

STAAR SURGICAL CO  
Form 10-Q  
May 04, 2011

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended: April 1, 2011

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 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)

(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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer     Accelerated filer     Non-accelerated filer     Smaller reporting company  
(Do not check if a smaller

reporting company)

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

The registrant has 35,542,259 shares of common stock, par value \$0.01 per share, issued and outstanding as of April 29, 2011.

---

STAAR SURGICAL COMPANY

INDEX

	PAGE NUMBER
<b>PART I – FINANCIAL INFORMATION</b>	<b>1</b>
Item 1. Financial Statements (Unaudited).	1
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.	11
Item 3. Quantitative and Qualitative Disclosures About Market Risk.	21
Item 4. Controls and Procedures.	22
<b>PART II – OTHER INFORMATION</b>	
Item 1. Legal Proceedings.	22
Item 1A. Risk Factors.	22
Item 6. Exhibits.	23

---

## PART I. FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

STAAR SURGICAL COMPANY  
 CONDENSED CONSOLIDATED BALANCE SHEETS  
 (In thousands, except par value amounts)  
 (Unaudited)

	April 1, 2011	December 31, 2010
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$10,212	\$ 9,376
Restricted cash	142	133
Accounts receivable trade, net	7,612	8,219
Inventories, net	9,967	10,543
Prepays, deposits and other current assets	2,193	1,715
<b>Total current assets</b>	<b>30,126</b>	<b>29,986</b>
Property, plant and equipment, net	3,505	3,732
Intangible assets, net	3,434	3,672
Goodwill	1,786	1,786
Deferred income taxes	202	202
Other assets	1,142	1,207
<b>Total assets</b>	<b>\$40,195</b>	<b>\$ 40,585</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable	\$3,648	\$ 3,717
Line of credit	2,420	2,460
Deferred income taxes	325	326
Obligations under capital leases	388	431
Other current liabilities	5,335	6,513
<b>Total current liabilities</b>	<b>12,116</b>	<b>13,447</b>
Obligations under capital leases	1,354	1,403
Deferred income taxes	531	488
Other long-term liabilities	2,792	2,820
<b>Total liabilities</b>	<b>16,793</b>	<b>18,158</b>
<b>Commitments and contingencies (Notes 13)</b>		
<b>Stockholders' equity:</b>		
Common stock, \$0.01 par value; 60,000 shares authorized; 35,350 and 35,084 shares issued and outstanding at April 1, 2011 and December 31, 2010	354	351
Additional paid-in capital	153,007	152,014
Accumulated other comprehensive income	1,779	2,100
Accumulated deficit	(131,738 )	(132,038 )
<b>Total stockholders' equity</b>	<b>23,402</b>	<b>22,427</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$40,195</b>	<b>\$ 40,585</b>

See accompanying notes to the condensed consolidated financial statements.

STAAR SURGICAL COMPANY  
CONDENSED CONSOLIDATED STATEMENTS OF INCOME  
(In thousands, except per share amounts)  
(Unaudited)

	Three Months Ended	
	April 1, 2011	April 2, 2010
Net sales	\$14,849	\$13,778
Cost of sales	5,220	4,949
Gross profit	9,629	8,829
General and administrative	3,530	3,389
Marketing and selling	4,459	3,831
Research and development	1,432	1,533
Operating income	208	76
Other income (expense):		
Interest income	13	1
Interest expense	(153 )	(406 )
Gain (loss) on foreign currency	372	(50 )
Other income, net	163	41
Total other income (expense)	395	(414 )
Income (loss) before provision for income taxes	603	(338 )
Provision for income taxes	303	298
Income (loss) from continuing operations	300	(636 )
Income from discontinued operations, net of income taxes	—	4,166
Net income	\$300	\$3,530
Net income (loss) per share from continuing operations – basic	\$0.01	\$(0.02 )
Net income(loss) per share from continuing operations - diluted	\$0.01	\$(0.02 )
Income per share from discontinued operations – basic and diluted	\$—	\$0.12
Net income per share – basic	\$0.01	\$0.10
Net income per share - diluted	\$0.01	0.10
Weighted average shares outstanding – basic	35,188	34,750
Weighted average shares outstanding - diluted	36,389	34,750

See accompanying notes to the condensed consolidated financial statements.

STAAR SURGICAL COMPANY  
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
(In thousands)  
(Unaudited)

	Three Months Ended	
	April 1, 2011	April 2, 2010
<b>Cash flows from operating activities:</b>		
Net income	\$300	\$3,530
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Income from discontinued operations	—	(4,166 )
Depreciation of property and equipment	307	442
Amortization of intangibles	197	200
Amortization of discount	—	125
Fair value adjustment of warrant	(103 )	25
Deferred income taxes	44	—
Loss on disposal of property and equipment	(14 )	—
Change in net pension liability	60	93
Stock-based compensation expense	355	311
Other	(81 )	95
Changes in working capital:		
Accounts receivable	666	881
Inventories	548	417
Prepays, deposits and other current assets	(473 )	(405 )
Accounts payable	(87 )	(1,426 )
Other current liabilities	(1,169 )	(888 )
Net cash used in operating activities of discontinued operations	—	(635 )
Net cash provided by (used in) operating activities	550	(1,401 )
<b>Cash flows from investing activities:</b>		
Proceeds from sale of subsidiary, net of transaction costs	—	12,051
Deposit to restricted escrow account	—	(136 )
Acquisition of property and equipment	(44 )	(106 )
Proceeds from sale of property and equipment	26	—
Net change in other assets	48	(2 )
Net cash used in investing activities of discontinued operations	—	(50 )
Net cash provided by investing activities	30	11,757
<b>Cash flows from financing activities:</b>		
Repayment of capital lease lines of credit	(131 )	(276 )
Proceeds from the exercise of stock options	606	—
Net cash used in financing activities of discontinued operations	—	(50 )
Net cash provided by (used in) financing activities	475	(326 )
Effect of exchange rate changes on cash and cash equivalents	(219 )	(86 )
Increase in cash and cash equivalents	836	9,944

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

Cash and cash equivalents, at beginning of the period	9,376	6,330
Cash and cash equivalents, at end of the period	\$10,212	\$16,274

See accompanying notes to the condensed consolidated financial statements.



STAAR SURGICAL COMPANY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

April 1, 2011  
(Unaudited)

Note 1 — Basis of Presentation and Significant Accounting Policies

The consolidated financial statements of the Company present the financial position, results of operations, and cash flows of STAAR Surgical Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated. The accompanying unaudited condensed consolidated financial statements, have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities Exchange Commission. Accordingly, certain information and footnote disclosures normally included in comprehensive financial statements have been condensed or omitted pursuant to such rules and regulations. The consolidated balance sheet as of December 31, 2010 was derived from the audited financial statements at that date, but does not include all the information and footnotes required by GAAP. 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 31, 2010.

The condensed consolidated financial statements for the three months ended April 1, 2011 and April 2, 2010, in the opinion of management, include all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the Company’s financial condition and results of operations. The results of operations for the three months ended April 1, 2011 and April 2, 2010 are not necessarily indicative of the results to be expected for any other interim period or for the entire year. As fully discussed in Note 2, on March 2, 2010, the Company disposed of all of its interests in its subsidiary, Domilens GmbH (“Domilens”).

Each of the Company's reporting periods ends on the Friday nearest to the quarter ending date and generally consists of 13 weeks. Unless the context indicates otherwise “we,” “us,” the “Company,” and “STAAR” refer to STAAR Surgical Company and its consolidated subsidiaries.

Note 2 — Disposal of Domilens subsidiary

On March 2, 2010 (the “Closing Date”), STAAR Surgical Company completed the divestiture (the “Transaction”) of all of its interest in its German distribution subsidiary, Domilens GmbH (“Domilens”) through a management buyout led by funds managed by Hamburg-based Small Cap Buyout Specialist BPE Unternehmensbeteiligungen GmbH (“BPE”). To effectuate the Transaction “STAAR Surgical AG” (“STAAR AG”), STAAR’s Swiss subsidiary and holder of 100% of the shares of Domilens, signed a Stock Purchase Agreement (the “Agreement”) with Domilens Akquisitionen GmbH (“Domilens Akquisitionen”) on February 24, 2010. Domilens Akquisitionen became a newly formed entity 74% owned by BPE and 26% owned by management of Domilens.

The following selected financial information included in net income from discontinued operations for the Domilens subsidiary (in thousands, except per share amounts):

	Three Months Ended April 1, 2010
Net sales	\$ 3,584

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

Gain on disposal, net of \$46 of taxes	4,118
Income from operations of Domilens before taxes	64
Income tax expense	(16 )
Income from discontinued operations, net of income taxes	\$ 4,166
Income per share from discontinued operations – basic and diluted	\$ 0.12

See Note 3, Disposal of Domilens Subsidiary, to the consolidated financial statements accompanying the 2010 Form 10-K for additional information regarding the sale of Domilens.

STAAR SURGICAL COMPANY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
April 1, 2011  
(Unaudited)

Note 3 — Restricted Cash

On March 2, 2010, as part of the disposition of Domilens, the Company deposited \$136,000 into a restricted escrow account to provide for the potential payment of unaccrued taxes assessed for periods prior to December 31, 2009. The balance of funds remaining, if any, after the payment of such taxes, will be distributed to STAAR from the escrow account, no later than December 31, 2011. As of April 1, 2011, restricted cash was \$142,000, an increase of \$6,000 due to the effect of foreign currency.

Note 4 — Inventories

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

	April 1, 2011	December 31, 2010
Raw materials and purchased parts	\$ 2,212	\$ 1,920
Work-in-process	1,925	2,255
Finished goods	6,879	7,349
	11,016	11,524
Inventory reserves	(1,049 )	(981 )
	\$ 9,967	\$ 10,543

Note 5 — Prepaids, Deposits, and Other Current Assets

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

	April 1, 2011	December 31, 2010
Prepaids and deposits	\$ 1,340	\$ 1,219
Other current assets	853	496
	\$ 2,193	\$ 1,715

Note 6 – Amortizable Intangible Assets

Amortizable intangible assets consisted of the following (in thousands):

	April 1, 2011			December 31, 2010		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Amortized intangible assets:						
Patents and licenses	\$ 10,814	\$ (9,171 )	\$ 1,643	\$ 10,827	\$ (9,064 )	\$ 1,763
	1,898	(617 )	1,281	1,929	(579 )	1,350

C u s t o m e r relationships						
D e v e l o p e d technology	1,206	(696 )	510	1,226	(667 )	559
Total	\$ 13,918	\$ (10,484 )	\$ 3,434	\$ 13,982	\$ (10,310 )	\$ 3,672

As of April 1, 2011 the gross carrying amount of amortizable intangible assets decreased by \$64,000 due to changes in the foreign exchange rate.

STAAR SURGICAL COMPANY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
April 1, 2011  
(Unaudited)

Note 7 – Other Current Liabilities

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

	April 1, 2011	December 31, 2010
Accrued salaries and wages	1,912	\$ 2,121
Accrued audit fees	290	417
Customer credit balances	578	566
Accrued bonuses	409	751
Accrued income taxes	140	147
Accrued insurance	459	422
Accrued severance	421	570
Other	1,126	1,519
	\$ 5,335	\$ 6,513

Note 8 – Pension Plans

The following table summarizes the components of net periodic pension cost recorded for the Company's defined benefit pension plans (in thousands):

	Three Months Ended April 1, 2011	Three Months Ended April 2, 2010
Service cost	\$ 140	\$ 139
Interest cost	34	33
Expected return on plan assets	(26 )	(23 )
Amortization of unrecognized transitional obligation	4	—
Recognized actuarial (gain) loss	(6 )	14
	\$ 146	\$ 163

During the three months ended April 1, 2011, the Company made cash contributions totaling approximately \$68,000 to its Swiss pension plan and expects to make additional cash contributions totaling approximately \$203,000 during the remainder of 2011. The Company is not required to and does not make contributions to its Japan pension plan. Benefits are paid from operating cash flows and were not material during the quarter ended April 1, 2011.

Note 9 — Lines of Credit and Capital Lease Obligations

Lines of Credit

The Company's Japanese subsidiary, STAAR Japan, has an agreement, as amended on June 30, 2009, with Mizuho Bank which provides for borrowings of up to 300,000,000 Yen (approximately \$3.6 million based on the rate of exchange on April 1, 2011), at an interest rate equal to the Tokyo short-term prime interest rate (approximately

1.475% as of April 1, 2011) plus 1.125% and may be renewed annually (the current line expires on April 2, 2012). The credit facility is not collateralized. The Company had 200,000,000 Yen outstanding on the line of credit as of April 1, 2011 and December 31, 2010, (approximately \$2.4 million and \$2.5 million based on the foreign exchange rates on April 1, 2011 and December 31, 2010) which approximates fair value due to the short-term maturity and market interest rates of the line of credit. In case of default, the interest rate will be increased to 14% per annum. As of April 1, 2011, 100,000,000 Yen (approximately \$1.2 million based on the rate of exchange on April 1, 2011) of the line was available for borrowing.

In August 2010, the Company's wholly-owned Swiss subsidiary, STAAR Surgical AG, entered into a credit agreement with Credit Suisse (the "Bank"). The credit agreement provides for borrowings of up to 1,000,000 Swiss Francs (\$1,091,000 at the rate of exchange on April 1, 2011), to be used for working capital purposes. Accrued interest and 0.25% commissions on average outstanding borrowings is payable quarterly and the interest rate will be determined by the Bank based on the then prevailing market conditions at the time of borrowing. The credit agreement is automatically renewed on an annual basis based on the same terms assuming there is no default. The credit agreement may be terminated by either party at any time in accordance with its general terms and conditions. The credit facility is not collateralized and contains certain conditions such as providing the Bank with audited financial statements annually and notice of significant events or conditions as defined in the credit agreement. The Bank may also declare all amounts outstanding to be immediately due and payable upon a change of control or a "material qualification" in STAAR Surgical AG's independent auditors' report. There were no borrowings outstanding as of April 1, 2011 and the full amount of the line was available for borrowing.

STAAR SURGICAL COMPANY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
April 1, 2011  
(Unaudited)

### Capital Lease Obligations

The Company leases certain property, plant, and equipment under non-cancelable capital lease agreements. These leases vary in amount, duration, and rates.

Estimated future minimum payments under capital lease obligations are as follows (in thousands):

Fiscal Year	April 1, 2011	December 31, 2010
2011	\$ 857	\$ 938
2012	763	763
2013	627	627
2014	68	68
2015	36	36
Thereafter	—	—
<b>Total minimum lease payments</b>	<b>\$ 2,351</b>	<b>\$ 2,432</b>
Less: interest	(609 )	(598 )
<b>Total lease obligation</b>	<b>\$ 1,742</b>	<b>\$ 1,834</b>
<b>Current</b>	<b>\$ 388</b>	<b>\$ 431</b>
<b>Long-term</b>	<b>\$ 1,354</b>	<b>\$ 1,403</b>

Borrowings available under the Company's lease lines of credit with Farnam Street Financial are approximately \$268,000. See Note 10, Notes Payable, to the consolidated financial statements accompanying the 2010 Form 10-K for additional information regarding the Company's capital lease agreements.

### Covenant Compliance

The Company is in compliance with the covenants of its credit facilities as of the date of this report.

### Note 10 — Basic and Diluted Income Per Share

The following table sets forth the computation of basic and diluted net income per share (in thousands except per share amounts):

	Three Months Ended	
	April 1, 2011	April 2, 2010 (Note A)
<b>Numerator:</b>		
Net Income	\$ 300	\$ 3,530
<b>Denominator:</b>		
	35,307	34,789

Weighted average common shares and denominator for basic calculation:

Weighted average common shares outstanding		
Less: Unvested restricted stock	(119 )	(39 )
Denominator for basic calculation	35,188	34,750

Weighted average effects of dilutive equity-based compensation awards:

Employee stock options	785	—
Warrants	416	—
Denominator for diluted calculation	36,389	34,750

Net income per share – basic	\$ 0.01	\$ 0.10
Net income per share - diluted	\$ 0.01	\$ 0.10



STAAR SURGICAL COMPANY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
April 1, 2011  
(Unaudited)

Note A: For 2010, although the Company reported net income as a result of the gain on sale of Domilens, it used the net loss from continuing operations as the control number in determining whether including potential common shares in the diluted income per share calculation would be dilutive or anti-dilutive.

The following table sets forth (in thousands) the weighted average number of options and warrants to purchase shares of common stock, restricted stock and preferred stock which were not included in the calculation of diluted per share amounts because the effects would be anti-dilutive.

	Three Months Ended	
	April 1, 2011	April 2, 2010
Options and restricted stock	1,167	3,876
Warrants	70	1,470
Preferred Stock	—	1,700
Total	1,237	7,046

Note 11 — Comprehensive Income

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

	Three Months Ended	
	April 1, 2011	April 2, 2010
Net income	\$ 300	\$ 3,530
Other comprehensive income (loss):		
Minimum pension liability adjustment	(15 )	3
Foreign currency translation adjustment	(306 )	(2,297 )(1)
Comprehensive loss	(321 )	(2,294 )
Total comprehensive income (loss)	\$ (21 )	\$ 1,236

(1) Includes \$2,256 related to the sale of Domilens.

Note 12 — Geographic and Product Data

The Company reports segment information in accordance with ASC 280, "Segment Reporting". Under ASC 280 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 more than 50 countries and has manufacturing sites in the United States, Switzerland and Japan. Other than the United States, Japan, Korea, and China, 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 is set forth below (in thousands):

	Three Months Ended	
	April 1, 2011	April 2, 2010
United States	\$ 3,533	\$ 4,022
Japan	4,090	3,503
Korea	1,384	1,486
China	1,033	855
Other*	4,809	3,912
Total	\$ 14,849	\$ 13,778

STAAR SURGICAL COMPANY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
April 1, 2011  
(Unaudited)

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 intraocular lenses ("IOLs") used in cataract surgery and implantable Collamer lenses ("ICLs") used in refractive surgery. The composition of the Company's net sales by product line is as follows (in thousands):

	Three Months Ended	
	April 1, 2011	April 2, 2010
IOLs	\$ 7,129	\$ 6,877
ICLs	6,889	5,860
Other Surgical Products	831	1,041
Total	\$ 14,849	\$ 13,778

The Company sells its products internationally, which subjects the Company to several potential risks, including fluctuating foreign currency exchange rates (to the extent the Company's transactions are not in U.S. dollar), regulation of fund transfers by foreign governments, United States and foreign export and import duties and tariffs, and political instability.

Note 13 — Commitments and Contingencies

On May 24, 2010, STAAR accrued \$700,000 in executive termination benefit costs in connection with the notice of non-renewal given under an executive employment agreement. This accrual represents STAAR's current best estimate of the contractual termination benefits due to the former executive. The actual amount ultimately paid to the former executive may be different than the amount estimated. These costs are expected to be paid out to the former executive over the 15 month period beginning August 27, 2010, which included a three-month period during which the executive remained employed but had no further obligation to perform his duties as an executive. As of April 1, 2011, accrued severance was approximately \$400,000.

Note 14 — Stock-Based Compensation

The cost that has been charged against income for stock-based compensation is set forth below (in thousands):

	Three Months Ended	
	April 1, 2011	April 2, 2010
Stock-based compensation expense	\$ 270	\$ 248
Restricted stock expense	96	34
Consultant compensation	(11 )	29
Total	\$ 355	\$ 311

There was no net 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 \$35,000 and \$23,000 of stock compensation to inventory for the three months ended April 1, 2011 and April 2, 2010, respectively, and recognizes those amounts as expense in Cost of Sales as the inventory is sold.



STAAR SURGICAL COMPANY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

April 1, 2011

(Unaudited)

### 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”). On May 19, 2010, the stockholders of STAAR approved the Restated 2003 Omnibus Plan, which increased the number of shares available for grants under the plan by 2,000,000 shares and extended the term of the plan to May 18, 2020. As of April 1, 2011, there were 1,896,529 shares authorized and available for grants under the Restated 2003 Omnibus Plan. 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, restricted stock and unrestricted share grants. 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). Pursuant to the plan, options for 3,538,139 shares were outstanding at April 1, 2011 with exercise prices ranging between \$0.95 and \$8.12 per share. Restricted stock grants under the 2003 Plan generally vest over a period of one, three or four years. There were 155,500 shares of restricted stock outstanding at April 1, 2011.

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. Pursuant to the plan, options for 7,000 shares were outstanding at April 1, 2011 with an exercise price of \$3.60 per share. 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. Pursuant to this plan, options for 25,100 shares were outstanding at April 1, 2011 with an exercise price of \$1.70 per share. No further awards may be made under this plan.

### Assumptions

The fair value of each option award is estimated on the date of grant using a Black-Scholes option valuation model applying 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. Options granted with a three-year vesting life during the three months ended April 1, 2011 and April 2, 2010 had an expected term of 5.49 and 5.60 years, respectively, and were derived from historical exercise and termination activity. The Company has calculated a 10.05% estimated forfeiture rate used in the model for fiscal year 2011 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.

	Three Months Ended	
	April 1, 2011	April 2, 2010
Expected dividend yield	0 %	0 %
Expected volatility	76.96 %	80.49 %

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

Risk-free interest rate	2.01	%	2.35	%
Expected term (in years)	5.49		5.60	

A summary of option activity under the Plans as of April 1, 2011 is presented below:

Options	Shares (000's)	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term	Aggregate Intrinsic Value (000's)
Outstanding at December 31, 2010	3,331	\$ 4.35		
Granted	424	5.49		
Exercised	(160 )	3.78		
Forfeited or expired	(25 )	3.42		
Outstanding at April 1, 2011	3,570	\$ 4.52	6.70	\$ 6,253
Exercisable at April 1, 2011	2,438	\$ 4.34	5.41	\$ 4,916

STAAR SURGICAL COMPANY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

April 1, 2011

(Unaudited)

The weighted-average grant-date fair value of options granted during the three months ended April 1, 2011 and April 2, 2010 was \$3.59 and \$2.36 per option. The total fair value of options vested during the three months ended April 1, 2011 and April 2, 2010 was \$285,049 and \$285,000, respectively. There were 160,165 options exercised with an intrinsic value of \$333,215 during the three months ended April 1, 2011 and no options were exercised during the three months ended April 2, 2010.

A summary of the status of the Company's non-vested shares as of April 1, 2011 and changes during the period is presented below:

	Shares (000's)	Weighted- Average Grant Date Fair Value
Nonvested Shares		
Nonvested at December 31, 2010	885	\$ 2.89
Granted	424	3.59
Vested	(152 )	1.87
Forfeited	(25 )	3.58
Nonvested at April 1, 2011	1,132	\$ 3.27

As of April 1, 2011, there was \$3.0 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plans. That cost is expected to be recognized over a weighted-average period of 1.63 years.

Note 15 — Supplemental Disclosure of Cash Flow Information

Interest paid was \$153,757 and \$552,000 for the three months ended April 1, 2011 and April 2, 2010, respectively. Income taxes paid amounted to approximately \$30,245 and \$583,000 for the three months ended April 1, 2011 and April 2, 2010, respectively.

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

	April 1, 2011	April 2, 2010
Non-cash investing and financing activities:		
Assets obtained by capital lease	\$ 36	\$ —
Disposal of Domilens transaction costs included in accounts payable	—	273

Note 16 — New Accounting Pronouncements

During the three months ended April 1, 2011, there were no new accounting pronouncements that would have had a material effect on our unaudited condensed consolidated financial statements. For a description of recent accounting pronouncements relevant to us, please refer to "Recent Accounting Pronouncements" included in Note 1 of our Annual Report on Form 10-K for the year ended December 31, 2010.

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 we believe that the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risks and STAAR 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 STAAR. These factors include, without limitation, those described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010 under the heading “Risk Factors.” STAAR 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.



STAAR SURGICAL COMPANY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

April 1, 2011  
(Unaudited)

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

#### Overview

STAAR Surgical Company designs, develops, manufactures and sells implantable lenses for the eye. We are the world's leading manufacturer of phakic intraocular lenses used in corrective or "refractive" surgery, and we also make lenses for use in surgery that treats cataracts. All of the lenses we make are foldable, which permits the surgeon to insert them through a small incision in minimally invasive surgery. Cataract surgery is a relatively common outpatient procedure where the eye's natural lens is removed and replaced with an artificial lens called an intraocular lens (IOL) to restore the patient's vision. Refractive surgery is performed to correct the type of visual disorders that have traditionally been treated with glasses or contact lenses. We refer to our lenses used in refractive surgery as "implantable Collamer® lenses" or "ICLs" and sell them under the Visian® brand name. The field of refractive surgery includes both lens-based procedures, using products like the Visian ICL, and laser-based procedures like LASIK. Successful refractive surgery can correct common vision disorders such as myopia, hyperopia and astigmatism.

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

STAAR Surgical Company, Visian®, Collamer®, STAARVISC®, Elastimide®, nanoFLEX™, nanoPOINT™, Epiphany™ and AquaFlow™ are trademarks or registered trademarks of STAAR in the U.S. and other countries.

Collamer® is the brand name for STAAR's proprietary collagen copolymer lens material.

#### Background Regarding Our Business

A detailed description of STAAR's business appears in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010, along with a glossary explaining many of the specialized terms used in describing our products and our business. We recommend that readers unfamiliar with STAAR refer to that description.

IOLs - Intraocular Lenses for Cataract Surgery. We generate approximately half of our sales by manufacturing and selling foldable IOLs for use in minimally invasive cataract surgery. Our range of IOLs includes the following:

- Aspheric IOLs, available in silicone and in Collamer®, STAAR's proprietary biocompatible collagen copolymer lens material. Aspheric IOLs are designed to provide a clearer image than earlier spherical IOL designs.
- The nanoFLEX IOL, a single-piece Collamer aspheric IOL that can be implanted through a 2.2 mm incision with the nanoPOINT injector system.
- The Preloaded Injector, a three-piece silicone or acrylic IOL preloaded into a single-use disposable injector and currently available outside the U.S. The acrylic Preloaded Injector uses an acrylic lens sourced from another manufacturer.

- The silicone Toric IOL, used in cataract surgery to treat preexisting astigmatism. Astigmatism is a condition that causes blurred vision due to the irregular shape of the cornea which prevents light from focusing properly on the retina.

Because most cataract patients are elderly, government agencies or government sponsored entities generally pay the cost of IOLs in our major markets, including the U.S. As a result, IOL revenues will likely remain relatively stable even under adverse conditions in the general economy. However, changes in reimbursement policy under these agencies and entities can adversely affect our selling prices or reduce the volume of cataract procedures.

Sales of IOLs during the three months ended April 1, 2011 were \$7.1 million, compared to \$6.9 million for the same period in the prior year, and represented approximately 48% of total net sales in the three-month period

STAAR SURGICAL COMPANY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

April 1, 2011

(Unaudited)

Visian Implantable Collamer Lenses. Made from our proprietary biocompatible Collamer material, STAAR's VISIAN ICL and VISIAN Toric ICL, or TICL™, treat refractive disorders such as myopia (near-sightedness), hyperopia (far-sightedness) and astigmatism. The surgeon implants the foldable Visian lens through a tiny incision, under topical anesthesia. STAAR began selling the Visian ICL outside the U.S. in 1996 and inside the U.S. in 2006. STAAR began selling the Visian TICL outside the U.S. in 2002. STAAR's goal is position of the ICL and TICL throughout the world as primary choices for refractive surgery.

Sales of ICLs during the three months ended April 1, 2011 were \$6.9 million compared to \$5.9 million for the same period in the prior year, representing approximately 46% of total net sales in the three-month period.

Other Surgical Products. We also sell other instruments, devices, and equipment used in cataract or refractive surgery, which we either manufacture or have manufactured for us. However, we have been deemphasizing these products since 2009 because of their lower overall gross profit margins. We also make the AquaFlow Collagen Glaucoma Drainage Device, an implantable device used for surgical treatment of glaucoma.

Sales of other surgical products during the three months ended April 1, 2011 were \$0.8 million compared to \$1.0 million for the same period in the prior year, representing approximately 6% of total net sales in the three month period.

#### Operations

STAAR has significant operations both within and outside the U.S. Sales from activities outside the U.S. accounted for about 76% of our total sales for the quarter ended April 1, 2011. STAAR operates its global administrative headquarters and a manufacturing facility in Monrovia, California. STAAR operates an administrative, manufacturing and distribution facility in Nidau, Switzerland under its wholly owned subsidiary, STAAR Surgical AG. STAAR operates administrative, manufacturing and distribution facilities in Chiba Prefecture, Japan under its wholly owned subsidiary, STAAR Japan Inc.

The global nature of STAAR's business operations subjects it to risks, including the effect of changes in currency exchange rates, differences in laws, including laws protecting intellectual property and regulating medical devices, political risks and the challenge of managing foreign subsidiaries.

#### Strategy and Key Operational Metrics

STAAR's strategy is to be valued as a leading global provider of innovative intraocular lens system technologies. STAAR will employ a focused commercialization strategy which enables sustainable profitable growth.

STAAR's key operational metrics in 2011 are guided by two overriding strategic goals: to achieve and maintain profitability and to lay the groundwork for further growth. In pursuit of these goals, STAAR has aligned its principal business initiatives during 2011 along the following four key operational metrics, which STAAR plans to use to gauge its progress during the year:

- Increase total revenue by double-digits.

- Grow Visian ICL and TICL sales by 25%.
- Continuously increase gross profit margin each quarter so as to finish the year at 66%.
- Achieve profitability in at least three of the four quarters of 2011, and for the full year.

Increase total revenue by double digits. During 2010 STAAR's total revenue increased by 8% and its revenue from sales of core products – IOLs and ICLs – increased by 10%. In the first quarter of 2011, STAAR achieved growth of 8% in total revenue and 10% in core product revenue. As STAAR continues to de-emphasize its less profitable non-core products, it is targeting double digit growth in total revenue during 2011. Achieving this goal will require continued strong growth in sales of our core products, especially ICLs. We have established a specific metric for ICL sales, as described below.

Grow Visian ICL and TICL sales by 25%. During 2010, global sales of Visian ICLs and TICLs increased by 16%. STAAR has set a goal of increasing this growth rate to 25% for fiscal year 2011. In the first quarter, we achieved a level of 18% growth, with growth of 26% outside the U.S., partially offset by a 7% decrease in the U.S. Over the past two years, Visian sales have followed a pattern of slow or negative growth in the U.S. but strong growth outside the U.S. Because Visian products are used in elective surgery, the rate of sales growth depends on continued improvement in global economic conditions. We discuss recent trends in Visian sales in greater detail below under the heading Visian ICL and TICL sales.

STAAR SURGICAL COMPANY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

April 1, 2011  
(Unaudited)

Continuously expand gross profit margin each quarter so as to finish the year at 66%. STAAR's gross profit margin for the first quarter of 2011 was 64.8%. STAAR is targeting a level of 66% by the fourth quarter of 2011. While cost savings have contributed to improving margins, the biggest factor has been the change in our product mix. Visian products yield a significantly higher profit margin than IOLs. Among IOLs, STAAR has increased average selling prices by emphasizing sales of its higher value IOLs, such as nanoFLEX and our Toric IOL. Preloaded IOL sales in some territories, especially Japan, have historically yielded good profit margins and their sales increased during the first quarter. Since 2009 STAAR has de-emphasized lower margin sales of non-IOL, non-ICL products.

Achieve profitability in at least three of the four quarters of 2011, and for the full year. STAAR achieved net earnings of \$0.3 million, or \$0.01 per share, in the first quarter of 2011, marking the first quarter since 1999 during which STAAR has reported net income from continuing operations. While STAAR also had net earnings in the first quarter and full year for 2010, those earnings were derived from the proceeds of selling Domilens, our German distribution subsidiary, and in those periods STAAR reported losses from its continuing operations, that is, from the non-Domilens portion of its business. STAAR believes that its achievement of net income from continuing operations represents a turning point for the company and enhances its prospects for achieving the goal of profitability in at least three quarters of 2011 and for the full year. We caution that STAAR has just crossed the threshold of profitability, and sustained profitability remains vulnerable to the competitive nature of our industry and to the risk factors described in our Annual Report on Form 10-K.

#### Other Highlights

##### Global Visian ICL and TICL Sales

STAAR continues to focus its Visian marketing and sales efforts in the key territories where it has established significant market share, based on the success of this strategy in 2009 and 2010. The key territories in which STAAR is currently seeking to enhance Visian sales are the U.S., Japan, Korea, China, India, Italy, Middle East, Germany, U.K., and Latin America.

Since 2009, STAAR has experienced a breakthrough in market penetration in Korea, where it believes implants of Visian products have exceeded 12% of the total volume of refractive surgery procedures. Revenues from sales of Visian ICL products in Korea decreased 7% in the first quarter of 2011 following an increase of 13% during 2010 over 2009. Because of the rapid growth of Visian ICL sales and market share in Korea, STAAR is using Korea as a model of best practices for marketing that may serve to significantly increase market share in other key territories. Territories where Visian products experienced significant growth in the first quarter of 2011 over prior year were China, Japan, Germany, the Middle East and India.

In September 2010, STAAR launched version V4b of the Visian product line, which offers an expanded range of correction, in territories that recognize the CE Mark. The expanded range includes ICLs with lower levels of myopia correction in quarter-diopter increments, Toric hyperopic ICLs to treat astigmatism and far-sightedness, and Toric ICLs in the low to zero range of myopia to treat patients primarily affected by astigmatism. These product line extensions more than double the number of patients who could benefit from Visian products in Europe and other territories that accept the CE Mark. In the first quarter of 2011, approximately 8% of the V4b sales in the markets in which it is available were in the new expanded treatment range.

Late in April, 2011, STAAR received CE Mark approval for the new V4c version of the myopic ICL and myopic Toric ICL. The V4c design incorporates a proprietary port in the center of the ICL optic of a size determined to optimize the flow of fluid within the eye, and eliminates the need for the surgeon to perform a YAG peripheral iridotomy procedure days before the ICL implant. STAAR believes that V4c represents a significant advance in the commercial appeal of the Visian ICL: by simplifying the ICL procedure and increasing patient comfort the V4c makes the implantation experience closer to LASIK and should attract new surgeons and patients to the product. STAAR plans to make a limited pre-release of V4c before its full launch of the product in countries that accept the CE Mark. In some key markets of the Asia Pacific region where STAAR has not yet introduced the V4b, STAAR plans to seek approval of the V4c and to move directly to that model.

STAAR is currently seeking approval of the TICL in the U.S. and Japan.

STAAR SURGICAL COMPANY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
April 1, 2011  
(Unaudited)

STAAR's ability to maintain or accelerate the rate of growth in Visian ICL sales will partly depend on continued improvement in worldwide economic conditions and progress with regulatory agencies. ICL surgery is a relatively expensive elective procedure and is seldom reimbursed by insurers or government agencies. STAAR believes that the global recession reduced overall demand for refractive surgery particularly in the U.S., and it has been reported that consumer spending and consumer confidence has not returned to pre-recession levels.

Following the February 2, 2010 approval of the ICL in Japan, Japan was added to our list of targeted territories based on its potential market share. Japan has a higher prevalence rate of myopia than other countries, which makes it a promising new market, and ICL sales in the first quarter of 2011 were 275% above prior year on a smaller base. The Japan Earthquake and tsunami, which devastated parts of northeastern Japan on March 11, 2011, has disrupted the Japanese economy and may have a prolonged effect on consumer attitudes as Japanese society focuses on rebuilding and relief for the survivors of the disaster. We may therefore experience delay in realizing the full potential for the Visian ICL in the Japanese market. The aftereffects of the earthquake and tsunami have not significantly affected other aspects of our business, as described below under the heading Effect of Earthquake on Japan Operations.

#### U.S. Visian ICL Sales

We consider Visian ICL sales growth in the U.S. market important because of the size of the U.S. refractive surgery market and the perceived worldwide leadership of the U.S. in adopting innovative medical technologies. The Visian ICL was approved by the FDA for treatment of myopia on December 22, 2005.

U.S. sales of ICLs declined by 7% in the first quarter compared to prior year. This decline was due to a 60% decline in sales to military facilities. Sales in the private segment increased by 12% in the quarter which compares very favorably to the Market Scope estimates for total refractive procedures in the US market which it anticipates will increase year over year by only 5% in the quarter. STAAR believes that the increase in U.S. private sector purchases of ICLs in the first quarter results from small improvements in general economic conditions and consumer confidence. If expected improvements occur in the economy, and overall refractive procedures volume experiences the predicted increase, STAAR could see further growth in private sector ICL sales in the U.S.

STAAR believes that the drop in military sales resulted from changes in military medical staff, including the effect of retirement and redeployment, and these effects are likely short term. Surgeons affiliated with the U.S. Army have noted the benefits of the Visian ICL and have presented data based on military experience showing that ICL provides superior visual outcomes to LASIK, even in younger patients with relatively lower levels of myopia.

STAAR believes that the FDA's scrutiny of patient satisfaction levels following laser refractive surgery, which began in 2008, has affected the overall U.S. market for refractive surgery. The negative publicity generated by that regulatory activity continued in 2010 after a former FDA official publicly petitioned FDA to revoke its approval of LASIK. Patient concerns about LASIK could increase interest in the Visian ICL as an alternative for patients who have a greater risk of complications from LASIK. The fact that the Visian ICL is removable if a patient is dissatisfied with the outcome may also be appealing to some patients with new concerns about risks of refractive surgery. However, STAAR believes in the short term the negative publicity concerning LASIK has decreased patient interest in all refractive surgery, including Visian ICL. Because nearly all candidates for refractive surgery can achieve acceptable vision through the use of spectacles or contact lenses, for most patients the decision to have refractive surgery is a lifestyle choice that depends on high confidence in achieving a satisfactory outcome.

In addition to poor conditions in the general economy, in particular the refractive surgery market, and negative publicity concerning LASIK, other challenges to resumed growth in U.S. Visian ICL sales include the following:

- the U.S. refractive surgery market has been dominated by corneal laser-based techniques, which continue to be better known than the Visian ICL among potential refractive patients;
- other newly introduced surgical products will continue to compete with the Visian ICL for the attention of surgeons seeking to add new, high value surgical products, in particular multifocal and accommodating IOLs; and
- the fact that FDA approval of the TICL has not yet been obtained, which STAAR sells in 45 international markets for treating patients affected by both myopia and astigmatism.



STAAR SURGICAL COMPANY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

April 1, 2011  
(Unaudited)

To help address these challenges, since the fourth quarter of 2010 STAAR has been testing a direct-to-consumer advertising campaign on the internet and has initiated a test campaign in movie theaters in selected markets. During the second quarter test campaign are planned on cable and network television. This campaign seeks to increase potential refractive patient visits and to encourage patients to inquire specifically about the Visian ICL by distinguishing it from other refractive treatments. The current materials for the campaign are a series of humorous videos contrasting the Visian ICL with LASIK, eyeglasses and contact lenses. The videos highlight certain benefits of the ICL over other treatments, including clarity of vision, absence of surgically induced dry eye, removability and ultraviolet protection. We are assessing the data obtained to date to determine whether, and in what form, to launch a broader direct-to-consumer campaign.

Global IOL Sales.

STAAR pioneered the development of folding lenses for use in cataract surgery, and IOLs continue to represent about half of STAAR's business. During the first quarter of 2011, worldwide IOL sales was \$7.1 million, or 3.7%, over the same period last year. However, \$0.5 million of this increase resulted from changes in currency exchange rates.

Late in April, 2011, STAAR received CE Mark approval for its nanoFLEX Collamer Single Piece IOL which can be injected through a 2.2 mm incision with the nanoPOINT™ Injector System. nanoFLEX has been STAAR's fastest growing IOL product in U.S. markets and STAAR believes the lens has the capability of becoming the first Collamer IOL to receive broad commercial acceptance outside the U.S. STAAR hopes that the biocompatibility and outstanding optical properties of Collamer, with which surgeons have become acquainted through the ICL, will build interest in the nanoFLEX IOL worldwide. STAAR's Collamer Accommodating Study Team (CAST) used the nanoFLEX lens in its 2009 tests and reported promising assessments regarding initial intermediate and near vision results. These properties of nanoFLEX may also spur interest in the lens in new markets, especially among surgeons seeking an IOL for monovision treatment.

Among STAAR's initiatives to grow its IOL business are the following:

- we plan to seek further approvals for the nanoFLEX in an effort to build a global product franchise for Collamer IOLs;
- we are seeking approval to introduce the silicone Preloaded Injector in the U.S. market to enhance our U.S. IOL offering and help STAAR maintain or increase its market share in the silicone IOL segment;
- we plan to introduce a new version of the hydrophobic acrylic Preloaded Injector, featuring the popular single-piece IOL format, into international markets in 2011;
- we plan to introduce a preloaded injector for the nanoFLEX in 2012;
- we are developing a Collamer Toric IOL on the nanoFLEX platform to complement our pioneering silicone Toric IOL and better compete with the Alcon acrylic Toric IOL; and
- we are researching accommodating and/or multifocal designs that exploit the unique optical properties of the Collamer material.

STAAR cautions that the successful development and introduction of new products is subject to risks and uncertainties, including the risk of unexpected delays and, in some cases, approval of regulatory authorities.

In the first quarter of 2010 STAAR initiated a program called the “nanoFLEX challenge” to facilitate an interest in surgeon’s evaluation of the visual outcomes for patients receiving nanoFLEX IOLs compared to the outcomes from any other standard IOL currently used by the surgeon. STAAR believes that its marketing efforts, along with the features and benefits of the nanoFLEX lens and nanoPOINT injector system, are responsible for the product’s 20% sales growth in the U.S. during 2010. Notwithstanding the slower rate of growth in the first quarter of 2011, STAAR believes the product is capable of winning additional market share in the future.

STAAR’s efforts to increase U.S. IOL sales face a number of short and long-term challenges, including successfully meeting its objectives to develop new and enhanced products and marketing them with limited resources. The U.S. IOL market has recently become more fragmented with the entry of new competitors, including Hoya Surgical Optics and Lenstec, Inc., resulting in greater competition for market share. We cannot assure that our efforts will ultimately be successful.

STAAR SURGICAL COMPANY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

April 1, 2011  
(Unaudited)

**Effect of Earthquake on Japan Operations.** On March 11, 2011, a 9.0 magnitude earthquake struck northeastern Japan, followed by a tsunami that devastated the region's coastal communities. The earthquake and tsunami have not materially affected the business of STAAR Japan, which has its facilities in the greater Tokyo area in Urayasu City and Ichikawa City, Chiba Prefecture. STAAR Japan's staff and their immediate families suffered no serious injuries. STAAR's manufacturing facilities suffered only minor damage and resumed operations on Wednesday, March 16, 2011. STAAR Japan is monitoring its products for radioactivity and certifying for export that they are unaffected by the radioactive material released from the damaged Fukushima Dai-Ichi nuclear power plant following the earthquake and tsunami.

To date, STAAR's Japan's revenues and its domestic IOL and ICL business have not been harmed by the disaster. Revenues in the first quarter were 12.3% higher than prior year, and revenues in March, the month of the earthquake, were 12.9% higher than March, 2010. STAAR attributes the remarkable continuity of its Japanese business to the extraordinary efforts of its employees in Japan.

Like other businesses in Japan, STAAR faces the following challenges as the country recovers from the disaster:

- transportation and other infrastructure have not returned to pre-earthquake levels;
- our supply chain may be interrupted;
- Manufacturing and surgical procedures must be scheduled with rolling power blackouts in mind;
- Releases of radiation from damaged nuclear reactors may continue, which could affect our product or harm the general reputation of Japanese products for export; and
- Japanese consumers who are potential patients for refractive surgery may feel constrained from making such purchases while significant parts of the country continue to be affected by the disaster.

**Status of U.S. TICL Submission.** STAAR submitted a Pre-Market Approval Application (PMA) supplement for the TICL to the FDA on April 28, 2006, which the agency has designated as a panel-track supplement. In August 2007, following negative inspectional observations and a Warning Letter from FDA's Division of Bioresearch Monitoring ("BIMO"), the FDA Office of Device Evaluation placed an integrity hold on STAAR's TICL application. Over a two-year period STAAR took a number of corrective actions to address BIMO's concerns and to remove the integrity hold, including engaging an independent third party to conduct a 100% audit of patient records in the TICL clinical study, along with an audit of clinical systems to ensure accuracy and completeness of data before resubmitting the application. On July 21, 2009, the FDA notified STAAR that as a result of STAAR's corrective actions the FDA had removed the integrity hold on our application for approval of the TICL, and would resume its consideration of the application. During August and September 2009, the agency and STAAR resolved a number of questions related to the TICL supplement in an interactive process. On February 3, 2010, STAAR received a letter of deficiency from the FDA outlining additional questions. On August 2, 2010 the Company responded to the FDA's deficiency letter. Since that response, STAAR has been in dialogue with the agency, working interactively to resolve a series of follow-up questions. On April 22, 2011, STAAR responded to the most recent questions from the agency, which concerned the basis for an increase in the number of reported patient follow-up visits following the independent third party audit of the clinical data. STAAR cannot predict when, or if, the FDA may grant approval of the Visian Toric

ICL.

Status of Japan TICL Submission. On February, 2, 2010, Japan's Ministry of Health, Labor and Welfare (MHLW) approved the sale of the Visian ICL. STAAR submitted a partial change application for approval of the Visian Toric ICL to the Pharmaceuticals and Medical Device Agency (PMDA) on April 9, 2010. While STAAR did receive initial comments within approximately two months of submission, MHLW generally requires approximately one year to eighteen months to fully process a partial change application. That timeline can change based on the nature of the product under review. The Company does not anticipate approval in 2011.

STAAR SURGICAL COMPANY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

April 1, 2011

(Unaudited)

**Change in Australian Distribution.** Until the first quarter of 2011, STAAR distributed its products in Australia through a wholly owned subsidiary, ConceptVision Australia Pty Ltd. On March 9, 2011, STAAR entered into a distribution agreement with independent distributor Ellex Australia, providing for the exclusive distribution of STAAR IOLs and ICLs in Australia and New Zealand. In connection with the transaction Ellex purchased the inventory of ConceptVision for approximately \$400,000. STAAR has closed all operations of ConceptVision.

#### Critical Accounting Policies

Management's Discussion and Analysis of Financial Condition and Results of Operations are based on our unaudited Condensed Consolidated 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 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 April 1, 2011 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 31, 2010.

#### Results of Operations

The following table shows the percentage of our total sales represented by the specific items listed in our statements of operations for the periods indicated, and the percentage by which these items increased or decreased over the prior period.

	Percentage of Net Sales for		Percentage
	Three Months		Change for
	April 1,	April 2,	Three
	2011	2010	Months
			2011
			vs. 2010
Net sales	100.0 %	100.0 %	7.8 %
Cost of sales	35.2	35.9	5.5
Gross profit	64.8	64.1	9.1
General and administrative	23.7	24.6	4.2
Marketing and selling	30.0	27.8	16.5

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

Research and development	9.6	11.1	(6.7 )
Operating income	1.5	0.6	— *
Other income (expense), net	2.7	(3.0 )	— *
Income (loss) before provision for income taxes	4.2	(2.4 )	— *
Provision for income taxes	2.0	2.2	1.6
Income (loss) from continuing operations	2.2	(4.6 )	— *
Income from discontinued operations, net of taxes	—	30.2	(100.0 )
Net income	2.2 %	25.6 %	(91.5 )%

\* Denotes change is greater than +100%.

STAAR SURGICAL COMPANY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

April 1, 2011

(Unaudited)

#### Net Sales

Net sales for the three months ended April 1, 2011 were \$14.8 million, an increase of approximately 7.8% compared with \$13.8 million reported during the same period of 2010. The increase in net sales was due to a 10.1% increase in our core product sales (IOL and ICL). Core product sales represented 94.4% of total net sales compared with 92.4% in the first quarter of 2010. Changes in currency had a \$0.5 million favorable impact on net sales for the first quarter of 2011.

Total IOL sales for the three months ended April 1, 2011 were \$7.1 million, an increase of 3.7% compared with \$6.9 million for the same period of 2010. The increase in IOL sales is due to increased preloaded, nanoFLEX, and Toric IOL sales, partially offset by decreased spherical and three-piece aspheric IOL sales. IOL sales represent 48.0% and 49.9% of the sales for the three months ended April 1, 2011 and April 2, 2010.

Total ICL sales for the three months ended April 1, 2011 were \$6.9 million, an increase of 17.6% compared with \$5.9 million for the same period of 2010. The increase in ICL sales was primarily due to continued strong international sales in the following markets; China, Japan, Germany, the Middle East and India. ICL sales represent 46.4% and 42.5% of the sales for the three months ended April 1, 2011 and April 2, 2010.

#### Gross Profit

Gross profit for the first quarter was \$9.6 million, or 64.8% of revenue, compared with \$8.8 million, or 64.1% of revenue, in the prior year period. The increase in gross profit and gross profit margin was due to the 18% increase in ICL volume resulting in a higher mix of ICL's and within ICLs, an increased mix of Toric ICLs.

#### General and Administrative

General and administrative expenses for the quarter were \$3.5 million, an increase of 4.2% when compared with \$3.4 million reported last year. The increase is due primarily to an increase in bonus accruals partially offset by decreased legal fees.

#### Marketing and Selling

Marketing and selling expenses for the quarter were \$4.5 million, an increase of 16.5% when compared with \$3.8 million reported last year. The increase is primarily due to increased salaries and travel due to the timing of the ASCRS trade show which was held in the first quarter of 2011 and the second quarter of 2010.

#### Research and Development

Research and development expense for the quarter was \$1.4 million, a decrease of 6.7% when compared with \$1.5 million reported last year. The decrease is due to decreased costs in Japan, partially offset by increased regulatory costs of Toric ICL in the U.S.

#### Other Income/Expenses, Net

Other income, net was \$0.4 million compared with other expenses, net of \$0.4 million in the first quarter of 2010. This \$0.8 million favorable change compared to prior year quarter was principally due to a decrease in interest expense as a result of repayment of Broadwood note in 2010, foreign exchange gains recorded in first quarter of 2011 compared with exchange losses recorded during the first quarter of 2010 and an increase in the fair value of outstanding warrants during the first quarter of 2011 compared to prior year.

#### Liquidity and Capital Resources

The Company's liquidity requirements arise from the funding of its working capital needs, primarily inventory and accounts receivable. The Company's primary sources for working capital and capital expenditures are cash flows from operating activities, proceeds from the exercise of stock options, and borrowings under the Company's 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.



STAAR SURGICAL COMPANY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

April 1, 2011  
(Unaudited)

The Company believes its current cash balances coupled with cash flow from operating activities will be sufficient to meet its working capital requirements for the foreseeable future. STAAR's need for working capital, and the terms on which financing may be available, will depend in part on its degree of success in achieving and maintaining positive cash flow and earnings through the strategies described above under the caption "Strategy." STAAR cannot assure that such financing will be available on acceptable terms, if at all, if the need arises.

#### Overview of Changes in Cash and Cash Equivalents and Other Working Capital Accounts.

As of April 1, 2011 and December 31, 2010, the Company had \$10.4 million and \$9.5 million, respectively, of cash and cash equivalents and restricted cash.

Net cash provided by operating activities was \$0.6 million for the three months ended April 1, 2011, compared to \$1.4 million in net cash used by operating activities for the three months ended April 2, 2010 and consisted of net income of \$0.3 million, plus \$0.8 million in non-cash items, offset by \$0.5 million decrease in working capital. The increase in net cash provided by operating activities is due to the increase in net income from continuing operations and the reduction of accounts payable to normalized levels since the first quarter of 2010.

Net cash provided by investing activities was \$0.03 million for the three months ended April 1, 2011, compared with \$11.8 million for the three months ended April 2, 2010. Net cash provided by investing activities was mainly due to \$0.05 million in acquisitions of property, plant and equipment, \$0.02 million in proceeds from the sale of property, plant and equipment and a \$0.05 million decrease in other assets resulting from the return of deposits based on the Company's improved financial condition. The decrease in cash provided by investing activities is due to proceeds from the sale of a subsidiary received in the first quarter of 2010 that were not received in the first quarter of 2011.

Net cash provided by financing activities was \$0.5 million for the three months ended April 1, 2011, compared to net cash used in financing activities of \$0.3 million for the three months ended April 2, 2010 and consisted of \$0.6 million in proceeds from stock options, partially offset by \$0.1 million in capital lease repayments. The increase in net cash provided by financing activities was due to an increase in proceeds from the exercise of stock options and a decrease in the repayments of capital lease lines of credit.

#### Credit Facilities, Contractual Obligations and Commitments

##### Accrued Termination Benefits for Executive

On May 24, 2010, STAAR accrued \$700,000 in executive termination benefit costs in connection with the notice of non-renewal given under an executive employment agreement. This accrual represents STAAR's current best estimate of the contractual termination benefits due to the former executive. The actual amount ultimately paid to the former executive may be different than the amount estimated. These costs are expected to be paid out to the former executive over the 15 month period beginning August 27, 2010, which included a three-month period during which the executive remained employed but had no further obligation to perform his duties as an executive. The balance of accrued severance at April 1, 2011 was approximately \$400,000.

##### Lines of Credit

The Company's Japanese subsidiary, STAAR Japan, has an agreement, as amended on June 30, 2009, with Mizuho Bank which provides for borrowings of up to 300,000,000 Yen (approximately \$3.6 million based on the rate of exchange on April 1, 2011), at an interest rate equal to the Tokyo short-term prime interest rate (approximately 1.475% as of April 1, 2011) plus 1.125% and may be renewed annually (the current line expires on April 2, 2012). The credit facility is not collateralized. The Company had 200,000,000 Yen outstanding on the line of credit as of April 1, 2011 and December 31, 2010, (approximately \$2.4 million and \$2.5 million based on the foreign exchange rates on April 1, 2011 and April 2, 2010) which approximates fair value due to the short-term maturity and market interest rates of the line of credit. In case of default, the interest rate will be increased to 14% per annum. As of April 1, 2011, 100,000,000 Yen (approximately \$1.2 million based on the rate of exchange on April 1, 2011) of the line was available for borrowing.

STAAR SURGICAL COMPANY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
April 1, 2011  
(Unaudited)

In August 2010, the Company's wholly-owned Swiss subsidiary, STAAR Surgical AG, entered into a credit agreement with Credit Suisse (the "Bank"). The credit agreement provides for borrowings of up to 1,000,000 Swiss Francs (\$1,091,000 at the rate of exchange on April 1, 2011), to be used for working capital purposes. Accrued interest and 0.25% commissions on average outstanding borrowings is payable quarterly and the interest rate will be determined by the Bank based on the then prevailing market conditions at the time of borrowing. The credit agreement is automatically renewed on an annual basis based on the same terms assuming there is no default. The credit agreement may be terminated by either party at any time in accordance with its general terms and conditions. The credit facility is not collateralized and contains certain conditions such as providing the Bank with audited financial statements annually and notice of significant events or conditions as defined in the credit agreement. The Bank may also declare all amounts outstanding to be immediately due and payable upon a change of control or a "material qualification" in STAAR Surgical AG's independent auditors' report. There were no borrowings outstanding as of April 1, 2011 and the full amount of the line was available for borrowing.

#### Capital Lease Obligations

The Company leases certain property, plant, and equipment under non-cancelable capital lease agreements. These leases vary in amount, duration, and rates.

Estimated future minimum payments under capital lease obligations were as follows (in thousands):

Fiscal Year	April 1, 2011	April 2, 2010
2011	\$ 857	\$ 938
2012	763	763
2013	627	627
2014	68	68
2015	36	36
Thereafter	—	—
Total minimum lease payments	\$ 2,351	\$ 2,432
Less: interest	(609 )	(598 )
Total lease obligation	\$ 1,742	\$ 1,834
Current	\$ 388	\$ 431
Long-term	\$ 1,354	\$ 1,403

Borrowings available under the Company's lease lines of credit with Farnam Street Financial are approximately \$268,000. See Note 10, Notes Payable, to the consolidated financial statements accompanying the 2010 Form 10-K for additional information regarding the Company's capital lease agreements.

#### Covenant Compliance

The Company is in compliance with the covenants of its credit facilities as of the date of this report.

#### 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 31, 2010.

STAAR SURGICAL COMPANY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
April 1, 2011  
(Unaudited)

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our CEO and CFO, of the effectiveness of the design and operation of the disclosure controls and procedures of STAAR Surgical Company and its subsidiaries (the "Company"). Based on that evaluation, our CEO and CFO concluded, as of the end of the period covered by this quarterly report on Form 10-Q, that our disclosure controls and procedures were effective. For purposes of this statement, the term "disclosure controls and procedures" means controls and other procedures of the Company that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act (15 U.S.C. 78a et seq.) is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

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 or 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.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended April 1, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time the Company may be subject to various claims and legal proceedings arising out of the normal course of our business. These claims and legal proceedings may relate to contractual rights and obligations, employment matters, or claims of product liability. STAAR maintains insurance coverage for product liability claims. While the Company does not believe that any of the claims known is likely to have a material adverse effect on its financial condition or results of operations, new claims or unexpected results of existing claims could lead to significant financial harm.

ITEM 1A. RISK FACTORS

Information concerning certain risks and uncertainties appears in “Part I—Item 1A—Risk Factors” of the Company’s Form 10-K for the fiscal year ended December 31, 2010. You should carefully consider these risks and uncertainties before making an investment decision with respect to shares of our common stock. Such risks and uncertainties could materially adversely affect our business, financial condition or operating results.

During the period covered by this Quarterly Report, there have been no material changes from the risk factors previously disclosed in the Company’s Form 10-K for the fiscal year ended December 31, 2010 or filings subsequently made with the SEC.

STAAR SURGICAL COMPANY  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
April 1, 2011  
(Unaudited)

ITEM 6. EXHIBITS

- 3.1 Certificate of Incorporation, as amended to date.(1)
- 3.2 By-laws, as amended to date.(2)
- †4.2 1991 Stock Option Plan of STAAR Surgical Company.(4)
- †4.3 1998 STAAR Surgical Company Stock Plan, adopted April 17, 1998.(5)
- 4.4 Form of Certificate for Common Stock, par value \$0.01 per share.(6)
- †4.5 Amended and Restated 2003 Omnibus Equity Incentive Plan, and form of Option Grant and Stock Option Agreement.(3)
- †4.6 Form of Performance Accelerated Restricted Stock Purchase Agreement pursuant to the Amended and Restated 2003 Omnibus Equity Incentive Plan.
- 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 Annual Report on Form 10-K for the fiscal year ended December 28, 2007, as filed with the Commission on March 12, 2008.
  - (2) Incorporated by reference to 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 Quarterly Report on Form 10-Q for quarter ended July 2, 2010, filed with the Commission on August 11, 2010.
  - (4) Incorporated by reference to the Company's Registration Statement on Form S-8, File No. 033-76404, as filed with the Commission on March 11, 1994.
  - (5) Incorporated by reference to the Company's Proxy Statement for its Annual Meeting of Stockholders held on May 29, 1998, filed with the Commission on May 1, 1998.

(6) Incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the Company's Registration Statement on Form 8-A/A, as filed with the Commission on April 18, 2003.

\* Filed herewith.

† Management contract or compensatory plan or arrangement

23

---



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

Date: May 3, 2011

By: /s/ DEBORAH  
ANDREWS

Deborah Andrews

Chief Financial Officer  
(on behalf of the Registrant and as  
its  
principal financial officer)