

Edgar Filing: STAAR SURGICAL COMPANY - Form 8-K

STAAR SURGICAL COMPANY
Form 8-K
January 09, 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): January 7, 2004

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

| | | |
|---|--------------------------|---|
| Delaware | 0-11634 | 95-3797439 |
| (State or other jurisdiction of incorporation or organization) | (Commission File Number) | (I.R.S. Employer Identification No.) |

| | |
|--|------------|
| 1911 Walker Avenue, Monrovia, California | 91016 |
| (Address of principal executive offices) | (Zip Code) |

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

Item 5. Other Events and Regulation FD Disclosure.

THE BUSINESS OF STAAR SURGICAL COMPANY (THE "COMPANY") IS SUBJECT TO NUMEROUS RISKS AND UNCERTAINTIES THAT ARE BEYOND ITS CONTROL, INCLUDING, BUT NOT LIMITED TO, THOSE SET FORTH BELOW 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.

Our operations are subject to periodic inspection by the U.S. Food and Drug Administration (the "FDA"). Such inspection may result in the FDA ordering changes in our business practices, which changes could be costly for the Company and have a material adverse effect on our business and results of operations. On December 29, 2003, the Company received a Warning Letter issued by the FDA, a copy of which is attached hereto as Exhibit 99.1. While we are acting to quickly correct the deficiencies identified in the Warning Letter, until the FDA is satisfied with our response we will not be granted approval to market the ICL in

Edgar Filing: STAAR SURGICAL COMPANY - Form 8-K

the United States and we may face FDA restrictions on our established domestic lines of business. Even if the FDA approves our corrective action, the publication of the Warning Letter or similar actions in the future could harm our reputation and reduce sales.

Item 7. Financial Statements and Exhibits

(c) Exhibits.

| Exhibit Number | Description |
|----------------|---|
| ----- | ----- |
| 99.1 | Warning Letter dated December 22, 2003 from the U.S. Food and Drug Administration. |
| 99.2 | Press release dated January 7, 2004. |
| 99.3 | Transcript of conference call conducted by STAAR Surgical Company on January 7, 2004. |

Item 9. Regulation FD Disclosure.

On January 7, 2004, the Company issued a press release announcing that it is aggressively pursuing corrective actions to remedy issues cited in a Warning Letter received by the Company on December 29, 2003 from the FDA. A copy of the press release is attached as Exhibit 99.2 to this report and is incorporated herein by this reference.

On January 7, 2004, the Company held a conference call to discuss the Warning Letter. A transcript of the call is attached to this report as Exhibit 99.3 and is incorporated herein by this reference.

Item 12. Results of Operations and Financial Condition.

On January 7, 2004, the Company held a conference call during which it gave information regarding revenues for the fourth fiscal quarter of 2003. A transcript of the call is attached to this report as Exhibit 99.3 and is incorporated herein by this reference.

The information furnished pursuant to Items 9 and 12 of this Current Report on Form 8-K, including the exhibits, will not be treated as "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section. This information will not be incorporated by reference into a filing under the Securities Act of 1933, or into another filing under the Exchange Act, unless that filing expressly refers to specific information in this report.

-2-

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.

Date: January 9, 2004

STAAR SURGICAL COMPANY

By: /s/ John Bily

Edgar Filing: STAAR SURGICAL COMPANY - Form 8-K

John Bily
Chief Financial Officer

-3-

Exhibit Index

| <u>EXHIBIT NUMBER</u> | <u>DESCRIPTION</u> |
|-----------------------|---|
| 99.1 | Warning Letter dated December 22, 2003 from the U.S. Food and Drug Administration. |
| 99.2 | Press release dated January 7, 2004. |
| 99.3 | Transcript of conference call conducted by STAAR Surgical Company on January 7, 2004. |

