

STAAR SURGICAL COMPANY
Form 10-Q/A
November 20, 2003
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q/A
Amendment No. 1

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

For the quarterly period ended: July 4, 2003

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)

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-Q/A

Delaware
(State or other jurisdiction of
incorporation or organization)

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

1911 Walker Avenue

Monrovia, California 91016

(Address of principal executive offices) (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 a check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes No

The registrant has 18,396,123 shares of common stock, par value \$0.01 per share, issued and outstanding as of November 18, 2003.

Table of Contents

EXPLANATORY NOTE

STAAR Surgical Company (the Company) is filing this Amendment No. 1 to its Quarterly Report on Form 10-Q for the period ended July 4, 2003 (the Report) to restate its financial statements for the three and six months ended July 4, 2003 and June 28, 2002, as more fully discussed in Note 11 of the notes to the financial statements. This Amendment No. 1 corrects the Company's second quarter financial statements to include accrued interest income on notes receivable of officers and directors.

To make these corrections and related changes, the Company is amending and restating Items 1 and 2 of the Report. Pursuant to Rule 12b-15, the Company is also including currently dated certifications of the Chief Executive Officer and Chief Financial Officer. While the remainder of the Report is unchanged, the Company is reproducing the Report in its entirety to provide a complete presentation to the reader. This Amendment No. 1 speaks as of the original date of the filing date of the Report, except for certifications, which speak as of their respective dates and the filing date of this Amendment No. 1. Except as specifically indicated, the Report has not been updated to reflect events occurring subsequently to the original filing date.

Table of Contents

STAAR SURGICAL COMPANY

INDEX

	PAGE
	NUMBER
PART I FINANCIAL INFORMATION	
Item 1	
Financial Statements	
<u>Condensed Consolidated Balance Sheets July 4, 2003 and January 3, 2003</u>	1
<u>Condensed Consolidated Statements of Operations Three and Six Months Ended July 4, 2003 and June 28, 2002</u>	2
<u>Condensed Consolidated Statements of Cash Flows Six Months Ended July 4, 2003 and June 28, 2002</u>	3
<u>Notes to Condensed Consolidated Financial Statements</u>	4
Item 2	
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	10
Item 3	
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	23
Item 4	
<u>Controls and Procedures</u>	23
PART II OTHER INFORMATION	
Item 1	
<u>Legal Proceedings</u>	25
Item 2	
<u>Changes in Securities and Use of Proceeds</u>	25
Item 3	
<u>Defaults Upon Senior Securities</u>	25
Item 4	
<u>Submission of Matters to a Vote of Security Holders</u>	25
Item 5	
<u>Other Information</u>	25
Item 6	
<u>Exhibits and Reports on Form 8-K</u>	25
<u>Signatures</u>	27

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

(In thousands, except par value)

	July 4, 2003 Restated <u>(Unaudited)</u>	January 3, 2003 Restated <u>(Audited)</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 8,414	\$ 1,009
Accounts receivable, net	6,932	5,992
Inventories	11,874	11,761
Prepays, deposits, and other current assets	2,436	2,813
	<u>29,656</u>	<u>21,575</u>
Total current assets		
Investment in joint venture	462	462
Property, plant and equipment, net	6,682	7,438
Patents and licenses, net	8,566	9,038
Goodwill	6,427	6,427
Other assets	173	280
	<u>51,966</u>	<u>45,220</u>
Total assets		
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Notes payable	\$ 3,063	\$ 5,845
Accounts payable	4,439	4,394
Other current liabilities	4,799	4,241
	<u>12,301</u>	<u>14,480</u>
Total current liabilities		
Other long-term liabilities	86	89
	<u>12,387</u>	<u>14,569</u>
Total liabilities		

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-Q/A

Minority interest	162	100
	<u> </u>	<u> </u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$.01 par value; 10,000 shares authorized, none issued		
Common stock, \$.01 par value; 30,000 shares authorized, issued and outstanding 18,228 and 16,962 shares		
	182	169
Additional paid-in capital	85,085	74,977
Accumulated other comprehensive income (loss)	21	(111)
Accumulated deficit	(42,916)	(40,789)
	<u> </u>	<u> </u>
	42,372	34,246
Notes receivable from officers and directors	(2,955)	(3,695)
	<u> </u>	<u> </u>
Total stockholders' equity	39,417	30,551
	<u> </u>	<u> </u>
Total liabilities and stockholders' equity	\$ 51,966	\$ 45,220
	<u> </u>	<u> </u>

Note: The amounts presented in the January 3, 2003 balance sheet are derived from the restated audited financial statements for the year ended January 3, 2003. See accompanying notes to the condensed consolidated financial statements.

Table of Contents

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended		Six Months Ended	
	July 4, 2003	June 28, 2002	July 4, 2003	June 28, 2002
	Restated	Restated	Restated	Restated
Sales	\$ 12,950	\$ 12,008	\$ 25,729	\$ 23,639
Royalty and other income	1	80	48	180
Total revenues	12,951	12,088	25,777	23,819
Cost of sales	5,895	6,064	11,742	12,083
Gross profit	7,056	6,024	14,035	11,736
Selling, general, and administrative expenses:				
General and administrative	2,218	2,298	4,504	4,700
Marketing and selling	4,421	4,500	8,582	8,502
Research and development	1,374	977	2,551	2,053
Other charges		1,225		1,225
Total selling, general, and administrative expenses	8,013	9,000	15,637	16,480
Operating loss	(957)	(2,976)	(1,602)	(4,744)
Other income (expense):				
Equity in operations of joint venture	(31)	(6)	75	6
Interest income	(41)	84	84	137
Interest expense	(63)	(166)	(206)	(293)
Other income (expense)	262	(422)	208	(445)
Total other income (expense)	127	(510)	161	(595)
Loss before income taxes and minority interest	(830)	(3,486)	(1,441)	(5,339)
Income tax expense (benefit)	315	304	644	(628)
Minority interest	24	54	42	95
Net loss	\$ (1,169)	\$ (3,844)	\$ (2,127)	\$ (4,806)
Basic and diluted net loss per share	\$ (.07)	\$ (.22)	\$ (.12)	\$ (.28)
Weighted average shares outstanding Basic and diluted	17,289	17,163	17,148	17,161



See accompanying notes to the condensed consolidated financial statements.

Table of Contents

STAAR SURGICAL COMPANY AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Six Months Ended	
	July 4, 2003	June 28, 2002
	Restated	Restated
Cash flows from operating activities:		
Net loss	\$ (2,127)	\$ (4,806)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	962	1,188
Amortization of intangibles	490	467
Loss on disposal of fixed assets	64	
Equity in operations of joint venture	(76)	34
Stock-based compensation expense	172	127
Notes receivable reserve	(83)	
Subsidiary closure charges		1,225
Other	(57)	(100)
Minority interest	62	(5)
Changes in working capital:		
Accounts receivable	(940)	566
Inventories	(113)	1,546
Prepays, deposits, and other current assets	377	(338)
Accounts payable	51	(348)
Other current liabilities	558	138
	<u>(660)</u>	<u>(306)</u>
Cash flows from investing activities:		
Acquisition of property and equipment	(270)	(472)
Increase in patents and licenses	(18)	(74)
Decrease (increase) in other assets	107	(79)
Dividend received from joint venture	76	
Proceeds from notes receivable and other	874	
	<u>769</u>	<u>(625)</u>
Cash flows from financing activities:		
Decrease in borrowings under notes payable	(2,785)	(19)
Net proceeds from private placement	8,982	
Proceeds from stock options	967	6
	<u>7,164</u>	<u>(13)</u>

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-Q/A

Effect of exchange rate changes on cash and cash equivalents	132	706
Increase (decrease) in cash and cash equivalents	7,405	(238)
Cash and cash equivalents, at the beginning of the period	1,009	853
Cash and cash equivalents, at the end of the period	\$ 8,414	\$ 615

See accompanying notes to the condensed consolidated financial statements.

Table of Contents

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

July 4, 2003

1. Basis of Presentation

The accompanying condensed consolidated financial statements include the accounts of the Company, its wholly owned and its majority owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation. Assets and liabilities of foreign subsidiaries are translated at rates of exchange in effect at the close of the period. Revenues and expenses are translated at the weighted average of exchange rates in effect during the period. The resulting translation gains and losses are deferred and are shown as a separate component of stockholders' equity as accumulated other comprehensive income (loss). During the six months ended July 4, 2003 and June 28, 2002, the net foreign currency translation gain was \$132,000 and \$706,000, respectively. Net foreign currency transaction gain (loss) for the three and six months ended July 4, 2003 and June 28, 2002 was \$197,000 and \$141,000; and (\$341,000) and (\$344,000), respectively.

Investment in the Company's Japanese joint venture is accounted for using the equity method of accounting.

The accompanying unaudited 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 and six months ended July 4, 2003 and June 28, 2002, 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 January 3, 2003. The results of operations for the three months ended July 4, 2003 and June 28, 2002 are not necessarily indicative of the results to be expected for any other interim period or the entire year.

The Company has restated its previously issued consolidated financial statements for the three and six months ended July 4, 2003 and June 28, 2002 to correct interest income on notes receivable from officers and directors on an accrual basis consistent with accounting principles generally accepted in the United States of America. The impact of the restatement on interest income and loss per share for the periods is as follows (in thousands):

	Three Months Ended			Six Months Ended		
	July 4, 2003			July 4, 2003		
	Previously Reported	Inc (Dec)	Restated	Previously Reported	Inc (Dec)	Restated
Interest income	\$ 12	\$ (53)	\$ (41)	\$ 348	\$ (264)	\$ 84

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-Q/A

Loss per share \$ (0.06) \$ (0.01) \$ (0.07) \$ (0.11) \$ (0.01) \$ (0.12)

	Three Months Ended			Six Months Ended		
	June 28, 2002			June 28, 2002		
	Previously Reported	Inc (Dec)	Restated	Previously Reported	Inc (Dec)	Restated
Interest income	\$ 19	\$ 65	\$ 84	\$ 37	\$ 100	\$ 137
Loss per share	\$ (0.23)	\$ 0.01	\$ (0.22)	\$ (0.29)	\$ 0.01	\$ (0.28)

There is no income tax effect of the restatement on earnings for the periods presented in 2003 and 2002 since the Company reported losses and did not record income tax benefits thereon.

Table of Contents

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The impact of the restatement on the consolidated balance sheet is as follows (in thousands):

	As Previously Reported July 4, 2003	As Revised July 4, 2003	As Previously Reported June 28, 2002	As Revised June 28, 2002
Prepays, deposits, and other current assets (1)	\$ 2,586	\$ 2,436	\$ 2,877	No Change
Deferred tax asset non-current (2)		No Change	\$ 3,982	\$ 3,828
Accumulated deficit	\$ 43,284	\$ 42,916	\$ 29,169	\$ 28,817
Notes receivable from officers and directors	\$ 2,438	\$ 2,955	\$ 3,308	\$ 3,814

- (1) The revised consolidated balance sheet as of July 4, 2003 includes a reclass of \$150,000 of accrued interest on officer's notes from prepaids, deposits, and other current assets to notes receivable from officers and directors.
- (2) The revised consolidated balance sheet as of June 28, 2002 includes a reduction to the Company's net deferred tax assets by \$154,000 related to a decrease in net operating losses as a result of accrued interest income.

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

Pro forma net loss and loss per share for the three and six months ended July 4, 2003 and June 28, 2002, had the Company accounted for stock options issued to employees and others in accordance with the fair value method of SFAS 123, are as follows (in thousands, except per share data):

		Three Months Ended		Six Months Ended	
		July 4, 2003	June 28, 2002	July 4, 2003	June 28, 2002
Net loss	As reported	\$ (1,169)	\$ (3,844)	\$ (2,127)	\$ (4,806)
Add:	Stock-based employee compensation expense included in reported net loss, net of related tax effects				
Deduct:	Total stock-based employee compensation expense determined under fair value based methods for all awards, net of related tax effects	(421)	(415)	(818)	(804)

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-Q/A

Net loss	Pro forma	\$ (1,590)	\$ (4,259)	\$ (2,945)	\$ (5,610)
		<u> </u>	<u> </u>	<u> </u>	<u> </u>
Loss per share:	Basic and diluted				
As reported		\$ (0.07)	\$ (0.22)	\$ (0.12)	\$ (0.28)
		<u> </u>	<u> </u>	<u> </u>	<u> </u>
Pro forma		\$ (0.09)	\$ (0.25)	\$ (0.17)	\$ (0.33)
		<u> </u>	<u> </u>	<u> </u>	<u> </u>

Table of Contents**STAAR SURGICAL COMPANY AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. Geographic and Product Data**

The Company develops, manufactures and distributes medical devices used in minimally invasive ophthalmic surgery. The Company distributes its medical devices in the cataract, refractive and glaucoma sectors within ophthalmology. During the periods presented, revenues from the refractive and glaucoma sectors were less than 10% of total revenue, which is not significant enough for the Company to account for these products separately or to justify segmented reporting by product type.

The Company markets and sells its products in over 39 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 in that country exceed 5% of the Company's consolidated sales. Sales are attributed to countries based on the location of customers. The composition of the Company's sales to unaffiliated customers between those in the United States, Germany, and other locations for each period is set forth below (in thousands):

	Three Months Ended		Six Months Ended	
	July 4,	June 28,	July 4,	June 28,
	2003	2002	2003	2002
Sales to unaffiliated customers				
United States	\$ 5,941	\$ 6,136	\$ 11,700	\$ 12,263
Germany	5,103	3,995	10,132	7,687
Other	1,906	1,877	3,897	3,689
Total	\$ 12,950	\$ 12,008	\$ 25,729	\$ 23,639

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 possible political instability.

3. Inventories

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-Q/A

Inventories are stated at the lower of cost, determined on a first-in, first-out basis, or market and consisted of the following at July 4, 2003 and January 3, 2003 (in thousands):

	July 4,	January 3,
	2003	2003
Raw materials and purchased parts	\$ 817	\$ 710
Work-in-process	702	798
Finished goods	10,355	10,253
	<u>\$ 11,874</u>	<u>\$ 11,761</u>

4. Intangible Assets

The Company has intangible assets consisting of patents and licenses, with a gross book value of \$14.0 million and accumulated amortization of \$5.5 million as of July 4, 2003. The Company capitalizes the costs of acquiring patents and licenses as well as the legal costs of successfully defending its rights to these patents. Amortization is computed on the straight-line basis over the estimated useful lives, which are based on

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

legal and contractual provisions, and range from 10 to 20 years. Amortization expense for the three and six months ended July 4, 2003 and June 28, 2002, was \$249,000 and \$490,000; and \$240,000 and \$467,000, respectively.

The weighted average amortization period for other intangible assets is approximately 15 years. The following table shows the estimated amortization expense for these assets for each of the five succeeding years (in thousands):

Fiscal Year	
2003	\$ 1,001
2004	719
2005	719
2006	715
2007	543
Total	\$ 3,697

5. Notes Payable

On March 26, 2003, the Company and its domestic lender executed an agreement to extend the maturity date of the Company's \$3.0 million line of credit for one year to March 31, 2004. The line of credit carried an interest rate equal to the prime rate (4.04% at July 4, 2003) plus an interest margin of 5%. In addition, the Company was required to pay a commitment fee of 1.25% per annum of the unused amount of the line of credit. The line of credit was secured by a first priority lien on substantially all of the Company's assets and required the Company to comply with certain financial covenants including the maintenance of specified levels of liquidity, tangible net worth, operating cash flow and operating income. During the quarter ended July 4, 2003, the Company paid off and cancelled the line of credit.

6. Reclassifications

Certain reclassifications have been made to the 2002 condensed consolidated financial statements to conform to the 2003 presentation. These reclassifications have had no effect on previously reported results of operations or retained earnings.

7. Net Loss Per Share

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-Q/A

Basic net earnings (loss) per common share is computed by dividing the net earnings (loss) applicable to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted net earnings (loss) per common share is determined using the weighted-average number of shares outstanding during the period, adjusted for the dilutive effect of common stock equivalents, consisting of shares that might be issued upon exercise of common stock options. In periods where losses are reported, the weighted-average number of common shares outstanding excludes common stock equivalents, because their inclusion would be anti-dilutive.

8. Supply Agreement

In May 1999, the Company entered into a license and supply agreement with another manufacturer to license and re-sell one of the manufacturer's products. Under the terms of the agreement, the Company was committed to purchase the specified product for a total sum of \$3.2 million over 18 months. In September 2001,

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

the supply agreement was amended reducing the minimum contractual amount that the Company is obligated to purchase from the manufacturer to \$2.5 million over a 24-month period commencing September 1, 2001. The agreement, as amended, can be cancelled at the end of the 24-month period by either party upon four months written notice with a maximum liability of \$100,000 should the Company fail to meet the minimum contractual quantities under the agreement. Purchases under the agreement for the three and six months ended July 4, 2003 were approximately \$257,000 and \$547,000, respectively.

In December 2000, the Company entered into a minimum purchase agreement with another manufacturer for the purchase of viscoelastic solution. In addition to the minimum purchase requirement, the Company is also obligated to pay an annual regulatory maintenance fee. The agreement contains provisions to increase the minimum annual purchases in the event that the Seller gains regulatory approval of the product in other markets, as requested by the Company. Purchases under the agreement during the three and six months ended July 4, 2003 were approximately \$128,000 and \$270,000, respectively.

As of July 4, 2003, estimated annual purchase commitments under these contracts are as follows (in thousands):

Fiscal Year	
2003	\$ 863
2004	600
2005	600
2006	200
Total	\$ 2,263

9. New Accounting Pronouncements

In June 2002, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 146, Accounting for Costs Associated with Exit or Disposal Activities, which addresses accounting for restructuring and similar costs. SFAS No. 146 supersedes previous accounting guidance, principally Emerging Issues Task Force (EITF) Issue No. 94-3. The Company will adopt the provisions of SFAS No. 146 for restructuring activities initiated after December 31, 2002. SFAS No. 146 requires that the liability for costs associated with an exit or disposal activity be recognized when the liability is incurred. Under EITF No. 94-3, a liability for an exit cost was recognized at the date of a company's commitment to an exit plan. SFAS No. 146 also establishes that the liability should initially be measured and recorded at fair value. Accordingly, SFAS No. 146 may affect the timing of recognizing future restructuring costs as well as the amount recognized.

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-Q/A

In November 2002, the FASB issued Interpretation No. 45, Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness to Others, an interpretation of FASB Statements No. 5, 57 and 107 and a rescission of FASB Interpretation No. 34. This interpretation elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under guarantees issued. The interpretation also clarifies that a guarantor is required to recognize, at inception of a guarantee, a liability for the fair value of the obligation undertaken. The initial recognition and measurement provisions of the interpretation are applicable to guarantees issued or modified after December 31, 2002. The disclosure requirements are effective for financial statements of interim and annual periods ending after December 31, 2002. No guarantees were entered into or modified after December 31, 2002. Significant guarantees of the Company as of July 4, 2003 are disclosed in Note 8 of the consolidated financial statements.

Table of Contents

STAAR SURGICAL COMPANY AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*, which amends SFAS No. 123, *Accounting for Stock-Based Compensation*. SFAS 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS 148 amends the disclosure requirements of SFAS 123 to require more prominent and more frequent disclosures in financial statements of the effects of stock-based compensation. The transition guidance and annual disclosure provisions of SFAS 148 are effective for fiscal years ending after December 15, 2002. The interim disclosure provisions are effective for financial reports containing condensed financial statements for interim periods beginning after December 15, 2002. The adoption of SFAS 148 did not have a material impact on the Company's financial position or results of operations. The Company has provided the interim disclosures required by SFAS 148 in Note 1 of the consolidated financial statements.

In January 2003, the FASB issued FASB Interpretation No. 46, *Consolidation of Variable Interest Entities*, an interpretation of Accounting Research Bulletins (ARB) No. 51, *Consolidated Financial Statements (FIN 46)*. FIN 46 clarifies the application of ARB No. 51 to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. The Company does not believe the adoption of FIN 46 will have a material impact its financial position or results of operations.

In April 2003, the FASB issued SFAS No. 149, *Amendment of Statement of Accounting Standards 133 on Derivative Instruments and Hedging Activities (SFAS 149)*. SFAS 149 amends and clarifies the accounting for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. SFAS 149 is generally effective for contracts entered into or modified after June 30, 2003 and for hedging relationships designated after June 30, 2003. The adoption of SFAS 149 is not expected to have a material effect on the Company's financial position, results of operations, or cash flows.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Instruments with Characteristics of Both Liabilities and Equity*, (SFAS 150) which establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. SFAS 150 requires that an issuer classify a financial instrument that is within its scope, which may have previously been reported as equity, as a liability (or an asset in some circumstances). This statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003 for public companies. The Company does not believe the adoption of SFAS 150 will have a material impact on its financial statements.

10. Subsequent Event

On July 10, 2003, the Company received early repayment on the note of a former officer of the Company totaling \$2.2 million plus accrued interest. The note would have matured on March 29, 2006.

Table of Contents

STAAR SURGICAL COMPANY AND SUBSIDIARIES

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 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 below under the heading Factors That May Affect Future Results of Operations. The Company undertakes no obligation to publicly release the result of any revisions to these forward-looking statements that may be made to reflect events or circumstances after the date of this report or to reflect the occurrence of unexpected events.

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

Results of Operations

The following table sets forth the percentage of total revenues 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.

	<i>Percentage of Total</i>		<i>Percentage</i>	<i>Percentage of Total</i>		
	<i>Revenues for</i>		<i>Change for</i>	<i>Revenues for</i>		<i>Percentage</i>
	<i>Three Months</i>		<i>Three Months</i>	<i>Six Months</i>		<i>Change for</i>
			<i>2003</i>			<i>2003</i>
	<i>July 4,</i>	<i>June 28,</i>	<i>vs.</i>	<i>July 4,</i>	<i>June 28,</i>	<i>vs.</i>
	<i>2003</i>	<i>2002</i>	<i>2002</i>	<i>2003</i>	<i>2002</i>	<i>2002</i>
	<i>Restated</i>	<i>Restated</i>	<i>Restated</i>	<i>Restated</i>	<i>Restated</i>	<i>Restated</i>
Total revenues	100.0 %	100.0 %	7.1 %	100.0 %	100.0 %	8.2 %
Cost of sales	45.5	50.2	(2.8)	45.6	50.7	(2.8)
Gross profit	54.5	49.8	17.1	54.4	49.3	19.6
Costs and expenses:						
General and administrative	17.2	19.0	(3.5)	17.5	19.8	(4.2)

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-Q/A

Marketing and selling	34.1	37.2	(1.8)	33.3	35.7	0.9
Research and development	10.6	8.1	40.6	9.9	8.6	24.2
Other charges		10.1	(100.0)		5.1	(100.0)
	<u> </u>	<u> </u>		<u> </u>	<u> </u>	
Total costs and expenses	61.9	74.4	(11.0)	60.7	69.2	(5.1)
	<u> </u>	<u> </u>		<u> </u>	<u> </u>	
Operating loss	(7.4)	(24.6)	(67.8)	(6.3)	(19.9)	(66.2)
Other income (expense), net	1.0	(4.2)		0.6	(2.5)	
	<u> </u>	<u> </u>		<u> </u>	<u> </u>	
Loss before income taxes	(6.4)	(28.8)	(76.2)	(5.6)	(22.4)	(73.0)
Income taxes	2.4	2.5	(3.6)	2.5	(2.6)	
Minority interest	0.2	0.4	(56.6)	0.1	0.4	(56.0)
	<u> </u>	<u> </u>		<u> </u>	<u> </u>	
Net loss	(9.0)%	(31.7)%	(69.6)%	(8.3)%	(20.2)%	(55.7)%
	<u> </u>	<u> </u>		<u> </u>	<u> </u>	

Revenues

Revenues for the three months ended July 4, 2003 were \$13.0 million, which is \$.9 million or 7.1% greater than the \$12.1 million in revenues for the three months ended June 28, 2002. Sales increases were realized across

Table of Contents

STAAR SURGICAL COMPANY AND SUBSIDIARIES

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION

AND RESULTS OF OPERATIONS (Continued)

all product lines over the same period last year, except in silicone intraocular lenses (IOLs) and the AquaFlow device. The most significant increases were the result of a 38% increase in sales internationally of the Company's implantable contact lens (ICL) and an 18.3% increase in sales (primarily in the U.S.) of the Company's specialty lenses, the Toric silicone IOL and the Collamer IOL. ICL unit volume increased 32% while average selling price (ASP) increased 4% over the same quarter last year. Revenues in international markets also benefited from the favorable impact of exchange rate changes relative to the U.S. dollar. Sales of the AquaFlow device decreased 8.5% (3.1% decrease in volume and a 5.6% decrease in ASP) over the same quarter last year. This sales decrease was a result of sales and marketing resources which have been diverted from AquaFlow proctoring and training to trouble-shooting injection system issues and preparing for possible U.S. Food and Drug Administration approval of the ICL.

Total IOL sales increased .1% over the second quarter of 2002 despite a 40% decrease in unit volume of the Company's single-piece silicone IOL, primarily in the U.S. market, as a result of problems with its delivery system and believed contraction of this market segment. The decrease in sales of the single-piece silicone IOL was partially offset by increased sales in the U.S. of Collamer IOLs (37% increase in volume partially offset by an 8% decrease in ASP) and other IOL models sold in international markets which were favorably impacted by exchange rate changes offset partially by decreased volume. As a result of the decreased IOL sales in the U.S., overall sales in that market declined 3%. The Company expects IOL sales to increase in the U.S. in the second half of the year as it resolves its delivery system issues.

Revenues for the six months ended July 4, 2003 were \$25.8 million, which is \$2.0 million or 8.2% greater than the \$23.8 million in revenues for the six months ended June 28, 2002. Sales increases over the same period last year were realized across all product lines, except in silicone intraocular lenses (IOLs) and the AquaFlow device. The most significant increases were the result of a 42% increase in sales internationally of the Company's implantable contact lens (ICL) and a 10.8% increase in sales (primarily in the U.S.) of the Company's specialty lenses, the Toric silicone IOL and the Collamer IOL. ICL unit volume increased 38% while average selling price (ASP) increased 2.8% over the same period last year. Revenues in international markets also benefited from the favorable impact of exchange rate changes relative to the U.S. dollar. Sales of the AquaFlow device decreased 16% (16.6% decrease in volume and a .6% decrease in ASP) over the same quarter last year. This sales decrease was a result of sales and marketing resources which have been diverted from AquaFlow proctoring and training to trouble-shooting injection system issues and preparing for possible U.S. Food and Drug Administration approval of the ICL.

Total IOL sales increased .2% over the first six months of 2002 despite a 30% decrease in unit volume of the Company's single-piece silicone IOL, primarily in the U.S. market, as a result of problems with its delivery system and believed contraction of this market segment. The decrease in sales of the single-piece silicone IOL was partially offset by increased sales in the U.S. of Collamer IOLs (23% increase in volume partially offset by an 5% decrease in ASP) and other IOL models sold in international markets which were favorably impacted by exchange rate changes offset partially by decreased volume. As a result of the decreased IOL sales in the U.S., overall sales in that market declined 5%.

Gross Profit Margin

Gross profit margin increased to 54.5% and 54.4% of revenues for the three and six months ended July 4, 2003, respectively from 49.8% and 49.3% of revenues for the three and six months ended June 28, 2002, respectively. The increase in gross profit margin is principally due to

reduced cost structures in the Company's manufacturing facilities, production yield and efficiency increases, and increased sales of the higher margin ICL

Table of Contents

STAAR SURGICAL COMPANY AND SUBSIDIARIES

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION

AND RESULTS OF OPERATIONS (Continued)

in international markets. These improvements were partially offset by unfavorable mix among sales of IOLs due to the decline in the U.S. IOL market which realizes higher gross margins than the international IOL market.

Research and Development

Research and development expense increased to 10.6% and 9.9% of revenues for the three and six months ended July 4, 2003, respectively, from 8.1% and 8.6% of revenues for the three and six months ended June 28, 2002, respectively. The increased spending is related to costs associated with the filing of the pre-market approval application for the ICL with the U.S. Food and Drug Administration (FDA), costs incurred in the clinical investigation of the Toric ICL, and costs from lens insertion system development projects.

Other Income (Expense)

Other income for the three and six months ended July 4, 2003 was \$127,000 and \$161,000, respectively, as compared to other expense of \$510,000 and \$595,000 for the three and six months ended June 28, 2002, respectively. The increase in other income for the quarter is the result of foreign currency transaction gains, decreased expense associated with legal settlements, and decreased interest expense as a result of lower borrowings. The increase in other income for the six months is the result of foreign currency transaction gains, decreased expense associated with legal settlements, increased income from the Company's joint venture with Canon-STAAR, and increased interest income.

Income Taxes

The Company recorded income taxes for the three and six months ended July 4, 2003 of \$315,000 and \$644,000, respectively, based on the income of its German subsidiary. For the three and six months ended June 28, 2002, the Company recorded income taxes (net benefit) of \$304,000 and (\$628,000), respectively. The income tax benefit of \$932,000 was recorded based on legislation enacted March 9, 2002 (HR 3090), which enabled the Company to carryback portions of its federal 2000 and 2001 losses to 1996, 1997 and 1998.

Liquidity and Capital Resources

Cash and cash equivalents at July 4, 2003 increased by approximately \$7.4 million relative to January 3, 2003, as a result of net proceeds of \$9.0 million, received during the quarter, from a private placement of the Company's common stock and \$966,000 received in proceeds from the

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-Q/A

exercise of stock options. The Company used approximately \$2.1 million of the proceeds to pay off the note to its domestic lender. Cash and cash equivalents also increased as a result of the early repayment of a loan obligation to the Company of a former officer of the Company totaling \$659,000 plus accrued interest of \$171,000. The notes, which would have matured on September 4, 2003, were paid in full on May 6, 2003.

During the quarter ended July 4, 2003, accounts receivable increased \$940,000 relative to January 3, 2003. The increase in accounts receivable relates to extended terms given to certain international customers. Day's sales outstanding (DSO) were 49 days at July 4, 2003 compared to 45 days at January 3, 2003. The Company expects to maintain DSO within a range of 45 to 50 days during the course of the 2003 fiscal year.

Other current liabilities during the quarter ended July 4, 2003 increased \$558,000 relative to January 3, 2003. The increase in other current liabilities is due to an increase in accrued salaries and wages and taxes payable.

Table of Contents

STAAR SURGICAL COMPANY AND SUBSIDIARIES

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION

AND RESULTS OF OPERATIONS (Continued)

On March 26, 2003, the Company and its domestic lender executed an agreement to extend the maturity date of the Company's \$3.0 million line of credit for one year to March 31, 2004. The line of credit carried an interest rate equal to the prime rate (4.04% at July 4, 2003) plus an interest margin of 5%. In addition, the Company was required to pay a commitment fee of 1.25% per annum of the unused amount of the line of credit. The line of credit was secured by a first priority lien on substantially all of the Company's assets and required the Company to comply with certain financial covenants including the maintenance of specified levels of liquidity, tangible net worth, operating cash flow and operating income. During the quarter ended July 4, 2003, the Company paid off and cancelled the line of credit.

A subsidiary of the Company has a revolving credit facility with a Swiss bank, which, as amended in fiscal 2001, provides for borrowings of up to 4.25 million Swiss Francs - CHF (\$3.1 million based on the exchange rate on July 4, 2003). The credit facility is divided into two parts: Part A provides for borrowings of up to CHF 3.0 million (\$2.2 million based on the exchange rate on July 4, 2003) and does not have a termination date; Part B provides for borrowings of up to CHF 1.25 million (\$0.9 million based on the exchange rate on July 4, 2003). The loan amount under Part B of the agreement reduces by CHF 250,000 (\$185,000 based on the exchange rate on July 4, 2003) semi-annually beginning June 30, 2002. The credit facility is secured by a general assignment of claims and includes positive and negative covenants, which among other things requires the subsidiary to maintain equity at or above CHF 15.8 million (approximately \$11.7 million based on the exchange rate on July 4, 2003), prevents the subsidiary from entering into secured obligations except as already disclosed to the lender or guaranteeing the obligations of its subsidiaries or any third party. The agreement also prevents payment on loans made to the subsidiary by the Company without prior consent of the lender.

The loan agreement provides for borrowings on a current or fixed-term basis. The interest rate on current advances is 6.0% per annum at July 4, 2003 plus a commission rate of 0.25%, payable each quarter. The base interest rate for fixed-term advances follows Euromarket conditions for loans of a corresponding term and currency plus an individual margin. The fixed-term rate at July 4, 2003 was 4.3%. There were no borrowings outstanding under the current account as of July 4, 2003. Fixed term advances at July 4, 2003 were CHF 4.0 million (\$2.9 million based on the exchange rate on July 4, 2003).

A subsidiary of the Company has a revolving credit facility with a German bank which provides for borrowings of up to approximately 50,000 EUR (\$57,000 at the exchange rate on July 4, 2003) at an interest rate of 8.5%. The loan, originally due February 28, 2003, was extended on October 8, 2002 to August 31, 2003. Payments in the amount of 50,000 EUR (\$57,000 at the exchange rate on July 4, 2003) were due monthly beginning December 31, 2001. The amended agreement reduced the monthly payment to 25,000 EUR (\$28,000 at the exchange rate on July 4, 2003). The bank also agreed to waive the September 2002 and October 2002 payments. There were no other changes to the original terms of the agreement. The loan is secured by an assignment of the subsidiary's accounts receivable and inventory and is personally guaranteed by the subsidiary's president. There are no financial covenants included in the agreement and no borrowings outstanding as of July 4, 2003.

The subsidiary of the Company negotiated another credit facility with a different German bank to replace the one that expires on August 31, 2003. The new agreement, effective January 13, 2003, provides for borrowings of up to 210,000 EUR (\$241,000 at the exchange rate on July 4, 2003) at an interest rate of 8.5%. The note is due November 30, 2003 and is personally guaranteed by the subsidiary's president. The agreement includes a covenant which prevents the subsidiary from paying dividends. Borrowings outstanding as of July 4, 2003 were 93,000 EUR (\$107,000 at the exchange rate on July 4, 2003).

Table of Contents**STAAR SURGICAL COMPANY AND SUBSIDIARIES****MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION****AND RESULTS OF OPERATIONS (Continued)**

The following table represents the Company's known contractual obligations at July 4, 2003 (in thousands).

Contractual Obligations	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Long-term debt obligations	\$ 3,063	\$ 3,063	\$	\$	\$
Capital lease obligations	137	46	91		
Operating lease obligations	2,303	412	1,602	289	
Purchase obligations	2,263	863	1,400		
Total	\$ 7,766	\$ 4,384	\$ 3,093	\$ 289	\$

As of July 4, 2003, the Company had a current ratio of 2.4:1, net working capital of \$17.4 million and net equity of \$39.4 million compared to January 3, 2003 when the Company's current ratio was 1.5:1, its net working capital was \$7.1 million, and its net equity was \$30.6 million.

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, proceeds from the private placement of Common Stock, proceeds from option exercises, debt repayments by former officers, and borrowings under the Company's bank credit facilities. Any withdrawal of support from its banks could have serious consequences on the Company's liquidity. The Company's liquidity is dependent, 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.

Table of Contents

STAAR SURGICAL COMPANY AND SUBSIDIARIES

Critical Accounting Policies

The preparation of financial statements in accordance with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an on-going basis, we evaluate our estimates, including those related to revenue recognition, allowance for doubtful accounts, inventory reserves and income taxes, among others. Our estimates are based upon historical experiences, market trends and financial forecasts and projections, and upon various other assumptions that management believes to be reasonable under the circumstances and at that certain point in time. Actual results may differ, significantly at times, from these estimates under different assumptions or conditions.

The Company believes the following represent its critical accounting policies.

Revenue Recognition. In general, the Company supplies foldable IOLs on a consignment basis to customers, primarily ophthalmologists, surgical centers, hospitals and other eye care providers, and recognizes sales when the IOLs are implanted. Sales of all other products, including sales to foreign distributors, are generally recognized upon shipment, which is when title passes.

Revenue from license and technology agreements is recorded as income, when earned, according to the terms of the respective agreements.

Impairment of Long-Lived Assets. Intangible and other long lived-assets are reviewed for impairment whenever events such as product discontinuance, plant closures, product dispositions or other changes in circumstances indicate that the carrying amount may not be recoverable. In reviewing for impairment, the Company compares the carrying value of such assets to the estimated undiscounted future cash flows expected from the use of the assets and their eventual disposition. When the estimated undiscounted future cash flows are less than their carrying amount, an impairment loss is recognized equal to the difference between the assets' fair value and their carrying value.

Goodwill, which has an indefinite life and was previously amortized on a straight-line basis over the periods benefited, is no longer amortized to earnings, but instead is subject to periodic testing for impairment. Intangible assets determined to have definite lives are amortized over their remaining useful lives. Goodwill of a reporting unit is tested for impairment on an annual basis or between annual tests if an event occurs or circumstances change that would reduce the fair value of a reporting unit below its carrying amount. As of July 4, 2003, the carrying value of goodwill was \$6.4 million.

The Company also has other intangible assets consisting of patents and licenses, with a gross book value of \$14.0 million and accumulated amortization of \$5.5 million as of July 4, 2003. The Company capitalizes the costs of acquiring patents and licenses as well as the legal costs of successfully defending its rights to these patents. Amortization is computed on the straight-line basis over the estimated useful lives, which are based on legal and contractual provisions, and range from 10 to 20 years.

Deferred Taxes. The Company recognizes deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of the Company's assets and liabilities along with net operating loss and credit carryforwards. A valuation

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-Q/A

allowance is recognized if, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax asset may not be realized. The impact on deferred taxes of changes in tax rates and laws, if any, are applied to the years during which temporary differences are expected to be settled and reflected in the financial statements in the period of enactment.

Table of Contents

STAAR SURGICAL COMPANY AND SUBSIDIARIES

Critical Accounting Policies (continued)

In 2002, due to the Company's recent history of losses, an increase to the valuation allowance was recorded as a non-cash charge to tax expense in the amount of \$9.0 million. As a result, the valuation allowance fully offsets the value of deferred tax assets on the Company's balance sheet as of July 4, 2003. If in the future the Company determines it will be able to utilize all or part of the deferred tax assets, which have a valuation allowance of \$18.6 million at July 4, 2003, we would reverse the valuation allowance, which would result in an income tax benefit.

Factors That May Affect Future Results of Operations

Our short and long-term success is subject to many factors that are beyond our control. You should consider carefully the following risk factors, in addition to other information contained in this report. This Quarterly Report on Form 10-Q contains forward-looking statements, which are subject to a variety of risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors including those set forth below.

We have a history of losses.

We have reported losses in each of the last three fiscal years and have an accumulated deficit of \$42.9 million as of July 4, 2003. If losses from operations continue, they could adversely affect the market price for our common stock and our ability to obtain new financing. In June 2000, we began implementing a restructuring plan aimed at reducing costs and improving operating efficiency. In connection with this plan, we recognized pre-tax charges to earnings of \$15.3 million, \$7.8 million, and \$1.5 million in fiscal 2000, 2001 and 2002. While the restructuring plan has generally improved our profit margins, we cannot be certain that we will succeed in restoring our profitability.

We have been in default of the terms of our domestic loan agreement and have limited access to credit.

We have recently failed to comply with some of the financial covenants of our principal domestic loan agreement, including a failure to maintain minimum levels of tangible net worth in the first fiscal quarter of 2003, a failure to maintain minimum levels of operating income in the second and third fiscal quarters of 2002 and a failure to maintain minimum levels of cash flow in the second fiscal quarter of 2002. Accordingly, we have had to obtain waivers from our lender or modifications of our loan agreement. As of June 19, 2003, we have paid off and eliminated our domestic loan, and have outstanding balances on the loans of our European subsidiaries of approximately \$3.1 million, based on exchange rates on July 4, 2003. In the near term, we believe that sufficient cash to fund operations and current growth plans will be provided by cash generated from operations and the proceeds of our June 11, 2003 private placement, in which we raised proceeds, net of placement agent fees, of approximately \$9 million by selling 1,000,000 shares of the Company's common stock. However, it is likely that in the future we will need access to credit to finance operations and fund future growth. Because of our history of losses we may not be able secure adequate financing for these purposes on terms that are favorable to us or on any terms.

Our success depends on the ICL, which has not been approved for use in the United States.

We have devoted significant resources and management attention to the development and introduction of our ICL and TICL. Our management believes that the future success of STAAR depends on the approval of the ICL by the FDA and a successful launch of the ICL in North America. The ICL is already approved for use in Europe and Canada and in parts of Asia. The TICL is approved for use in Europe. In May 2003, we submitted the final module of our Pre-Market Approval Submission for the ICL to the FDA, which granted expedited review

Table of Contents

STAAR SURGICAL COMPANY AND SUBSIDIARIES

status to the submission on July 1, 2003. If the FDA does not grant approval of the ICL, or significantly delays its approval, our prospects for success will be severely diminished.

Our success depends on the successful marketing of the ICL in the United States market.

Even if it is approved by the FDA, the ICL will not reach its full sales potential unless we successfully plan and execute its launch and marketing in the United States. This will present new challenges to our sales and marketing staff and to our independent manufacturers' representatives. In countries where the ICL has been approved to date, our sales have grown steadily, but slowly. In the United States in particular, 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. As a result, we expect to make extensive use of advertising and promotion targeted through providers to potential patients, and to carefully manage the introduction of the ICL. We do not have unlimited resources and we cannot predict whether the particular marketing, advertising and promotion strategies we pursue will be as successful as we intend. If we do not successfully market the ICL in the United States, we will not achieve our planned profitability and growth.

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

STAAR pioneered the foldable IOL for use in cataract surgery, and the foldable silicone IOL remains our largest source of revenue. Since we introduced the product, however, competitors have introduced IOLs employing a variety of designs and materials. Over the years these products have gradually taken a larger share of the IOL market, while the market share for STAAR IOLs has decreased. In particular, many surgeons now choose lenses made of acrylic material rather than silicone for their typical patients. In an effort to maintain our competitive position we have introduced a new biocompatible lens material, Collamer, to our line of IOLs. We have also introduced new IOL designs, such as the Toric IOL, pioneered cartridge-injector systems for lens insertion, and have continued to improve and refine the silicone IOL. Sales of these new products, however, have only partially offset declining sales of our silicone IOLs.

We depend on independent manufacturer's representatives.

In an effort to reduce costs and bring our products to a wider market, we have entered into long-term agreements with several independent regional manufacturers' representatives, who introduce our products to eye surgeons and provide proctoring 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. We have been relying on the independent representatives to introduce our new products like Collamer IOLs, Toric IOLs and the AquaFlow Device, and we will rely on them, in part, to help introduce the ICL if it is approved. However, we are also introducing a direct sales force to assist in marketing and surgeon training to minimize the risks of complete dependence on independent representatives. If we do not introduce a direct sales force and 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.

Implantable medical devices must be manufactured to the highest standards and tolerances, and often incorporate newly developed technology. Despite all efforts to achieve the highest level of quality control and

Table of Contents

STAAR SURGICAL COMPANY AND SUBSIDIARIES

advance testing, 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. Recalls significantly impacted our revenue in 2001 when, in separate instances, we voluntarily recalled our three-piece Collamer lens and certain silicone lenses, and as a result wrote down approximately \$3.4 million in inventory in that year. 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 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 some professionals to discontinue using our products.

We compete with much larger companies.

Our competitors, including Bausch & Lomb, Inc., Advanced Medical Optics, Inc. (AMO), Alcon, Inc., Pfizer, Inc. and the CIBA Vision division of Novartis AG, 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 facility in Monrovia, California or our facility in Nidau, 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.

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 revenue 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 substantially superior product, or if we announce a new product of our own. Similarly, 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 of time; 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.

Table of Contents

STAAR SURGICAL COMPANY AND SUBSIDIARIES

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

We spent 9.9% of our revenue on research and development in during the first six months of 2003 and we expect to spend comparable amounts annually in the future. 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. It is possible that few or none of the products currently under development will become commercially successful.

Failure of users of our products to obtain adequate reimbursement from third-party payors could limit market acceptance of our products, which could affect our sales and profits.

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 or Medicaid. These third-party payors have recently been trying to contain costs by restricting the types of procedures they reimburse to those viewed as most cost-effective and capping or reducing reimbursement rates. These policies could adversely affect sales and prices of our products. Physicians, hospitals and other health care providers may be reluctant to purchase our products if third-party payors do not adequately reimburse them for the cost of our products and the use of our surgical equipment. For example:

Major third-party payors for hospital services, including government insurance plans, Medicare, Medicaid and private health care insurers, have substantially revised their payment methodologies during the last few years, resulting in stricter standards for reimbursement of hospital and outpatient charges for some medical procedures, including cataract procedures and IOLs;

Numerous legislative proposals have been considered that, if enacted, would result in major reforms in the United States health care system, which could have an adverse effect on our business;

Our competitors may reduce the prices of their products, which could result in third-party payors favoring our competitors;

There are proposed and existing laws and regulations governing maximum product prices and the profitability of companies in the health care industry; and

There have been recent initiatives by third-party payors to challenge the prices charged for medical products. Reductions in the prices for our products in response to these trends could reduce our profits. Moreover, our products may not be covered in the future by third-party payors, which would also reduce our sales.

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

Government regulations and agency oversight apply to every aspect of our business, including testing, manufacturing, safety and environmental controls, efficacy, labeling, advertising, promotion, record keeping, the sale and distribution of products and samples. We are also subject to

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-Q/A

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 United States, we must obtain approval from the FDA for each product that we market. Competing in the ophthalmic products industry requires us to continuously introduce new or improved products and processes,

Table of Contents

STAAR SURGICAL COMPANY AND SUBSIDIARIES

and to submit these to the FDA for approval. Obtaining FDA approval is a long and expensive process, and approval is never certain.

Products distributed outside of the United States are also subject to government regulation, which may be equally or more demanding. 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 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.

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

Our products are sold in more than 39 countries. Revenues from international operations make up a significant portion of our total revenue, reaching 55% for the six months ended July 4, 2003. The results of operations and the financial position of our offshore operations are generally reported in the relevant local currencies and then translated into United States dollars at the applicable exchange rates for inclusion in our consolidated financial statements, exposing us to translation risk. In 2003, our most significant currency exposures were to the Euro, the Swiss Franc, and the Australian dollar. The exchange rates between these and other local currencies and the United States dollar may fluctuate substantially. 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 revenues are received. We have not attempted to offset our exposure to these risks by investing in derivatives or engaging in other hedging transactions. Fluctuations in the value of the United States dollar against other currencies have had a material adverse effect on our operating margins and profitability in the past, and may have similar effects in the future.

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 United States 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 all 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 revenues. Inflation in emerging markets also makes our products more expensive there and increases the credit risks to which we are exposed. We have experienced currency fluctuations, inflation and volatile economic conditions, which have affected our profitability in the past in several markets, including Japan, Switzerland, the European Union and Australia, and we may experience such effects in the future.

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

We have numerous patents and pending patent applications. We rely on a combination of 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. Furthermore, we cannot be certain that any pending patent application held by us will result in an issued patent or that if patents are issued to us, the patents

Table of Contents

STAAR SURGICAL COMPANY AND SUBSIDIARIES

will 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 not fully resolved.

Any litigation or claims against us, whether or not successful, could result in substantial costs and harm our reputation. In addition, intellectual property litigation or claims could force us to do one or more of the following: to cease selling or using any of our products that incorporate the challenged intellectual property, which would adversely affect our revenue; to 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 to 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 obtain some of the components of our products from a single source, and an interruption in the supply of those components could reduce our revenue.

We obtain some of the components for our products from a single source. For example, only one supplier produces the raw material for the STAARVISC II viscoelastic product. Although we believe we could find alternate supplies for any of these components, the loss or interruption of any of these suppliers could increase costs, reducing our revenue and profitability, or harm our customer relations by delaying product deliveries.

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

Most of our products are covered by patents that 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 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 charge a lower price in order to maintain sales of our products, which could make these products 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 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.

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

Our manufacturing, research and development practices involve the controlled 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. Although we believe that our safety and environmental procedures for handling and disposing of these materials comply with legally prescribed standards, 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

STAAR SURGICAL COMPANY AND SUBSIDIARIES

We risk losses through litigation.

We are currently 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 and motivate other highly skilled personnel. Failure to do so may adversely affect future results.

Risks Related to Ownership of Our Common Stock

Our Certificate of Incorporation 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. We also have a Stockholders Rights Plan, which could discourage a third party from making an offer to acquire us. 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 would be in the interest of a significant number 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 bylaws contain other provisions that could have an anti-takeover effect, including the following:

only one of the three classes of directors is elected each year;

stockholders have limited ability to remove directors;

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.

Future sales of our common stock may depress our stock price.

The market price of our common stock could be subject to downward price pressure as a result of sales of our recent private placement of 1,000,000 shares of common stock, which have been registered for resale, or the perception that these sales could occur. In addition, the perception that we might conduct similar private placements followed by public offering of the privately placed shares could make it more difficult for us to raise funds through future offerings of common stock. As of August 22, 2003, there were 18,291,682 shares of our common stock outstanding, with another 2,439,710 shares of common stock issuable upon exercise of options granted under our stock option plans or under certain agreements with our senior officers. Some of the stock underlying these options has been registered for resale with the SEC.

Table of Contents

STAAR SURGICAL COMPANY AND SUBSIDIARIES

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

Our stock price has fluctuated widely, ranging from \$2.10 to \$15.44 within the past year. As of August 21, 2003, the closing price of our common stock was \$11.35. Our stock price could continue to experience significant fluctuations 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.

ITEM 3 QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

In the normal course of business, our operations are exposed to risks associated with fluctuations in interest rates and foreign currency exchange rates. The Company manages its risks based on management's judgment of the appropriate trade-off between risk, opportunity and costs. Management does not believe that market risks are material to the results of operations or cash flows of the Company, and, accordingly, does not generally enter into interest rate or foreign exchange rate hedge instruments.

Interest rate risk. Our \$3.1 million of debt is based on the borrowings of our international subsidiaries. The majority of our international borrowings bear an interest rate that is linked to Euro market conditions and, thus, our interest rate expense will fluctuate with changes in those conditions. If interest rates were to increase or decrease by 1% for the year, our annual interest rate expense would increase or decrease by approximately \$30,000.

Foreign currency risk. Our international subsidiaries operate in and are net recipients of currencies other than the U.S. dollar and, as such, we benefit from a weaker dollar and are adversely affected by a stronger dollar relative to major currencies worldwide (primarily, the Euro and Australian dollar). Accordingly, changes in exchange rates, and particularly the strengthening of the US dollar, may negatively affect our consolidated sales and gross profit as expressed in U.S. dollars. Additionally, approximately 97% of our debt is denominated in Swiss Francs and as such, we are subject to fluctuations of the Swiss Franc as compared to the U.S. dollar in converting the value of the debt in U.S. dollars. The U.S. dollar value of the debt is increased by a weaker dollar and decreased by a stronger dollar relative to the Swiss Franc.

ITEM 4 CONTROLS AND PROCEDURES

The Company's Chief Executive Officer, David Bailey, and Chief Financial Officer, John Bily, with the participation of the Company's management, carried out an evaluation of the effectiveness of the Company's disclosure controls and procedures pursuant to Exchange Act Rule 13a-15(e). Based upon that evaluation, the Chief Executive Officer and the Chief Financial Officer believe that, as of the end of the period covered by this report, the Company's disclosure controls and procedures are effective in making known to them material information relating to the Company (including its consolidated subsidiaries) required to be included in this report.

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-Q/A

Disclosure controls and procedures, no matter how well designed and implemented, can provide only reasonable assurance of achieving an entity's disclosure objectives. The likelihood of achieving such objectives is affected by limitations inherent in disclosure controls and procedures. These include the fact that human judgment in decision-making can be faulty and that breakdowns in internal control can occur because of human failures such as simple errors, mistakes or intentional circumvention of the established processes.

Table of Contents

STAAR SURGICAL COMPANY AND SUBSIDIARIES

There was no change in the Company's internal control over financial reporting, known to the Chief Executive Officer or the Chief Financial Officer, that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

Table of Contents**STAAR SURGICAL COMPANY AND SUBSIDIARIES****PART II OTHER INFORMATION*****ITEM 1 LEGAL PROCEEDINGS***

We are currently 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. 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 2 CHANGES IN SECURITIES AND USE OF PROCEEDS

Not applicable

ITEM 3 DEFAULTS UPON SENIOR SECURITIES

Not applicable

ITEM 4 SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

- a. The annual meeting of the stockholders of the Company (the Annual Meeting) was convened and voting on Proposal No. 1 was concluded on June 18, 2003. The Annual Meeting was adjourned until June 25, 2003, and voting on Proposal No. 2 was concluded on that date.
- b. At the Annual Meeting, Proposal No. 1 for the election to the board of two Class II directors to serve until the annual meeting of stockholders in 2006 and until their successors are duly elected and qualified was submitted to the stockholders. The nominees of the Board of Directors were re-elected as follows:

	Number of Shares	
	For	Withheld
Mr. Donald Duffy	14,956,378	248,589
Dr. Volker Anhaeusser	14,910,593	294,374

Edgar Filing: STAAR SURGICAL COMPANY - Form 10-Q/A

- c. At the Annual Meeting, Proposal No. 2 to approve the STAAR Surgical Company 2003 Omnibus Equity Incentive Plan was submitted to the stockholders. The proposal was approved as follows:

Number of Shares		
For	Against	Abstain
5,531,319	5,137,721	31,917

ITEM 5 OTHER INFORMATION

Not applicable

ITEM 6 EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

- 3.1 Certificate of Incorporation, as amended.(1)
- 3.2 By-laws, as amended.(2)
- 4.5 Stockholders Rights Plan, dated effective April 20, 1995.(2)

Table of Contents

- 4.7 Amendment No. 1 to Stockholders Rights Plan, dated April 21, 2003.(3)
- 31 Certifications 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 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 from the Company s Annual Report on Form 10-K for the year ended December 31, 1999, as filed on March 30, 2000.
- (2) Incorporated by reference from the Company s Annual Report on Form 10-K for the year ended December 29, 2000, as filed on March 29, 2001.
- (3) Incorporated by reference to the Company s Quarterly Report on Form 10-Q for the quarter ended April 4, 2003 as filed on May 19, 2003.

(b) Reports on Form 8-K

On June 6, 2003, the Company filed a Current report on Form 8-K, furnishing under Item 4 its decision not to engage BDO Seidman, LLP as its principal independent accountant for the fiscal year ending January 2, 2004.

On June 13, 2003, the Company filed a Current report on Form 8-K, furnishing under Item 4 its decision to engage McGladrey & Pullen, LLP as its principal accountant for the fiscal year ending January 2, 2004.

