STAAR SURGICAL CO
Form 8-K
March 21, 2007

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): March 14, 2007

STAAR Surgical Company

(Exact name of registrant as specified in its charter)

Delaware	0-11634	95-3797439
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)
1911 Walker Ave, Monrovia, California		91016
(Address of principal executive offices)		(Zip Code)

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))

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Item 1.01 Entry into a Material Definitive Agreement.

On March 21, 2007, the Company entered into a loan arrangement with Broadwood Partners, L.P. ("Broadwood"). Pursuant to a Promissory Note (the "Note") between the Company and Broadwood, Broadwood will lend $4 million to the Company. The Note has a term of three years and bears interest at a rate of 10% per annum. The Note is not secured by any collateral, may be pre-paid by the Company at any time without penalty, and is not subject to covenants based on financial performance or financial condition (except for insolvency). As additional consideration for the loan the Company also entered into a Warrant Agreement (the "Warrant Agreement") with Broadwood granting the right to purchase up to 70,000 shares of Common Stock at an exercise price of $6, exercisable for a period of six years. The Note also provides that so long as a principal balance remains outstanding on the Note the Company will grant additional warrants each quarter on the same terms as the Warrant Agreement.

The foregoing summary is not a complete description of the terms of the Note and the Warrant Agreement. The summary is qualified in its entirety by reference to the full text of the agreements, which are filed as Exhibit 10.63 and 10.64 to this Report and are incorporated herein by this reference.

The proceeds of the loan will be used for working capital and general corporate purposes. Based in part on the Company’s recent increases in revenue and profit margins, as well as forecasts of future growth, the Company believes that its cash resources and funds from operations should be sufficient to meet its needs for liquidity in the fiscal year ending December 28, 2007. The proceeds of the loan will provide an additional source of liquidity for contingencies and new initiatives in marketing and product development.

The loan will not affect any of the Company's existing credit agreements with lenders.

Item 7.01 Regulation FD Disclosure.

On March 14, 2007, the Company held a conference call to discuss the financial results for the fiscal year and quarter ended December 29, 2006. An archive of the webcast of the conference call has been posted on the Company's website at www.staar.com. In accordance with the Company’s practice, a transcript of the conference call is furnished as Exhibit 99.1 to this report and is incorporated herein by this reference.

Among the forward looking statements made in the conference call based on contemporary expectations and assumptions was a discussion of the Company’s anticipated timing for filing an amendment to the Supplemental Pre-Market Approval application for the Toric Implantable Collamer® Lens ("TICL") originally submitted by the Company on April 28, 2006. As described in further detail below, the Company has revised its plans for submission of the amended TICL application.

On March 14, 2007, the Bioresearch Monitoring Program of the FDA Office of Regulatory Affairs ("BIMO") concluded a routine audit of the Company’s clinical trial records as a sponsor of biomedical research in connection with the Company’s Supplemental Pre-Market Approval application for the Toric Implantable Collamer® Lens. At the conclusion of the audit the Company received eight Inspectional Observations on FDA Form 483 noting noncompliance with regulations. The Company is preparing its response to the Inspectional Observations and expects to address the concerns raised by BIMO through voluntary corrective actions. Most of the observed instances of non-compliance took place during the 2000-2004 period and the Company expects to show that some of these have already been addressed by corrective actions made in response to BIMO’s observations of December 11, 2003 in connection with the Company’s application for the Implantable Collamer Lens ("ICL").

As previously announced, the Company received a letter from the FDA Office of Device Evaluation (the "ODE")on November 20, 2006 requesting that the Company submit an amended application for approval of the TICL within 180 days. The Company had expected to submit its amended TICL application prior to the expiration of the 180-day deadline on May 15, 2007. However, after reviewing the Inspectional Observations with its regulatory experts and consultants, the Company has determined that it should place a priority on responding to the Inspectional Observations. To ensure sufficient time for a comprehensive response to the Inspectional Observations and to the November 20, 2006 comments, and to prepare for an expected review by the FDA Ophthalmic Devices Panel, the Company now expects to request an extension to allow up to an additional 180 days for submission of its amended TICL application.

The Company does not believe that the Inspectional Observations affect the integrity of the Toric clinical study. However, the determination of whether the Inspectional Observations affect the use of the Toric clinical study in the Toric application will be at the discretion of the ODE. Obtaining FDA approval of medical devices is never certain. The Company cannot assure investors that the ODE will grant approval to the TICL, or that the scope of requested TICL approval could not be limited by the FDA or the Ophthalmic Devices Panel.

All statements in this Report and its attached exhibits that are not statements of historical fact are forward-looking statements, including any projections of earnings, revenue, sales, cash or other financial items, any statements regarding the anticipated effect on the Company of recent Inspectional Observations and the anticipated timing of the Company's amended TICL application; the Companies needs for cash and the adequacy of its reserves, the plans, strategies, and objectives of management for future operations, any statements regarding expectations for success of the ICL or TICL other products in U.S. or international markets, any statements concerning proposed new products and government approval of new products, services or developments, the resolution of financial irregularities at Domilens and the success of the transition to new management there, statements of expectations regarding pending transactions, any statements regarding future economic conditions or performance, statements of belief and any statements of assumptions underlying any of the foregoing. These statements are based on expectations and assumptions as of the date of this press release and are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those described in the forward-looking statements. The risks and uncertainties include our limited capital resources and limited access to financing, the challenge of adapting our largely independent marketing model to the challenges of the refractive market, our ability to overcome negative publicity resulting from warning letters and other correspondence from the FDA Office of Compliance, the challenge of managing foreign subsidiaries, the willingness of surgeons and patients to adopt a new product and procedure, and our ability to successfully launch and market the ICL in the U.S. while overcoming the foregoing challenges. Our ability to capitalize on the opportunity presented by the U.S. ICL approval depends on our overall financial condition, which can be adversely affected by general economic conditions, and other factors beyond our control, including those detailed from time to time in our reports filed with the Securities and Exchange Commission. STAAR assumes no obligation to update its forward-looking statements to reflect future events or actual outcomes and does not intend to do so.

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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 hereunto duly authorized.

STAAR Surgical Company

March 21, 2007

By: /s/ David Bailey

Name: David Bailey
Title: President and CEO

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Exhibit Index

Exhibit No.	Description
10.63	Promissory Note between STAAR Surgical Company and Broadwood Partners, L.P., dated March 21, 2007.
10.64	Warrant Agreement between STAAR Surgical Company and Broadwood Partners, L.P., dated March 21, 2007.
99.1	Transcript of Conference Call held on March 14, 2007.