STAAR SURGICAL CO Form 10-Q November 02, 2011

#### **UNITED STATES**

# SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended: September 30, 2011

Or

oTRANSITION 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 b 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 b 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):

reporting company)

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

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

The registrant has 36,096,107 shares of common stock, par value \$0.01 per share, issued and outstanding as of October 25, 2011.

### STAAR SURGICAL COMPANY

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# STAAR SURGICAL COMPANY CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except par value amounts) (Unaudited)

(Ollaudited)			
	S	eptember 30,	· ·
ASSETS		2011	2010
ASSETS			
Current assets:			
Cash and cash equivalents	\$	16,755	\$ 9,376
Restricted cash		136	133
Accounts receivable trade, net		6,786	8,219
Inventories, net		10,612	10,543
Prepaids, deposits and other current assets		1,498	1,715
Total current assets		35,787	29,986
Property, plant and equipment, net		3,710	3,732
Intangible assets, net		3,210	3,672
Goodwill		1,786	1,786
Deferred income taxes		202	202
Other assets		1,202	1,207
Total assets	\$	45,897	\$ 40,585
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			
Accounts payable	\$	3,586	\$ 3,717
Line of credit		2,600	2,460
Deferred income taxes		326	326
Obligations under capital leases		590	431
Other current liabilities		5,722	6,513
Total current liabilities		12,824	13,447
Obligations under capital leases		990	1,403
Deferred income taxes		638	488
Other long-term liabilities		3,068	2,820
Total liabilities		17,520	18,158
Commitments and contingencies (Note 13)			
Stockholders' equity:			
Common stock, \$0.01 par value; 60,000 shares authorized; 35,932 and 35,084			
shares issued and outstanding at September 30, 2011 and December 31, 2010		359	351
Additional paid-in capital		156,429	152,014
Accumulated other comprehensive income		2,388	2,100
Accumulated deficit		(130,799	(132,038)
Total stockholders' equity		28,377	22,427
Total liabilities and stockholders' equity	\$	45,897	\$ 40,585

See accompanying notes to the condensed consolidated financial statements.

# STAAR SURGICAL COMPANY CONDENSED CONSOLIDATED STATEMENTS OF INCOME

(In thousands, except per share amounts) (Unaudited)

Chac	Three Mor	nths Ended	Nine Months Ended			
	September 30,		September 30, October 1			
	2011	2010	2011	2010		
Net sales	\$15,266	\$13,152	\$46,385	\$40,569		
Cost of sales	4,816	4,892	15,445	14,801		
	,	,	-, -	,		
Gross profit	10,450	8,260	30,940	25,768		
0.000 p.0.00	10,.00	<b>3,2</b> 33	20,510	20,700		
General and administrative	3,820	3,591	11,448	10,247		
Marketing and selling	4,439	4,552	13,098	12,517		
Research and development	1,454	1,309	4,279	4,218		
Other general and administrative expenses		_	<u> </u>	700		
S						
Operating income (loss)	737	(1,192	) 2,115	(1,914	)	
-1	, , ,	(-,-,-	, =,	(-)2 - 1		
Other income (expense):						
Interest income	7	7	24	22		
Interest expense	(134)	(152	) (440	) (783	)	
Gain (loss) on foreign currency transactions	(277 )		167	6		
Loss on early extinguishment of note payable	_	_	_	(267	)	
Other (expense) income, net	(42)	89	358	77		
Other (expense) income, net	(446 )		109	(945	)	
cuiti (enpense) moome, net	(1.10 )		10)	(> 10		
Income (loss) before provision for income taxes	291	(802	) 2,224	(2,859	)	
Provision for income taxes	214	356	985	563		
Income (loss) from continuing operations	77	(1,158	) 1,239	(3,422	)	
means (1888) from Commoning operations	, ,	(1,100	, 1,200	(0,122	,	
Income from discontinued operations, net of income taxes	_	_	_	4,166		
Net income (loss)	\$77	\$(1,158	) \$1,239	\$744		
Tito moonio (1666)	<i>Ψ.,</i>	ф (1,123	, 41,200	Ψ /		
Net income (loss) per share from continuing operations –						
basic	\$0.00	\$(0.03	) \$0.04	\$(0.10	)	
Net income (loss) per share from continuing operations	Ψ 0.00	4 (0.02	, 40.0.	Ψ(0.10		
-diluted	\$0.00	\$(0.03	\$0.03	\$(0.10	)	
diluted	Ψ 0.00	Ψ (0.02	) 40.05	Ψ(0.10	,	
Income per share from discontinued operations – basic and						
diluted	<b>\$</b> —	<b>\$</b> —	<b>\$</b> —	\$0.12		
unucu	Ψ	Ψ	Ψ	ψ0.12		
Net income (loss) per share - basic	\$0.00	\$(0.03	) \$0.04	\$0.02		
The meetic (1000) per bilate busic	ΨΟ.ΟΟ	Ψ(0.03	, ψυ.υτ	Ψ 0.02		
Net income (loss) per share - diluted	\$0.00	\$(0.03	\$0.03	\$0.02		
The meeting (1000) per bilate anatou	Ψ0.00	Ψ(0.03	, ψ0.03	Ψ 0.02		
Weighted average shares outstanding - basic	35,539	34,831	35,304	34,790		
Weighted average shares outstanding - diluted	36,953	34,831	36,507	34,790		
11 Organica average shares outstanding - unuted	50,755	57,051	30,307	57,770		

See accompanying notes to the condensed consolidated financial statements.

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

(Ollaudited)		
	Nine Mon	ths Ended
	September 30,	October 1,
	2011	2010
Cash flows from operating activities:		
Net income	\$1,239	\$744
Adjustments to reconcile net income to net cash provided byoperating activities:		
Income from discontinued operations	_	(4,166)
Depreciation of property and equipment	890	1,191
Amortization of intangibles	595	607
Amortization of discount	_	236
Loss on early extinguishment of note payable	_	267
Deferred income taxes	150	_
Fair value adjustment of warrant	(29)	117
Gain (loss) on disposal of property and equipment	(14)	4
Change in net pension liability	147	256
Stock-based compensation expense	1,330	945
Other	(70)	40
Changes in working capital:		
Accounts receivable	1,630	862
Inventories	241	1,042
Prepaids, deposits and other current assets	331	717
Accounts payable	(201)	(1,395)
Other current liabilities	(829)	(5,462)
Net cash used in operating activities of discontinued operations	<u> </u>	(635)
Net cash provided by (used in) operating activities	5,410	(4,630
	,	,
Cash flows from investing activities:		
Proceeds from sale of subsidiary, net of transaction costs	_	11,824
Release of restricted cash	_	7,396
Deposit to restricted escrow account	_	(136 )
Acquisition of property and equipment	(722)	(247
Proceeds from sale of property and equipment	26	
Net change in other assets	48	10
Net cash used in investing activities of discontinued operations	_	(50)
Net cash (used in) provided by investing activities	(648)	18,797
( ) I was a grant	( /	- <b>,</b>
Cash flows from financing activities:		
Repayment of notes payable	_	(5,000)
Redemption of Series A preferred stock	_	(6,800)
Repayment of capital lease obligations	(412)	(609)
Proceeds from exercise of stock options	2,983	292
Net cash used in financing activities of discontinued operations		(50)
Net cash provided by (used in) financing activities	2,571	(12,167)
processor processor (about in) riminology activities	2,571	(12,107)

Effect of exchange rate changes on cash and cash equivalents	46	158
3		

	Nine Months Ended		
	September 30,	October 1,	
	2011	2010	
Increase in cash and cash equivalents	7,379	2,158	
Cash and cash equivalents, at beginning of the period	9,376	6,330	
Cash and cash equivalents, at end of the period	\$16,755	\$8,488	

See accompanying notes to the condensed consolidated financial statements.

# STAAR SURGICAL COMPANY NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS September 30, 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. In accordance with those rules and regulations 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 derives 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 and nine months ended September 30, 2011 and October 1, 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 and nine months ended September 30, 2011 and October 1, 2010 are not necessarily indicative of the results to be expected for any other interim period or for the entire year. As discussed in Note 2, on March 2, 2010, the Company disposed of all of its interests in a subsidiary, Domilens GmbH ("Domilens"), and in accordance with GAAP reported the income received from Domilens prior to the disposition as "income from discontinued operations." Income from continuing operations does not include the results of operations of 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").

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

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 September 30, 2011, restricted cash was \$136,000, an increase of \$3,000 from December 31, 2010, due to the effect of foreign currency translation.

# 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):

	Septe	September 30, December 31,						
	,	2011		2010				
Raw materials and purchased parts	\$	1,986	\$	1,920				
Work-in-process		2,108		2,255				
Finished goods		7,295		7,349				
-		11,389		11,524				
Inventory reserves		(777	)	(981)				
	\$	10,612	\$	10,543				

# STAAR SURGICAL COMPANY NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS September 30, 2011 (Unaudited)

Note 5 — Prepaids, Deposits, and Other Current Assets

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

	September 30, December 31						
		2011		2010			
Prepaids and deposits	\$	816	\$	1,219			
Other current assets		682		496			
	\$	1,498	\$	1,715			

Note 6 – Amortizable Intangible Assets

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

	S	eptember 30, 2	011	December 31, 2010					
				Gross					
	Gross Carryin	ng Accumulated		Carrying	Accumulate	ed			
	Amount	Amortization	Net	Amount	Amortizatio	n Net			
Amortized intangible assets:									
Patents and licenses	\$10,875	\$ (9,400	\$1,475	\$10,827	\$ (9,064	) \$1,763			
Customer relationships	2,039	(765	) 1,274	1,929	(579	) 1,350			
Developed technology	1,296	(835	) 461	1,226	(667	) 559			
Total	\$14,210	\$ (11,000	) \$3,210	\$13,982	\$ (10,310	) \$3,672			

As of September 30, 2011 the gross carrying amount of amortizable intangible assets increased by \$228,000 due to changes in the foreign exchange rate.

Note 7 – Other Current Liabilities

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

	Sep	cember 31,		
		2011		2010
Accrued salaries and wages	\$	1,853	\$	2,121
Accrued audit fees		408		417
Customer credit balances		572		566
Accrued bonuses		1,070		751
Accrued income taxes		165		147
Accrued insurance		120		422
Accrued severance		104		570
Other		1,430		1,519
	\$	5,722	\$	6,513

# STAAR SURGICAL COMPANY NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS September 30, 2011 (Unaudited)

#### 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 MonthsThree Months Nine Months Nine Months									ths
	Ended			Ended En			Ended	Ended End		
	Sep	tember 3	30,	Oc	tober 1	, Sep	tember	30, O	ctober	1,
		2011			2010		2011		2010	
Service cost	\$	161		\$	144	\$	423	\$	421	
Interest cost		42			35		104		103	
Expected return on plan assets		(34	)		(25	)	(83	)	(73	)
Amortization of unrecognized										
transition obligation		4					12			
Amortization of prior service cost		(1	)		_		(1	)	_	
Recognized actuarial (gain) loss		(2	)		13		(18	)	41	
	\$	170		\$	167	\$	437	\$	492	

During the nine months ended September 30, 2011 and October 1, 2010, the Company made cash contributions totaling approximately \$203,000 and \$183,000 to its Swiss defined benefit pension plan. The Company expects to make additional cash contributions totaling approximately \$68,000 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 September 30, 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 \$3.9 million based on the rate of exchange on September 30, 2011), at an interest rate equal to the Tokyo short-term prime interest rate (approximately 1.475% as of September 30, 2011) plus 1.125%. The agreement 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 September 30, 2011 and December 31, 2010, (approximately \$2.6 million and \$2.5 million based on the foreign exchange rates on September 30, 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 increase to 14% per annum. As of September 30, 2011, 100,000,000 Yen (approximately \$1.3 million based on the rate of exchange on September 30, 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 (\$1,114,000 at the rate of exchange on September 30, 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 renews automatically 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 customary 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 September 30, 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 are as follows (in thousands):

# STAAR SURGICAL COMPANY NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS September 30, 2011 (Unaudited)

	Sep	tember 3	0, Dec	cember 3	1,
Fiscal Year		2011		2010	
2011	\$	187	\$	938	
2012		844		763	
2013		595		627	
2014		75		68	
2015				36	
Thereafter					
Total minimum lease payments	\$	1,701	\$	2,432	
Less: interest		(121	)	(598	)
Total lease obligation	\$	1,580	\$	1,834	
Current	\$	590	\$	431	
Long-term	\$	990	\$	1,403	

Borrowings available under the Company's lease lines of credit with Farnam Street Financial are approximately \$238,350. See Note 10, Notes Payable, to the consolidated financial statements accompanying the 2010 Annual Report 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						Nine Months En				Ended October 1,		
	Sep	tember 3011	0,	C	October 1, 2010	Sej	ptember 30	0,		2010 (Note A)			
Numerator:													
Net Income (loss)	\$	77		\$	(1,158	) \$	1,239		\$	744			
Denominator:													
Weighted average common shares and denominator for basic calculation:													
Weighted average common shares													
outstanding		35,695			34,945		35,442			34,879			
Less: Unvested restricted stock		(156	)		(114	)	(138	)		(89	)		
Denominator for basic calculation		35,539			34,831		35,304			34,790			

Weighted average effects of dilutive equity-based compensation awards:

equity sused compensation awards.					
Employee stock options	846	_		751	_
Warrants	568			452	
Denominator for diluted calculation	36,953	34,831		36,507	34,790
Net income (loss) per share – basic	\$ 0.00	\$ (0.03)	) \$	0.04	\$ 0.02
Net income (loss) per share - diluted	\$ 0.00	\$ (0.03)	) \$	0.03	\$ 0.02

# STAAR SURGICAL COMPANY NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS September 30, 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 Mon	ths Ended	Nine Months Ended		
	September 30,	October 1,	September 30,	October 1,	
	2011	2010	2011	2010	
Options and restricted stock	1,405	3,929	1,279	3,900	
Warrants	70	1,470	70	1,470	
Preferred Stock	0	0	0	897	
Total	1,475	5,399	1,349	6,267	

# Note 11 — Comprehensive Income

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

	Three Months Ended			Nine Months Ended			nded			
	September 30,		October 1,		September 30,		30,	October 1,		
		2011		2010		2011			2010	
Net income (loss)	\$	77	\$	(1,158	) \$	1,239		\$	744	
Other comprehensive income (loss):										
Minimum pension liability adjustment		19		3		(22	)		9	
Foreign currency translation adjustment		407		519		310			(1,414	)(1)
Comprehensive income (loss)		426		522		288			(1,405	)
Total comprehensive income (loss)	\$	503	\$	(636	) \$	1,527		\$	(661	)

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

# Note 12 — Geographic and Product Data

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 Mont	ths Ended	Nine Months Ended		
	September 30,	October 1,	September 30,	October 1,	
	2011	2010	2011	2010	
United States	\$ 3,211	\$ 3,727	\$ 10,448	\$ 11,560	

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Japan	4,037	3,283	11,772	10,170
Korea	2,069	1,710	5,463	4,356
China	1,825	785	4,832	2,641
Other	4,124	3,647	13,870	11,842
Total	\$ 15,266	\$ 13,152	\$ 46,385	\$ 40,569

# STAAR SURGICAL COMPANY NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS September 30, 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 implantable Collamer lenses ("ICLs") used in refractive surgery and intraocular lenses ("IOLs") used in cataract surgery. The composition of the Company's net sales by product line is as follows (in thousands):

	Three Mon	ths Ended	Nine Months Ended		
	September 30,	October 1,	September 30,	October 1,	
	2011	2010	2011	2010	
ICLs	\$ 7,902	\$ 6,034	\$ 23,093	\$ 17,757	
IOLs	6,571	6,559	20,767	20,442	
Core products	14,473	12,593	43,860	38,199	
Other Surgical Products	793	559	2,525	2,370	
Total	\$ 15,266	\$ 13,152	\$ 46,385	\$ 40,569	

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, the Company accrued \$700,000 in executive termination benefit costs in connection with the notice of non-renewal given under an executive employment agreement. This accrual represented the Company's 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. As of September 30, 2011, accrued unpaid severance was approximately \$104,000.

#### Note 14 — Stock-Based Compensation

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

	Three Mon	ths Ended	Nine Months Ended		
	September 30,	October 1,	September 30,	October 1,	
	2011	2010	2011	2010	
SFAS 123R expense	\$ 363	\$ 200	\$ 978	\$ 642	
Restricted stock expense	115	77	320	214	
Consultant compensation	45	19	32	89	
Total	\$ 523	\$ 296	\$ 1,330	\$ 945	

The Company recognized no net income tax benefit in its income statement for share-based compensation arrangements because the Company fully offsets net deferred tax assets with a valuation allowance. In addition, the Company capitalized \$33,000 and \$109,000 of stock compensation to inventory for the three and nine months ended September 30, 2011, and \$22,000 and \$65,000, respectively, for the three and nine months ended October 1, 2010. It recognizes those amounts as expense in Cost of Sales as the inventory is sold.

### 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 September 30, 2011, there were 1,755,697 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 3,121,972 shares were outstanding at September 30, 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 September 30, 2011.

# STAAR SURGICAL COMPANY NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS September 30, 2011 (Unaudited)

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 September 30, 2011 with an exercise price of \$3.60 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 nine months ended September 30, 2011 and October 1, 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	Three Months Ended				Nine Months Ended			
	September 3	September 30,		S	September 30,		October 1,		
	2011		2010		2011		2010		
Expected dividend yield	0	%	0	%	0	%	0	%	
Expected volatility	76.99	%	80.17	%	76.93	%	80.53	%	
Risk-free interest rate	1.12	%	1.40	%	1.94	%	2.15	%	
Expected term (in years)	5.49		5.6		5.49		5.6		

A summary of option activity under the Plans as of September 30, 2011 is presented below:

				Weighted-	-
		W	eighted-	Average	Aggregate
		A	verage	Remaining	g Intrinsic
	Shares	$\mathbf{E}$	xercise	Contractua	al Value
Options	(000's)	Pı	rice	Term	(000's)
Outstanding at December 31, 2010	3,331	\$	4.35	_	\$ —
Granted	629		5.59	_	
Exercised	(742	)	4.02	_	
Forfeited or expired	(88)	)	5.41	_	_
Outstanding at September 30,					
2011	3,130	\$	4.65	6.69	3,245
Exercisable at September 30, 2011	1,996	\$	4.37	5.30	\$ 2,784

The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2011 and October 1, 2010 was \$3.63 and \$2.84 per option. The total fair value of options vested during the nine months ended September 30, 2011 and October 1, 2010 was \$806,000 and \$995,000, respectively. There were 742,264 and 84,732

options exercised with an intrinsic value of \$1,823,000 and \$152,000 during the nine months ended September 30, 2011 and October 1, 2010.

A summary of the status of the Company's non-vested shares as of September 30, 2011 and changes during the period is presented below:

		Weighted- Average
	Shares	Grant Date
Nonvested Shares	(000's)	Fair Value
Nonvested at December 31, 2010	885	\$ 2.89
Granted	629	3.63
Vested	(330	) 2.45
Forfeited	(65	3.73
Nonvested at September 30, 2011	1,119	\$ 3.67

# STAAR SURGICAL COMPANY NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS September 30, 2011 (Unaudited)

As of September 30, 2011, the Company had \$2.9 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 1.80 years.

Note 15 — Supplemental Disclosure of Cash Flow Information

Interest paid was \$374,000 and \$930,000 for the nine months ended September 30, 2011 and October 1, 2010, respectively. Income taxes paid amounted to approximately \$648,000 and \$1,081,000 for the nine months ended September 30, 2011 and October 1, 2010, respectively.

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

	September 30, 2011	October 1, 2010
Non-cash investing and financing activities:		
Assets obtained by capital lease	\$ 79	\$ 776

#### Note 16 — New Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU No. 2011-05) "Comprehensive Income (Topic 220) — Presentation of Comprehensive Income." ASU 2011-05 requires that all nonowner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In both choices, an entity is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. ASU 2011-05 is effective retrospectively for fiscal years, and interim periods within those years, beginning after December 15, 2011. We are assessing the impact of ASU 2011-05 on our comprehensive income presentation.

In May 2011, the FASB issued ASU No. 2011-04 "Fair Value Measurement (Topic 820) - Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs." ASU 2011-04 changes the wording used to describe many of the requirements in U.S. GAAP for measuring fair value and for disclosing information about fair value measurements. Consequently, the amendments in this update result in common fair value measurement and disclosure requirements in U.S. GAAP and IFRSs (International Financial Reporting Standards). ASU 2011-04 is effective prospectively during interim and annual periods beginning on or after December 15, 2011. We are assessing the impact of ASU 2011-04 on our fair value disclosures.

# 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 and in this Quarterly Report 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.

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 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 allows the surgeon to insert them into the eye through a small incision during minimally invasive surgery. Cataract surgery is a relatively common outpatient procedure where the eye's natural lens that has become cloudy with age is removed and replaced with an artificial lens called an intraocular lens (IOL) to restore the patient's vision. Refractive surgery is performed to treat the type of visual disorders that have traditionally been corrected using eyeglasses or contact lenses. We refer to our lenses used in refractive surgery as "implantable Collamer® lenses" or "ICLs" and market 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<sup>TM</sup>, nanoPOINT<sup>TM</sup>, CentraFLOW<sup>TM</sup>, AquaPORT<sup>TM</sup>, Epiphany<sup>TM</sup> and AquaFlow<sup>TM</sup> 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.

Visian Implantable Collamer Lenses. Sales of refractive lenses make up approximately half of our total sales. Made from our proprietary biocompatible Collamer material, STAAR's VISIAN ICL and VISIAN Toric ICL, or TICL<sup>TM</sup>, treat refractive disorders such as myopia (near-sightedness), hyperopia (far-sightedness) and astigmatism. The surgeon

implants the foldable Visian lens through a tiny incision, generally 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 to position the ICL and TICL throughout the world as primary choices for refractive surgery.

Sales of ICLs during the three months and nine months ended September 30, 2011 were \$7.9 million and \$23.1 million, compared to \$6.0 million and \$17.8 million for the same periods in the prior year. Having surpassed our sales of IOLs for the first time in the second quarter of 2011, ICL sales represented approximately 52% of total net sales in the three-month period and 50% in the nine-month period.

IOLs - Intraocular Lenses for Cataract Surgery. Sales of foldable IOLs used in minimally invasive cataract surgery made up approximately 43% of our total sales in the third quarter. 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 improve the patient's quality of vision when compared to 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 is available in the U.S and other territories that accept the CE Mark.
- 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 which is currently available in the U.S. Astigmatism is a condition that causes blurred vision when an irregular shape of the cornea 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 reduce our selling prices or reduce the volume of cataract procedures.

Sales of IOLs during the three months and nine months ended September 30, 2011 were \$6.6 million and \$20.8 million, compared to \$6.6 million and \$20.4 million for the same periods in the prior year. IOL sales represented approximately 43% of total net sales in the three-month period and 45% in the nine-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 and nine months ended September 30, 2011 were \$0.8 million and \$2.5 million, compared to \$0.6 million and \$2.4 million for the same periods in the prior year, representing approximately 5% of total net sales in both the three-month and nine-month periods.

#### **Operations**

STAAR has significant operations both within and outside the U.S. Sales from activities outside the U.S. accounted for approximately 79% of our total sales for the quarter ended September 30, 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. We also have a manufacturing facility in Aliso Viejo, California.

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.

STAAR has developed a plan to methodically consolidate its manufacturing in a single site at its Monrovia, California location by the end of 2013, which is expected subsequently to yield significant savings in cost of goods and to lower our global administrative and regulatory costs. This plan, which is subject to significant risks, is described in greater detail in Management's Discussion and Analysis of Financial Condition under the caption "Manufacturing"

Consolidation Project and Tax Strategy."

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 that enables sustainable profitable growth.

STAAR's key operational metrics in 2011 are guided by two principal strategic goals: to achieve and maintain profitability and to lay the groundwork for further growth. In pursuit of these goals, STAAR has aligned its business initiatives during 2011 along four key operational metrics it uses to gauge its success during the year. Based on performance in excess of targets during the second quarter, STAAR increased the targets for three of the four metrics, and they are currently established as follows:

- Increase total revenue by double digits.
- Grow Visian ICL and TICL sales by 30%.

- Continuously increase gross profit margin each quarter to achieve a level of 66.5% for the full year.
  - Achieve profitability in all four quarters of 2011.

STAAR satisfied all four of the metrics, including the three increased metrics, during the third quarter of 2011.

Increase total revenue by double digits. As STAAR continues to place less emphasis on its less profitable non-core products and experiences increasing revenue in its higher value core products, it has set a target of double digit growth in total revenue during 2011. In the third quarter of 2011, STAAR achieved year-over-year total revenue growth of 16%, and for the nine-month period it achieved growth of 14% in total revenue.

Grow Visian ICL and TICL sales by 30%. STAAR achieved a growth rate of 31% in the third quarter, and 30% growth for the first nine months of the year. We have been pursuing the goal of increased ICL and TICL sales by identifying the top ten markets and concentrating our sales and marketing efforts on increasing our market share in those regions. Growth rates in the top ten markets on which we currently focus were 33% during the third quarter, and 32% for the first nine months of the year. STAAR launched its new Visian V4c with CentraFLOW<sup>TM</sup> technology in the countries covered by the CE Mark in the third week of September 2011, which is expected to positively affect sales growth in Europe in the fourth quarter. U.S. ICL sales have continued a trend of relatively slow growth seen over the last two years, and experienced a decline of 7% for the third quarter and declined 2% for the first nine months of 2011. Our goal had originally been to increase Visian ICL and TICL sales by 25%; we increased the goal after exceeding the target level in the second quarter. 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.

Continuously expand gross profit margin each quarter to achieve a level of 66.5% for the full year. STAAR's gross profit margin was 68.5% for the third quarter and 66.7% for the first nine months 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 half of 2011. Since 2009 STAAR has de-emphasized lower margin sales of non-IOL, non-ICL products. Based on performance in the first half of 2011, STAAR raised this target to 66.5% for the full year from an initial target of 66%.

Achieve profitability in all four quarters of 2011. In the third quarter STAAR achieved net earnings of \$0.08 million, or \$0.00 per share. STAAR's achievement of net earnings of \$0.3 million in the first quarter of 2011 was the first quarter since 1999 during which the company reported net income from continuing operations. Based on this performance STAAR increased this metric from an original target of profitability in three of four quarters. 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, Spain, 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 reached approximately 15% of the total volume of refractive surgery procedures. Revenues from sales of Visian ICL products in Korea increased 22% in the third quarter and 26% in the first nine months of 2011. 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. Other territories where Visian products have experienced significant growth in the first nine months of 2011 over prior year were China, Japan, Germany, the Middle East and India.

In September 2011, STAAR launched the V4c model of the Visian ICL with CentraFLOW technology in countries that recognize the CE Mark. The CentraFLOW technology uses 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 or a surgical iridotomy at time of implant. By simplifying the procedure and increasing patient comfort, the V4c makes the superior visual outcomes of the Visian ICL available through a surgical implantation experience closer to LASIK, which should attract new surgeons and patients to the product. STAAR believes that a number of presentations by surgeons at the September 2011 Congress of the European Society of Cataract and Refractive Surgery demonstrated keen interest in V4c among surgeons. Based on these clinical presentations and early ordering activity for the V4c, STAAR believes the product has the potential to further increase the rate of global Visian sales growth. Availability of the V4c will begin to affect sales in the fourth quarter of 2011, so it is too early to determine whether and to what degree the product will actually affect sales.

The launch of V4c follows the September 2010 introduction of the V4b model, 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 nine months of 2011, approximately 7 % of the V4b sales in the markets in which it is available were in the new expanded treatment range.

STAAR believes that, where available, the V4c and V4b models have significantly improved the competitiveness of the Visian product line and have moved STAAR closer to its goal of positioning the ICL and TICL throughout the world as primary choices for refractive surgery. Visian products now address all degrees of refractive error that can be treated with laser eye surgery, as well as moderate and severe errors beyond the effective range of laser eye surgery.

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'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.

In May 2011 STAAR received approval to market the Visian model V4 ICL in Brazil. This approval helped to drive STAAR's decision to target the Latin American market for Visian ICL growth, and it intends to add sales and marketing resources in the region to capitalize on the new opportunity. In addition, STAAR is working to expand regulatory approvals in the market.

#### 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 decreased by 7% in the third quarter and 2% for the first nine months of 2011, compared to prior year. Sales in the private sector continued to increase by 1% in the quarter and were up 13% for the nine months. Sales to the military declined 15% in the quarter bringing the year to date decline to 37%. This percentage decline has decreased on a sequential quarterly basis, the first quarter and second quarter declines were 57% and 34% respectively, and we anticipate this trend will continue and that military sales will return to growth in 2012. Military sales accounted for 16% of total US ICL sales in the first nine months, compared to 25% in the same period last year. The increase in private sector sales, which STAAR believes resulted from its efforts to drive greater adoption and increased usage of the lower diopter range among its existing customer base. If the economy continues to improve, and overall refractive procedures volume increases, STAAR could see further growth in private sector ICL sales in the U.S.

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 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;
- the fact that the FDA has not granted approval to sell the TICL, which STAAR sells in over 50 international markets for treating patients affected by both myopia and astigmatism; and.
- •FDA approval of the V4c is expected to be significantly more time consuming than regulatory approval in most international markets.

Beginning the fourth quarter of 2010 STAAR has been testing direct-to-consumer advertising initiatives online and has used conventional DTC media to test a campaign in selected markets. This activity 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. STAAR is assessing the data obtained to date to determine whether, and in what form, to launch a broader direct-to-consumer campaign

Additionally, STAAR has begun efforts to increase the visibility of the Visian ICL technology on social network sites. The Facebook Visian ICL Contest was just completed which saw the fan base for the Visian ICL more than double in size. Contestants developed videos in which they were trying to convince voters why they needed a free Visian ICL procedure. STAAR worked with nine ophthalmic practices across the U.S. and five winners were determined based upon consumer voting on the network. The Visian ICL procedures are now being arranged along with a focus to drive local media around the event. During the recent American Academy of Ophthalmology meeting STAAR offered online marketing consulting for key practices to support their viral efforts around the Visian ICL technology. STAAR has decided to expand its social networking department in 2012 in order to more effectively drive consumer testimonials and respond to consumer questions.

#### Global IOL Sales.

STAAR pioneered the development of folding lenses for use in cataract surgery, and IOLs continue to represent approximately 45% of STAAR's business. Sales of IOLs during the three months and nine months ended September 30, 2011 were \$6.6 million and \$20.8 million, compared to \$6.6 million and \$20.4 million for the same periods in the prior year.

In September 2011, STAAR launched its nanoFLEX Collamer Single Piece IOL which can be injected through a 2.2 mm incision with the nanoPOINT<sup>TM</sup> Injector System, in the territories that the recognize the CE Mark. This follows the April 2011 CE Mark approval of the product. nanoFLEX has been STAAR's fastest growing IOL product in U.S. markets and STAAR believes the lens can 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 clinical observations 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 hospital based segment;
- •a new version of the hydrophobic acrylic Preloaded Injector, featuring the popular single-piece IOL format, received CE Mark approval in May 2011, and STAAR plans to introduce it into international markets in the 2012;
  - we plan to introduce a preloaded injector for the nanoFLEX;
- we are developing a Collamer Toric IOL on the nanoFLEX platform to complement our pioneering silicone Toric IOL and better compete with other Toric IOL;
- •we have recently seen renewed interest in our silicone Toric IOL among U.S. surgeons and are ramping up marketing efforts for the lens; 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.

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, resulting in greater competition for market share. We cannot assure that our efforts will ultimately be successful.

Manufacturing Consolidation Project and Tax Strategy. During 2011 STAAR has devoted significant resources to two initiatives: a project to consolidate global manufacturing, and development of a strategy to optimize our global organization for tax purposes. The goal of both of these strategies is to continue our improvement in gross profit margin by reducing costs and to position the company for future growth.

STAAR currently manufactures its products in four facilities worldwide. It has developed a plan to methodically consolidate its manufacturing in a single site at its Monrovia, California location by the end of 2013, which is expected subsequently to yield significant savings in cost of goods and to lower our global administrative and regulatory costs.

In addition, as STAAR's profitability grows, its liability for income taxes in various jurisdictions has also increased. STAAR has developed a strategy to minimize its future tax liabilities as its business grows. Among other things, STAAR seeks to utilize the approximately \$125 million in net operating losses that it has accumulated in the U.S.

In connection with its Centers of Excellence project in 2009 and 2010, STAAR successfully transferred manufacturing of some of its products; STAAR believes this experience will be helpful in undertaking the more ambitious transfers involved in the manufacturing consolidation project.

STAAR expects these initiatives to cost approximately \$6 million over a three-year period, of which it has spent approximately \$0.5 million for the nine months ended September 30, 2011 and expects to spend approximately \$150,000 in the fourth quarter of 2011. Expenditures to date have largely consisted of professional fees to advisors and consultants. We expect approximately \$1 million in additional capital expenditures to consolidate our manufacturing. STAAR anticipates that the two initiatives could yield savings of \$100 million over the period 2014 to 2020, and could result in profit margin in the 75% range.

We cannot assure that we will achieve the expected benefits of these initiatives. Among other things, costs could exceed current estimates, product manufacturing transfers can result in delays or supply interruptions, changes in tax laws could reduce or eliminate expected benefits of some or our tax strategies, and future profit margins can be affected by a variety of factors unrelated to our level of manufacturing efficiency.

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. STAAR Japan's staff and their immediate families suffered no serious injuries. STAAR's manufacturing facilities in Ichikawa City, Chiba Prefecture, suffered only minor damage and resumed operations on Wednesday, March 16, 2011. Despite the disaster, STAAR Japan's revenues and its domestic IOL and ICL business have continued to grow; revenues in the third quarter were 32% higher than prior year and revenues in the first nine months of 2011 were 21% higher than prior year. Nevertheless, widespread disruptions in the Japanese economy and infrastructure may have slowed the rate of growth in STAAR Japan's recently launched ICL business, and that effect may continue until recovery is complete.

Backlog. The ICL is manufactured to precisely address refractive prescriptions across a broad range of correction, resulting in a large number of Stock Keeping Units (SKUs) .. The challenge of maintaining inventory in all models, combined with rapidly increasing global demand for the ICL, can result in a backlog in customer orders. While the dollar amount of backlog orders is not currently significant in relation to our total annual sales, unexpectedly large orders for ICLs could increase our backlog. STAAR believes it has sufficient capacity to ramp up production levels to meet demand and that any backlogs will be temporary. However, delays in filling orders can result in lost sales if alternative refractive treatments are available to the patient. Because Toric ICLs treat an even greater variety of refractive errors and at times must be custom made for the patient, customers are accustomed to a special order procedure and do not expect immediate delivery of Toric ICLs from inventory.

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 we 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, and has responded to additional follow-up questions after that date. 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. PMDA conducted an audit of clinical practices related to the application during August 2011, and subsequent to quarter end the Company received notice from the PMDA that the TICL application will not need to go before the Approval Committee. In addition the PMDA and MHLW have permitted STAAR to add the clinical data collection on the Toric ICL Post Market Studies (PMS) to the current PMS protocols underway for the Visian ICL. Final regulatory approval in Japan will require that the DFU (Directions for Use) be finalized, the Post Market Study protocol for the Toric ICL be completed, and the GCP (Good Clinical Practices) audit of the U.S. clinical trial data be finalized. We believe that these items can be completed within the fourth quarter and final approval should be announced shortly after their completion.

# **Critical Accounting Policies**

This Management's Discussion and Analysis of Financial Condition and Results of Operations discusses and analyzes data in our unaudited Condensed Consolidated Financial Statements, which we have prepared in accordance with U.S. generally accepted accounting principles. 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 conditions may differ from our assumptions and actual results may differ from our estimates.

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 nine months ended September 30, 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.

					Percenta	_					Percentag	_
	Danasatas	C 1	Mat Calas	£	Change			C N	Ja4 Calaa	£	Change	
	Percentag			IOT	Three		Percentag			ЮГ	for Nine	
			Ionths	1	Month	S			onths	1	Months	1
	September	30,		1,	2011	0	Septemb		October	1,	2011	`
NY . 1	2011	OH.	2010	C/	vs. 201		30, 201		2010	O.	vs. 2010	
Net sales	100.0	%	100.0	%	16.1	%	100.0	%	100.0	%	14.3	%
Cost of sales	31.5		37.2		(1.6	)	33.3		36.5		4.4	
Gross profit	68.5		62.8		26.5		66.7		63.5		20.1	
General and administrative	25.0		27.3		6.4		24.7		25.3		11.7	
Marketing and selling	29.1		34.6		(2.5	)	28.2		30.9		4.6	
Research and development	9.5		10.0		11.1		9.2		10.4		1.4	
Other general and												
administrative expenses						*			1.7		(100.0)	)
	63.6		71.9		2.8		62.1		68.2		4.1	
Operating income (loss)	4.8		(9.1	)	_	*	4.6		(4.7	)	_	*
Other expense, net	(2.9	)	3.0		_	*	0.2		(2.3	)	_	*
•	· ·								`			
Income (loss) before												
provision for income taxes	1.9		(6.1	)	_	*	4.8		(7.0	)	_	*
Provision for income taxes	1.4		2.7		(39.9	)	2.1		1.4		75.0	
Income (loss) from												
continuing operations	0.5		(8.8)	)	_	*	2.7		(8.4	)	_	*
Income from discontinued												
operations, net of taxes	_								10.3		(100.0	)
Net income (loss)	0.5	%	(8.8)	) %		*	2.7	%	1.8	%	66.5	%

<sup>\*</sup> Denotes change is greater than +100%.

Net Sales

Net sales for the three and nine months ended September 30, 2011 were \$15.3 million and \$46.4 million, an increase of approximately 16.1% and 14.3%, respectively, compared with \$13.2 million and \$40.6 million for the three and nine months ended October 1, 2010. The increase in net sales was due primarily to increased sales of ICLs. Changes in currency had a \$0.4 million and \$1.4 million favorable impact on net sales, respectively for the three and nine months ended September 30, 2011.

Total ICL sales for the three and nine months ended September 30, 2011 were \$7.9 million and \$23.1 million, an increase of 31% and 30% respectively, compared with \$6.0 million and \$17.8 million for the comparable periods in 2010. The increase in ICL sales primarily resulted from a 33% increase in our top ten refractive markets during the third quarter. ICL sales represented 52% and 50%, respectively, of our total sales for the three and nine months ended September 30, 2011.

Total IOL sales for the three and nine months ended September 30, 2011 were \$6.6 million and \$20.8 million, an increase of 0.2% and 1.6% respectively, compared with \$6.6 million and \$20.4 million for the three and nine months ended October 1, 2010. The increase in IOL sales is due to the favorable effect of currency. IOL sales represent 43.0% and 44.8% of the sales for the three and nine months ended September 30, 2011.

## **Gross Profit**

Gross profit for the third quarter was \$10.5 million, or 68.5% of revenue, compared with \$8.3 million, or 62.8% of revenue, in the prior year period. During the nine months of 2011, gross profit was \$30.9 million, or 66.7% of revenue, compared with \$25.8 million, or 63.5% of revenue, in the prior year period. The increase in gross profit and gross profit margin was largely attributable to a higher mix of ICL sales and improved margins on IOL sales.

#### General and Administrative

General and administrative expenses increased by 6.4% to \$3.8 million in the third quarter of 2011 from the \$3.6 million reported in the third quarter of 2010. General and administrative expenses for the nine months ended September 30, 2011 were \$11.4 million, an increase of 11.7% when compared with \$10.2 million reported last year. The increase in both periods was primarily due to increased bonus accruals and professional fees incurred in evaluating future manufacturing and tax strategies.

## Marketing and Selling

Marketing and selling expenses decreased by 2.5% to \$4.4 million in the third quarter of 2011, compared with \$4.6 million in the third quarter of 2010. Marketing and selling expenses for the nine months ended September 30, 2011 were \$13.1 million, an increase of 4.6% when compared with \$12.5 million reported last year. The decrease for the third quarter resulted from transition of the Company's Australia business to a distribution model. For the nine month period the increase in expense was primarily due to increased salaries and promotional activities.

## Research and Development

Research and development expenses increased by 11.1% to \$1.5 million in the third quarter of 2011, compared with \$1.3 million in the third quarter of 2010. Research and development expenses for the nine months ended September 30, 2011 were \$4.3 million, an increase of 1.4% when compared with \$4.2 million reported last year. The increases for both periods resulted from increased payroll and patent related cost.

## Other General and Administrative Expenses

Other general and administrative expenses in 2010 reflected a \$700,000 charge for executive termination benefits cost recorded in connection with the non-renewal of an executive employment agreement. There was no corresponding expense in 2011.

#### Other Income (Expense), net

Other expenses total \$0.4 million, compared with other income in the third quarter of 2010 of \$0.4 million. This \$0.8 million swing is due primarily to foreign exchange losses of \$0.3 million recorded during the quarter compared with \$0.4 in exchange gain which was recorded in the third quarter of 2010. In addition, other expense increased approximately \$0.2 million as a result of the fair value adjustment of outstanding warrants. For the nine months of 2011, other income was \$0.1 million, compared with other expense of \$0.9 million for the nine months of 2010. This swing is due to reduced interest and other expense resulting from the repayment of the Broadwood note in 2010, foreign exchange gains, increased royalty income, and income from the fair value adjustment of outstanding warrants.

## Liquidity and Capital Resources

STAAR's liquidity requirements arise from the funding of our working capital needs, primarily inventory and accounts receivable. Our primary sources for working capital and capital expenditures are cash flows from operating activities, proceeds from the exercise of stock options, and borrowings under our credit facilities. Our 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 STAAR's cash flow. In addition, any abnormal product returns or pricing adjustments may also affect our short-term funding.

STAAR 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, including the estimated \$6 million cost associated with the

manufacturing consolidation plan. 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 maintaining positive cash flow and earnings through the strategies described above under the caption "Strategy." If the need for financing arises, STAAR cannot assure that it will be available on acceptable terms, if at all.

STAAR's cash balances have steadily increased over the last two years. To the extent STAAR's cash balances exceed levels needed for working capital and as a cushion for unforeseen demands, STAAR intends to invest its cash in expanding and improving its business. It does not anticipate paying dividends from its earnings for the foreseeable future.

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

As of September 30, 2011 and December 31, 2010, STAAR had \$16.9 million and \$9.5 million, respectively, of cash and cash equivalents and restricted cash.

Net cash provided by operating activities was \$5.4 million for the nine months ended September 30, 2011, compared to \$4.6 million in net cash used by operating activities for the nine months ended October 1, 2010. For the nine months ended September 30, 2011, net cash provided by operating activities consisted of net income of \$1.2 million, \$3.0 million in non-cash activities and \$1.2 million generated from working capital. For the nine months ended October 1, 2010, net cash provided by investing activities was due to the \$11.8 million net cash proceeds from the sale of our German subsidiary in March 2010 and the release of the \$7.4 million restricted deposit, including interest, by the Court, offset by \$0.2 million of acquisitions of property, plant and equipment.

Net cash used in investing activities was \$0.6 million for the nine months ended September 30, 2011, compared with cash provided by investing activities of \$18.8 million for the nine months ended October 1, 2010. Net cash used in investing activities was mainly due to \$0.7 million in acquisitions of property, plant and equipment. For the nine months ended October 1, 2010, net cash provided by investing activities was mainly due to \$11.8 million of net cash proceeds from sale of our German subsidiary in March 2010 and the release of the \$7.3 million restricted deposit by the Court in June 2010, offset by \$0.3 million of acquisitions of property, plant and equipment.

Net cash provided by financing activities was \$2.6 million for the nine months ended September 30, 2011, compared to net cash used in financing activities of \$12.2 million for the nine months ended October 1, 2010. Net cash provided by financing activities consisted of \$3.0 million in proceeds from the exercise of stock options, partially offset by \$0.4 million in capital lease repayments. For the nine months ended October 1, 2010, net cash used in financing activities was due to the \$5 million payment of the Broadwood note, the \$6.8 million cash redemption of the Series A preferred shares and repayment of our capital lease obligations of \$0.6 million, partially offset by \$0.2 million in proceeds from stock option exercises.

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 represented STAAR's 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. The balance of accrued unpaid severance at September 30, 2011 was approximately \$104,000.

#### 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 \$3.9 million based on the rate of exchange on September 30, 2011), at an interest rate equal to the Tokyo short-term prime interest rate (approximately 1.475% as of September 30, 2011) plus 1.125%. The agreement 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 September 30, 2011 and December 31, 2010, (approximately \$2.6 million and \$2.5 million based on the foreign exchange rates on September 30, 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 increase to 14% per annum. As of September 30, 2011, 100,000,000 Yen (approximately \$1.3 million based on the rate of

exchange on September 30, 2011) of the line was available for borrowing.

In August 2010, our 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 (\$1,114,000 at the rate of exchange on September 30, 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 September 30, 2011 and the full amount of the line was available for borrowing.

#### Capital Lease Obligations

STAAR 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):

	S	eptember			
		30,	De	December 3	
Fiscal Year		2011		2010	
2011	\$	187	\$	938	
2012		844		763	
2013		595		627	
2014		75		68	
2015		_		36	
Thereafter		_			
Total minimum lease payments	\$	1,701	\$	2,432	
Less: interest		(121	)	(598	)
Total lease obligation	\$	1,580	\$	1,834	
Current	\$	590	\$	431	
Long-term	\$	990	\$	1,403	

Borrowings available under our lease lines of credit with Farnam Street Financial are approximately \$238,350. See Note 10, Notes Payable, to the consolidated financial statements accompanying the 2010 Form 10-K for additional information regarding STAAR's 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.

#### 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 September 30, 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

Our short and long-term success is subject to many factors that are beyond our control. Investors and prospective investors should consider carefully the following risk factors, in addition to other information contained in this report and the risks and uncertainties described in "Part I—Item 1A—Risk Factors" of the Company's Form 10-K for the fiscal year ended December 31, 2010.. Such risks and uncertainties could materially adversely affect our business, financial condition or operating results.

We may not realize the expected benefits of our manufacturing consolidation project and tax strategies. Beginning in 2011 STAAR has invested significant resources in a manufacturing consolidation project and a tax strategy initiative, and it expects to invest several million dollars to complete the projects. The goal of these projects is to increase profit margins by improving manufacturing efficiency, simplifying administrative and regulatory functions, and reducing tax liabilities. We cannot assure that we will achieve the expected benefits of these initiatives. Among other things, costs could exceed current estimates, product manufacturing transfers can be affected by delays or cause supply interruptions, changes in tax laws could reduce or eliminate expected benefits of some of our tax strategies, and future profit margins can be affected by a variety of factors unrelated to our level of manufacturing efficiency.

We may experience backlog in ICL orders due to rapid increases in demand. The challenge of maintaining inventory across the large number of ICL models, combined with rapidly increasing global demand for the ICL, has from time to time resulted in a backlog in customer orders. While the dollar amount of backlog orders is not currently significant in relation to our total annual sales, unexpectedly large orders for ICLs could increase our backlog to levels that are financially significant. In addition, delays in filling orders can result in lost sales if alternative refractive treatments are available to the patient. If we are unable to ramp up production to meet growing demand we may not achieve our growth targets.

#### ITEM 5.

#### OTHER INFORMATION

a. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

The following information is provided pursuant to Item 5.02(e) of Form 8-K:

Compensatory Arrangements of Certain Officers

On November 2, 2011, STAAR entered into an Executive Severance Agreement and Executive Change in Control Agreement with each of the following Named Executive Officers: Deborah Andrews (Chief Financial Officer) and Robin Hughes (Vice President, Global Marketing).

In each case the Executive Severance Agreement and Executive Change in Control Agreement replaces and supersedes any other prior agreements, arrangements and understandings between the officer and STAAR with respect to rights upon severance or a change in control, except rights expressly provided under option agreements and other equity compensation agreements. Stock options and other equity compensation awards will continue to be governed by the original agreements in place with respect to the awards.

A summary of the terms and conditions of the agreements is provided below.

Severance Agreement. If the officer is terminated without cause or resigns for good reason (except in connection with a change in control of STAAR), the officer will receive the following, subject to the officer entering into a release of claims with STAAR:

- Six months' base salary at the rate applicable at the time of termination; and
  - Six months' continuation of group health and dental benefits.

Change in Control Agreement. If the officer is terminated within 12 months after a change in control of STAAR, or resigns for good reason within 15 months after a change in control of STAAR, the officer will receive the following, subject to the officer entering into a release of claims with the employer:

- One year's base salary at the greater of the rate applicable at the time of termination or the rate applicable immediately prior to the announcement of the change in control;
- •One year's target cash bonus amount, plus the greater of the amount of any bonus earned in the year of termination and the provided amount of the previous year's bonus;
  - One year's continuation of group health and dental benefits; and
- •Limited roll-backs or deferrals in compensation if necessary to reduce liability for excise taxes under Section 280G of the Internal Revenue Code, but no provision of any kind for the gross-up of payments for taxes or for any other purpose

Under both forms of agreement, resignation "for good reason" generally means that an employer has adversely changed the officer's salary, location or other terms and conditions of employment to such a degree that the executive is entitled to voluntarily resign and to receive severance benefits.

The foregoing summary of the terms of the Executive Severance Agreements and Executive Change in Control Agreement is qualified in its entirety by reference to the full text of the forms of the agreements, copies of which are

attached to this Report as Exhibit 10.88 and Exhibit 10.89, and which are incorporated into this Report by this reference.

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)
†10.88	Form of Executive Severance Agreement. *
†10.89	Form of Executive Change in Control Agreement. *
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- 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. \*
- 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. \*
- Financial statements from the quarterly report on Form 10-Q of STAAR Surgical Company for the quarter ended July 1, 2011, formatted in XBRL, are filed herewith and include: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Income, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) the Notes to Condensed Consolidated Financial Statements tagged as blocks of text.
- (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

## **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: November 2, 2011 By: /s/ DEBORAH ANDREWS

Deborah Andrews

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