testing. Shortly thereafter, ST&P shifted its near-term research focus to a technological development phase focused upon reducing

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the carcinogenic TSNAs in the tobacco leaf and tobacco smoke. In February 1998, ST&P merged with Eye Technology, Inc., a publicly-held OTC Bulletin Board company based in Minneapolis, Minnesota. While Eye Technology technically was the surviving corporation, in effect, control of the surviving corporation shifted to the former stockholders of ST&P and the management of ST&P became the control management of the survivor in the merger. By December 30, 1998, the assets and liabilities that comprised the pre-merger business of Eye Technology, Inc. had been sold or liquidated, and the stockholders of Eye Technology voted to change its name to Star Scientific, Inc. The Company's primary corporate focus from that time forward has centered upon the development of reduced toxin, and potentially reduced risk, tobacco products, plus continued focus upon the long term development of smoking cessation products either with a joint venture partner or a corporate pharmaceutical partner.

Thereafter, in pursuance of the Company's focus to reduce the carcinogenic TSNAs in the tobacco leaf and tobacco smoke, the Company obtained the exclusive right to patents and patent applications which are now pending, pertaining to various aspects of the tobacco leaf curing process which has been named StarCure(TM). The proprietary StarCure(TM) process, to which the Company has

an exclusive license from Regent Court Technologies LLC (as discussed herein), involves the use of specially designed curing barns and a microwave curing process using specially designed industrial size microwave ovens (operated presently from its Chase City, Virginia processing center). This proprietary StarCure(TM) process virtually precludes and/or substantially reduces the formation in the tobacco leaf of the carcinogenic TSNAs, which are widely believed by medical and scientific experts to be among the most potent and powerful cancer-causing toxins present in tobacco and in side stream tobacco smoke. In 1999, the Company processed over 3.5 million pounds of very low-TSNA flue-cured tobacco using the StarCure (TM) process, and believes that this process is applicable to burley and other varieties of tobacco on a broad-scale commercial basis.

The Company's long-term strategy is to aggressively increase and expand its production capacity for its proprietary StarCure(TM) process to produce very low-TSNA tobacco (carcinogenic NNKs and NNNs at less than 400 parts per billion). Further, the Company is committed to continue to explore the development of potentially less harmful smoked and smokeless tobacco products, as well as the development of tobacco cessation products. The Company has started the process of integrating its very low-TSNA StarCure(TM) tobacco into its present discount cigarette brands. Star presently markets four brands, namely, SPORT(R), MAINSTREET(R), VEGAS(R) and G-SMOKE(R) all of which now have activated charcoal filters and contain approximately 3% of very low-TSNA flue-cured tobacco because of limited availability of very low-TSNA tobacco at this time. It is anticipated that in light of Star's projected increased StarCure(TM) production during the year 2000, in excess of 20 million pounds of very low-TSNA tobacco will be processed during this year's growing season. With such increased production, Star expects to be able to totally phase into its four brands all very low-TSNA flue-cured tobacco over the next 24 months, to launch a new very low-TSNA cigarette brand that also will have activated charcoal filters, and contemporaneously to fulfill its tobacco supply commitments to Brown & Williamson Tobacco Corporation (B&W), the third largest tobacco company in the United States. (See Relationship with B&W.)

The Company has announced plans to launch before the end of the third quarter of 2000, the first very low-TSNA cigarette. This cigarette, which will have a new name chosen by late Spring 2000, will have an activated charcoal filter. The Company's central focus will continue to be to be aimed at reducing the health hazards associated with the use of smoked and smokeless tobacco products. The Company fully accepts the evidence showing links between tobacco smoking and a variety of diseases and premature death and believes that it is unlikely that the health risks of smoked tobacco can be completely eliminated. Nevertheless, in a world where 1.1 billion people smoke and use other tobacco products, there is an urgent need to reduce the toxicity of tobacco products to the maximum extent possible using available technology. The Company believes that it has a corporate responsibility to continue to expand its research and development efforts to manufacture tobacco products that are as safe as technologically possible. The Company has now demonstrated that the method it has developed for curing tobacco using its proprietary StarCure(TM) process, can be scaled up to meet broad commercial needs in the United States and abroad. The Company's new brand will be the first cigarette to be launched in the United States which utilizes StarCure(TM) very low-TSNA flue-cured tobacco, as well as burley tobacco selected for its low-TSNA content, and a small portion of sun dried oriental tobacco. The Company's new brand will also use an activated charcoal filter aimed at reducing the levels of certain vapor phase toxins.

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PRODUCTS

Discount Cigarettes

Star currently manufactures and sells four brands of discount cigarettes, MAINSTREET(R), SPORT(R), VEGAS(R) and G-SMOKE(R) (formerly GUNSMOKE(TM)), through approximately 325 tobacco distributors throughout the United States. The cigarettes are sold as discount brands. Star does not engage in extensive advertising or marketing programs for its cigarette products, but relies primarily upon price communications with distributors and, to a lesser extent, on product appearance and taste in order to compete in the marketplace. There were no export sales by the Company in 1999.

In an effort to implement Star's corporate mission to develop potentially less harmful tobacco products, Star intends to phase its very low-TSNA tobacco which has been cured through its proprietary StarCure(TM) process into its discount cigarettes within the next 24 months. As of July 1, 1999, Star changed all of its filters to activated charcoal because of recommendations from leading health advocates and respected research scientists to the effect that activated charcoal filters reduce certain vapor phase toxins in tobacco smoke. Star intends to continue to use activated charcoal filters in all of its discount cigarettes, as well as in its new brand.

Processed Tobacco

In 1999, Star processed and sold over 3.5 million pounds of low-TSNA flue-cured tobacco that had been cured using its proprietary StarCure(TM) process. All of these sales were made to B&W, pursuant to Star's contractual arrangements with B&W described elsewhere in this Report. These sales accounted for approximately 10% of the Company's net sales in 1999. During 2000, Star expects to process, sell and/or use for its own brands in excess of 20 million pounds of very low-TSNA tobacco cured using the StarCure(TM) process. Star expects that a minimum of 8 million pounds will be sold to B&W pursuant to its Supply Agreement. The remaining portion will be integrated into Star's own discount cigarette brands over the next 24 months and/or will be available for sale to B&W or other cigarette manufacturers. The Company's long-term goal is to derive an increasingly larger percentage of its revenues from sub-licensing its StarCure(TM) process to major cigarette manufacturers.

Smokeless Tobacco Products Containing Very Low-TSNA Tobacco

Scientific research has shown that TSNA's may be the most significant carcinogens in smokeless tobacco products commonly known as chew, dip and snuff. Accordingly, in the year 2000 Star intends to devote substantial resources toward the development of very low-TSNA smokeless tobacco products. Star expects to undertake those projects in concert with a major tobacco company as a strategic partner or licensee. No assurance can be given at this time that such a product will be developed and successfully commercialized.

Tobacco-Flavored Chewing Gum and Lozenges and Chewing Gum Containing Tobacco Extract

The Company is in current discussions with a major pharmaceutical company to joint venture, partner and/or license its technology to produce tobacco cessation products. Star has produced for pilot Phase I testing both a chewing gum and a tobacco lozenge, each containing very low-TSNA tobacco, as potential smoking cessation products. The gum/lozenge products contain nicotine, as well as the MAO-inhibitor known to be present in tobacco. In anticipation of a then pending legislative proposal to provide the FDA with new legislative authority to regulate tobacco products, Star submitted and received approval of an IND for the gum product from the FDA. Star commenced a Phase I Human Clinical Trial in the second quarter of 1998 in order to demonstrate the safety of the product for smoking cessation purposes. Star has developed lozenges which contain tobacco extract. Star has not yet filed an IND application with the FDA covering lozenges, and in the current regulatory environment it is unlikely to do

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so. Neither the gum nor the lozenge may be sold in the United States as pharmaceutical products unless and until the FDA has approved a New Drug Application for such products. No assurances can be given when or if Star might obtain such approvals or that, even if such approvals are obtained, whether there will be significant revenues from the sale of either. Given the present uncertain status of the FDA's authority to regulate tobacco products, it now appears that to be sold as pharmaceutical products these tobacco-containing cessation products would be required to undergo all of the preclinical and clinical testing required of a new drug product. It seems unlikely at the present time that undertaking such testing would produce an adequate return on investment. Star continues to investigate and explore opportunities for these products in Western and Eastern Europe, and in other countries where regulating authorities appear to be more receptive to the development of reduced risk and less hazardous tobacco products. Star has taken a public position, unanimously supported by its Board of Directors, that it is in favor of comprehensive FDA regulation of all tobacco products.

SALES AND MARKETING

Star's four brands of discount cigarettes are each sold in a variety of sizes and styles, i.e., king size and 100s, soft pack and hinged box, regular flavor and menthol, and full flavor, lights and ultra lights. Star utilizes its own specified blend of tobaccos in each brand. The blend consists of Virginia flue-cured, burley and oriental varieties of tobacco, which is typical of American-style cigarettes.

Star uses stylized packaging designs for its four brands of discount cigarettes. As is typical in the cigarette industry, Star utilizes different colors, e.g., green for menthol and similar designs on its packaging to denote different product styles. Star primarily conducts trade journal and direct mail advertising to the industry and not advertising directed to consumers. Star does provide to its distributor customers, for redistribution to retailers, point-of-sale materials such as posters, pull signs, display racks as well as counter top and floor displays. Also, Star produces marketing materials for use by distributors and their direct sales force to promote Star cigarettes to their retail customers.

It is Star's strategy to rely to a large degree upon distributors to promote and sell Star's brands to retail customers. In 1999 Star sold its discount cigarettes to a total of approximately 325 distributors located in 48 states. The distributors maintain state and, where applicable, municipal government tobacco product licenses, apply state and/or local cigarette tax stamps when needed, and resell the cigarettes to retailers. Star delivers its products directly to distributors mainly by common carrier trucks. Star's distributor customers primarily serve convenience stores, gas stations and other outlets and stores. No one distributor accounted for more than 10% of Star's revenues in 1999.

During 1999, Star experienced substantial sales growth. Star believes that the price increases imposed upon the major cigarette manufacturers created an increased demand for low-price cigarettes. In late 1999, Star initiated an aggressive expansion of its marketing and sales organization to respond to its anticipated increase in demand, not only for its present products, but for what the Company believes will be a demand by knowledgeable smokers for products which deliver less toxins, i.e. Star's new brand expected to be launched in the third quarter. This growth began under the leadership of its Chief Executive Officer, Mr. Jonnie R. Williams, and then under the leadership of its Vice President of Sales and Marketing, Mr. David M. Dean and Mr. Sheldon Bogaz, Vice President of Trade Operations. Mr. Dean, who came to Star with extensive health care oriented marketing expertise, supervises a staff of eleven regional sales representatives who direct a field sales force. By the end of 2000, Star plans to increase its sales force to cover a greater number of distributors located throughout the 48 contiguous states.

PURCHASING

During 1999, the majority of tobacco used in Star's cigarettes was purchased from a recognized leaf dealer in cut rag form, meaning that the tobacco has been cut, processed and flavored to Star's specifications, and is ready when delivered to Star for the manufacturing process. The Company expects

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during 2000 and thereafter to purchase increasing amounts of the tobacco needed for its business directly from tobacco farmers.

MANUFACTURING

All of the tobacco planned to be used by the Company in 2000 in the production of its very low-TSNA tobacco either for sale to B&W and potentially other parties, or for incorporation into Star's own cigarettes, or in the development by Star of smokeless tobacco products, will be cured using Star's proprietary StarCure(TM) process. The StarCure(TM) process utilizes specially equipped curing barns and microwave technology. The specially designed curing barns, which incorporate the StarCure(TM) processing technology, are manufactured exclusively for Star by Powell Manufacturing Company of Bennettsville, South Carolina (Powell). Powell is the largest manufacturer of curing barns in the U.S. These specially designed barns are erected on site at the tobacco farms which provide Star with its tobacco. Approximately 550 of these barns have already been manufactured and delivered and contracts with tobacco farmers for approximately 350 additional curing barns have either been executed or are being finalized. Star anticipates that Powell will have provided Star with over 1,000 such barns by the end of 2000. Financing for a majority of these barns is provided by B&W (see Relationship With B&W). The Company's StarCure(TM) very low-TSNA tobacco is also processed in specially designed microwaves at its StarCure(TM) processing facility, a leased facility in Chase City, Virginia. Star's processing facility in Chase City is presently undergoing construction to substantially expand its capacity to process larger amounts of very low-TSNA tobacco. Star anticipates that it will be able to produce in excess of 20 million pounds of StarCure(TM) tobacco (both flue-cured and burley) during the year 2000 growing season.

Star's cigarettes are manufactured at its facility in Petersburg, Virginia and under contract. The tobacco is combined with filters and paper in a maker which produces finished cigarettes, which in turn are placed in a packer which provides packaging into standard 20-cigarette packs and ten-pack cartons. Star believes its manufacturing facilities, plus the additional manufacturing contract relationship now in place with B&W, will allow Star to respond to its growing demand for the foreseeable future.

RELATIONSHIP WITH B&W

On October 12, 1999, the Company and B&W entered into the Supply Agreement under which B&W agreed to purchase Star Cure(TM) tobacco. During the third quarter and early fourth quarter of 1999, the Company produced and delivered to B&W approximately 3.5 million pounds of very low-TSNA Star Cure(TM) processed tobacco. This tobacco will be used to explore the production feasibility and commercial acceptance of very low-TSNA cigarettes. In each of the years 2000 and 2001, B&W is obligated to purchase from Star five million pounds of Virginia flue-cured tobacco that has been cured using the Star Cure(TM) process; and B&W has an option to purchase three million pounds of burley tobacco cured using the same process. B&W also has the option to become the exclusive purchaser of tobacco cured using the Star Cure(TM) process in each of the years 2002 through 2004, if it purchases from the Company at least 30 million pounds of tobacco in each of those years. During the same period and beyond that period if certain conditions are met, the Company has agreed to provide sufficient quantities of tobacco cured using the Star Cure(TM) process to meet the demands of B&W and all participating B&W affiliates, including British American Tobacco PLC, the second largest tobacco company in the world.

Further, B&W has agreed to finance the Company's purchase of 600 of the specially designed curing barns and, subject to certain preconditions, an additional 400 such barns. In addition, B&W has agreed to collaborate with the Company in the development of a new very low-TSNA cigarette and the possible licensing of trademark rights to B&W in connection with the sale of this new product.

Star in 1999 entered into a manufacturing agreement under which B&W has agreed to manufacture cigarettes for Star. Also, Star has entered into an agreement under which B&W is supplying leaf tobacco to Star for use in its tobacco products.

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COMPETITION

Star's primary competition for conventional cigarettes is from the four majors, that is, Philip Morris, the brands of which accounted for approximately 50% of all cigarette sales in the United States in 1999, R.J. Reynolds, B&W and Lorillard, each of which has substantially greater financial and operating resources than Star. Star also encounters significant competition from several other smaller U.S. manufacturers of cigarettes, as well as importers of cigarettes manufactured in foreign countries. Many of these manufacturers and importers have substantially greater financial, manufacturing, marketing and other resources than Star.

Star's current conventional smoked products compete principally on the basis of price and possibly quality of product. Generally

speaking, there are three price categories of cigarettes in the United States, premium, which includes such brands as Marlboro(R) and Camel(R), full-price, which includes such brands as Doral(R) and GPC(R), and discount, which as a group account for only a small percentage (approximately 3%) of the U.S. cigarette market. Each of Star's brands is priced in the discount category. Other competitive factors include package design, taste and the amount of marketing support provided to distributors and retailers. At the consumer level, brand loyalty also is a significant factor.

Star is not aware of any other company which currently produces very low-TSNA tobacco on a commercial basis, although one Swedish company, Swedish Match, has worked with various varieties of tobacco under crop management environments and other methods in an effort to maintain low-TSNAs in its smokeless products. Star is not aware of any other company that now incorporates very low-TSNA tobacco into their cigarettes or other tobacco products. B&W now has in its possession approximately 3.5 million pounds of very low-TSNA tobacco, but has not made a public announcement of when it will start using that tobacco in its current products or in a new product. However, recent announcements by several of the major tobacco companies indicate that certain of these companies either have commenced exploration or intend to explore the production of low-TSNA tobacco in the next few years and the incorporation of low-TSNA tobacco into their cigarettes. Star believes that if it is successful in commercializing its unique very low-TSNA cigarettes and/or in developing and commercializing very low-TSNA smokeless tobacco, it is inevitable that many of the major tobacco companies will follow its lead.

If the Company is successful in developing and commercializing smoking reduction or cessation products, it will encounter stiff competition. Smoking cessation products that are approved for sale in the United States by the FDA are primarily nicotine delivery products (nicotine only) designed to wean the patient from nicotine addiction over a period of time ranging from 30 days to six weeks. Three products, Nicorette(R), a nicotine chewing gum, and Nicotrol(R) and NicoDerm(R), both transdermal nicotine patches, constituted substantially all of the U.S. pharmaceutical nicotine market in 1999. All of these products are sold over-the-counter. Zyban(R), (bupropion), a prescription drug which originally was developed and is still sold under another proprietary name as an antidepressant was introduced to the market in 1997 and has been demonstrated to be useful as a cessation product. Star understands that sales of Zyban(R) to date have been substantial and that Zyban(R) is often prescribed by physicians to be used in conjunction with nicotine delivery products.

Star's principal competitors in the cessation and reduction market include Smith Kline Beecham, the McNeil Consumer Division of Johnson & Johnson, Glaxo-Wellcome and Pharmacia-Upjohn, all of which have capital resources, research and development staffs, facilities, experience in conducting clinical trials and obtaining regulatory approvals, and experience in manufacturing and marketing their products which are significantly greater than those of Star. In addition, there are several companies developing new technologies aimed at smoking cessation therapies. There also are a number of consumer products which do not require FDA approval as therapeutic drug products but which nevertheless are advertised as alternatives to smoking or as help in the reduction of smoking. For example, at least one of

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the leading United States confectionery chewing gum manufacturers has advertised its gum products as an alternative to cigarettes. 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 Star can overcome regulatory barriers to marketing its tobacco-containing cessation products or that Star's competitors will not succeed in developing technologies and products that are more effective than Star's product candidates, that are less toxic than Star's products or that would render Star's products obsolete or non-competitive.

GOVERNMENT REGULATION

The manufacture and sale of cigarettes and other tobacco products and of pharmaceutical products are subject to extensive federal and state governmental regulation in the United States and by comparable authorities in many foreign countries. These national agencies and other federal, state and local entities regulate, among other things, research and development activities and the testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of Star's products.

There are multiple bills pending before the 106th Congress and in several state legislatures which, if enacted, would significantly change the United States tobacco industry. Some of these federal bills contain provisions which would provide substantial federal government funds for smoking cessation programs and products, as well as incentives to tobacco companies and others to produce less harmful or reduced-risk tobacco products. Star is unable to predict what effect, if any, these provisions, if enacted, would have on Star's technology for very low-TSNA tobacco or the sale of Star's smoking cessation products and/or reduced-risk tobacco products. The Company believes, however, that any bill that requires manufacturers to reduce or disclose levels of TSNAs in tobacco or tobacco smoke would be beneficial. Star announced on February 29, at a press conference held at the Dirksen Senate Office Building, its support of a bi-partisan tobacco labeling Bill (S. 2125) introduced by Senators Frank Lautenberg (D. N.J.), Richard Lugar (R. IND.), Richard J. Durbin, (D. ILL.), and Lincoln D. Chafee (R. R.I.). The Senate Bill, entitled the Smoker's Right to Know and Truth in Tobacco Labeling Act, would, if enacted, significantly enhance the current tobacco package warning labels and require disclosure of

toxic ingredients and health affects. The Bill would require all manufacturers to disclose cancer-causing agents, including carcinogenic TSNA's, as well as the percentage of such carcinogens relative to the average of such concentration of such carcinogen in the sales weighted average of all cigarettes marketed in the United States. If enacted, Star believes such mandated disclosure would be beneficial to informed adult smokers, as well as the Company.

FDA Regulation

The FDA has promulgated regulations governing the sale and advertising of tobacco products 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. A federal District Court upheld the FDA's authority to promulgate such regulations but ruled that certain of the regulations restricting advertising were invalid as violative of the constitutional right of free speech. On appeal, the United States Court of Appeals for the Fourth Circuit affirmed portions of the District Court opinion that held the FDA could not regulate tobacco advertising and ruled that the executive branch of the United States government, in particular the FDA, does not have any authority to regulate tobacco products generally. The federal government appealed the Appeals Court's ruling and the matter was heard by the United States Supreme Court in late 1999.

On March 21, 2000, the Supreme Court in a five to four decision held that the Congress has not given the FDA authority to regulate tobacco products as customarily marketed. Given the decision by the

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Supreme Court it is unclear whether the 106th or 107th Congress will act to grant such authority to the FDA, although legislation that would create such authority has already been introduced in Congress.

Star believes that in the future reasoned FDA regulation will better enable the Company to compete in its particular market niche. Accordingly, the Company has publicly announced its support for comprehensive FDA regulation of tobacco products. The Company has shared the results of its proprietary curing process with the FDA. The Company believes that the commercial value of its proprietary StarCure(TM) tobacco curing process will depend in part upon its validation by the scientific, health care and public health communities. The Company believes that well designed and carefully executed tests and clinical trials with resulting data shared with the scientific and public health communities would further its objective of attaining more general acceptance for its unique proprietary StarCure(TM) technology.

Federal Trade Commission

The requirements for health warnings on cigarettes is governed by the Federal Cigarette Labeling and Advertising Act (Labeling Act). The Labeling Act imposes labeling and advertising requirements on the manufacturers, packagers, and importers of cigarettes and requires any company wishing to sell cigarettes within the United States to submit a plan to the Federal Trade Commission explaining how it will comply with the warning label display requirements. Star has submitted such plans in the past, and the Federal Trade Commission has approved its labeling plans.

Bureau of Alcohol, Tobacco and Firearms

Manufacturers and importers of tobacco products are taxed pursuant to regulations promulgated by the federal Bureau of Alcohol, Tobacco and Firearms under authority of the Internal Revenue Code of 1986, as amended. The Company's tobacco products are subject to tax under such regulations.

State and Municipal Laws

The sale of tobacco products is subject to taxation in all fifty states. In addition, some states permit municipalities to impose an additional sales tax, and many municipalities do so. The state and municipal taxes are imposed upon wholesalers and/or retailers but not manufacturers, and therefore Star has no liability for such taxes. Star is required by many states, however, to report its shipments of cigarettes to distributors/retailers located within their jurisdiction. Star is aware of at least two states, Massachusetts and Minnesota, which have recently adopted laws and regulations regarding the disclosure by manufacturers of certain chemical constituents in their products. Star intends to fully comply with such laws and believes it will benefit from such disclosure.

Master Tobacco Settlement Agreement

In November 1998, 46 states and several U.S. territories entered into a settlement agreement (the Master Settlement Agreement) to resolve litigation that had been instituted by them against the major tobacco 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 Master Settlement Agreement. As a nonparticipating manufacturer, the Company is required to satisfy certain escrow obligations under statutes which the Master Settlement Agreement required participating states to pass, if they were to receive the full benefits of the settlement. The so-called level playing field statutes require nonparticipating manufacturers to fund escrow accounts that could be