

STAAR SURGICAL CO
Form 10-Q
November 05, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended: September 28, 2012

Or

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

For the transition period from _____ to _____

Commission file number: 0-11634

STAAR SURGICAL COMPANY

(Exact name of registrant as specified in its charter)

Delaware 95-3797439
(State or other jurisdiction of (I.R.S. Employer

incorporation or organization) Identification No.)

1911 Walker Avenue

Monrovia, California 91016

(Address of principal executive offices)

(626) 303-7902

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

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

<input type="checkbox"/> Large accelerated filer	<input type="checkbox"/> Non-accelerated filer	<input type="checkbox"/> Smaller reporting company
<input type="checkbox"/> Accelerated filer	(Do not check if a smaller reporting company)	

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

The registrant has 36,604,844 shares of common stock, par value \$0.01 per share, issued and outstanding as of October 31, 2012.

STAAR SURGICAL COMPANY

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

	September 28, 2012	December 30, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 19,753	\$ 16,582
Restricted cash	—	129
Accounts receivable trade, net	8,142	9,089
Inventories, net	11,793	10,933
Prepays, deposits and other current assets	1,840	1,921
Total current assets	41,528	38,654
Property, plant and equipment, net	4,698	4,222
Intangible assets, net	2,458	2,989
Goodwill	1,786	1,786
Deferred income taxes	149	152
Other assets	1,210	1,203
Total assets	\$ 51,829	\$ 49,006
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 3,818	\$ 4,261
Line of credit	2,580	2,580
Deferred income taxes	472	472
Obligations under capital leases	933	597
Other current liabilities	6,348	6,106
Total current liabilities	14,151	14,016
Obligations under capital leases	534	1,124
Deferred income taxes	824	708
Other long-term liabilities	723	940
Pension obligation	2,982	2,760
Total liabilities	19,214	19,548
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Common stock, \$0.01 par value; 60,000 shares authorized; 36,323 and 36,041 shares issued and outstanding at September 28, 2012 and December 30, 2011	363	360

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Additional paid-in capital	160,910	157,383
Accumulated other comprehensive income	2,381	2,405
Accumulated deficit	(131,039)	(130,690)
Total stockholders' equity	32,615	29,458
Total liabilities and stockholders' equity	\$ 51,829	\$ 49,006

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended		Nine Months Ended	
	September	September	September	September
	28,	30,	28,	30,
	2012	2011	2012	2011
Net sales	\$ 15,866	\$ 15,266	\$ 47,316	\$ 46,385
Cost of sales	4,690	4,816	14,194	15,445
Gross profit	11,176	10,450	33,122	30,940
General and administrative	3,450	3,683	10,942	10,985
Marketing and selling	5,507	4,439	15,536	13,098
Research and development	1,582	1,454	4,640	4,279
Other general and administrative expenses	728	137	1,980	463
Operating income (loss)	(91)	737	24	2,115
Other income (expense):				
Interest income	7	7	14	24
Interest expense	(65)	(134)	(227)	(440)
Gain (loss) on foreign currency transactions	191	(277)	9	167
Other income (expense), net	87	(42)	610	358
Other income (expense), net	220	(446)	406	109
Income before provision for income taxes	129	291	430	2,224
Provision for income taxes	219	214	779	985
Net income (loss)	\$ (90)	\$ 77	\$ (349)	\$ 1,239
Net income (loss) per share - basic	\$ (0.00)	\$ 0.00	\$ (0.01)	\$ 0.04
Net income (loss) per share - diluted	\$ (0.00)	\$ 0.00	\$ (0.01)	\$ 0.03
Weighted average shares outstanding - basic	36,292	35,539	36,206	35,304
Weighted average shares outstanding - diluted	36,292	36,953	36,206	36,507

See accompanying notes to the condensed consolidated financial statements.

STAAR SURGICAL COMPANY**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)****(In thousands, except par value amounts)****(Unaudited)**

	Three Months Ended		Nine Months Ended	
	September 28, 2012	September 30, 2011	September 28, 2012	September 30, 2011
Net income (loss)	\$ (90)	\$ 77	\$ (349)	\$ 1,239
Other comprehensive income:				
Foreign currency translation	201	19	15	(22)
Pension liability adjustment	(12)	407	(36)	310
Other comprehensive income	189	426	(21)	288
Comprehensive income (loss)	\$ 99	\$ 503	\$ (370)	\$ 1,527

See accompanying notes to the condensed consolidated financial statements.

STAAR SURGICAL COMPANY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended	
	September 28, 2012	September 30, 2011
Cash flows from operating activities:		
Net income (loss)	\$ (349)	\$ 1,239
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation of property and equipment	989	890
Amortization of intangibles	525	595
Deferred income taxes	114	150
Fair value adjustment of warrant	(217)	(29)
Loss (gain) on disposal of property and equipment	47	(14)
Change in net pension liability	187	147
Stock-based compensation expense	2,317	1,330
Other	40	(70)
Changes in working capital:		
Accounts receivable	910	1,630
Inventories	(734)	241
Prepays, deposits and other current assets	85	331
Accounts payable	(444)	(201)
Other current liabilities	236	(829)
Net cash provided by operating activities	3,706	5,410
Cash flows from investing activities:		
Release of restricted cash	129	—
Acquisition of property and equipment	(1,161)	(722)
Proceeds from sale of property and equipment	—	26
Net change in other assets	—	48
Net cash used in investing activities	(1,032)	(648)
Cash flows from financing activities:		
Repayment of capital lease obligations	(619)	(412)
Proceeds from exercise of stock options	1,102	2,983
Net cash provided by financing activities	483	2,571
Effect of exchange rate changes on cash and cash equivalents	14	46

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Increase in cash and cash equivalents	3,171	7,379
Cash and cash equivalents, at beginning of the period	16,582	9,376
Cash and cash equivalents, at end of the period	\$ 19,753	\$ 16,755

See accompanying notes to the condensed consolidated financial statements.

STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 28, 2012

(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 30, 2011 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 30, 2011.

The condensed consolidated financial statements for the three and nine months ended September 28, 2012 and September 30, 2011, 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 28, 2012 and September 30, 2011 are not necessarily indicative of the results to be expected for any other interim period or for the entire year.

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

Note 2 — Restricted Cash

On March 2, 2010, as part of the disposition of our former German subsidiary, 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. As of December 30, 2011, restricted cash was \$129,000, a decrease of \$7,000 due to the effect of foreign currency translation. The balance of funds remaining on December 30, 2011, if any, after the payment of such taxes, were to be distributed to STAAR from the escrow account. During February 2012, the Company received the full amount of the deposit.

Note 3 — 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):

	September 28, 2012	December 30, 2011
Raw materials and purchased parts	\$ 1,877	\$ 1,883
Work-in-process	1,849	2,055
Finished goods	8,587	7,476
	12,313	11,414
Inventory reserves	(520)	(481)
	\$ 11,793	\$ 10,933

Note 4 — Prepaids, Deposits, and Other Current Assets

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

	September 28, 2012	December 30, 2011
Prepaid vendors	\$ 931	\$ 844
Prepaid insurance	317	486
Other current assets	592	591
	\$ 1,840	\$ 1,921

STAAR SURGICAL COMPANY**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****September 28, 2012****(Unaudited)****Note 5 — Property, Plant and Equipment**

Property, plant and equipment consisted of the following (in thousands):

	September 28, 2012	December 30, 2011
Machinery and equipment	\$ 13,578	\$ 13,654
Furniture and fixtures	5,487	4,324
Leasehold improvements	4,850	4,783
	23,915	22,761
Less accumulated depreciation	19,217	18,539
	\$ 4,698	\$ 4,222

Note 6 – Amortizable Intangible Assets

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

	September 28, 2012			December 30, 2011		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Amortized intangible assets:						
Patents and licenses	\$10,868	(9,835)) \$1,033	\$10,868	\$ (9,508)) \$1,360
Customer relationships	2,023	(961)) 1,062	2,023	(809)) 1,214
Developed technology	1,286	(923)) 363	1,286	(871)) 415
Total	\$14,177	\$ (11,719)) \$2,458	\$14,177	\$ (11,188)) \$2,989

Note 7 – Other Current Liabilities

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

	September 28, 2012	December 30, 2011
Accrued salaries and wages	\$ 2,272	\$ 2,051
Accrued bonuses	378	1,520
Accrued audit fees	488	322
Accrued income taxes	1,191	324
Customer credit balances	359	559
Accrued insurance	135	392
Other	1,525	938
	\$ 6,348	\$ 6,106

Note 8 – Pension Plans

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

	Three Months Ended September 28, 2012	Three Months Ended September 30, 2011	Nine Months Ended September 28, 2012	Nine Months Ended September 30, 2011
Service cost	\$ 122	\$ 161	\$ 364	\$ 423
Interest cost	34	42	102	104
Expected return on plan assets	(28)	(34)	(81)	(83)
Amortization of unrecognized transitional obligation	4	4	12	12
Amortization of prior service cost	—	(1)	(1)	(1)
Recognized actuarial gain	(1)	(2)	(4)	(18)
	\$ 131	\$ 170	\$ 392	\$ 437

STAAR SURGICAL COMPANY**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****September 28, 2012****(Unaudited)**

During the nine months ended September 28, 2012 and September 30, 2011, the Company made cash contributions totaling approximately \$176,000 and \$203,000 to its Swiss pension plan and expects to make additional cash contributions totaling approximately \$58,000 during the remainder of 2012. The Company is not required to and does not make contributions to its Japan pension plan.

Note 9 — 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 Ended	
	September 28, 2012	September 30, 2011	September 28, 2012	September 30, 2011
Numerator:				
Net (loss) income	\$ (90)	\$ 77	\$ (349)	\$ 1,239
Denominator:				
Weighted average common shares and denominator for basic calculation:				
Weighted average common shares outstanding	36,495	35,695	36,378	35,442
Less: Unvested restricted stock	203	156	172	138
Denominator for basic calculation	36,292	35,539	36,206	35,304
Weighted average effects of dilutive equity-based compensation awards:				
Employee stock options	—	846	—	751
Warrants	—	568	—	452
Denominator for diluted calculation	36,292	36,953	36,206	36,507

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Net (loss) income per share – basic	\$ (0.00)	\$ 0.00	\$ (0.01)	\$ 0.04
Net (loss) income per share - diluted	\$ (0.00)	\$ 0.00	\$ (0.01)	\$ 0.03

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

	Three Months Ended		Nine Months Ended	
	September 28, 2012	September 30, 2011	September 28, 2012	September 30, 2011
Options and restricted stock	3,183	1,405	1,813	1,279
Warrants	605	70	806	70
Total	3,788	1,475	2,619	1,349

STAAR SURGICAL COMPANY**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****September 28, 2012****(Unaudited)****Note 10 — Geographic and Product Data**

The Company markets and sells its products in approximately 60 countries and has manufacturing sites in the United States, Switzerland and Japan. Other than the United States, Japan, Korea, and China, the Company does not conduct business in any country in which its sales exceed 5% of consolidated sales. Sales are attributed to countries based on location of customers. The composition of the Company's net sales to unaffiliated customers is set forth below (in thousands):

	Three Months Ended		Nine Months Ended	
	September 28, 2012	September 30, 2011	September 28, 2012	September 30, 2011
United States	\$ 3,038	\$ 3,211	\$ 9,428	\$ 10,448
Japan	4,237	4,037	12,187	11,772
Korea	1,755	2,069	5,379	5,463
China	2,444	1,825	6,691	4,832
Other	4,392	4,124	13,631	13,870
Total	\$ 15,866	\$ 15,266	\$ 47,316	\$ 46,385

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 Months Ended		Nine Months Ended	
	September 28, 2012	September 30, 2011	September 28, 2012	September 30, 2011
ICLs	\$ 9,111	\$ 7,902	\$ 26,321	\$ 23,091
IOLs	6,052	6,571	19,185	20,767
Core products	15,163	14,473	45,506	43,860

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Other Surgical Products	703	793	1,810	2,527
Total	\$ 15,866	\$ 15,266	\$ 47,316	\$ 46,385

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. dollars), regulation of fund transfers by foreign governments, United States and foreign export and import duties and tariffs, and political instability.

Note 11— Commitments and Contingencies

The Company has accrued \$0.6 million as of September 28, 2012 in termination benefit costs in connection with its manufacturing consolidation project. The accrual represents STAAR's current best estimate of the termination benefits that will be paid to the eligible employees. The total severance of approximately \$1.4 million is expected to be paid out by first quarter of 2014. In addition, the Company expects to spend approximately \$700,000 on tenant improvements during the fourth quarter of 2012.

Note 12 — Stock-Based Compensation

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

	Three Months Ended		Nine Months Ended	
	September 28, 2012	September 30, 2011	September 28, 2012	September 30, 2011
ASC 718 expense	\$ 660	\$ 363	\$ 1,850	\$ 978
Restricted stock expense	170	115	433	320
Consultant compensation	8	45	34	32
Total	\$ 838	\$ 523	\$ 2,317	\$ 1,330

STAAR SURGICAL COMPANY**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****September 28, 2012****(Unaudited)**

Stock Option Plans

The Amended and Restated 2003 Omnibus Equity Incentive Plan (“the Plan”) provides for various forms of stock-based incentives. To date, of the available forms of awards under the Plan, the Company has granted only stock options, restricted stock, unrestricted share grants, and may grant in the future performance contingent shares. Options under the plan are granted at fair market value on the date of grant, become exercisable over a three year period, or as determined by the Board of Directors, and expire over periods not exceeding 10 years from the date of grant. Certain option and share awards provide for accelerated vesting if there is a change in control (as defined in the Plan). Pursuant to the Plan, options for 3,479,111 shares were outstanding at September 28, 2012 with exercise prices ranging between \$0.95 and \$11.02 per share. Restricted stock grants under the Plan generally vest over a period of one, three or four years. There were 204,500 shares of restricted stock outstanding at September 28, 2012. As of September 28, 2012, there were 969,035 shares authorized and available for grants under the 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. The Company has calculated a 9.92% estimated forfeiture rate used in the model for fiscal year 2012 option grants based on historical forfeiture experience. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

	Three Months Ended				Nine Months Ended			
	September 28, 2012		September 30, 2011		September 28, 2012		September 30, 2011	
Expected dividend yield	0	%	0	%	0	%	0	%
Expected volatility	80.28	%	76.99	%	79.48	%	76.93	%

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Risk-free interest rate	0.63	%	1.12	%	0.82	%	1.94	%
Expected term (in years)	5.21		5.49		5.21		5.49	

A summary of option activity under the Plan as of September 28, 2012 is presented below:

Options	Shares
	(000's)
Outstanding at December 30, 2011	3,064
Granted	677
Exercised	(223)
Forfeited or expired	(39)
Outstanding at September 28, 2012	3,479
Exercisable at September 28, 2012	2,178

Note 13 — Manufacturing Consolidation Project and Tax Strategy

Since 2011 the Company devoted significant resources to two initiatives: a project to consolidate global manufacturing and product development of part of a strategy to optimize its global organization for tax purposes. The goal of both of these strategies is to continue the Company's 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 consolidate its manufacturing in a single site at its Monrovia, California location by the end of 2014, which is expected subsequently to yield significant savings in cost of goods and to lower its global administrative and regulatory costs and reduce income taxes.

STAAR SURGICAL COMPANY**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****September 28, 2012****(Unaudited)**

The Company expects these initiatives to cost approximately \$6 million over a three-year period, of which it has incurred approximately \$3.0 million to date. These expenses are included in “other general and administrative expenses” in consolidated statement of income for the period ended September 28, 2012. Expenses to date have largely consisted of professional fees to advisors and consultants, travel, salaries and severance accrual. The Company also expects to spend approximately \$2.5 million in capital expenditures to consolidate its manufacturing.

A summary of the activity for these initiatives is presented below as of September 28, 2012 (in thousands):

	Termination Benefits	Other Associated Costs	Total
Liability at December 31, 2010	\$ —	\$ —	\$—
Costs incurred and charged to expense	36	1,024	1,060
Cash payments	—	(678) (678)
Liability at December 30, 2011	\$ 36	\$ 346	\$382
Costs incurred and charged to expense	\$ 665	\$ 1,315	\$1,980
Cash payments	\$ (99) \$ (1,270) \$(1,369)
Liability at September 28, 2012	\$ 602	\$ 391	\$993
Total costs incurred to date	\$ 701	\$ 2,339	\$3,040
Total costs expected to be incurred	\$ 1,437	\$ 4,563	\$6,000

Note 14— New Accounting Pronouncements

During the three months ended September 28, 2012, there were no new accounting pronouncements that would have a material effect on our unaudited condensed consolidated financial statements. For a description of recent accounting pronouncements relevant to us, please refer “Recent Accounting Pronouncements” included in Note 1 of our Annual Report on Form 10-K for the year ended December 30, 2011.

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 30, 2011. STAAR undertakes no obligation to update these forward-looking statements 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 (“we,” “us,” the “Company,” and “STAAR”) designs, develops, manufactures and sells implantable lenses for the eye and injector devices used to deliver these lenses into the eye through a small incision. 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 to treat 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. 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. Astigmatism is a condition that causes blurred vision when an irregular shape of the cornea prevents light from focusing properly on the retina. Cataract surgery is a 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.

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

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

Products

A detailed description of STAAR's business appears in our Annual Report on Form 10-K for the fiscal year ended December 30, 2011, 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.

ICLs - Visian Implantable Collamer Lenses. Sales of refractive lenses make up over half of our total sales. Made from our proprietary biocompatible Collamer material, STAAR's range of Visian ICL products includes the following:

The Visian ICL treats refractive disorders such as myopia (near-sightedness) and hyperopia (far-sightedness). STAAR began selling the Visian ICL outside the U.S. in 1996 and inside the U.S. in 2006.

The Visian Toric ICL®, or TICL®, treats myopic and hyperopic patients with astigmatism. STAAR began selling the Visian TICL outside the U.S. in 2002. The TICLs are available for sale in outside the U.S.

STAAR currently sells several versions of the Visian ICL and Visian TICL; the original V4, the V4b, which expands the population of eligible patients to individuals in the lower diopter range (from -3.0 to +3.0), and the V4c, which includes the proprietary CentraFLOW technology (a port in the center of the myopic ICL and TICL) that eliminates the need for a peripheral iridectomy or iridotomy procedure prior to implanting the ICL.

STAAR's goal is to position the Visian ICL and TICL products throughout the world as primary choices for refractive surgery.

IOLs - Intraocular Lenses for Cataract Surgery. Our range of foldable IOLs for patients undergoing cataract surgery includes the following:

Aspheric IOLs, available in single-piece and three-piece designs made from Collamer, STAAR's proprietary biocompatible collagen copolymer lens material and from silicone. Aspheric IOLs are designed to improve the patient's quality of vision when compared to earlier spherical IOL designs. The three piece aspheric silicone lens is available in all major markets globally and is sold preloaded in markets outside of the U.S. The Collamer three piece lens is only marketed and sold in the U.S.

The nanoFLEX IOL, a single-piece Collamer aspheric IOL that can be implanted through a micro-incision with a single-use disposable nanoPOINT injector system is available in the U.S and 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 IOL Preloaded Injector uses an acrylic lens sourced from another manufacturer. The KS-SP, a single-piece preloaded acrylic IOL that can be implanted through a micro-incision with a single-use disposable injector system became available through a limited launch in Europe during the third quarter of 2012.

STAAR Toric IOL is a single piece silicone toric IOL, used in cataract surgery to treat preexisting astigmatism and is currently only marketed in the U.S and Canada. A Collamer version of our toric IOL –nanoFLEX Toric has CE mark approval and should be available in markets covered by CE during the fourth quarter of 2012.

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, cataract procedures volumes 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.

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.

Operations

STAAR operates its global administrative headquarters and a manufacturing facility in Monrovia, California, and also maintains manufacturing facilities in Nidau, Switzerland, Chiba Prefecture, Japan, and Aliso Viejo, California.

STAAR is implementing a project to consolidate its manufacturing into a single site at its Monrovia, California location by the end of 2014, which we expect to yield significant savings in cost of goods, lower our global administrative and regulatory costs and reduce income taxes. During September 2012, 75% of all non-sterile silicone IOLs for Japan were manufactured in the U.S. We expect to build the first Visian ICLs in the U.S. during the first quarter of 2013. This project, which is subject to significant risks, is further described under Note 13, “*Manufacturing Consolidation Project and Tax Strategy.*”

On August 17, 2012, STAAR entered into a commercial lease for the real property located at 1941 S. Walker Avenue, Monrovia, California, including a commercial building of approximately 26,000 square feet. The lease begins on November 1, 2012 and has an initial term of eight years. The Company has two options to extend the lease, each for a period of five years. The Company expects to spend approximately \$700,000 on tenant improvements during the fourth quarter of 2012. The premises adjoin STAAR’s headquarters at 1911 S. Walker Avenue.

Strategy and Key Operational Metrics

STAAR’s strategy is to be a leading global provider of innovative intraocular lens system technologies. STAAR employs a focused commercialization strategy, consisting of direct and indirect sales personnel in over 60 markets, including eleven targeted markets that enables sustainable profitable growth.

STAAR’s key operational metrics for 2012 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 2012 along five key operational metrics it uses to gauge its success during the year. Those metrics are as follows:

Increase total revenue by high single digits (on August 1, 2012, we changed this metric from its original metric of 15% for 2012).

-The Company is expecting its year-over-year fourth quarter growth to exceed its third quarter growth rate. However, it would be beyond our current expectations to be in high single digit growth for the year.

Grow Visian ICL sales by 25% for the second half of 2012 and 20% for the year (on August 1, 2012, we changed this metric from its original metric of 32% or greater for 2012).

-The Company is expecting strong ICL revenue growth during the fourth quarter. However, without a solid rebound in Asia Pacific markets, this metric would be beyond our current expectations.

· Increase gross profit margins to achieve a level of 71% for the full year.

-Based upon the Company's performance during the three months ended September 28, 2012, and the Company's estimates for the fourth quarter, the Company is expecting to achieve this metric for the fourth quarter and for the full year.

Achieve profitability in three quarters of 2012 (on August 1, 2012, we changed this goal from achieving profitability in all four quarters of 2012).

-Though the Company was unprofitable during the three months ended September 28, 2012 based upon the Company's estimates for the fourth quarter, we are expecting to achieve this metric for the fourth quarter and for the full year.

· Manage the manufacturing consolidation with no material disruption to customer supply requirements.

-The Company's consolidation efforts are proceeding according to plans and the Company expects this to continue during the fourth quarter.

Other Highlights

STAAR continues to strengthen its direct sales and marketing business in Spain. We hired an additional employee in Spain and hosted a series of events during the Spanish Annual Ophthalmic Meeting in Barcelona, Spain in September. We incurred \$0.4 million in selling expenses related to the change in distribution in Spain, and we expect the expense associated with the transition in Spain will continue through February 2013, at which time the normal logistics costs of being direct in a market will begin. The on-going weakness and uncertainty in the Spanish economy may affect the magnitude and timing of future benefits from our direct model in Spain.

Status of Regulatory Submissions. Regarding our PMA Supplement submission to the FDA seeking approval for the TICL, by a letter dated April 30, 2012 the FDA rejected our most recent proposed approach to respond to the FDA's concerns regarding timing of follow-up visits for certain patients in the study cohort at certain sites. STAAR remains in dialogue with the agency to find a resolution to the timing concerns and will submit a response to the FDA by November 16, 2012. STAAR believes that these issues do not affect the scientific integrity of the data in establishing the safety and effectiveness of our TICL product. STAAR cannot predict when, or if, the FDA will grant approval of the TICL for use in the United States.

On October 9, 2012, STAAR submitted to the FDA a 180 day PMA Supplement regarding the V4c version of the Visian ICL. To date, STAAR has not received a response from the FDA. We'll continue to seek approval for our key products in our target markets.

Organizational Developments.

On September 4, 2012, STAAR announced the hiring of James Francese as V.P., Global Marketing, the transition of Robin Hughes from V.P., Global Marketing to V.P., Research & Development, and the transition of Craig Felberg from V.P., Research & Development to the V.P., Business Development, a newly created role. These leadership transitions are designed to help fuel revenue growth in three ways: more effectively market STAAR products globally, bring new internally-developed products to market more quickly and evaluate additional new externally-developed technologies and business opportunities, which will allow us to grow within our area of strategic focus.

On September 13, 2012, STAAR announced the appointment of Charles Slacik, CPA, to the Board of Directors. Mr. Slacik has over 30 years of executive level experience in the health care industry, serving most recently as the Senior Vice President and Chief Financial Officer of Beckman Coulter Inc. His appointment brings the number of directors on the STAAR Surgical Board to seven. STAAR also announced that the current chairman of the Audit Committee, Don Duffy, has advised the Board he intends to retire at the end of his current term in May, 2013 after holding the position for 10 years. We expect Mr. Slacik to replace Mr. Duffy as chairman of the Audit Committee and the transition to go smoothly.

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 28, 2012 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 30, 2011.

Results of Operations

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

	Percentage of Net Sales for Three Months			Percentage Change for Three Months	Percentage of Net Sales for Nine Months			Percentage Change for Nine Months
	Three Months				Nine Months			
	September 28, 2012	September 30, 2011	2012 vs. 2011		September 28, 2012	September 30, 2011	2012 vs. 2011	
Net sales	100.0 %	100.0 %	3.9 %		100.0 %	100.0 %	2.0 %	

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Cost of sales	29.6	31.5	(2.6)	30.0	33.3	(8.1)
Gross profit	70.4	68.5	6.9	70.0	66.7	7.1
General and administrative	21.7	24.1	(6.3)	23.1	23.7	(0.4)
Marketing and selling	34.7	29.1	24.1	32.8	28.2	18.6
Research and development	10.0	9.5	8.8	9.8	9.2	8.4
Other general and administrative expenses	4.6	0.9	—*	4.2	1.0	—*
	71.0	63.6	16.0	69.9	62.1	14.8
Operating income(loss)	(0.6)	4.8	—*	0.1	4.6	(98.9)*
Other income (expense), net	1.4	(2.9)	—*	0.9	0.2	—*
Income (loss) before provision for income taxes	0.8	1.9	(55.7)*	0.9	4.8	(80.7)*
Provision for income taxes	1.4	1.4	2.3	1.6	2.1	(20.9)
Net income (loss)	(0.6)%	0.5 %	—*	(0.7)%	2.7 %	—*

*Denotes change is greater than $\pm 100\%$.

Net Sales

	Three Months Ended		Percentage Change for Three Months		Nine Months Ended		Percentage Change for Nine Months	
	September 28, 2012	September 30, 2011	2012 vs. 2011		September 28, 2012	September 30, 2011	2012 vs. 2011	
Net sales	\$ 15,866	\$ 15,266	3.9	%	\$ 47,316	46,385	2.0	%
ICL	9,111	7,902	15.3		26,321	23,091	14.0	
IOL	6,052	6,571	(7.9)	19,185	20,767	(7.6)
Other	703	793	(11.3)	1,810	2,527	(28.4)

Net sales for the three months ended September 28, 2012 were \$15.9 million, an increase of 3.9% compared to the \$15.3 million reported during the three months ended September 30, 2011. Net sales for the nine months ended September 28, 2012 were \$47.3 million, a 2.0% increase compared with \$46.4 million reported during the nine months ended September 30, 2011. As described below, the increase in net sales for the three and nine-month periods primarily resulted from increased sales of ICLs, which were largely offset by decreased sales of IOLs and Other surgical products.

Total Visian ICL sales for the three months ended September 28, 2012 were \$9.1 million, an increase of 15.3% compared with \$7.9 million reported during the three months ended September 30, 2011. Total Visian ICL sales for the nine months ended September 28, 2012 were \$26.3 million, an increase of 14.0% compared with \$23.1 million reported during the nine months ended September 30, 2011. The increase in Visian ICL sales for the three-month period is due to increased sales in China, Spain, Japan, India, Italy, Latin America, U.K., and the U.S., partially offset by decreased sales in Korea, Middle East and Germany. Sales in Europe, Middle East, Africa, and Latin America (“EMEA”) grew by 17%. Visian ICL with CentraFLOW™ technology represented approximately 82% of total ICL sales in Europe, with over 7,000 implants in Europe since introduction and is performing as expected. Sales in North America increased by 11% during the three months ended September 28, 2012 due to increased promotional activities including initial benefits from social media activities. Sales to private sector accounts in the U.S. increased by 20%, while military sales of Visian ICLs declined 12%, due to a year-end military order during the third quarter of 2011. Sales in the Asia Pacific market increased 15% led by Japan (56% increase), China (52% increase) and India (24% increase); offset by a decline in our largest market, Korea (15% decrease). The increase in Visian ICL sales for the nine-month period was due to a 16% increase in sales in our top eleven refractive markets. Visian ICL sales represented 57% and 56%, respectively, of our total sales for the three and nine months ended September 28, 2012, compared to 52% and 50%, respectively for the three and nine months ended September 30, 2011.

Total IOL sales for the three months ended September 28, 2012 were \$6.1 million, a decrease of 7.9%, when compared with the \$6.6 million reported for the three months ended September 30, 2011. Total IOL sales for the nine months ended September 28, 2012 were \$19.2 million, a decrease of 7.6%, when compared with the \$20.8 million reported for the nine months ended September 28, 2011. IOL sales represented 38% and 41% of sales for the three and nine months ended September 28, 2012, compared to 43% and 45%, respectively for the three and nine months ended September 30, 2011. We believe the decline in net IOL sales resulted from an overall global cataract procedure decline and delays in the launch of the KS-SP Preloaded IOL in Europe and Japan and the Toric Collamer IOL in Europe. The Company expects to launch the KS-SP during the fourth quarter of 2012 and the Toric Collamer IOL during the first quarter of 2013.

Other product sales for the three and nine months ended September 28, 2012 were \$0.7 million and \$1.8 million, a decrease of 11.3% and 28.4%, respectively, when compared with \$0.8 million and \$2.5 million for the three and nine months ended September 30, 2011. The Company expects to continue to see declines in its other product sales as it has deemphasized these products.

Gross Profit

	Three Months Ended			Percentage Change for Three Months		Nine Months Ended			Percentage Change for Nine Months	
	September 28, 2012	September 30, 2011		2012 vs. 2011	September 28, 2012	September 30, 2011		2012 vs. 2011		
Gross Profit	\$ 11,176	\$ 10,450		6.9 %	\$ 33,122	\$ 30,940		7.1 %		
Gross Profit Margin	70.4 %	68.5 %			70.0 %	66.7 %				

Gross profit for the third quarter was \$11.2 million, or 70.4% of revenue, compared with \$10.5 million, or 68.5% of revenue, in the prior year period. During the first nine months of 2012, gross profit was \$33.1 million, or 70.0% of revenue, compared with \$30.9 million, or 66.7% of revenue, in the prior year period. The increase in gross profit and gross profit margin is due to higher mix of ICLs and improved manufacturing cost on ICL's. IOL gross margin was 60% for both the three and nine months periods of 2012, respectively, compared with 59% for the three months and 58% for the nine months periods of 2011.

Marketing and Selling

	Three Months Ended			Percentage Change for Three Months	Nine Months Ended			Percentage Change for Nine Months
	September 28, 2012	September 30, 2011	2012 vs. 2011		September 28, 2012	September 30, 2011	2012 vs. 2011	
Marketing and Selling	\$ 5,507	\$ 4,439	24.1	%	\$ 15,536	\$ 13,098	18.6	%
Percentage of Sales	34.7 %	29.1 %			32.8 %	28.2 %		

Marketing and selling expenses increased by 24.1% to \$5.5 million in the third quarter of 2012, compared with \$4.4 million in the third quarter of 2011. Marketing and selling expenses for the nine months ended September 28, 2012 were \$15.5 million, an increase of 18.6% when compared with \$13.1 million for the nine months ended September 30, 2011. The increase for both periods is due to increased headcount, increased stock-based compensation, and increased costs associated with the move to a direct distribution model in Spain.

Research and Development

	Three Months Ended			Percentage Change for Three Months	Nine Months Ended			Percentage Change for Nine Months
	September 28, 2012	September 30, 2011	2012 vs. 2011		September 28, 2012	September 30, 2011	2012 vs. 2011	
Research and Development	\$ 1,582	\$ 1,454	8.8	%	\$ 4,640	\$ 4,279	8.4	%
Percentage of Sales	10.0 %	9.5 %			9.8 %	9.2 %		

Research and development expense increased in the third quarter of 2012, by 8.8% to \$1.6 million, compared with \$1.5 million in the third quarter of 2011. Research and development expense for the nine months ended September 28, 2012 was \$4.6 million, an increase of 8.4% when compared with \$4.3 million reported last year. The increase for both periods was primarily due to increased salaries and associated stock-based compensation.

Other General and Administrative Expenses

	Three Months Ended		Percentage Change for Three Months	Nine Months Ended		Percentage Change for Nine Months		
	September 28, 2012	September 30, 2011		2012 vs. 2011	September 28, 2012		September 30, 2011	2012 vs. 2011
	Other General and Administrative Expenses	\$ 0.7		\$ 0.1	— *		\$ 1,980	\$ 0.5
Percentage of Sales	4.6 %	0.9 %		4.2 %	1.0 %			

*Denotes change is greater than $\pm 100\%$.

Other general and administrative expenses for the third quarter were \$0.7 million, compared with \$0.1 million in the third quarter of 2011. Other general and administrative expenses for the nine months ended September 28, 2012 were \$2.0 million, compared with \$0.5 million, during the first nine months of 2011. The increase in both periods resulted from accrued severance, salaries, travel, consulting fees and other expenses associated with the consolidation of the Company's manufacturing facilities. The Company expects to incur a total of approximately \$2.5 million in manufacturing consolidation expenses in 2012.

Other Income, (Expense) Net

	Three Months Ended		Percentage Change for Three Months	Nine Months Ended		Percentage Change for Nine Months		
	September 28, 2012	September 30, 2011		2012 vs. 2011	September 28, 2012		September 30, 2011	2012 vs. 2011
	Other Income (Expense), Net	\$ 0.2		\$ (0.4)	— *		\$ 0.4	\$ 0.1

*Denotes change is greater than $\pm 100\%$.

Other income, net, for the three and nine months ended September 28, 2012, was \$0.2 and \$0.4 million, respectively, compared to other expense of \$0.4 million and other income of \$0.1 million for the three and nine months ended September 30, 2011, respectively. The year over year increase in other income, net for both periods is due to foreign exchange gains, an increase in royalty income, and decreased interest expense.

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 previously discussed by us and further described in Note 13, "*Manufacturing Consolidation Project and Tax Strategy*." If the need for financing arises, STAAR cannot assure that it will be available on acceptable terms, if at all. STAAR's Japanese and Swiss subsidiaries have bank lines of credit in place for working capital purpose, but STAAR does not maintain such a credit line in the U.S.

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 28, 2012 and December 30, 2011, respectively, STAAR had \$19.8 million and \$16.7 million, of cash and cash equivalents and restricted cash.

Net cash provided by operating activities for the nine months ended September 28, 2012 and September 30, 2011, respectively, was \$3.7 million and \$5.4 million. Net cash provided by operations for nine months ended September 28, 2012 consisted of net loss of \$0.3 million plus \$4.0 million in non-cash items, offset by \$.05 million increase in

working capital.

Net cash used by investing activities for the nine months ended September 28, 2012 and September 30, 2011, respectively, was \$1.0 million and \$0.6 million. Net cash used in investing activities was mainly due to \$1.1 million in acquisition of property, plant and equipment, partially offset by \$0.1 million resulting from the release of escrowed funds.

Net cash provided by financing activities for the nine months ended September 28, 2012 and September 30, 2011, respectively, was \$0.5 million and \$2.6 million. Net cash provided by financing activities consisted of \$1.1 million in proceeds from stock options, partially offset by \$0.6 million in capital lease repayments.

Credit Facilities, Contractual Obligations and Commitments

Accrued Termination Benefits for Manufacturing Consolidations Project

The Company has accrued \$0.6 million as of September 28, 2012 in termination benefit costs in connection with its manufacturing consolidation project. The accrual represents STAAR's current best estimate of the termination benefits that will be paid to the eligible employees. The total anticipated severance of approximately \$1.4 million is expected to be paid out by first quarter of 2014.

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 28, 2012), at an interest rate equal to the Tokyo short-term prime interest rate (approximately 1.475% as of September 28, 2012) plus 1.125%. The Company had 200,000,000 Yen outstanding on the line of credit as of September 28, 2012 and December 30, 2011 (approximately \$2.6 million based on the foreign exchange rates on September 28, 2012 and December 30, 2011). As of September 28, 2012, 100,000,000 Yen (approximately \$1.3 million based on the rate of exchange on September 28, 2012) 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 (approximately \$1.0 million at the rate of exchange on September 28, 2012), to be used for working capital purposes. There were no borrowings outstanding as of September 28, 2012 and the full amount of the line was available for borrowing.

Covenant Compliance

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

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):

Fiscal Year	September 28, 2012	December 30, 2011
2012	\$ 286	\$ 947
2013	895	774
2014	277	152

2015	95	39
Thereafter	10	—
Total minimum lease payments	\$ 1,563	\$ 1,912
Less: interest	(96)	191
Total lease obligation	\$ 1,467	\$ 1,721
Current	\$ 933	\$ 597
Long-term	\$ 534	\$ 1,124

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 30, 2011.

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 28, 2012 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 30, 2011. Such risks and uncertainties could materially adversely affect our business, financial condition or operating results.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

Not Applicable.

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)
 - 10.90 Standard Industrial/Commercial Single-Tenant Lease. (7)
 - 31.1 Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *
 - 31.2 Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *
 - 32.1 Certification Pursuant to 18 U.S.C. Section 1350, Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *
- 101 Financial statements from the quarterly report on Form 10-Q of STAAR Surgical Company for the quarter ended September 28, 2012, 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, (iv) the Consolidated Statements of Comprehensive Loss, and (v) 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.

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- (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.
- (7) Incorporated by reference to Exhibit 10.90 to the Company's Current Report on Form 8-K filed with the Commission on August 17, 2012.

* 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 5, 2012 By: /s/ DEBORAH ANDREWS
Deborah Andrews

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