

STAAR SURGICAL CO
Form 8-K
December 02, 2013

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): December 2, 2013

STAAR Surgical Company

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction

of incorporation)

0-11634

(Commission

File Number)

95-3797439

(I.R.S.

Employer

Identification
No.)

1911 Walker Ave, Monrovia, California

(Address of principal executive offices)

91016

(Zip Code)

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

Not Applicable

Former name or former address, if changed since last report

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 7.01 Regulation FD Disclosure.

On November 21, 2013, STAAR Surgical Company received verbal notice from the FDA indicating the agency's intent to review STAAR's PMA Supplement regarding its toric ICL at the Ophthalmic Devices Agency Panel meeting scheduled for February 14, 2014 (this notice was followed by a November 22, 2013 written communication from the FDA).

We expect the Federal Register Notice of this upcoming panel meeting to occur in early January. The Panel meeting is subject to postponement or cancellation, at the agency's discretion, and subject to STAAR providing meeting-related documentation to the FDA pursuant to the FDA's schedule.

STAAR's President and Chief Executive Officer, Barry Caldwell, will give presentations to investors on December 3, 2013. A copy of the slide presentation Mr. Caldwell will use in his presentations is furnished as Exhibit 99.1 to this Report, and is incorporated herein by this reference.

The information furnished herewith pursuant to Item 7.01 of this Current Report, including Exhibit 99.1, shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section. The information in Item 7.01 of this Current Report shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date of this Current Report, regardless of any general incorporation language in the filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No. Description

99.1 Slide Presentation dated December 2013.

SIGNATURES

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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 hereunto duly authorized.

STAAR Surgical Company

December 2, 2013 By: /s/ Barry G. Caldwell
Barry G. Caldwell
President and Chief Executive Officer