STAAR SURGICAL CO
Form 8-K
September 29, 2004

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

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

Date of Report (Date of earliest event reported): September 23, 2004

STAAR SURGICAL COMPANY
(Exact name of registrant as specified in its charter)

Delaware	0-11634	(I.R.S.
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	

1911 Walker Avenue, Monrovia, California
(Address of principal executive offices)

(626) 303-7902
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

[ ] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

[ ] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

ITEM 5.02. DEPARTURE OF DIRECTORS OR PRINCIPAL OFFICERS; ELECTION OF DIRECTORS; APPOINTMENT OF PRINCIPAL OFFICERS.

On September 25, 2004, John R. Gilbert resigned from the Board of Directors for personal reasons, including a death and a serious illness in his family. The Company has been advised that Mr. Gilbert has resigned his directorship in each company which has a class of securities registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange

Act"), or subject to the requirements of Section 15(d) of the Exchange Act.

ITEM 8.01. OTHER EVENTS.

As previously announced, the Company received a warning letter from the United States Food and Drug Administration (the "FDA") on December 29, 2003 (the "Warning Letter"), following the FDA's inspection of the Company's facility in Monrovia, California. A copy of the Warning Letter is attached as Exhibit 99.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 9, 2004.

The Company engaged the services of Quintiles Consulting ("Quintiles"), a well regarded consulting organization that specializes in FDA related compliance matters, to assist it in correcting the issues raised in the Warning Letter. The Company, with Quintiles' help, has assessed the state of its quality system in light of the FDA's concerns and has developed an improvement plan. This plan was submitted to the FDA. It provided details of a systematic approach for reviewing and improving all of the Company's quality system procedures. The following are some of the actions that the Company has taken in consultation with Quintiles:

- conducted a retrospective review of complaint files from the last three years and conducted root cause analysis;

- implemented more rigorous quality processes for complaint investigation, root cause analysis, trend analysis and reporting;

- submitted a quality system improvement plan to the FDA that details a systematic approach for reviewing and improving all of the Company's quality systems procedures;

- strengthened the expertise in several critical business functions, including quality, clinical, regulatory, manufacturing and research and development. Specifically, the Company expanded the Complaint Handling staff, hiring an M.D. to manage the department, and hired a Vice President of Research and Development, a Vice President of Regulatory Affairs/Quality Assurance, and various quality and manufacturing engineering employees;

- successfully completed the FDA's pre-approval inspection of the Company's Nidau, Switzerland manufacturing facility with no observations; and

- re-engineered several key quality systems including failure investigation, root cause analysis, complaint handling and medical device reporting, clinical systems, management review, corrective and preventive action, trending and analysis practices, and validation.

On July 28, 2004, the FDA commenced an inspection of the Monrovia facility to determine the progress of the Company's corrective actions. On September 23, 2004, the FDA completed the inspection and issued a form "FDA 483 Inspectional Observations" (the "FDA 483"). The FDA 483 contains observations that, in the opinion of the FDA investigators, represent deviations from the

FDA's regulatory requirements. Observations listed on the FDA 483 do not necessarily represent a final FDA determination as to the state of the Company's compliance. The FDA 483 contains 36 observations addressing the following areas: production and process controls, corrective and preventative action, quality system requirements, statistical techniques, complaint handling system, medical device reporting, design controls, acceptance criteria, and document controls and records.

During the meeting with the FDA at the conclusion of the inspection, the Company provided an initial response to each of the observations. In response to some of the observations, the Company provided evidence, and the FDA verified, that corrective action had been taken. With respect to other observations, the Company provided evidence of corrective action which requires verification by the FDA. In addition, the Company promised to undertake corrective action with respect to some of the observations, and gave no response to other observations pending further evaluation.

The Company is preparing a written response to the FDA 483 to be submitted as soon as practicable. Until the FDA is satisfied with the adequacy of the Company's corrective action, it may take further actions which could include conducting another inspection, seizure of the Company's products, injunction of the Monrovia facility to compel compliance (which may include suspension of production operations and/or recall of products), or other actions. Such actions could have a material adverse effect on the Company's established lines of business, results of operations and liquidity. Furthermore, until the FDA is satisfied with the Company's response, it is unlikely to grant the Company approval to market the ICL in the United States.

The Company is not able to predict whether the FDA will conclude that the Company's corrective actions to date or those to be included in its response to the FDA 483 satisfactorily resolve its concerns. Nor can the Company predict the likelihood, nature of, or timing of any additional action by the FDA or the impact of the FDA 483 or any other FDA action on the Company's established lines of business, results of the operations or liquidity or the approval of the ICL for the United States market. The Company does not believe that it will receive approval of the ICL before the October 22, 2004 meeting of the American Academy of Ophthalmologists.

The business of the Company is subject to numerous risks and uncertainties that are beyond its control, including, but not limited to, those set forth above and in the other reports filed by the Company with the Securities and Exchange Commission. Such risks and

uncertainties could have a material adverse effect on the Company's business, financial condition, operating results and cash flows.

SIGNATURES

Pursuant to the requirements 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.

STAAR SURGICAL COMPANY

Date: September 28, 2004 By /s/ John Bily

John Bily,
Chief Financial Officer