

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, 2001

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
(I.R.S. 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 pursuant to Section 12(g) of the Act:

Common Stock, \$.0001 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 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.

The aggregate market value of the Registrant's voting stock held by non-affiliates of the Registrant as of March 1, 2002 is approximately \$33,412,119. Shares of voting stock held by each executive officer and director and by each person who owns 5% 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 of each class of common equity as of March 1, 2002: 59,741,460 shares of Common Stock.

DOCUMENTS INCORPORATED BY REFERENCE:
None

NOTE ON FORWARD-LOOKING STATEMENTS

This report on Form 10-K contains certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The Company has tried, whenever possible, to identify these forward-looking statements using words such as "anticipates", "believes", "estimates", "expects", "plans", "intends" and similar expressions. These statements reflect the Company's current beliefs and are based upon information currently available to it. Accordingly, such forward-looking statements involve known and unknown risks, uncertainties and other factors which could cause the Company's actual results, performance or achievements to differ materially from those expressed in, or implied by, such statements. These risks, uncertainties and contingencies include, without limitation, the challenges inherent in new product development initiatives particularly in the smokeless tobacco area, the uncertainties inherent in the progress of scientific research, the Company's ability to raise the capital necessary to grow its business, potential disputes concerning the Company's intellectual property, risks associated with litigation regarding such intellectual property, potential delays in obtaining any necessary government approvals of the Company's low-TSNA tobacco products, market acceptance of the Company's proposed new smokeless tobacco products, competition from companies with greater resources than the Company, the Company's decision not to join the Master Settlement Agreement ("MSA") and its decision to challenge the constitutionality of the MSA, the effect of state statutes adopted under the MSA and any subsequent modification of the MSA, the Company's dependence on key employees and on its strategic relationships with Brown & Williamson Tobacco Corporation. The impact of potential litigation, if initiated against or by individual states that have adopted the MSA, could be materially adverse to the Company.

See additional discussion under "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

Star Scientific, Inc. ("Star") and its wholly-owned subsidiary, Star Tobacco, Inc. ("ST", formerly Star Tobacco & Pharmaceuticals, Inc., and together with Star, the "Company") are technology-oriented tobacco companies with a mission to reduce toxins in tobacco leaf and tobacco smoke. The Companies are engaged in: (1) the development and implementation of scientific technology for the curing of StarCured(TM) tobacco so as to retard or significantly reduce the formation of carcinogenic toxins present in tobacco and tobacco smoke, primarily the tobacco specific nitrosamines ("TSNAs"); (2) the sales, marketing and development of tobacco products that expose adult tobacco users to substantially lower levels of carcinogenic toxins, namely TSNAs, that are sold with enhanced health warnings and comparative content information so that adult tobacco consumers will have the option to make informed choices about the use of tobacco products which pose a range of serious health risks (the TSNA levels in the Company's tobacco products will continue to be reduced to very low levels, measured in parts per billion, using the StarCured(TM) tobacco curing process); (3) the sales, marketing and development of very low-nitrosamine smokeless tobacco products which also carry enhanced warnings beyond those required by the Surgeon General (in 2001, the Company introduced three new smokeless products, Stonewall(TM) moist and dry snuffs, and ARIVA(TM) compressed powdered tobacco cigarette(TM) pieces); (4) the manufacture and sale of four discount cigarette brands which currently contain 24% very low-TSNA StarCured(TM) tobacco; and (5) in the future continued focus on developing smoking cessation products if it can secure a joint venture partner or corporate pharmaceutical partner with a significant regulatory infrastructure.

The Company's primary focus will continue to be the research, development and sale of products that expose adult tobacco users to lower levels of toxins. The Company's overall objective is to ultimately reduce the range of serious health hazards associated with the use of smoked and smokeless tobacco products. Accordingly, its primary corporate mission is to demonstrate the commercial viability of products that expose adult tobacco users to fewer toxins and are potentially less harmful, although, given the present limited state of the research efforts of Star and others in this area, the Company in discussing its low-TSNA products has shared with adult consumers the fact that there is not now sufficient evidence to demonstrate that reduced toxin delivery can be quantified in terms of reduced health risk. The Company fully accepts the evidence that links smoking tobacco 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. Star believes it was the first Company to state unequivocally that "there is no such thing as a safe cigarette", and to affix to the back of the package of its first premium low-TSNA product, Advance(R), a package "onsert" which contained not only scientifically verified comparative content data, but also additional health warnings. Nevertheless, in a world where an estimated 1.2 billion people smoke and use other conventional tobacco products, there is an urgent need to reduce the toxicity of tobacco products to the maximum extent possible. Accordingly, the Company believes that it has a corporate responsibility to continue to expand its research and development efforts to manufacture tobacco products in the least hazardous manner possible given available technology, particularly through the StarCured(TM) tobacco curing process. The Company believes it has the technology to reduce carcinogenic TSNAs, particularly the subgroups of nitrosamines which are commonly referred to as NNNs and NNKs, to the lowest possible levels and has demonstrated that the method it has developed for curing tobacco using the StarCured(TM) tobacco curing process can be scaled up to meet broad commercial needs in the United States and abroad. Given the fact that tobacco smoke contains over 4,000 constituents, 43 of which are known carcinogens, the Company's focus over the last two years has been directed to the development and introduction of very low-TSNA smokeless tobacco products which can be used as an alternative to cigarettes in situations where adult tobacco users either cannot or choose not to smoke. The Company expects that in the future its focus will continue to be on the sale of smokeless tobacco products. The Company is also committed to continuing to advocate meaningful federal regulation for all tobacco products and has publicly announced its support for reasoned regulation of tobacco products by the United States Food and Drug Administration (the "FDA").

The Company has an exclusive, worldwide license under patents issued and patents pending relating to methods to prevent or substantially reduce the formation of TSNAs in tobacco including the StarCured(TM) tobacco curing process.

The Company's revenues are generated principally through ST. ST'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 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 commenced a program of research and development relating to the development of a range of tobacco products that deliver less toxins as well as tobacco cessation products. Shortly thereafter, ST 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. In February 1998, ST 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 and the management of ST became the 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 on the sales, marketing and development of tobacco products which expose adult tobacco users to lower levels of toxins and potentially may be proven to reduce risk, and, on a more long-term basis, development of smoking cessation products either with a joint venture partner or a corporate pharmaceutical partner with significant resources, and/or experience in scientific and regulatory infrastructure that can assist and accelerate the FDA's New Drug Application regulatory process necessary for market entry.

The StarCured(TM) tobacco curing process, to which the Company has an exclusive license, as discussed herein, from Regent Court Technologies, LLC ("Regent Court"), involves the control of certain conditions in tobacco curing barns, and in certain applications, uses microwave and/or electronic beam technology. The StarCured(TM) process retards or substantially reduces the formation in the tobacco leaf of the carcinogenic TSNAs, which are widely believed by recognized medical and scientific experts to be among the most abundant and powerful cancer-causing toxins present in tobacco and in tobacco smoke. In 2000 and again in 2001, the Company processed approximately 19 million pounds of very low-TSNA flue-cured tobacco using the StarCured(TM) process. Star has focused on the production of StarCured(TM) flue-cured tobacco since this variety is used exclusively in the Company's new smokeless products. At the same time, the Company believes that this process can be applicable to burley and other varieties of tobacco on a broad-scale commercial basis and continues to support research and technological development directed to varieties other than flue-cured tobacco.

Star's long-term strategy is to encourage other tobacco manufacturers to sublicense the StarCured(TM) tobacco curing technology to produce very low-TSNA tobacco (with carcinogenic NNKs and NNNs that measure 200 parts per billion and below). Further, Star is committed to continuing to explore the development of products that expose adult tobacco users to lower levels of toxins and are potentially less harmful than conventional smoked tobacco, such as smokeless tobacco products, as well as in the future the development of tobacco cessation products. In September 2001, the Company introduced two very low-TSNA snuff products (a moist and a dry snuff) under the brand name Stonewall(TM). In November 2001, the Company initiated the test market of its compressed powdered tobacco "cigalatt"(TM) pieces under the brand name ARIVA(TM). The tobacco in both Stonewall(TM) and ARIVA(TM) is 100% StarCured(TM) very low-TSNA tobacco. The Company also markets four brands of discount cigarettes, namely, SPORT(R), MAINSTREET(R), VEGAS(R) and G-SMOKE(R), all of which contain 24% very low-TSNA flue-cured tobacco, and utilize a carbon/acetate filter that reduces additional toxins found in cigarette smoke.

On April 25, 2001, the Company and Brown & Williamson Tobacco Corporation ("B&W"), the third largest tobacco company in the United States, entered into a series of new comprehensive long-term agreements (the "April 25, 2001 Agreements") that amended agreements previously entered into with B&W. Among other things, the agreements provide for B&W to take over all aspects of the sale of Advance(R), the low-TSNA cigarette which was jointly developed by the Company and B&W and first test marketed by the Company in October 2000, in return for royalty payments to the Company. B&W subsequently launched an expanded test market of Advance(R) in approximately 1,500 stores in Indianapolis, Indiana in November 2001 and potentially may market this brand on a national basis, if the current market test is successful. The agreements also provide B&W with the exclusive marketing rights for the Company's compressed powdered cigalatt(TM) pieces in the United States (subject to the

Company's own rights), in return for paying the Company a royalty plus the cost of manufacturing the cigarettes(TM). Among other things, the agreements also restate various loan agreements made by B&W to the Company during 1999 and 2000, and provide for the purchase of StarCured(TM) tobacco by B&W over the growing seasons from 2001-2003, with the right to purchase additional tobacco in future years (see "Relationship with B&W").

Segments and Products

See Note 12 of the Company's Consolidated Financial Statements for financial information about the Company's segments.

Leaf Tobacco

In 1999, Star processed and sold over 3.5 million pounds of StarCured(TM) very low-TSNA tobacco. In each of 2000 and 2001, Star processed and sold approximately 19 million pounds of very low-TSNA flue-cured tobacco that had been cured using the StarCured(TM) tobacco curing process. The vast majority 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 20.6%, 20.7%, and 10.0% of the Company's net sales in 2001, 2000 and 1999, respectively. This included a royalty of \$1.5 million in 2001 from B&W on its purchases of other low-TSNA tobacco. Under the April 25, 2001 Agreements, it is anticipated the Company will process approximately 18-20 million pounds of very low-TSNA flue-cured tobacco in each of the next two growing seasons, for sale to B&W and for use in the Company's own brands. The tobacco will be cured using the StarCured(TM) tobacco curing process.

The bulk of processed tobacco sales occur in the third and fourth quarter of each year, resulting in higher revenues in those quarters. The Company's long-term goal is to derive an increasingly larger percentage of its revenues from sublicensing the StarCured(TM) tobacco curing process to major cigarette manufacturers. During 2001, approximately eighty-five percent (85%) of all flue-cured tobacco in the U.S. was cured in a manner to reduce the levels of TSNA's in the cured tobacco leaf. In May 2001, the Company filed suit against R. J. Reynolds Tobacco Company ("R.J. Reynolds") for patent infringement relating to R.J. Reynolds' efforts to have farmers produce low-TSNA tobacco using the technology to which Star is the exclusive licensee.

Smokeless Tobacco Products

Over the past two years, the Company has been engaged in the development of smokeless tobacco products that could provide adult tobacco users with a viable alternative to cigarettes in situations and environments when they can't smoke or when they would prefer not to smoke. This effort was encouraged by the Company's Scientific Advisory Board and other independent scientific, medical, and public health advisors who encouraged Star to accelerate the development of smokeless products using 100% StarCured(TM) low-TSNA tobacco, because smokeless products have far fewer toxins than conventional cigarettes. Cigarette smoke contains more than 4,000 chemical compounds, 43 of which are known to be carcinogenic. A number of respected scientists and researchers believe that the major or significant toxins in smokeless tobacco are the TSNA's, particularly the NNN's and NNK's. In labelling and promoting its smokeless tobacco products, the Company has made no direct or implied health or therapeutic claims, consistent with its stated belief that, at this time, there is not sufficient peer reviewed scientific evidence to demonstrate that reduced toxin delivery can be quantified in terms of reduced health risk.

On September 28, 2001, the Company introduced its first two very low-TSNA snuff products (a moist and a dry snuff) under the brand name Stonewall(TM). On November 14, 2001, Star introduced its flagship hard tobacco cigarette(TM) pieces (ARIVA(TM)). ARIVA(TM) is a compressed powdered tobacco product designed to dissolve completely in the mouth without leaving any residue. Sales of Star's smokeless products were de minimus in 2001. ARIVA(TM) and Stonewall(TM) are being marketed nationwide by ST through its network of established tobacco distributors and through new distributors with whom ST has not previously had a relationship. In addition, the Company has sought to introduce ARIVA(TM) and Stonewall(TM) through direct arrangements with several national retail chains and through national distributors experienced with consumer products. Following the successful limited test market of its smokeless products, Star decided it was appropriate to expand distribution. Accordingly, by March 2002, the Company's smokeless products had been placed in more than 10,000 convenience and retail store locations. The Company anticipates greatly expanding the number of stores in which its smokeless products will be available during 2002.