

STAAR SURGICAL CO  
Form 10-Q  
May 09, 2007

Table of Contents

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**

**Form 10-Q**

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
**For the quarterly period ended: March 30, 2007**
- OR**
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
**For the transition period from            to**

**Commission File Number: 0-11634**

**STAAR SURGICAL COMPANY**

*(Exact name of registrant as specified in its charter)*

**Delaware**  
*(State of incorporation)*

**95-3797439**  
*(I.R.S. Employer Identification No.)*

**1911 Walker Avenue**  
**Monrovia, California 91016**  
*(Address of principal executive offices, including zip code)*

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

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 whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes  No

The registrant has 29,306,259 shares of common stock, par value \$0.01 per share, issued and outstanding as of May 1, 2007.

---

**STAAR SURGICAL COMPANY**

**INDEX**

**Page  
Number**

**PART I FINANCIAL INFORMATION**

<u>Item 1.</u>	<u>Financial Statements (Unaudited)</u>	
	<u>Condensed Consolidated Balance Sheets March 30, 2007 and December 29, 2006.</u>	1
	<u>Condensed Consolidated Statements of Operations Three Months Ended March 30, 2007 and March 31, 2006.</u>	2
	<u>Condensed Consolidated Statements of Cash Flows Three Months Ended March 30, 2007 and March 31, 2006.</u>	3
	<u>Notes to the Condensed Consolidated Financial Statements.</u>	4
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations.</u>	13
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk.</u>	26
<u>Item 4.</u>	<u>Controls and Procedures.</u>	26

**PART II OTHER INFORMATION**

<u>Item 1.</u>	<u>Legal Proceedings.</u>	29
<u>Item 1A.</u>	<u>Risk Factors.</u>	29
<u>Item 6.</u>	<u>Exhibits.</u>	39
<u>Signatures</u>		40
<u>EXHIBIT 31.1</u>		
<u>EXHIBIT 31.2</u>		
<u>EXHIBIT 32.1</u>		

---

**Table of Contents****PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****STAAR SURGICAL COMPANY AND SUBSIDIARIES****CONDENSED CONSOLIDATED BALANCE SHEETS**

	<b>March 30, 2007</b>	<b>December 29, 2006</b>
	<b>(Unaudited)</b>	
	<b>(In thousands, except par value)</b>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 9,098	\$ 7,758
Short-term investments restricted	150	150
Accounts receivable, net	6,988	6,524
Inventories	12,495	12,939
Prepays, deposits and other current assets	3,089	1,923
Total current assets	31,820	29,294
Investment in joint venture	409	397
Property, plant and equipment, net	5,746	5,846
Patents and licenses, net	4,319	4,439
Goodwill	7,534	7,534
Other assets	258	260
Total assets	\$ 50,086	\$ 47,770
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Notes payable	\$ 1,812	\$ 1,802
Accounts payable	5,105	5,055
Obligations under capital lease current	609	500
Other current liabilities	8,463	7,574
Total current liabilities	15,989	14,931
Obligations under capital lease long-term	1,158	957
Note payable, net	3,733	
Other long-term liabilities	2	122
Total liabilities	20,882	16,010

Commitments and contingencies and subsequent events (Note 8 and 12)

Stockholders' equity:

Preferred stock, \$.01 par value; 10,000 shares authorized, none issued or outstanding

Common stock, \$.01 par value; 60,000 shares authorized, issued and

outstanding 25,676 at March 30, 2007 and 25,618 at December 29, 2006

Additional paid-in capital

Accumulated other comprehensive income

Accumulated deficit

Total stockholders' equity

Total liabilities and stockholders' equity

257	256
118,214	117,312
951	889
(90,218)	(86,697)
29,204	31,760
\$ 50,086	\$ 47,770

See accompanying notes to the condensed consolidated financial statements.

Table of Contents

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

	<b>Three Months Ended</b>	
	<b>March 30,</b>	<b>March 31,</b>
	<b>2007</b>	<b>2006</b>
	<b>(Unaudited)</b>	
	<b>(In thousands, except per share amounts)</b>	
Net sales	\$ 14,917	\$ 13,465
Cost of sales	7,622	7,025
Gross profit	7,295	6,440
General and administrative	2,783	2,801
Marketing and selling	6,102	5,123
Research and development	1,610	1,726
Operating loss	(3,200)	(3,210)
Other income (expense):		
Equity in operations of joint venture	12	(5)
Interest income	23	118
Interest expense	(104)	(41)
Other income (expense)	17	(17)
Total other income (expense), net	(52)	55
Loss before provision for income taxes	(3,252)	(3,155)
Provision for income taxes	269	207
Net loss	\$ (3,521)	\$ (3,362)
Loss per share basic and diluted	\$ (0.14)	\$ (0.14)
Weighted average shares outstanding basic and diluted	25,652	24,857

See accompanying notes to the condensed consolidated financial statements.

**Table of Contents****STAAR SURGICAL COMPANY AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<b>Three Months Ended</b>	
	<b>March 30,</b>	<b>March 31,</b>
	<b>2007</b>	<b>2006</b>
	<b>(Unaudited)</b>	
	<b>(In thousands)</b>	
Cash flows from operating activities:		
Net loss	\$ (3,521)	\$ (3,362)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property, plant and equipment	466	490
Amortization of intangibles	120	120
Loss on disposal of fixed assets	53	46
Equity in operations of joint venture	(12)	5
Stock-based compensation	395	527
Other	107	(16)
Changes in working capital:		
Accounts receivable	(571)	(936)
Inventories	474	614
Prepays, deposits and other current assets	(1,166)	(416)
Accounts payable	13	(25)
Other current liabilities	916	(158)
Net cash used in operating activities	(2,726)	(3,111)
Cash flows from investing activities:		
Acquisition of property, plant and equipment	(164)	(451)
Decrease in other assets	2	3
Proceeds from notes receivable and other		20
Net cash used in investing activities	(162)	(428)
Cash flows from financing activities:		
Net payments under notes payable	(32)	(88)
Net payments under lease lines of credit	(13)	
Proceeds from note payable	4,000	
Proceeds from the exercise of stock options	211	491
Net cash provided by financing activities	4,166	403
Effect of exchange rate changes on cash and cash equivalents	62	92
Increase (decrease) in cash and cash equivalents	1,340	(3,044)
Cash and cash equivalents, at beginning of the period	7,758	12,708



Cash and cash equivalents, at end of the period	\$ 9,098	\$ 9,664
---	----------	----------

See accompanying notes to the condensed consolidated financial statements.

**Table of Contents**

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**March 30, 2007**

**Note 1 Basis of Presentation and Significant Accounting Policies**

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. The financial statements for the three months ended March 30, 2007 and March 31, 2006, in the opinion of management, include all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the financial condition and results of operations. These financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 29, 2006.

The results of operations for the three months ended March 30, 2007 and March 31, 2006 are not necessarily indicative of the results to be expected for any other interim period or the entire year.

Each of the Company's reporting periods ends on the Friday nearest to the quarter ending date and generally consists of 13 weeks.

***New Accounting Pronouncements***

Effective December 30, 2006, the Corporation adopted Financial Accounting Standards Board Interpretation No. 48 (FIN 48), Accounting for Uncertainty in Income Taxes, an interpretation of Statement of Financial Accounting Standards No. 109. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements. The Interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The adoption of FIN 48 did not have a material impact on The Company's Consolidated Financial Statements.

***Prior Year Reclassifications***

Certain reclassifications have been made to the prior financial statement information to conform with current period presentation.

**Note 2 Short-Term Investments - Restricted**

Short-term investments consist of a 12-month Certificate of Deposit with a 4.5% interest rate used to collateralize capital leases funded under a lease line of credit with Mazuma Capital Corporation (See Note 8).

**Note 3 Inventories**

Inventories are stated at the lower of cost, determined on a first-in, first-out basis, or market and consisted of the following (in thousands):

**March 30,      December 29,**

	<b>2007</b>	<b>2006</b>
Raw materials and purchased parts	\$ 594	\$ 690
Work-in-process	1,626	1,669
Finished goods	10,275	10,580
	\$ 12,495	\$ 12,939

**Table of Contents****STAAR SURGICAL COMPANY AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Note 4 Prepaids, Deposits, and Other Current Assets**

Prepaids, deposits, and other current assets consisted of the following (in thousands):

	<b>March 30, 2007</b>	<b>December 29, 2006</b>
Prepaids and deposits	\$ 2,023	\$ 1,455
Other current assets	1,066	468
	<b>\$ 3,089</b>	<b>\$ 1,923</b>

**Note 5 Note Payable**

On March 21, 2007, STAAR entered into a loan arrangement with Broadwood Partners, L.P. ( Broadwood ). Pursuant to a Promissory Note (the Note ) between STAAR and Broadwood, Broadwood loaned \$4 million to STAAR. The term of the Note is three years and bears interest at a rate of 10% per annum, payable quarterly. The Note is unsecured, may be pre-paid by STAAR 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 STAAR 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.

In accordance with Accounting Principles Board ( APB ) Opinion No. 14, Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants, the purchase price was allocated to the two instruments based on their relative fair values. The fair value for the warrants was calculated using the Black- Scholes valuation model, while the fair value of the notes was calculated by calculating the present value of the future stream of payments. The relative fair value of the warrants and the note were \$267,000 and \$3,733,000, respectively as of the date the loan and warrant agreements were consummated. The Note also provides that so long as a principal balance remains outstanding on the Note, STAAR will grant additional warrants each quarter on the same terms as the Warrant Agreement. The warrant agreement provides that STAAR will register the stock for resale with the SEC.

**Note 6 Stockholders Equity**

The consolidated interim condensed financial statements include basic and diluted per share information. Basic per share information is calculated by dividing net loss by the weighted average number of shares outstanding. Diluted per share information is calculated by also considering the impact of potential common stock on both net income and the weighted number of shares outstanding. As the Company was in a loss position, potential common shares of 2,811,359 for the three months ended March 30, 2007 and 2,796,755 for the three months ended March 31, 2006, respectively, were excluded from the computation as the shares would have had an anti-dilutive effect.

***Comprehensive loss***

The components of comprehensive loss are as follows (in thousands):

	<b>March 30, 2007</b>	<b>March 31, 2006</b>
Net loss	\$ (3,521)	\$ (3,362)
Foreign currency translation adjustment	62	92
Total comprehensive loss	\$ (3,459)	\$ (3,270)

**Table of Contents****STAAR SURGICAL COMPANY AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Note 7 Geographic and Product Data**

The Company reports segment information in accordance with SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information ( SFAS 131 ). Under SFAS 131 all publicly traded companies are required to report certain information about the operating segments, products, services and geographical areas in which they operate and their major customers.

The Company markets and sells its products in approximately 50 countries and has manufacturing sites in the United States and Switzerland. Other than the United States and Germany, the Company does not conduct business in any country in which its sales exceed 5% of consolidated sales. Sales are attributed to countries based on location of customers. The composition of the Company's net sales to unaffiliated customers between those in the United States, Germany, and other locations for each year, is set forth below (in thousands):

	<b>Three Months Ended</b>	
	<b>March 30, 2007</b>	<b>March 31, 2006</b>
United States	\$ 5,094	\$ 5,621
Germany	6,045	5,244
Other	3,778	2,600
Total	\$ 14,917	\$ 13,465

100% of the Company's sales are generated from the ophthalmic surgical product segment and, therefore, the Company operates as one operating segment for financial reporting purposes. The Company's principal products are intra-ocular lenses ( IOLs ) and ancillary products used in cataract and refractive surgery. The composition of the Company's net sales by surgical line is as follows (in thousands):

	<b>Three Months Ended</b>	
	<b>March 30, 2007</b>	<b>March 31, 2006</b>
Cataract	\$ 11,024	\$ 10,766
Refractive	3,720	2,522
Glaucoma	173	177
Total	\$ 14,917	\$ 13,465

The Company sells its products internationally, which subjects the Company to several potential risks, including fluctuating exchange rates (to the extent the Company's transactions are not in U.S. dollars), regulation of fund

transfers by foreign governments, United States and foreign export and import duties and tariffs, and political instability.

**Note 8 Commitments and Contingencies**

***Litigation***

From time to time the Company is subject to various claims and legal proceedings arising out of the normal course of our business. These claims and legal proceedings relate to contractual rights and obligations, employment matters, and claims of product liability. We do not believe that any of the claims known to us is likely to have a material adverse effect on our financial condition or results of operations.

***Lines of Credit***

The Company and its subsidiaries have credit facilities with different lenders to support operations in the U.S., and Germany, respectively.

**Table of Contents**

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

On June 8, 2006 the Company signed a Credit and Security agreement with Wells Fargo Bank for a revolving credit facility. The credit facility provides for borrowings of 85% of eligible accounts receivable with a maximum of \$3.0 million, carries an interest rate of prime plus 1.5%, and is secured by substantially all of the assets of the Company's U.S. operations. The term of the agreement is three years and it contains certain financial covenants, among others, relating to minimum calculated net worth, net loss, liquidity and restrictions on Company investments or loans to affiliates and investments in capital expenditures, with which the Company must comply to borrow or to maintain an outstanding advance. As of March 30, 2007, there were no borrowings outstanding. As the Company does not satisfy minimum financial covenants in its U.S. operations that are a condition to borrowing, no borrowings are available.

The Credit and Security Agreement with Wells Fargo Bank prohibits STAAR, without the consent of the Bank, from incurring indebtedness, making loans to its subsidiaries, investing in its subsidiaries or other entities or paying dividends on its common stock. The Credit and Security Agreement also provides that a change of control of STAAR will constitute a default of the agreement. A change of control under the agreement includes the acquisition of 15% or more of STAAR's capital stock by any person or group, a change in composition of the Board of Directors over a two-year period that results in the directors in place at the beginning of the period no longer constituting a majority, or David Bailey's ceasing to actively manage STAAR. Wells Fargo Bank waived a covenant prohibiting STAAR from incurring additional indebtedness on March 21, 2007, which permitted STAAR to enter into the Promissory Note with Broadwood Partners, LP on that date and on May 9, 2007, which permitted STAAR to borrow \$2,000,000 from a subsidiary.

STAAR may terminate the Credit and Security Agreement with Wells Fargo Bank, subject to a termination fee of \$90,000 if terminated before the first anniversary, \$60,000 if terminated between the first and second anniversary, and \$30,000 if terminated after the second anniversary but prior to maturity. If STAAR has outstanding advances it must give 90 days advance written notice of termination or pay additional interest for the period from termination to the date 90 days after notice was actually given.

The Company's lease agreement with Farnam Street Financial, Inc., as amended on October 9, 2006, provided for purchases of up to \$1,500,000 of property, plant and equipment. In accordance with the requirements of SFAS 13 Accounting for Leases, purchases under this facility are accounted for as capital leases and have a three-year term. Under the agreement, the Company has the option to purchase any item of the leased property, at the end of the respective items lease terms, at a mutually agreed fair value. Approximately \$395,000 in borrowings were available under this facility as of March 30, 2007.

The Company's lease agreement with Mazuma Capital Corporation, as amended on August 16, 2006, provides for purchases of up to \$301,000 of property, plant and equipment. In accordance with the requirements of SFAS 13 Accounting for Leases, purchases under this facility are accounted for as capital leases and have a two-year term. The Company is required to open a certificate of deposit as collateral in STAAR Surgical Company's name at the underwriting bank for 50% of the assets funded by Mazuma. As of March 27, 2007, the Company had a certificate of deposit for approximately \$150,000 recorded as short-term investment restricted with a 12-month term at a fixed interest rate of 4.5%. The agreement also provides that the Company may elect to purchase any item of the leased property at the end of its lease term for \$1. No borrowings were available under this facility as of March 30, 2007.

The Company's German subsidiary, Domilens, entered into a credit agreement at August 30, 2005. The renewed credit agreement provides for borrowings of up to 100,000 EUR (\$133,000 at the rate of exchange on March 30, 2007), at a



rate of 8.5% per annum and does not have a termination date. The credit facility is not secured. There were no borrowings outstanding as of March 30, 2007 and December 29, 2006.

**Table of Contents****STAAR SURGICAL COMPANY AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Note 9 Stock-Based Compensation**

The Company has adopted Statement of Financial Accounting Standards No. 123 (revised) Share Based Payment, (SFAS 123R) effective December 31, 2005. The Company previously applied APB Opinion No. 25 Accounting for Stock Issued to Employees in accounting for stock option plans and in accordance with the Opinion, no compensation cost has been recognized for employee option grants for these plans in the prior period financial statements because there was no difference between the exercise and market price on the date of grant. The Company has elected to apply the Modified Prospective Application (MPA) in its implementation of SFAS 123R and its subsequent amendments and clarifications. Under this method, the Company has recognized stock based compensation expense only for awards newly made or modified on or after the effective date and for the portion of the outstanding awards for which requisite service will be performed on or after the effective date. Expenses for awards previously granted and earned have not been restated.

As of March 30, 2007, the Company has multiple share-based compensation plans, which are described below. The Company issues new shares upon option exercise once the optionee remits payment for the exercise price. The compensation cost that has been charged against income for the 2003 Omnibus Plan and the 1998 Stock Option Plan totaled \$376,000 for the three months ended March 30, 2007 which included \$352,000 of expense under SFAS 123R, and \$24,000 for restricted stock grants. For the three months ended March 31, 2006, there was \$407,000 of compensation cost charged against income for the 2003 Omnibus Plan and the 1998 Stock Option Plan, which included \$391,000 for the implementation of SFAS 123R, and \$16,000 for restricted stock grants. There was no income tax benefit recognized in the income statement for share-based compensation arrangements as the Company fully offsets net deferred tax assets with a valuation allowance. In addition, the Company capitalized \$30,000 and \$25,000 of SFAS 123R compensation to inventory for the three months ended March 30, 2007 and March 31, 2006 respectively.

***Stock Option Plans***

In fiscal year 2003, the Board of Directors approved the 2003 Omnibus Equity Incentive Plan (the 2003 Plan ) authorizing awards of equity compensation, including options to purchase common stock and restricted shares of common stock. The 2003 Plan amends, restates and replaces the 1991 Stock Option Plan, the 1995 Consultant Stock Plan, the 1996 Non-Qualified Stock Plan and the 1998 Stock Option Plan (the Restated Plans ). Under provisions of the 2003 Plan, all of the unissued shares in the Restated Plans are reserved for issuance in the 2003 Plan. Each year the number of shares reserved for issuance under the 2003 Plan is increased if necessary to provide that 2% of the total shares of common stock outstanding on the immediately preceding December 31 will be reserved for issuance. The 2003 Plan provides for various forms of stock-based incentives. To date, of the available forms of awards under the 2003 Plan, the Company has granted only stock options and restricted stock. Options under the plan are granted at fair market value on the date of grant, become exercisable over a three- or four-year period, or as determined by the Board of Directors, and expire over periods not exceeding 10 years from the date of grant. Certain option and share awards provide for accelerated vesting if there is a change in control (as defined in the 2003 Plan). Restricted stock grants under the 2003 Plan generally vest over a period of three or four years. Pursuant to the plan, options for 1,812,334 shares were outstanding at March 30, 2007 with exercise prices ranging between \$3.81 and \$11.24 per share. There were 50,984 shares of restricted stock outstanding at March 30, 2007.

In fiscal year 2000, the Board of Directors approved the Stock Option Plan and Agreement for the Company's Chief Executive Officer authorizing the granting of options to purchase common stock or awards of common stock. The

options under the plan were granted at fair market value on the date of grant, become exercisable over a three-year period, and expire 10 years from the date of grant. Pursuant to this plan, options for 500,000 were outstanding at March 30, 2007 with an exercise price of \$11.125.

In fiscal year 1998, the Board of Directors approved the 1998 Stock Option Plan, authorizing the granting of options to purchase common stock or awards of common stock. Under the provisions of the plan, 1.0 million shares were reserved for issuance; however, the maximum number of shares authorized may be increased provided such

**Table of Contents**

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

action is in compliance with Article IV of the plan. During fiscal year 2001, pursuant to Article IV of the plan, the stockholders of the Company authorized an additional 1.5 million shares. Generally, options under the plan are granted at fair market value at the date of the grant, become exercisable over a three-year period, or as determined by the Board of Directors, and expire over periods not exceeding 10 years from the date of grant. Pursuant to the plan, options for 921,000 were outstanding at March 30, 2007 with exercise prices ranging between \$2.96 and \$13.625 per share. No further awards may be made under this plan.

In fiscal year 1996, the Board of Directors approved the 1996 Non-Qualified Stock Plan, authorizing the granting of options to purchase common stock or awards of common stock. Under provisions of the Non-Qualified Stock Plan, 600,000 shares were reserved for issuance. Generally, options under the plan were granted at fair market value at the date of the grant, become exercisable over a three-year period, or as determined by the Board of Directors, and expire over periods not exceeding 10 years from the date of grant. The options were originally issued with an exercise price of \$12.50 per share. During fiscal year 1998 the exercise price of options held by employees was reduced to \$6.25 per share by action of the Board of Directors. As of March 30, 2007 there were no outstanding options. No further awards may be made under this plan.

In fiscal year 1995, the Company adopted the 1995 Consultant Stock Plan, authorizing the granting of options to purchase common stock or awards of common stock. Generally, options under the plan were granted at fair market value at the date of the grant, become exercisable on the date of grant and expire 10 years from the date of grant. Pursuant to this plan, options for 56,700 shares were outstanding at March 30, 2007 with exercise prices ranging from \$1.70 to \$3.00 per share. No further awards may be made under this plan.

Under provisions of the Company's 1991 Stock Option Plan, 2.0 million shares were reserved for issuance. Generally, options under this plan were granted at fair market value at the date of the grant, become exercisable over a three-year period, or as determined by the Board of Directors, and expire over periods not exceeding 10 years from the date of grant. Pursuant to this plan, options for 60,000 shares were outstanding at March 30, 2007 with exercise prices ranging from \$9.56 to \$10.18 per share. No further awards may be made under this plan.

During fiscal years 1999 and 2000, the Company issued non-qualified options to purchase shares of its Common Stock to employees and consultants. Pursuant to these agreements, options for 55,000 shares were outstanding at March 30, 2007 with exercise prices ranging between \$9.375 and \$10.63.

During the three months ended March 30, 2007, officers, employees and others exercised 60,157 options from the 1995, 1996, 1998, non qualified and 2003 stock option plans at prices ranging from \$2.96 to \$4.65 resulting in net cash proceeds to the Company totaling \$211,000.

***Assumptions***

The fair value of each option award is estimated on the date of grant using a Black-Scholes option valuation model that uses the assumptions noted in the following table. Expected volatilities are based on historical volatility of the Company's stock. The Company uses historical data to estimate option exercise and employee termination behavior. The expected term of options granted is derived from the historical exercise activity over the past 15 years, and represents the period of time that options granted are expected to be outstanding. The Company used the shortcut method to calculate the expected term of its options granted during the first quarter of 2006 that had a four year vesting life. The Company has calculated a 10.5% estimated forfeiture rate used in the model for fiscal year



**Table of Contents****STAAR SURGICAL COMPANY AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

2006 option grants based on historical forfeiture experience. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

	<b>Three Months Ended</b>	
	<b>March 30, 2007</b>	<b>March 31, 2006</b>
Expected dividends	*	0%
Expected volatility	*	70%
Risk-free rate	*	3.65%
Expected term (in years)	*	5.2 & 7

\* During the three months ended March 30, 2007 the Company did not grant any options.

A summary of option activity under the Plans as of March 30, 2007, and changes during the period then ended are presented below:

<b>Options</b>	<b>Shares (000 s)</b>	<b>Weighted-Average Exercise Price</b>	<b>Weighted-Average Remaining Contractual Term</b>	<b>Aggregate Intrinsic Value (000 s)</b>
Outstanding at December 29, 2006	3,472	\$ 5.62		
Granted				
Exercised	(60)	3.50		
Forfeited or expired	(7)	4.60		
Outstanding at March 30, 2007	3,405	\$ 6.91	5.45	\$ 2,433
Exercisable at March 30, 2007	2,549	\$ 7.38	4.43	\$ 1,746

The total fair value of options vested during the three months ended March 30, 2007, and March 31, 2006 was \$562,745 and \$439,000 respectively. The total intrinsic value of options exercised during the three months ended March 30, 2007 and March 31, 2006 was \$121,000 and \$512,000 respectively.

A summary of the status of the Company's nonvested shares as of March 30, 2007 and changes during the period is presented below:

<b>Nonvested Shares</b>	<b>Shares (000 s)</b>	<b>Weighted-Average Grant Date Fair Value</b>	
Nonvested at December 29, 2006	1,032	\$	3.30
Granted			
Vested	(172)		3.27
Forfeited	(4)		2.91
Nonvested at March 30, 2007	856	\$	3.31

As of March 30, 2007 there was \$1.6 million of total unrecognized compensation cost related to nonvested share-based compensation arrangements granted under the Plans. That cost is expected to be recognized over a weighted-average period of 1.47 years.

Table of Contents**STAAR SURGICAL COMPANY AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Note 10 Other Liabilities***Other Current Liabilities*

Other current liabilities consisted of the following (in thousands):

	<b>March 30, 2007</b>	<b>December 29, 2006</b>
Accrued salaries & wages	\$ 2,206	\$ 1,974
Accrued income taxes	1,144	830
Accrued commissions	707	800
Notes payable, current	810	770
Accrued audit expenses	400	517
Accrued insurance	483	484
Other	2,713	2,199
	<b>\$ 8,463</b>	<b>\$ 7,574</b>

**Note 11 Supplemental Disclosure of Cash Flow Information**

Interest paid was \$59,260 and \$9,315 for the quarters ended March 30, 2007 and March 31, 2006, respectively. Income taxes paid amounted to approximately \$207,000 and \$226,000 for the quarters ended March 30, 2007 and March 31, 2006, respectively.

The Company's non-cash investing and financing activities were as follows (in thousands):

	<b>March 30, 2007</b>	<b>March 31, 2006</b>
<b>Non-cash investing activities:</b>		
Purchase of fixed assets on terms	\$ 255	\$
<b>Non-cash financing activities:</b>		
Discount on Note Payable	(267)	
Fair value of Warrants	267	

**Note 12 Subsequent Events***U.S. Lease Line of Credit*



On April 1, 2007, the Company signed an additional leasing schedule with Farnam, which provides for additional purchases of \$800,000 during the next fiscal year. The terms of this new schedule conform to the amended agreement dated October 9, 2006.

***Swiss Credit Facility***

The Company's Swiss credit agreement with UBS AG was terminated subsequent to the end of the first fiscal quarter. The Master Credit Agreement with UBS AG, as amended on August 2, 2004, had provided for borrowings of up to 3 million Swiss Francs CHF (approximately \$2.4 million based on the rate of exchange on March 30, 2007), and permitted either fixed-term or current advances. As of March 30, 2007, advances of \$1,812,000 were outstanding under the line. STAAR AG repaid all advances in full on April 4, 2007 with cash from international operations. UBS AG elected to terminate the line, which was terminable by either party at any time without cause and without penalty, on April 26, 2007. At the time of termination the balance on the line was zero and STAAR was in compliance with all terms, conditions and covenants the Master Credit Agreement. STAAR's international

**Table of Contents**

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

operations generate sufficient positive cash flow to provide working capital for those operations and all anticipated needs without recourse to borrowing.

***Public Equity Offering***

The Company completed a public offering of its common stock on May 1, 2007. In the offering, the Company sold 3,600,000 shares of common stock at price to the public of \$5 per share, which yielded approximately \$16.6 million net proceeds. All shares of the common stock offered by the Company were sold pursuant to a shelf registration statement that was declared effective by the U.S. Securities and Exchange Commission on August 8, 2006 as supplemented by an additional registration statement filed on April 25, 2007 pursuant to Rule 462(b) under the Securities Act of 1933.

The public offering included all of the securities available for issuance under STAAR's shelf registration.

**Table of Contents**

**ITEM 2. *MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS***

The matters addressed in this Item 2 that are not historical information constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Although the Company believes that the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risks and the Company can give no assurances that its expectations will prove to be correct. Actual results could differ materially from those described in this report because of numerous factors, many of which are beyond the control of the Company. These factors include, without limitation, those described in this report and in our Annual Report on Form 10-K under the heading Risk Factors. The Company undertakes no obligation to update these forward-looking statements that may be made to reflect events or circumstances after the date of this report or to reflect actual outcomes.

The following discussion should be read in conjunction with the Company's interim condensed financial statements and the related notes provided under Item 1 Financial Statements above.

**Overview**

STAAR Surgical Company develops and manufactures visual implants and other innovative ophthalmic products to improve or correct the vision of patients with cataracts and refractive conditions. We distribute our products worldwide.

Originally incorporated in California in 1982, STAAR reincorporated in Delaware in 1986. Unless the context indicates otherwise, we, us, the Company and STAAR all refer to STAAR Surgical Company and its subsidiaries.

***Principal Products***

STAAR's products generally fall into two categories within the ophthalmic surgical product segment: products designed for cataract surgery and our Visian ICL<sup>tm</sup> line of products designed to surgically correct refractive conditions such as myopia (nearsightedness), hyperopia (farsightedness) and astigmatism.

*Intraocular Lenses (IOLs) and Related Cataract Treatment Products.* We produce and market a line of foldable IOLs for use in minimally invasive cataract surgical procedures. Cataracts are a common age-related disorder in which vision deteriorates as the eye's natural lens becomes cloudy. Treatment of cataracts typically involves surgically extracting the natural lens and replacing it with a prosthetic lens.

STAAR developed, patented and licensed the foldable intraocular lens, or IOL, which permitted surgeons for the first time to replace a cataract patient's natural lens through minimally invasive surgery. In minimally invasive cataract surgery, a procedure called phacoemulsification is first used to soften the natural lens with sound waves and withdraw it through a small incision. The foldable IOL is then inserted through the same small incision using an injector system. STAAR introduced its first version of the folding IOL, made of silicone, in 1991.

We currently manufacture foldable IOLs from both our proprietary Collamer<sup>®</sup> and silicone material. We make IOLs in each of the materials in two different configurations: the single-piece plate haptic design, and the three-piece design where the optic is combined with spring-like Polyimide<sup>tm</sup> loop haptics. The selection of one style over the other is primarily based on the preference of the ophthalmologist.

We have developed and currently market globally the Toric IOL, a toric version of our single-piece silicone IOL, which is specifically designed for cataract patients who also have pre-existing astigmatism. The Toric IOL is the first refractive product we offered in the U.S.

In late 2003, we introduced through our joint venture company, Canon Staar, the first preloaded lens injector system in international markets. The Preloaded Injector is a disposable lens delivery system containing a three-piece silicone IOL that is sterilized and ready for implant. We believe the Preloaded Injector offers surgeons improved convenience and reliability. The Preloaded Injector is not yet available in the U.S. In 2006 Canon Staar began selling in Japan an acrylic-lens-based Preloaded Injector employing a lens supplied by a Japanese ophthalmic company.

**Table of Contents**

During the quarter ended March 30, 2007, sales from IOLs accounted for approximately 41% of total sales compared with approximately 48% in the quarter ended March 31, 2006.

As part of our approach to providing complementary products for use in minimally invasive cataract surgery, we also market STAARVISC II, a viscoelastic material which is used as a protective lubricant and to maintain the shape of the eye during surgery, the STAARSonicWAVE Phacoemulsification System, a medical device system that uses ultrasound to remove a cataract patient's cloudy lens through a small incision and has low energy and high vacuum characteristics, and Cruise Control, a single-use disposable filter which allows for a faster, cleaner phacoemulsification procedure and is compatible with all phacoemulsification equipment utilizing Venturi and peristaltic pump technologies. We also sell other related instruments, devices, surgical packs and equipment that we manufacture or that are manufactured by others. Sales of other cataract products accounted for approximately 33% of our total sales for the quarter ended March 30, 2007 compared with 32% of total sales for the quarter ended March 31, 2006.

*Refractive Correction – Visian ICL.* ICLs are implanted into the eye to correct refractive disorders such as myopia, hyperopia and astigmatism. Lenses of this type are generically called phakic IOLs or phakic implants because they work along with the patient's natural lens, or phakos, rather than replacing it. The ICL is capable of correcting refractive errors over a wide diopter range.

The ICL is folded and implanted into the eye behind the iris and in front of the natural crystalline lens using minimally invasive surgical techniques similar to implanting an IOL during cataract surgery, except that the natural lens is not removed. The surgical procedure to implant the ICL is typically performed with topical anesthesia on an outpatient basis. Visual recovery is usually within one to 24 hours.

We believe the ICL will complement current refractive technologies and allow refractive surgeons to expand their treatment range and customer base.

The FDA approved the ICL for myopia for use in the United States on December 22, 2005. The ICL and TICL are approved in countries that require the Conformité Européenne Mark (or CE Mark) Canada, Korea and Singapore. Applications are pending in China and Australia, and STAAR is working to obtain new approvals for the ICL and TICL in other countries. STAAR submitted its application for U.S. approval of the TICL to the FDA in 2006.

The Hyperopic ICL, for treatment of far-sightedness or hyperopia, is approved for use in countries that require the CE Mark and in Canada, and is currently in clinical trials in the United States.

The ICL is available for myopia in the United States in four lengths and 27 powers for each length, and internationally in four lengths, with 41 powers for each length, and for hyperopia in four lengths, with 37 powers for each length, which equates to 420 inventoried parts. This requires STAAR to carry a significant amount of inventory to meet the customer demand for rapid delivery. The Toric ICL is available for myopia in the same powers and lengths but carries additional parameters of cylinder and axis with 11 and 180 possibilities, respectively. Accordingly, the Toric ICL is generally made to order.

Sales of ICLs (including TICLs) during the quarter ended March 30, 2007 accounted for approximately 24% of our total sales compared with 18% of total sales during the quarter ended March 31, 2006.

*Glaucoma Products.* Among our other products is the AquaFlow Collagen Glaucoma Drainage Device, an implantable device used for the surgical treatment of glaucoma. Glaucoma is a progressive ocular disease that manifests itself through increased intraocular pressure. The increased pressure may damage the optic disc and

decrease the visual field. Untreated, progressive glaucoma can cause blindness. Sales of AquaFlow devices during the quarters ended March 30, 2007 and March 31, 2006 accounted for approximately 1% of our total sales.

*Foreign Currency Fluctuations.* Our products are sold in approximately 50 countries. Sales from international operations represented 66% of total sales for the quarter ended March 30, 2007. The results of operations and the financial position of certain of our international operations are reported in the relevant local currencies and then translated into U.S. dollars at the applicable exchange rates for inclusion in our consolidated financial statements, exposing us to currency translation risk.

**Table of Contents**

***Strategy***

STAAR is currently focusing on the following four strategic goals:

building the U.S. market for the ICL and securing U.S. approval of the TICL;

generating further growth of the ICL and TICL in international markets;

reversing the decline in U.S. market share for our core cataract product lines by renewing and refining our product offering through enhanced R&D; and

maintaining our focus on regulatory compliance and continuous quality improvement.

*Building the U.S. market for the ICL and securing U.S. approval of the TICL.* Because the ICL's design has advantages over other refractive procedures for many patients and its proprietary nature permits STAAR to maintain its profit margin, STAAR's management believes that increased sales of the ICL are the key to the company's return to profitability. U.S. market penetration is considered essential because of the size of the U.S. refractive surgery market and the perceived leadership of the U.S. in adopting innovative medical technologies.

STAAR's strategy for the U.S. market is to educate eye care professionals on the high quality of visual outcomes of the ICL for a significant portion of patients seeking refractive surgery, and to make the ICL available to selected surgeons only after completion of a training program that includes proctoring of selected supervised surgeries. STAAR believes that this carefully guided method of product release is essential to help ensure the consistent quality of patient outcomes and the high levels of patient satisfaction needed to establish wide acceptance of the ICL as a choice for refractive surgery.

To develop specialized resources to meet the challenge of penetrating the refractive market, and to take advantage of opportunities to improve cataract product sales, STAAR divided its Sales and Marketing Department into two separate groups in the first quarter of 2007. Among other advantages, the split will enable the Sales Department to focus on the development of STAAR's direct sales model in regions where STAAR will sell directly, and to better coordinate sales initiatives with the independent Regional Marketing Representatives in those regions where STAAR will continue to rely on independent representatives.

STAAR has relied on a largely independent sales force to sell its cataract products, and over the last several months has worked to re-orient this sales force to deal with the very different practice environment for refractive products. While STAAR expects to continue to rely on its independent sales force in some regions, it has moved to a direct sales structure in other regions. Because the refractive surgery market has been dominated by corneal laser-based techniques, STAAR faces special challenges in introducing an intraocular refractive implant. STAAR has developed a number of marketing tools and practice support programs to increase the use of the ICL and awareness of its advantages at laser-oriented surgery centers.

The Visian ICL was approved by the FDA for treatment of myopia on December 22, 2005. The U.S. rollout of the product began in the first quarter of 2006. As of December 29, 2006, 306 surgeons had completed training and 352 had completed training by March 30, 2007. STAAR recognized \$4,172,000 of U.S. sales revenue from ICLs in 2006. It is too early to determine whether STAAR's strategy will be successful or to estimate the ultimate size of the U.S. market for ICLs.

STAAR believes that the Visian TICL, a variant of the ICL that corrects both astigmatism and myopia in a single lens, also has a significant potential market in the U.S. When measured six months after surgery, approximately 75% of the

patients receiving the TICL have shown better visual acuity than the best they previously achieved with glasses or contact lenses. Securing FDA approval of the TICL is therefore an integral part of STAAR's strategy to develop its U.S. refractive market. STAAR submitted a Pre-Market Approval (PMA) application for the TICL to the FDA on April 28, 2006, and received comments from the Office of Device Evaluation ( ODE ) on November 20, 2006 requesting that STAAR submit an amended application. In subsequent discussion the ODE indicated that it expects to submit the amended application to review by the FDA Ophthalmic Devices Panel. As of the date of this Report, STAAR is preparing an amendment to the TICL application addressing the ODE comments.



**Table of Contents**

STAAR's activities as a sponsor of biomedical research are subject to review by the Bioresearch Monitoring Program of the FDA Office of Regulatory Affairs (BIMO). On March 14, 2007, BIMO concluded a routine audit of STAAR's clinical trial records as a sponsor of biomedical research in connection with STAAR's Supplemental Pre-Market Approval application for the TICL. At the conclusion of the audit STAAR received eight Inspectional Observations on FDA Form 483 noting noncompliance with regulations. STAAR has submitted 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. STAAR expects to show that some of these observations have already been addressed by corrective actions made in response to BIMO's observations received on December 11, 2003 in connection with STAAR's application for the ICL.

STAAR 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 FDA Office of Device Evaluation. Obtaining FDA approval of medical devices is never certain. STAAR cannot assure investors that the Office of Device Evaluation 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.

*Generating further growth of the ICL and TICL in international markets.* The ICL and TICL are sold in more than 40 countries. International sales of refractive implants have continued a steady rate of growth, increasing approximately 50% in 2006 over the preceding year. STAAR believes that the international market for its refractive products has the potential for further growth, both through the introduction of the ICL and TICL in new territories and expanded market share in existing territories. In recent periods STAAR has received the majority of its revenue from international markets, and sales of ICLs have represented an increasing share of that revenue. STAAR received approval for the ICL in China on July 31, 2006 and we are awaiting approval of the TICL there as well. We also continue to seek new approvals for the ICL and TICL in other countries, but the timing of such approvals are at the discretion of the local authorities.

*Reversing the decline in U.S. market share for our cataract product lines by intensifying selling efforts and renewing and refining our product offering through enhanced R&D.* During the last several years STAAR has experienced a decline in U.S. sales of IOLs. STAAR's management believes the decline principally resulted from the slow pace of cataract product improvement and enhancement during a period when we had to devote most of our research and development resources to introducing the ICL and to resolving the regulatory and compliance issues raised by the FDA, and the harm to our reputation from warning letters and other correspondence with the FDA during 2004 and 2005.

STAAR seeks to reverse the decline in its domestic cataract market share by the introduction of enhanced design IOLs and improved delivery systems in 2007 and 2008. The completion in 2005 of initiatives to revamp STAAR's systems of regulatory compliance and quality management permitted STAAR to shift resources back to product development. In particular, STAAR has focused on the following projects intended to expand and improve our cataract product offering:

Development of a new three-piece Collamer IOL featuring a square edge and an aspheric optic design, which was introduced in April 2007;

Development of a new silicone IOL model featuring an aspheric optic and a squared edge configuration;

Development of a Collamer Toric IOL to complement our pioneering silicone Toric IOL;

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

Enhancements to the injector system for our three-piece Collamer IOL to improve delivery, and development of an all new injector system for the three-piece Collamer IOL;

Development of a micro-incision injector for the one-piece Collamer IOL; and

Development of a preloaded injector system for our new silicone aspheric IOL.

STAAR cautions that the successful development and introduction of new products is subject to risks and uncertainties, including the risk of unexpected delays.

**Table of Contents**

STAAR believes that expanding the U.S. market for the ICL should also improve the selling environment for STAAR's cataract products, especially cataract lenses made of the same biocompatible Collamer material used in the ICL. STAAR intends that the split of its Sales and Marketing Department will help it take advantage of the opportunities presented by the introduction of new cataract products and the improved selling environment for STAAR's products created by the ICL.

On January 22, 2007, the Centers for Medicare and Medicaid Services (CMS) issued a ruling that allows cataract patients receiving reimbursement by Medicare to choose a lens that also corrects astigmatism. Under the ruling, patients may elect to pay a premium for the correction of pre-existing astigmatism, while Medicare provides the customary reimbursement for cataract surgery. STAAR has been advised by CMS that its Toric IOL conforms with the CMS ruling and expects the lens to be available to patients under dual aspect reimbursement. In addition, STAAR expects to introduce a Toric IOL made of our proprietary Collamer material, which would also likely fall under the CMS ruling and compete with our competitor's acrylic model. STAAR cannot estimate the amount of any increased revenue that may result from the CMS ruling at this time.

To reverse the decline in U.S. IOL sales, STAAR must overcome several short and long-term challenges, including overcoming reputational harm from the FDA's past findings of compliance deficiencies, successfully completing planned development projects, and organizing and managing a combined direct and independent sales force. We cannot ensure that this strategy will ultimately be successful.

*Maintaining our focus on regulatory compliance and continuous quality improvement.* As a manufacturer of medical devices, STAAR's manufacturing processes and facilities are regulated by the FDA. We also must satisfy the requirements of the International Standards Organization (ISO) to maintain approval to sell products in the European Community and other regions. Failure to demonstrate substantial compliance with FDA regulations can result in enforcement actions that terminate, suspend or severely restrict the ability to continue manufacturing and selling medical devices. Between December 29, 2003 and July 5, 2005, STAAR received Warning Letters, Form 483 Inspectional Observations and other correspondence from the FDA indicating deficiencies in STAAR's compliance with the FDA's Quality System Regulations and Medical Device Reporting regulations and warning of possible enforcement action. In response, STAAR implemented numerous improvements to its quality system. Among other things, STAAR developed a Global Quality Systems Action Plan, which has been continuously updated since its adoption in April, 2004, and took steps to emphasize a focus on compliance throughout the organization.

The FDA's most recent general quality inspections of STAAR's facilities were a post-market inspection of the Monrovia, California and Aliso Viejo, California facilities between August 2, 2006 and August 7, 2006, and a post-market inspection of the Nidau, Switzerland facilities between September 26 and September 28, 2006. These inspections resulted in no observations of noncompliance. Based in part on these inspections and the FDA inspections conducted in 2005, STAAR believes that it is substantially in compliance with the FDA's Quality System Regulations and Medical Device Reporting regulations. Nevertheless, the FDA's past findings of compliance deficiencies have harmed our reputation in the ophthalmic industry and affected our product sales.

STAAR's ability to continue its U.S. business depends on the continuous improvement of its quality systems and its ability to demonstrate compliance with FDA regulations. Accordingly, for the foreseeable future STAAR's management expects its strategy to include devoting significant resources and attention to strict regulatory compliance and continuous improvement in quality.

As described above, 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 TICL. At the conclusion of

the audit the Company received eight Inspectional Observations on FDA Form 483 noting noncompliance with regulations. The Company has submitted 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 ICL. The Company does not believe that the Inspectional Observations affect the integrity of the Toric clinical study. However, the determination of whether

## **Table of Contents**

the Inspectional Observations affect the use of the Toric clinical study in STAAR's pending Toric application will be at the discretion of the ODE. Obtaining FDA approval of medical devices is never certain.

### ***Financing Strategy***

While STAAR's international business generates positive cash flow and 66% of STAAR's revenue, STAAR has reported losses on a consolidated basis over the last several years due to a number of factors, including eroding sales of cataract products in the U.S. and FDA compliance issues that consumed additional resources while delaying the introduction of new products in the U.S. market. During the last three years STAAR has secured additional capital to sustain operations through private sales of equity securities, exercise of options, the repayment of directors' notes and debt financing.

STAAR's management believes that in the near term its best prospect for returning its U.S. and consolidated operations to profitability is achieving significant U.S. sales of the ICL. In the longer term STAAR seeks to develop and introduce products in the U.S. cataract market to stop further erosion of its market share and resume growth in that sector. Nevertheless, success of these strategies is not assured and, even if successful, STAAR is not likely to achieve positive cash flow on a consolidated basis during fiscal 2007.

To provide additional working capital, STAAR completed a public offering of its common stock on May 1, 2007. In the offering, STAAR sold 3,600,000 shares of common stock at price to the public of \$5 per share, which yielded approximately \$16.6 million net proceeds to STAAR. All shares of the common stock offered by STAAR were sold pursuant to a shelf registration statement that was declared effective by the U.S. Securities and Exchange Commission on August 8, 2006 as supplemented by an additional registration statement filed on April 25, 2007 pursuant to Rule 462(b) under the Securities Act of 1933. STAAR intends to use the proceeds of the offering for general corporate purposes, including the repayment of \$4 million in indebtedness incurred under a Promissory Note with Broadwood Partners, L.P., which is discussed below under the heading *Liquidity and Capital Resources - Credit Facilities*, expansion of sales and marketing, working capital, capital expenditures, technology acquisition and continuing research and development. Other than repayment of indebtedness, we have not determined the amounts we plan to spend on any of the areas listed above or the timing of these expenditures. Until applied to those purposes, we intend to invest the net proceeds in investment-grade, interest-bearing securities.

As additional consideration for the loan STAAR 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, STAAR will grant additional warrants each quarter on the same terms as the Warrant Agreement. As a result, if STAAR has not repaid the promissory note by June 30, 2007, it will be obligated to issue a warrant to purchase an additional 30,000 shares of common stock at an exercise price of \$6 per share. The warrant agreement provides that STAAR will register the stock for resale with the SEC.

STAAR may seek additional debt or equity financing to provide working capital, finance new business initiatives, expand its business or make acquisitions. Because of our history of losses, our ability to obtain adequate financing on satisfactory terms is limited. STAAR's cash resources are discussed in further detail under the caption *Liquidity and Capital Resources* below.

### ***Investigation of Fraud at Domilens GmbH***

Domilens GmbH is a wholly owned indirect subsidiary of STAAR Surgical Company based in Hamburg, Germany. Domilens distributes ophthalmic products made by both STAAR and other manufacturers. During fiscal year 2006 Domilens reported sales of \$21.1 million.

Guenther Roepstorff founded Domilens in 1986 and operated it as an independent distributor of ophthalmic goods generally serving the market for cataract surgical products. STAAR's wholly owned Swiss subsidiary, STAAR Surgical AG, or STAAR AG, purchased 60% of Domilens in 1997, purchased another 20% in 1999, and in 2003 acquired the remaining 20%. In the 2003 transaction, Mr. Roepstorff transferred his shares to STAAR AG, and surrendered to STAAR all of his then outstanding stock options, in exchange for the cancellation of approximately \$1.03 million in indebtedness he had incurred by taking loans from Domilens without STAAR

**Table of Contents**

AG's approval. In the transfer agreement Mr. Roepstorff agreed that he would pay a 50% penalty on any future loans taken unilaterally and that taking any money from Domilens would be immediate cause for termination.

On January 18, 2007, Guenther Roepstorff, president of Domilens, notified STAAR he had admitted to the German Federal Ministry of Finance that without STAAR's knowledge he had diverted property of Domilens to a company under his control over a four-year period between 2001 and 2004. Mr. Roepstorff made this admission in connection with an audit conducted by the Ministry in 2006, which examined the financial records of Mr. Roepstorff, Domilens and the company to which he owned and diverted the property, Equimed GmbH (currently known as eyemaxx GmbH), covering the four-year period.

Immediately after learning these facts STAAR commenced an internal investigation of Domilens. On January 20, 2007, the Audit Committee of STAAR's Board of Directors engaged PricewaterhouseCoopers LLP ( PwC ) to conduct a forensic audit in connection with the investigation by legal counsel. The Committee subsequently engaged the law firm of Taylor Wessing, through its Hamburg office, as independent German legal counsel. The investigation included a comprehensive forensic review of the accounting records, documents and electronic records of Domilens and interviews of current employees and Mr. Roepstorff. On March 6, 2007, the Audit Committee of the Board of Directors of STAAR Surgical Company received PwC's final report.

*Key findings.* PwC investigated instances of misappropriation of corporate assets by Mr. Roepstorff between 2001 and 2006. Areas of fraudulent activity investigated by PwC included diversions of sales of IOLs and equipment to Equimed GmbH, payments to Mr. Roepstorff disguised as prepayments to suppliers and unauthorized borrowing. It is estimated that from 2001 through 2006 these activities diverted assets having a book value of approximately \$400,000 and resulted in unreported proceeds to Equimed and Mr. Roepstorff of approximately \$1,000,000.

PwC identified Mr. Roepstorff's ability to override the internal controls implemented by STAAR as a key factor in his ability to accomplish fraudulent transactions and avoid detection. In particular, they found that even after STAAR had acquired full control of Domilens and implemented further oversight he continued to run the company as his own and had a dominant presence with employees. PwC found evidence that, notwithstanding the requirements of STAAR's Code of Ethics, some Domilens employees had been aware of improper activities by Mr. Roepstorff and in some instances cooperated in documenting the activities in a manner that aided concealment. However, there is no evidence that other employees received any portion of the diverted assets or other payment for cooperation.

PwC also identified inadequate oversight of Domilens by STAAR AG and inadequate management oversight by STAAR as significant factors enabling Mr. Roepstorff to accomplish his actions. PwC has determined that a greater degree of scrutiny would have likely led to earlier detection of irregularities at Domilens.

*Impact on financial statements.* Domilens' financial results are consolidated into the audited financial statements of STAAR. STAAR has reviewed its historical financial statements, and has determined that properly accounting for past transactions in Domilens in light of the information provided by PwC's investigation did not result in a material change in STAAR's reported results of operations or reported financial condition for historical periods. STAAR has determined that the events at Domilens revealed a material weakness in its internal controls over financial reporting. Additional information on this material weakness in internal controls appears in our annual report on Form 10-K under Item 9A. Controls and Procedures Management Report on Internal Control over Financial Reporting.

*Expenses related to Domilens irregularities.* It is currently estimated that the fees and reimbursable expenses of advisors incurred by STAAR in connection with the investigation will total approximately \$800,000, which was recorded in marketing and selling expense during the first quarter of 2007. In addition, STAAR has reserved approximately \$700,000 against additional taxes that may be assessed for unreported sales, but will seek to reduce that amount in discussions with the German Ministry of Finance. The estimated tax liability was recorded in the fourth

quarter of fiscal year 2006.

*Other Actions.* STAAR suspended all of Mr. Roepstorff's duties as president on January 19, 2007. He voluntarily resigned from his employment with Domilens on January 23, 2007. STAAR will provide all of Domilens' employees further training in their duties as employees and in STAAR's Code of Ethics. STAAR has



## **Table of Contents**

terminated one STAAR AG employee whose responsibilities included financial oversight of Domilens. In addition, based on the advice of German counsel, the degree of individual culpability and other factors, STAAR may take other disciplinary actions, including possible termination of employees or monitoring of selected employees during a probationary period.

### ***Canon Staar Joint Venture***

STAAR is the 50% owner of a Japan-based joint venture, Canon Staar Co., Inc., which manufactures the Preloaded Injector, a silicone or acrylic IOL preloaded into a single-use disposable injector. The co-owners of the joint venture are the Japanese optical company Canon, Inc. and its affiliated marketing company, Canon Marketing Japan Inc. Canon Marketing distributes the Preloaded Injector in Japan, and STAAR's Swiss subsidiary, STAAR AG, distributes the silicone Preloaded Injector in Europe and Australia, and a non-exclusive basis in China and some other international markets. Canon Staar's silicone-lens-based Preloaded Injector was introduced in 2003. Canon Staar is currently seeking approval from the Japanese regulatory authorities to market in Japan the ICL, Collamer IOL and the AquaFlow Device manufactured by STAAR. The acrylic Preloaded Injector, introduced in Japan in 2006, employs a lens supplied by a Japanese ophthalmic company.

Canon Staar was created in 1988 pursuant to a Joint Venture Agreement between STAAR, Canon and Canon Marketing for the principal purpose of designing, manufacturing, and selling in Japan intraocular lenses and other ophthalmic products. The joint venture agreement provides that Canon Staar will not directly distribute its products but will distribute them worldwide through Canon, Canon Marketing, their subsidiaries, STAAR and such other distributors as the Board of Directors of Canon Staar may approve. The terms of any such distribution arrangement must be unanimously approved by the Canon Staar Board.

Several other matters require the unanimous approval of the Canon Staar Board of Directors, including appointment of key officers or directors with specific titles, acquiring or disposing of assets exceeding 20% of Canon Staar's total book value, borrowing in the principal amount of more than 20% of Canon Staar's total book value and granting a lien on any of Canon Staar's assets or contractual rights in excess of 20% of Canon Staar's total book value. STAAR is entitled to appoint, and has appointed, two of the five Canon Staar Board members. The president of Canon Staar is to be appointed, and has been appointed, by STAAR.

The Joint Venture Agreement contains numerous default provisions that give the non-defaulting party the right to acquire the defaulting party's entire interest in Canon Staar at book value. For this purpose, a party is in default under the Joint Venture Agreement (1) if the party cannot pay its debts or files for bankruptcy or similar protection, or voluntarily or involuntarily liquidates, (2) if the party defaults in its obligations under the Joint Venture Agreement and fails to cure the default within 90 days of receiving notice of default, (3) if the party undergoes a merger, acquisition or sale of substantially all of its assets, (4) if a material change occurs in management of the party, or (5) if any person or entity attempts to acquire all or a substantial portion of the party's capital stock by a tender offer or otherwise, or attempts to acquire a substantial portion of the party's business or assets.

The Joint Venture Agreement provides that the joint venture will be dissolved and its assets liquidated if an event of force majeure occurs, such as natural disaster, war, strike or governmental order, and the continuation of the event has a material adverse effect on the operations of Canon Staar. The joint venture will also be dissolved and its assets liquidated if a problem that materially affects Canon Staar or the continuation of its operations is not resolved after six months' negotiation.

In accordance with the Joint Venture Agreement, in 1988 Canon Staar and STAAR entered into a Technical Assistance and Licensing Agreement (the TALA), pursuant to which STAAR granted to the joint venture an irrevocable, exclusive license to STAAR's technology to make, have made, use, sell, lease or otherwise dispose of any

products in Japan. The Joint Venture Agreement also gives Canon Staar a right of first refusal on any distribution of STAAR's products in Japan, contemplates a Distribution Agreement to cover the resulting arrangement, gives Canon Staar the right to purchase from STAAR manufacturing equipment and tooling necessary to manufacture intraocular lenses, and contemplates a Supply Agreement to cover the resulting arrangement. The Joint Venture Agreement also contemplates that the relevant parties will enter into a Company's Name License Agreement giving Canon Staar a license to use the founding parties' names. To date, the parties have not entered into any such Distribution Agreement, Supply Agreement or Company's Name License Agreement.

**Table of Contents**

Under the TALA, STAAR granted Canon Staar a royalty free, fully paid-up, irrevocable, exclusive license to make, have made, use, sell, lease or otherwise dispose of any products in Japan using or incorporating STAAR's Licensed Technology. Licensed Technology means all intellectual property relating to intraocular lenses, surgical packs, phacoemulsification machines, ophthalmic solutions, other pharmaceuticals and medical equipment, owned or controlled by STAAR as of the date of the TALA or thereafter. Under the TALA, STAAR also granted Canon Staar a royalty-free, fully paid-up, irrevocable, non-exclusive license to use, sell, lease or otherwise dispose of any products in the rest of the world using or incorporating STAAR's Licensed Technology. The TALA also provides that STAAR will provide the Licensed Technology in written or other tangible form to enable Canon Staar to make, sell and service products and provide training and consulting services in connection with the manufacture of products. In consideration of the licenses and rights granted by STAAR under the TALA, Canon Staar paid STAAR \$3 million. The TALA continues in effect until such time as the parties agree to terminate it.

In 2001, the joint venture parties, including Canon Staar, entered into a Settlement Agreement under which they reconfirmed the Joint Venture Agreement and the TALA and STAAR agreed promptly to commence the transfer to Canon Staar under the TALA of all of its new or advanced technology, including technology related to collamer IOL, glaucoma wicks and ICL. In the Settlement Agreement STAAR also granted Canon Staar a royalty free, fully paid-up, perpetual, exclusive license to use STAAR's Licensed Technology to make and have made any products in China and sell such products in Japan and China (subject to STAAR's existing licenses and the existing rights of third parties). The Settlement Agreement also provided that STAAR would enter into a raw material supply agreement covering the supply of raw materials to Canon Staar and would continue to supply raw materials under existing arrangements until execution of the supply agreement. The Settlement Agreement further provided that Canon Marketing would enter into a distribution agreement with Canon Staar governing Canon Marketing's status as Canon Staar's exclusive distributor in Japan. The distribution agreement would provide that the selling prices by Canon Staar of its products to Canon Marketing will be in the range of 50% to 70% of the sales price of the products from Canon Marketing to its end customers through its own sales channel, with the pricing to be reviewed annually and subject to unanimous approval of the Canon Staar Board. The Settlement Agreement provides that until the distribution agreement is executed the Canon Staar will sell its products to Canon Marketing at its then current prices, provided the prices are within the 50-70% range. The parties also settled certain patent disputes. To date, the parties have not entered into the supply agreement or distribution agreement.

Canon Staar has a single class of capital stock, of which STAAR owns 50%. Accordingly, STAAR is entitled to 50% of any dividends or distributions by Canon Staar and 50% of the proceeds of any liquidation.

The foregoing description of the joint venture agreement, TALA and Settlement Agreement is qualified in its entirety by the full text of such agreements, which have been filed as exhibits or incorporated by reference to this report. The joint venture agreement, TALA and Settlement Agreement are governed by the laws of Japan, and contain provisions that may be open to different interpretations. Accordingly, these agreements may be interpreted in a manner that may be materially adverse to the interests of STAAR, and any description of these agreements is subject to uncertainty. See

**Risk Factors** We have licensed our technology to our joint venture company, which could cause our joint venture company to become a competitor ; and **Risk Factors** Our interest in Canon Staar may be acquired for book value on the occurrence of specified events, including a change in control of STAAR.

*Foreign Currency Fluctuations.* Our products are sold in approximately 50 countries. Sales from international operations represented 66% of total sales for the quarter ended March 30, 2007. The results of operations and the financial position of certain of our international operations are reported in the relevant local currencies and then translated into U.S. dollars at the applicable exchange rates for inclusion in our consolidated financial statements, exposing us to currency translation risk.

**Critical Accounting Policies**

Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our unaudited Consolidated Condensed Financial Statements, which we have prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. Management bases its estimates on historical experience and on

**Table of Contents**

various other assumptions that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Senior management has discussed the development, selection and disclosure of these estimates with the Audit Committee of our Board of Directors. Actual results may differ from these estimates under different assumptions or conditions.

An accounting policy is deemed critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, if different estimates reasonably could have been used, or if changes in the estimate that are reasonably likely to occur could materially impact the financial statements. Management believes that there have been no significant changes during the three months ended March 30, 2007 to the items that we disclosed as our critical accounting policies and estimates in Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the fiscal year ended December 29, 2006.

**Results of Operations**

The following table sets forth the percentage of total sales represented by certain items reflected in the Company's statements of operations for the periods indicated and the percentage increase or decrease in such items over the prior period.

	<b>Percentage of Total Sales for</b>		<b>Percentage Change for Three Months 2007 vs. 2006</b>
	<b>Three Months March 30, 2007</b>	<b>March 31, 2006</b>	
Net sales	100.0%	100.0%	10.8%
Cost of sales	51.1	52.2	8.5
Gross profit	48.9	47.8	13.3
General and administrative	18.7	20.8	(0.6)
Marketing and selling	40.9	38.0	19.1
Research and development	10.8	12.8	(6.7)
	70.4	71.6	8.8
Operating loss	(21.5)	(23.8)	(0.3)
Total other income, net	(0.3)	0.4	
Loss before income taxes and minority interest	(21.8)	(23.4)	3.1
Provision for income taxes	1.8	1.5	30.0
Net loss	(23.6)%	(24.9)%	4.7%

*Net Sales*

Net sales for the first quarter were \$14,917,000, an increase of 10.8% compared with \$13,465,000 reported for the same period of 2006. This sales level is the third highest quarterly sales achieved by the Company in its 25-year history. The year-over-year increase in sales during the first quarter of 2007 was the fourth consecutive quarter of year-over-year sales growth and was largely the result of increased Visian ICL™ sales in U.S. and international markets. Excluding the impact of changes in currency, first quarter 2007 sales were \$14,367,000, up 7% compared with \$13,465,000 reported in the first quarter of 2006.

International sales for the first quarter were \$9,823,000, up 20% compared with \$8,204,000 reported in the same period of the prior year. Excluding the impact of changes in currency, first quarter 2007 international sales were \$9,273,000 up 13% compared with the same period of last year. During the first quarter, international sales of ICLs and TICLs grew 53% to \$2,619,000 compared with the first quarter of 2006. International cataract sales for the first quarter were \$7,110,000, up 11% compared with \$6,404,000 reported in the same period of the prior year.

**Table of Contents**

Total U.S. sales for the first quarter fiscal 2007 were \$5,094,000, down 3% compared with \$5,261,000 reported in the same period of 2006, and down 10% compared with \$5,680,000 reported for the fourth quarter of 2006. First quarter U.S. Visian ICL<sup>tm</sup> sales were \$1,023,000, down 4% compared with \$1,060,000 for the fourth quarter of 2006 and up 49% compared with \$685,000 reported in the first quarter of 2006. U.S. cataract sales for the first quarter were \$3,914,000, down 10% compared with \$4,362,000 reported in the same period of the prior year.

Total ICL and TICL sales during the first quarter of 2007 grew 52% to \$3,642,000 compared with \$2,399,000 in the same period of 2006. Total cataract sales during the first quarter of 2007 grew 2% to \$11,024,000, compared with \$10,766,000 reported in the same period of the prior year.

***Gross Profit Margin***

Gross profit margin for the first quarter increased to 48.9% compared with 47.8% in the first quarter of 2006. This increase was primarily due to the year-over-year increase in high margin ICL products.

***Marketing and Selling***

Marketing and selling expenses for the first quarter of 2007 increased 19% to \$6,102,000 compared with \$5,123,000. The increase for the quarter is primarily due to the investigation costs of approximately \$800,000 related to our German subsidiary and the costs of increased headcount in the U.S. partially offset by a decrease in trade show expenses due to the timing of ASCRS.

***Research and Development***

Research and development expenses, including regulatory and clinical expenses, for the first quarter of 2007, decreased 7% to \$1,610,000 compared with \$1,726,000 reported for the first quarter of 2006. Research and development costs in the first quarter of 2006 were higher due to the costs associated with the Toric ICL<sup>tm</sup> FDA Pre-Market Approval submission.

***Liquidity and Capital Resources***

The Company has funded its activities over the past several years principally from cash flow generated from operations, credit facilities provided by institutional domestic and foreign lenders, the private placement of Common Stock, the repayment of former directors' notes, and the exercise of stock options.

As of March 30, 2007 and December 29, 2006, the Company had \$9.2 million and \$7.9 million, respectively, of cash and cash equivalents and restricted short-term investments.

Net cash used in operating activities was \$2.7 million for the three months ended March 30, 2007 versus \$3.1 million for the three months ended March 31, 2006. This improvement was due to management of cash resources.

Net cash provided by financing activities was \$4.2 million for the three months ended March 30, 2007 versus \$0.4 million for the three months ended March 31, 2006. The change was due primarily to the proceeds of \$4 million received during the first quarter of 2007 from a promissory note with Broadwood Partners, L.P.

Accounts receivable at March 30, 2007 increased \$0.6 million relative to December 31, 2006. The increase in accounts receivable relates primarily to increased international ICL sales during 2007 and the impact of foreign exchange. Days sales outstanding (DSO) were 43 days at March 30, 2007 compared to 39 days at December 29, 2006.

The Company expects to maintain DSO within a range of 40 to 45 days during the course of the 2006 fiscal year.

*Public Equity Offering*

STAAR's liquidity requirements arise from the funding of its working capital needs, primarily inventory, work-in-process and accounts receivable. While STAAR's international business generates positive cash flow and represents approximately 66% of consolidated net sales, we have reported losses on a consolidated basis for several years due to a number of factors, including eroding sales of cataract products in the U.S. and FDA compliance issues



**Table of Contents**

that consumed additional resources while delaying the introduction of new products in the U.S. market. As a result, during recent periods cash flow from operations has not been sufficient to satisfy our need for working capital and STAAR has relied on additional sources, including proceeds of the private placement of equity securities, proceeds of option exercises and borrowings on our lines of credit.

STAAR's management believes that in the near term its best prospect for returning its U.S. and consolidated operations to profitability is achieving significant U.S. sales of the ICL. In the longer term STAAR seeks to develop and introduce products in the U.S. cataract market to stop further erosion of its market share and resume growth in that sector. Nevertheless, success of these strategies is not assured and, even if successful, STAAR is not likely to achieve positive cash flow on a consolidated basis during fiscal 2007.

To provide additional working capital, STAAR completed a public offering of its common stock on May 1, 2007. In the offering, STAAR sold 3,600,000 shares of common stock at price to the public of \$5 per share, which yielded approximately \$16.6 million net proceeds to STAAR. All shares of the common stock offered by STAAR were sold pursuant to a shelf registration statement that was declared effective by the U.S. Securities and Exchange Commission on August 8, 2006 as supplemented by an additional registration statement filed on April 25, 2007 pursuant to Rule 462(b) under the Securities Act of 1933. STAAR intends to use the proceeds of the offering for general corporate purposes. After the expected repayment of \$4 million in indebtedness incurred under a Promissory Note with Broadwood Partners, L.P., which is discussed below, the remaining proceeds of the public offering will be available for working capital and other general corporate purposes. STAAR believes that with the proceeds of the public offering, along with expected cash from operations, it has sufficient cash to meet its funding requirements over the next year.

The public offering included all of the securities available for issuance under STAAR's shelf registration.

*Credit Facilities*

STAAR has credit facilities with different lenders to support operations in the U.S. and Germany.

STAAR has a revolving credit facility with Wells Fargo Bank pursuant to a Credit and Security Agreement entered into on June 8, 2006. The credit facility provides for borrowings of 85% of eligible accounts receivable with a maximum of \$3.0 million, carries an interest rate of prime plus 1.5%, and is secured by substantially all of the assets of the Company's U.S. operations. The Company has no availability under the line as of March 30, 2007. The term of the agreement is three years and it contains certain financial covenants relating to minimum calculated net worth, net loss, liquidity and restrictions on Company investments or loans to affiliates and investments in capital expenditures, with which the Company must comply to borrow or to maintain an outstanding advance. The Company has not borrowed against the facility as of March 30, 2007.

The Credit and Security Agreement with Wells Fargo Bank prohibits STAAR, without the consent of the Bank, from incurring indebtedness, making loans to its subsidiaries, investing in its subsidiaries or other entities or paying dividends on its common stock. The Credit and Security Agreement also provides that a change of control of STAAR will constitute a default of the agreement. A change of control under the agreement includes the acquisition of 15% or more of STAAR's capital stock by any person or group, a change in composition of the Board of Directors over a two-year period that results in the directors in place at the beginning of the period no longer constituting a majority, or David Bailey's ceasing to actively manage STAAR. Wells Fargo Bank waived a covenant prohibiting STAAR from incurring additional indebtedness on March 21, 2007, which permitted STAAR to enter into the Promissory Note with Broadwood Partners, LP on that date and on May 9, 2007, which permitted STAAR to borrow \$2,000,000 from a subsidiary.

STAAR may terminate the Credit and Security Agreement with Wells Fargo Bank, subject to a termination fee of \$90,000 if terminated before the first anniversary, \$60,000 if terminated between the first and second anniversary, and \$30,000 if terminated after the second anniversary but prior to maturity. If STAAR has outstanding advances it must give 90 days advance written notice of termination or pay additional interest for the period from termination to the date 90 days after notice was actually given.

On March 21, 2007, STAAR entered into a loan arrangement with Broadwood Partners, L.P. ( Broadwood ). Pursuant to a Promissory Note (the Note ) between STAAR and Broadwood, Broadwood loaned \$4 million to

**Table of Contents**

STAAR. The Note has a term of three years and bears interest at a rate of 10% per annum, payable quarterly. The Note is not secured by any collateral, may be pre-paid by STAAR 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 STAAR 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 STAAR will grant additional warrants each quarter on the same terms as the Warrant Agreement. The warrant agreement provides that STAAR will register the stock for resale with the SEC. Based on publicly available information filed with the Securities and Exchange Commission (the "SEC"), on the date of the transaction Broadwood Partners L.P. beneficially owned 2,492,788 shares of the Company's common stock, comprising 9.7% of the Company's common stock as of March 21, 2007, and Neal Bradsher, President of Broadwood Partners, L.P., may have been deemed to beneficially own 2,518,688 shares of the Company's common stock, comprising 9.8% of the Company's common stock as of that date.

The Company's lease agreement with Farnam Street Financial, Inc. ("Farnam"), as amended on October 9, 2006, provides for purchases of up to \$1,500,000 of property, plant and equipment. In accordance with the requirements of SFAS 13 Accounting for Leases, purchases under this facility are accounted for as capital leases and have a three-year term. Approximately \$395,000 in borrowings were available under this facility as of March 30, 2007.

On April 1, 2007, the Company signed an additional leasing schedule with Farnam, which provides for additional purchases of \$800,000 during the next fiscal year. The terms of this new schedule conform to the amended agreement dated October 9, 2006.

The Company's lease agreement with Mazuma Capital Corporation, as amended on August 16, 2006, provides for purchases of up to \$301,000 of property, plant and equipment. In accordance with the requirements of SFAS 13 Accounting for Leases, purchases under this facility are accounted for as capital leases and have a two-year term. The Company is required to open a certificate of deposit as collateral in STAAR Surgical Company's name at the underwriting bank for 50% of the assets funded by Mazuma. As of March 30, 2007, the Company had a certificate of deposit for approximately \$150,000 recorded as short-term investment restricted with a 12-month term at a fixed interest rate of 4.5%. The agreement also provides that the Company may elect to purchase any item of the leased property at the end of its lease term for \$1. No borrowings were available under this facility as of March 30, 2007.

STAAR AG's credit agreement with UBS AG was terminated subsequent to the end of the first fiscal quarter. The Master Credit Agreement with UBS AG, as amended on August 2, 2004, had provided for secured borrowings of up to 3 million Swiss Francs (CHF) (approximately \$2.4 million based on the rate of exchange on March 30, 2007), permitted either fixed-term or current advances and could be terminated by either party at any time. As of March 30, 2007, advances of \$1,812,000 were outstanding under the line. STAAR Surgical AG repaid all advances in full on April 4, 2007 with cash from international operations. UBS AG elected to terminate the credit agreement without cause and without penalty, on April 26, 2007. At the time of termination the balance on the line was zero and STAAR Surgical AG was in compliance with all terms, conditions and covenants of the Master Credit Agreement. The Company's international operations generate sufficient positive cash flow to provide working capital for those operations and all anticipated needs without recourse to borrowing.

The Company's German subsidiary, Domilens, entered into a credit agreement at August 30, 2005. The renewed credit agreement provides for borrowings of up to 100,000 EUR (\$133,000 at the rate of exchange on March 30, 2007), at a rate of 8.5% per annum. The credit agreement does not have a termination date but may be terminated by the lender in accordance with the lender's general terms and conditions. The credit facility is not secured. There were no borrowings outstanding as of March 30, 2007 and December 29, 2006. The Company was in compliance with the covenants of its German credit facility as of March 30, 2007.

As of March 30, 2007, the Company had a current ratio of 2.0:1, net working capital of \$15.8 million and net equity of \$29.2 million compared to December 29, 2006 when the Company's current ratio was 2.0:1, its net working capital was \$14.4 million, and its net equity was \$31.8 million.

## **Table of Contents**

As of March 30, 2007, the Company had \$531,000 available for borrowing under U.S. lease lines of credit and an International bank credit facility. These U.S. lease lines of credit which provide for borrowings of up to \$1.8 million with \$395,000 of availability as of March 30, 2007 which will be used to fund the majority of the Company's planned investments in property, plant and equipment. On April 1, 2007, the Company signed an additional leasing schedule with Farnam, which provides for additional purchases of \$800,000 during the next fiscal year. As described above, to support international operations, the Company's German subsidiary has a 100,000 EUR (\$136,000 at the rate of exchange on March 30, 2007) line of credit available to support German operations. However, given its history of losses and negative cash flows, it is possible that the Company will find it necessary to supplement these sources of capital with additional financing to sustain operations until the Company returns to profitability.

The credit facilities are subject to various financial covenants and if our losses continue, we risk defaulting on the terms of our credit facilities. Our limited borrowing capacity could cause a shortfall in working capital or prevent us from making expenditures to expand or enhance our business. A default on any of our loan agreements could cause our long term obligations to be accelerated, make further borrowing difficult and jeopardize our ability to continue operations.

The Company's liquidity requirements arise from the funding of its working capital needs, primarily inventory, work-in-process and accounts receivable. The Company's primary sources for working capital and capital expenditures are cash flow from operations, which will largely depend on the success of the ICL, proceeds of the public offering of common stock completed in the second fiscal quarter, proceeds from option exercises, and borrowings under the Company's bank credit facilities. The Company's liquidity also depends, in part, on customers paying within credit terms, and any extended delays in payments or changes in credit terms given to major customers may have an impact on the Company's cash flow. In addition, any abnormal product returns or pricing adjustments may also affect the Company's short-term funding. Changes in the market price of our common stock affect the value of our outstanding options, and lower market prices could reduce our expected revenue from option exercises.

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.

### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements, as that term is defined in the rules of the SEC, that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors.

### **ITEM 3. *QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK***

There have been no material changes in the Company's qualitative and quantitative market risk since the disclosure in the Company's Annual Report on Form 10-K for the year ended December 29, 2006.

### **ITEM 4. *CONTROLS AND PROCEDURES***

Attached as exhibits to this Quarterly Report on Form 10-Q are certifications of STAAR's Chief Executive Officer (CEO) and Chief Financial Officer (CFO), which are required in accordance with Rule 13a-14 of the Securities Exchange Act of 1934, as amended (the Exchange Act). This Controls and Procedures section includes information concerning the controls and controls evaluation referred to in the certifications.



## **Table of Contents**

### **Disclosure Controls and Procedures**

We maintain disclosure controls and procedures designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

The Company's management, with the participation of the CEO and the CFO, conducted an evaluation of the effectiveness of the Company's disclosure controls and procedures, as defined in Exchange Act Rule 13a-15(e), as of the end of the period covered by this Form 10-Q. Based on that evaluation and the identification of the material weakness in internal controls over financial reporting described below, the CEO and the CFO concluded that, as of the end of the period covered by this quarterly report on Form 10-Q, the Company's disclosure controls and procedures were not effective in accumulating and communicating to them in a timely manner material information relating to the Company (including its consolidated subsidiaries) required to be included in its periodic reports filed with the Securities Exchange Commission.

### **Internal Control over Financial Reporting**

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Exchange Act Rule 13a-15(f) and for assessing the effectiveness of its internal control over financial reporting. Our internal control system is designed to provide reasonable assurance to our management and Board of Directors regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with United States generally accepted accounting principles.

As discussed in our Annual Report on Form 10-K for the fiscal year ended December 29, 2006, the Audit Committee of the Company's Board of Directors commenced in January 2007, an independent investigation into reports to the Company's management by Guenther Roepstorff, president of Domilens GmbH, a subsidiary of STAAR located in Germany, that he admitted to the German Federal Ministry of Finance that without STAAR's knowledge he had diverted property of Domilens with a book value of approximately \$400,000 to a company under his control over a four-year period between 2001 and 2004. Mr. Roepstorff made this admission in connection with an audit conducted by the Ministry in 2006, which examined the financial records of Mr. Roepstorff, Domilens and the company to which he diverted the property, Equimed GmbH (currently known as eyemaxx GmbH), covering the four-year period. During the course of the investigation, the Company found that in addition to the diversions of property admitted by Mr. Roepstorff, payments were made to Mr. Roepstorff disguised as prepayments to suppliers and unauthorized borrowing occurred.

A material weakness is a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements would not be prevented or detected. In connection with the assessment described above, management identified a material weakness as of December 29, 2006 which was discussed in the Company's Annual Report on Form 10-K filed with the Commission on March 29, 2007. Because the Company's remediation efforts remained in progress, management identifies the same material weakness as of March 30, 2007, the end of the period covered by this report, as described below:

#### ***Failure to design and maintain controls over and in its German subsidiary sufficient to detect and prevent management override and fraud***

*Control Environment* The Company did not maintain an effective control environment because of the following: (a) the Company did not adequately and consistently reinforce the importance of adherence to

controls and the Company's code of conduct; (b) the Company failed to institute all elements of an effective program to help prevent and detect fraud by Company employees; and (c) the Company did not maintain effective corporate and regional management oversight and monitoring of operations to detect managements override of established financial controls and accounting policies, execution of improper transactions and accounting entries to impact revenue and earnings, and reporting of these transactions to the appropriate finance personnel or the Company's independent registered public accounting firm.



**Table of Contents**

Because of the material weakness described above, management concluded that, as of March 6, our internal control over financial reporting was not effective.

We have been implementing improvements to our internal controls to address the aforementioned material weakness and lack of effectiveness in our disclosure controls and internal controls, and continue to do so. We believe that the material weakness identified above has not yet been rectified. During the first quarter of 2007, the Company has:

obtained the immediate resignation of the president of Domilens GmbH

appointed the V.P. Sales and Marketing International, as interim president of Domilens

enhanced monitoring and oversight from STAAR's Swiss and U.S. operations

held meetings to discuss the Company's Code of Ethics and whistleblower policies with subsidiary employees as a bridge to more formal training

assigned oversight of corporate compliance programs and training to its corporate legal counsel

terminated the Director of Finance of our Swiss subsidiary, who was responsible for oversight of financial affairs and internal reporting at Domilens

re-educated employees in STAAR's Code of Ethics

enhanced whistleblower program for international operations of STAAR

reinforced the certification process to emphasize senior manager's accountability for maintaining an ethical environment

There were no other changes in the Company's internal control over financial reporting for the first quarter of 2007 that have materially affected, or are reasonably likely to materially affect the Company's internal control over financial reporting.

While we continue to devote significant resources to meeting the internal control over financial reporting requirements of the rules adopted by the SEC pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we cannot assure you that the policies and procedures we have adopted and our continued efforts will successfully remediate the material weakness we have identified and any control deficiencies or material weaknesses that we or our outside auditors may identify before the end of our fiscal year.

Our management, including the CEO and the CFO, do not expect that our disclosure controls and procedures or our internal control over financial reporting will necessarily prevent all fraud and material errors. An internal control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations on all internal control systems, our internal control system can provide only reasonable assurance of achieving its objectives and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more

people, or by management override of the control. The design of any system of internal control is also based in part upon certain assumptions about the likelihood of future events, and can provide only reasonable, not absolute, assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in circumstances, or the degree of compliance with the policies and procedures may deteriorate.

**Table of Contents**

**PART II OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

From time to time the Company is subject to various claims and legal proceedings arising out of the normal course of our business. These claims and legal proceedings relate to contractual rights and obligations, employment matters, and claims of product liability. We do not believe that any of the claims known to us is likely to have a material adverse effect on our financial condition or results of operations.

**ITEM 1A. RISK FACTORS**

Investment in securities of STAAR Surgical Company involves a high degree of risk. You should carefully consider the risks described below before making a decision to invest in the common stock. These risks are not the only ones we face.

**Risks Related to Our Business**

*We have a history of losses and anticipate future losses.*

We have reported losses in each of the last several fiscal years and have an accumulated deficit of \$90.2 million as of March 30, 2007. There can be no assurance that we will report net income in any future period.

*We have only limited working capital and limited access to financing.*

Our cash requirements continue to exceed the level of cash generated by operations and we expect to continue to seek additional resources to support and expand our business, such as debt or equity financing. Because of our history of losses and negative cash flows, our ability to obtain adequate financing on satisfactory terms is limited. Our ability to raise financing through sales of equity securities depends on general market conditions and the demand for STAAR's common stock. We may be unable to raise adequate capital through sales of equity securities, and if our stock has a low market price at the time of such sales our existing stockholders could experience substantial dilution. An inability to secure additional financing could prevent the expansion of our business and jeopardize our ability to continue operations.

*Our history of losses limits our access to credit and increases the risk of a default on our loan agreements.*

Under our U.S. and international bank credit facilities and lease lines of credit, we had \$3.2 million in outstanding indebtedness and \$531,000 available for borrowing as of March 30, 2007. On April 1, 2007 we increased the availability by \$800,000 on our leasing line of credit Farnam. On April 4, 2007 we repaid in full approximately \$1.8 million of outstanding indebtedness under our Swiss line of credit. The credit facilities are subject to various financial covenants. If our losses continue we risk defaulting on the terms of our credit arrangements. Our limited borrowing capacity could cause a shortfall in working capital or prevent us from making expenditures that are essential to our business. To the extent we borrow under our credit facilities, a subsequent default could cause our obligations to be accelerated, result in the assessment of default interest or penalties, make further borrowing difficult or impracticable and jeopardize our ability to continue operations.

*We may have limited ability to fully use our recorded tax loss carryforwards.*

We have accumulated approximately \$37.4 million of tax loss carryforwards to be used in future periods if we become profitable. If we were to experience a significant change in ownership, Internal Revenue Code Section 382 may restrict the future utilization of these tax loss carryforwards even if we become profitable.

***FDA compliance issues have harmed our reputation, and we expect to devote significant resources to maintaining compliance in the future.***

The Office of Compliance of the FDA's Center for Devices and Radiological Health regularly inspects STAAR's facilities to determine whether we are in compliance with the FDA Quality System Regulations relating to

**Table of Contents**

such things as manufacturing practices, validation, testing, quality control, product labeling and complaint handling, and in compliance with FDA Medical Device Reporting regulations.

Based on the results of the FDA inspections of STAAR's Monrovia, California facilities in 2005 and 2006, STAAR believes that it is substantially in compliance with the FDA's Quality System Regulations and Medical Device Reporting regulations. However, between December 29, 2003 and July 5, 2005 we received Warning Letters and other correspondence indicating that the FDA found STAAR's Monrovia, California facility in violation of applicable regulations, warning of possible enforcement action and suspending approval of new implantable devices. The FDA's findings of compliance deficiencies during that period harmed our reputation in the ophthalmic industry, affected our product sales and delayed FDA approval of the ICL.

At the March 14, 2007 conclusion of an audit of STAAR's clinical trial records by the Bioresearch Monitoring Program of the FDA Office of Regulatory Affairs, or BIMO, STAAR received eight Inspectional Observations on FDA Form 483 noting noncompliance with regulations. BIMO's oversight covers clinical research, rather than the manufacturing, quality and device reporting issues that have been STAAR's greatest focus in its recent compliance initiatives. If our efforts to promptly address the Inspectional Observations through voluntary corrective action are not successful, the FDA would take further action that could reduce or curtail our ability to sponsor clinical studies and use such studies to secure new product approvals.

STAAR's ability to continue its U.S. business depends on the continuous improvement of its quality systems and its compliance with FDA regulations. Accordingly, for the foreseeable future STAAR's management expects its strategy to include devoting significant resources and attention to those efforts. STAAR cannot ensure that its efforts will be successful. Any failure to demonstrate substantial compliance with FDA regulations can result in enforcement actions that terminate, suspend or severely restrict our ability to continue manufacturing and selling medical devices. Please see the related risks discussed under the headings *We are subject to extensive government regulation, which increases our costs and could prevent us from selling our products* and *We are subject to federal and state regulatory investigations*.

***Our strategy to restore profitability in the near term relies on successfully penetrating the U.S. refractive market.***

While products to treat cataracts continue to account for the majority of our revenue, we believe that increased income generated by sales of our Visian ICL refractive products, especially in the U.S., presents a near term opportunity for a return to profitability. The FDA approved the Visian ICL for treatment of myopia on December 22, 2005. Selling and marketing the ICL has presented a challenge to our sales and marketing staff and to our independent manufacturers representatives. In the U.S. patients who might benefit from the ICL have already been exposed to a great deal of advertising and publicity about laser refractive surgery, but have little if any awareness of the ICL. In addition, established refractive surgeons frequently have large and well developed practices that are oriented entirely toward the delivery of laser procedures. In countries where the ICL has been approved, our sales have grown steadily but slowly, and the U.S. appears to be following this pattern. A surgeon interested in implanting the ICL must first schedule training and certification and invest time in the training process. While STAAR has sufficient resources to make training available to qualified surgeons with minimal delay, the need to undergo training continues to limit the pace at which interested surgeons can begin providing the ICL to their patients. STAAR employs advertising and promotion targeted to potential patients through providers, but has limited resources for these purposes. Failure to successfully market the ICL in the U.S. will delay and may prevent growth and profitability.

***Our core domestic business has suffered declining sales, which sales of new products have only begun to offset.***

The foldable silicone IOL remains our largest source of sales. Since we introduced the product, however, competitors have introduced IOLs employing a variety of designs and materials. Over the years these products have taken an

increasing share of the IOL market, while the market share for STAAR silicone IOLs has decreased. In particular, many surgeons now choose lenses made of acrylic material rather than silicone for their typical patients. In addition, our competitors have begun to offer multifocal or accommodating lenses that claim to reduce the need

**Table of Contents**

for cataract patients to use reading glasses; the market for these presbyopic lenses is expected to grow as a segment of the cataract market. Our newer line of IOLs made of our proprietary biocompatible Collamer material, while intended to reverse the trend of declining domestic cataract product sales, may not permit us to recover the market share lost over the last several years.

***Strikes, slow-downs or other job actions by doctors can reduce sales of cataract-related products.***

In many countries where STAAR sells its products, doctors, including ophthalmologists, are employees of the government, government-sponsored enterprises or large health maintenance organizations. In recent years, employed doctors who object to salary limitations, working rules, reimbursement policies or other conditions have sought redress through strikes, slow-downs and other job actions. These actions often result in the deferral of non-essential procedures, such as cataract surgeries, which affects sales of our products. For example, in fiscal year 2006, strikes and slow-downs by doctors in Germany were partly responsible for a drop in sales by our wholly owned subsidiary Domilens GmbH, which distributes ophthalmic products in Germany. Such problems could occur again in Germany or other regions and, depending on the importance of the affected region to STAAR's business, the length of the action and its pervasiveness, job actions by doctors can materially reduce our sales revenue and earnings.

***Our sales are subject to significant seasonal variation.***

We generally experience lower sales during the third quarter due to the effect of summer vacations on elective procedures. In particular, because sales activity in Europe drops dramatically in July and August, and European sales have recently accounted for a greater proportion of our total sales, this seasonal variation in our results has become even more pronounced.

***We depend on independent manufacturers' representatives.***

In an effort to manage costs and bring our products to a wider market, we have entered into long-term agreements with independent regional manufacturers' representatives, who introduce our products to eye surgeons and provide the training needed to begin using some of our products. Under our agreements with these representatives, each receives a commission on all of our sales within a specified region, including sales on products we sell into their territories without their assistance. Because they are independent contractors, we have a limited ability to manage these representatives or their employees. In addition, a representative may represent manufacturers other than STAAR, although not in competing products. STAAR's strategy for growth involves the marketing of innovative products like the ICL, Collamer IOLs, Toric IOLs and the AquaFlow Device. We have relied on the independent representatives to implement the marketing of these products and to sustain the market for our more established products. Because our independent representatives generally have little experience dealing with surgeons who specialize in refractive procedures, we have faced greater challenges in developing the domestic market for the ICL. If our independent manufacturers' representatives do not devote sufficient resources to marketing our products, or if they lack the skills or resources to market our new products, our new products will fail to reach their full sales potential and sales of our established products could decline.

***Product recalls have been costly and may be so in the future.***

Medical devices must be manufactured to the highest standards and tolerances, and often incorporate newly developed technology. From time to time defects or technical flaws in our products may not come to light until after the products are sold or consigned. In those circumstances, we have previously made voluntary recalls of our products. We may also be subject to recalls initiated by manufacturers of products we distribute. In February 2006, our German subsidiary recalled all lots of a balanced salt solution it distributes due to the manufacturer's recall for possible endotoxin content. In 2005, we recalled one lot of phaco tubing manufactured by a third party, due to incorrect

labeling, and we recalled one lot of STAARVISC, also manufactured by a third party, due to a potential sterility breach of the packaging of the cannula that is packaged with the STAARVISC. The last recall of a product manufactured by STAAR took place during 2004, when we initiated several voluntary recalls including 33 lots of IOL cartridges, three lots of injectors, and 529 lenses, and in February 2004, in an action considered a recall but with no requirement for product to be returned to us, we issued a letter to healthcare professionals advising them of the



**Table of Contents**

potential for a change in manifest refraction over time in rare cases involving the single-piece Collamer IOL. We believe recalls have harmed our reputation and adversely affected our product sales, although the impact cannot be quantified. Similar recalls could take place again. Courts or regulators can also impose mandatory recalls on us, even if we believe our products are safe and effective.

Recalls can result in lost sales of the recalled products themselves, and can result in further lost sales while replacement products are manufactured, especially if the replacements must be redesigned. If recalled products have already been implanted, we may bear some or all of the cost of corrective surgery. Recalls may also damage our professional reputation and the reputation of our products. The inconvenience caused by recalls and related interruptions in supply, and the damage to our reputation, could cause professionals to discontinue using our products.

***We could experience losses due to product liability claims.***

We have been subject to product liability claims in the past and continue to be so. Our third-party product liability insurance coverage has become more expensive and difficult to procure. Product liability claims against us may exceed the coverage limits of our insurance policies or cause us to record a loss in excess of our deductible. A product liability claim in excess of applicable insurance could have a material adverse effect on our business, financial condition and results of operations. Even if any product liability loss is covered by an insurance policy, these policies have retentions or deductibles that provide that we will not receive insurance proceeds until the losses incurred exceed the amount of those retentions or deductibles. To the extent that any losses are below these retentions or deductibles, we will be responsible for paying these losses. The payment of retentions or deductibles for a significant amount of claims could have a material adverse effect on our business, financial condition, and results of operations.

Any product liability claim would divert managerial and financial resources and could harm our reputation with customers. We cannot assure you that we will not have product liability claims in the future or that such claims would not have a material adverse effect on our business.

***We compete with much larger companies.***

Our competitors, including Alcon, Advanced Medical Optics and Bausch & Lomb, have much greater financial resources than we do and some of them have large international markets for a full suite of ophthalmic products. Their greater resources for research, development and marketing, and their greater capacity to offer comprehensive products and equipment to providers, make it difficult for us to compete. We have lost significant market share to some of our competitors.

***Most of our products have single-site manufacturing approvals, exposing us to risks of business interruption.***

We manufacture all of our products either at our facilities in California or at our facility in Switzerland. Most of our products are approved for manufacturing only at one of these sites. Before we can use a second manufacturing site for an implantable device we must obtain the approval of regulatory authorities. Because this process is expensive, we have generally not sought approvals needed to manufacture at an additional site. If a natural disaster, fire, or other serious business interruption struck one of our manufacturing facilities, it could take a significant amount of time to validate a second site and replace lost product. We could lose customers to competitors, thereby reducing sales, profitability and market share.

***The global nature of our business may result in fluctuations and declines in our sales and profits.***

Our products are sold in approximately 50 countries. Sales from international operations make up a significant portion of our total sales. For the three months ended March 30, 2007, sales from international operations were 66% of our

total sales. The results of operations and the financial position of certain of our offshore operations are reported in the relevant local currencies and then translated into U.S. dollars at the applicable exchange rates for inclusion in our consolidated financial statements, exposing us to translation risk. In addition, we are exposed to transaction risk because some of our expenses are incurred in a different currency from the currency in which our

**Table of Contents**

sales are received. Our most significant currency exposures are to the Euro, the Swiss Franc, and the Australian dollar. The exchange rates between these and other local currencies and the U.S. dollar may fluctuate substantially. We have not attempted to offset our exposure to these risks by investing in derivatives or engaging in other hedging transactions.

Economic, social and political conditions, laws, practices and local customs vary widely among the countries in which we sell our products. Our operations outside of the U.S. are subject to a number of risks and potential costs, including lower profit margins, less stringent protection of intellectual property and economic, political and social uncertainty in some countries, especially in emerging markets. Our continued success as a global company depends, in part, on our ability to develop and implement policies and strategies that are effective in anticipating and managing these and other risks in the countries where we do business. These and other risks may have a material adverse effect on our operations in any particular country and on our business as a whole. We price some of our products in U.S. dollars, and as a result changes in exchange rates can make our products more expensive in some offshore markets and reduce our sales. Inflation in emerging markets also makes our products more expensive there and increases the credit risks to which we are exposed.

***The success of our international operations depends on our successfully managing our foreign subsidiaries.***

We conduct most of our international business through wholly owned subsidiaries. Managing distant subsidiaries and fully integrating them into STAAR's business is challenging. While STAAR seeks to integrate its foreign subsidiaries fully into its operations, direct supervision of every aspect of their operations is impossible, and as a result STAAR relies on its local managers and staff. Cultural factors and language differences can result in misunderstandings among internationally dispersed personnel. The risk that unauthorized conduct may go undetected will always be greater in foreign subsidiaries. For example, in early 2007 STAAR learned that the president of its German sales subsidiary, Domilens GmbH, had misappropriated corporate assets. Some countries may also have laws or cultural factors that make it difficult to impose uniform standards and practices. For example, while STAAR's Code of Ethics requires all employees to certify they are not aware of code violations by others, German legal counsel has advised STAAR that in Germany it cannot legally compel ordinary employees (that is, non-supervisors) to notify STAAR of breaches by others. STAAR believes the absence of such a requirement in its Code of Ethics for German employees is a risk inherent to doing business in Germany that may be mitigated, but not entirely eliminated, by other controls.

***We obtain some of the components of our products from a single source, and an interruption in the supply of those components could reduce our sales.***

We obtain some of the components for our products from a single source. For example, only one supplier produces our viscoelastic product. The loss or interruption of any of these suppliers could increase costs, reducing our sales and profitability, or harm our customer relations by delaying product deliveries. Even when substitute suppliers are available, the need to certify regulatory compliance and quality standards of substitute suppliers could cause significant delays in production and a material reduction in our sales. Even when secondary sources are available, the failure of one of our suppliers could be the result of an unforeseen industry-wide problem, or the failure of our supplier could create an industry-wide shortage affecting secondary suppliers as well.

***Our activities involve hazardous materials and emissions and may subject us to environmental liability.***

Our manufacturing, research and development practices involve the use of hazardous materials. We are subject to federal, state and local laws and regulations in the various jurisdictions in which we have operations governing the use, manufacturing, storage, handling and disposal of these materials and certain waste products. We cannot completely eliminate the risk of accidental contamination or injury from these materials. Remedial environmental actions could require us to incur substantial unexpected costs, which would materially and adversely affect our results

of operations. If we were involved in a major environmental accident or found to be in substantial non-compliance with applicable environmental laws, we could be held liable for damages or penalized with fines.

**Table of Contents**

***We risk losses through litigation.***

From time to time we are party to various claims and legal proceedings arising out of the normal course of our business. These claims and legal proceedings relate to contractual rights and obligations, employment matters, and claims of product liability. While we do not believe that any of the claims known to us is likely to have a material adverse effect on our financial condition or results of operations, new claims or unexpected results of existing claims could lead to significant financial harm.

***We depend on key employees.***

We depend on the continued service of our senior management and other key employees. The loss of a key employee could hurt our business. We could be particularly hurt if any key employee or employees went to work for competitors. Our future success depends on our ability to identify, attract, train, motivate and retain other highly skilled personnel. Failure to do so may adversely affect our results.

***We have licensed our technology to our joint venture company which could cause our joint venture company to become a competitor.***

We have granted to our Japanese joint venture, Canon Staar Co. Inc., an irrevocable, exclusive license to make, have made and sell products using our technology in Japan. We have also granted Canon Staar an irrevocable, exclusive license to make and have made products using our technology in China and to sell such products made in China in China and Japan. In addition, we have granted Canon Staar an irrevocable, non-exclusive license to sell products using our technology in the rest of the world. It is the intent of the Joint Venture Agreement that products be marketed indirectly through Canon, Inc., Canon Marketing Japan Inc., their subsidiaries, STAAR, and other distributors that the Canon Staar Board approves. The grant of such licenses and rights under STAAR's technology may result in Canon Staar becoming a competitor of STAAR, which could materially reduce STAAR's revenues and profits. See *Management's Discussion and Analysis of Financial Condition and Results of Operations - Canon Staar Joint Venture*.

***Our interest in Canon Staar may be acquired for book value on the occurrence of specified events, including a change in control of STAAR.***

If STAAR becomes insolvent or enters bankruptcy, dissolves, enters into a merger or other reorganization, is the subject of a take-over attempt or experiences other events of default under the joint venture agreement, the other joint venture partners will have the right to acquire STAAR's interest in Canon Staar at book value. Book value of STAAR's 50% interest in Canon Staar was \$3.6 million as of December 31, 2006. Book value may not represent the fair value of STAAR's interest in Canon Staar, and depending on the future condition of Canon Staar's business it may represent only a small fraction of fair value. STAAR's interest in Canon Staar is valued in Japanese yen and its value in U.S. dollars may vary significantly with fluctuations in currency exchange rates. See *Management's Discussion and Analysis of Financial Condition and Results of Operations - Canon Staar Joint Venture*.

***Changes in accounting standards could affect our financial results.***

The accounting rules applicable to public companies like STAAR are subject to frequent revision. Future changes in accounting standards could require us to change the way we calculate income, expense or balance sheet data, which could result in significant change to our reported results of operation or financial condition.

***We are subject to international tax laws that could affect our financial results.***

STAAR conducts international operations through its subsidiaries. Tax laws affecting international operations are highly complex and subject to change. STAAR's payment of income tax in the different countries where it operates depends in part on internal settlement prices and administrative charges among STAAR and its subsidiaries. These arrangements require judgments by STAAR and are subject to risk that tax authorities will disagree with those judgments and impose additional taxes, penalties or interest on STAAR. In addition, transactions that STAAR has arranged in light of current tax rules could have unforeseeable negative consequences if tax rules change.

**Table of Contents**

***If we suffer loss to our facilities due to catastrophe, our operations could be seriously harmed.***

We depend on the continuing operation of our manufacturing facilities in California and Switzerland, which have little redundancy or overlap among their activities. Our facilities are subject to catastrophic loss due to fire, flood, earthquake, terrorism or other natural or man-made disasters. Our California facilities are in areas where earthquakes could cause catastrophic loss. If any of these facilities were to experience a catastrophic loss, it could disrupt our operations, delay production, shipments and revenue and result in large expenses to repair or replace the facility. Our insurance for property damage and business interruption may not be sufficient to cover any particular loss, and we do not carry insurance or reserve funds for interruptions or potential losses arising from earthquakes or terrorism.

***If we are unable to protect our information systems against data corruption, cyber-based attacks or network security breaches, our operations could be disrupted.***

We are significantly dependent on information technology networks and systems, including the Internet, to process, transmit and store electronic information. In particular, we depend on our information technology infrastructure for electronic communications among our locations around the world and between our personnel and our subsidiaries, customers, and suppliers. Security breaches of this infrastructure can create system disruptions, shutdowns or unauthorized disclosure of confidential information. If we are unable to prevent such security breaches, our operations could be disrupted or we may suffer financial damage or loss because of lost or misappropriated information.

**Risks Related to the Ophthalmic Products Industry**

***If we fail to keep pace with advances in our industry or fail to persuade physicians to adopt the new products we introduce, customers may not buy our products and our sales may decline.***

Constant development of new technologies and techniques, frequent new product introductions and strong price competition characterize the ophthalmic industry. The first company to introduce a new product or technique to market usually gains a significant competitive advantage. Our future growth depends, in part, on our ability to develop products to treat diseases and disorders of the eye that are more effective, safer, or incorporate emerging technologies better than our competitors' products. Sales of our existing products may decline rapidly if one of our competitors introduces a superior product, or if we announce a new product of our own. If we fail to make sufficient investments in research and development or if we focus on technologies that do not lead to better products, our current and planned products could be surpassed by more effective or advanced products. In addition, we must manufacture these products economically and market them successfully by persuading a sufficient number of eye-care professionals to use them. For example, glaucoma requires ongoing treatment over a long period; thus, many doctors are reluctant to switch a patient to a new treatment if the patient's current treatment for glaucoma remains effective. This has been a challenge in selling our AquaFlow Device.

***Resources devoted to research and development may not yield new products that achieve commercial success.***

We spent 10.8% of our sales on research and development during the three months ended March 30, 2007, and we expect to spend approximately 10% for this purpose in future periods. Development of new implantable technology, from discovery through testing and registration to initial product launch, is expensive and typically takes from three to seven years. Because of the complexities and uncertainties of ophthalmic research and development, products we are currently developing may not complete the development process or obtain the regulatory approvals required for us to market the products successfully. Any of the products currently under development may fail to become commercially successful.

***Changes in reimbursement for our products by third-party payors could reduce sales of our products or make them less profitable.***

Many of our products, in particular IOLs and products related to the treatment of glaucoma, are used in procedures that are typically covered by health insurance, HMO plans, Medicare, Medicaid, or other governmental



## **Table of Contents**

sponsored programs in the U.S. and Europe. Third party payors in both government and the private sector continue to seek to manage costs by restricting the types of procedures they reimburse to those viewed as most cost-effective and by capping or reducing reimbursement rates. Whether they limit reimbursement prices for our products or limit the surgical fees for a procedure that uses our products, these policies can reduce the sales volume of our reimbursed products, their selling prices or both. In some countries government agencies control costs by limiting the number of surgical procedures they will reimburse. For example, a recent reduction in the number of authorized cataract procedures in Germany has affected the sales of our German subsidiary, Domilens. Similar changes could occur in our other markets. The U.S. Congress has considered legislative proposals that would significantly change the system of public and private health care reimbursement, and will likely consider such changes again in the future. We are not able to predict whether new legislation or changes in regulations will take effect at the state or federal level, but if enacted these changes could significantly and adversely affect our business.

***We are subject to extensive government regulation, which increases our costs and could prevent us from selling our products.***

STAAR is regulated by regional, national, state and local agencies, including the Food and Drug Administration, the Department of Justice, the Federal Trade Commission, the Office of the Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies, as well as governmental authorities in those foreign countries in which we manufacture or distribute products. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal and state statutes and regulations govern the research, development, manufacturing and commercial activities relating to medical devices, including their pre-clinical and clinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information and promotion. We are also subject to government regulation over the prices we charge and the rebates we offer to customers. Complying with government regulation substantially increases the cost of developing, manufacturing and selling our products.

In the U.S., we must obtain approval from the FDA for each product that we market. Competing in the ophthalmic products industry requires us to introduce new or improved products and processes continuously, and to submit these to the FDA for approval. Obtaining FDA approval is a long and expensive process, and approval is never certain. In addition, our operations are subject to periodic inspection by the FDA and international regulators. An unfavorable outcome in an FDA inspection may result in the FDA ordering changes in our business practices or taking other enforcement action, which could be costly and severely harm our business.

Our new products could take a significantly longer time than we expect to gain regulatory approval and may never gain approval. If a regulatory authority delays approval of a potentially significant product, the potential sales of the product and its value to us can be substantially reduced. Even if the FDA or another regulatory agency approves a product, the approval may limit the indicated uses of the product, or may otherwise limit our ability to promote, sell and distribute the product, or may require post-marketing studies. If we cannot obtain timely regulatory approval of our new products, or if the approval is too narrow, we will not be able to market these products, which would eliminate or reduce our potential sales and earnings.

***Regulatory investigations and allegations, whether or not they lead to enforcement action, can materially harm our business and our reputation.***

Failure to comply with the requirements of the FDA or other regulators can result in civil and criminal fines, the recall of products, the total or partial suspension of manufacture or distribution, seizure of products, injunctions, whistleblower lawsuits, failure to obtain approval of pending product applications, withdrawal of existing product approvals, exclusion from participation in government healthcare programs and other sanctions. Any threatened or actual government enforcement action can also generate adverse publicity and require us to divert substantial

resources from more productive uses in our business. Enforcement actions could affect our ability to distribute our products commercially and could materially harm our business.

From time to time STAAR is subject to formal and informal inquiries by regulatory agencies, which could lead to investigations or enforcement actions. Even when an inquiry results in no evidence of wrongdoing, is

**Table of Contents**

inconclusive or is otherwise not pursued, the agency generally is not required to notify STAAR of its findings and may not inform STAAR that the inquiry has been terminated.

As a result of widespread concern about backdating of stock options and similar conduct among U.S. public companies, during 2006 and early 2007 STAAR conducted an investigation of its practices from 1993 to the present in granting stock options to employees, directors and consultants. STAAR's investigation did not find evidence of fraud, deliberate backdating or similar practices. The investigation did uncover evidence of frequent administrative errors and delays, which STAAR investigated further and determined would not have a material effect on its historical financial statements, either individually or in aggregate. STAAR believes that its investigation, while limited in scope, was reasonably designed to detect fraud and backdating and determine any material effect on its financial statements. However, STAAR cannot ensure that a more exhaustive investigation would not find additional errors or irregularities in option granting practices, the effect of which could be material.

STAAR maintains a hotline for employees to report any violation of laws, regulations or company policies anonymously, which is intended to permit STAAR to identify and remedy improper conduct. Nevertheless, present or former employees may elect to bring complaints to regulators and enforcement agencies. The relevant agency will generally be obligated to investigate such complaints to assess their validity and obtain evidence of any violation that may have occurred. Even without a finding of misconduct, negative publicity about investigations or allegations of misconduct could harm our reputation with professionals and the market for our common stock. Responding to investigations can be costly, time-consuming and disruptive to our business.

***We depend on proprietary technologies, but may not be able to protect our intellectual property rights adequately.***

We rely on contractual provisions, confidentiality procedures and patent, trademark, copyright and trade secrecy laws to protect the proprietary aspects of our technology. These legal measures afford limited protection and may not prevent our competitors from gaining access to our intellectual property and proprietary information. Any of our patents may be challenged, invalidated, circumvented or rendered unenforceable. Any of our pending patent applications may fail to result in an issued patent or fail to provide meaningful protection against competitors or competitive technologies. Litigation may be necessary to enforce our intellectual property rights, to protect our trade secrets and to determine the validity and scope of our proprietary rights. Any litigation could result in substantial expense, may reduce our profits and may not adequately protect our intellectual property rights.

In addition, we may be exposed to future litigation by third parties based on claims that our products infringe their intellectual property rights. This risk is exacerbated by the fact that the validity and breadth of claims covered by patents in our industry may involve complex legal issues that are open to dispute. Any litigation or claims against us, whether or not successful, could result in substantial costs and harm our reputation. Intellectual property litigation or claims could force us to do one or more of the following:

cease selling or using any of our products that incorporate the challenged intellectual property, which would adversely affect our sales;

negotiate a license from the holder of the intellectual property right alleged to have been infringed, which license may not be available on reasonable terms, if at all; or

redesign our products to avoid infringing the intellectual property rights of a third party, which may be costly and time-consuming or impossible to accomplish.

***We may not successfully develop and launch replacements for our products that lose patent protection.***

Most of our products are covered by patents that, if valid, give us a degree of market exclusivity during the term of the patent. We have also earned revenue in the past by licensing some of our patented technology to other ophthalmic companies. The legal life of a patent in the U.S. is 20 years from application. Patents covering our products will expire from this year through the next 20 years. Upon patent expiration, our competitors may introduce products using the same technology. As a result of this possible increase in competition, we may need to reduce our prices to maintain sales of our products, which would make them less profitable. If we fail to develop and successfully launch new products prior to the expiration of patents for our existing products, our sales and profits

**Table of Contents**

with respect to those products could decline significantly. We may not be able to develop and successfully launch more advanced replacement products before these and other patents expire.

**Risks Related to Ownership of Our Common Stock**

***Our charter documents and contractual obligations could delay or prevent an acquisition or sale of our company.***

Our Certificate of Incorporation empowers the Board of Directors to establish and issue a class of preferred stock, and to determine the rights, preferences and privileges of the preferred stock. These provisions give the Board of Directors the ability to deter, discourage or make more difficult a change in control of our company, even if such a change in control could be deemed in the interest of our stockholders or if such a change in control would provide our stockholders with a substantial premium for their shares over the then-prevailing market price for the common stock. Our contractual obligations, including with respect to Canon Staar, could discourage a potential acquisition of our company. Our bylaws contain other provisions that could have an anti-takeover effect, including the following:

- stockholders have limited ability to remove directors;
- stockholders cannot act by written consent;
- stockholders cannot call a special meeting of stockholders; and
- stockholders must give advance notice to nominate directors.

***Anti-takeover provisions of Delaware law could delay or prevent an acquisition of our company.***

We are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock or preventing changes in our management.

***The market price of our common stock is likely to be volatile.***

Our stock price has fluctuated widely, ranging from \$5.30 to \$9.50 during the twelve month period ended March 30, 2007. Our stock price will likely continue to fluctuate in response to factors such as quarterly variations in operating results, operating results that vary from the expectations of securities analysts and investors, changes in financial estimates, changes in market valuations of competitors, announcements by us or our competitors of a material nature, additions or departures of key personnel, future sales of Common Stock and stock volume fluctuations. Also, general political and economic conditions such as recession or interest rate fluctuations may adversely affect the market price of our stock.

***Future sales of our common stock could reduce our stock price.***

Our Board of Directors could issue additional shares of common or preferred stock to raise additional capital or for other corporate purposes without stockholder approval. In addition, the Board of Directors could designate and sell a class of preferred stock with preferential rights over the common stock with respect to dividends or other distributions. Sales of common or preferred stock could dilute the interest of existing stockholders and reduce the market price of our common stock. Even in the absence of such sales, the perception among investors that additional sales of equity securities may take place could reduce the market price of our common stock.



**Table of Contents**

**ITEM 6. EXHIBITS**

**Exhibits**

- 1.01 Underwriting Agreement.(1)
- 3.1 Certificate of Incorporation, as amended to date.(2)
- 3.2 By-laws, as amended to date.(2)
- 10.63 Promissory Note between the Company and Broadwood Partners, L.P., dated March 21, 2007.(3)
- 10.64 Warrant Agreement between the Company and Broadwood Partners, L.P., dated March 21, 2007.(3)
- 31.1 Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.(\*)
- 31.2 Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.(\*)
- 32.1 Certification Pursuant to 18 U.S.C. Section 1350, Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.(\*)

(1) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Commission on April 26, 2007.

(2) Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on May 23, 2006.

(3) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Commission on March 21, 2007.

(\*) Filed herewith.

**Table of Contents**

**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

By: /s/ DEBORAH ANDREWS

**Deborah Andrews**  
**Chief Financial Officer**  
**(on behalf of the Registrant and as its**  
**chief accounting officer)**

Date: May 9, 2007