

STAAR SURGICAL CO  
Form 10-Q  
November 01, 2013

**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 27, 2013**

**Or**

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

**For the transition period from to**

**Commission file number: 0-11634**

**STAAR SURGICAL COMPANY**

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

**Delaware**

*(State or other jurisdiction of  
incorporation or organization)*

**95-3797439**

*(I.R.S. Employer  
Identification No.)*

**1911 Walker Avenue**

**Monrovia, California 91016**

*(Address of principal executive offices)*

**(626) 303-7902**

*(Registrant's telephone number, including area code)*

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

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

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

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

Large accelerated filer

Accelerated filer

Non-accelerated filer  
(Do not check if a smaller  
reporting company)

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 37,297,343 shares of common stock, par value \$0.01 per share, issued and outstanding as of October 25, 2013.

**STAAR SURGICAL COMPANY**

**INDEX**

		PAGE NUMBER
<b>PART I FINANCIAL INFORMATION</b>		
Item 1.	Financial Statements (Unaudited).	3
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations.	14
Item 3.	Quantitative and Qualitative Disclosures About Market Risk.	22
Item 4.	Controls and Procedures.	22
<b>PART II OTHER INFORMATION</b>		
Item 1.	Legal Proceedings.	22
Item 1A.	Risk Factors.	22
Item 4.	Mine Safety Disclosures.	22
Item 5.	Other Information.	22
Item 6.	Exhibits.	22

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

	September 27, 2013	December 28, 2012
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$23,351	\$21,675
Accounts receivable trade, net	9,467	8,543
Inventories, net	11,880	11,673
Deferred income taxes	483	
Prepays, deposits and other current assets	2,703	2,183
Total current assets	47,884	44,074
Property, plant and equipment, net	6,512	5,439
Intangible assets, net	1,567	2,142
Goodwill	1,786	1,786
Deferred income taxes	732	187
Other assets	1,056	1,131
Total assets	\$59,537	\$54,759
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Line of credit	\$5,050	\$5,850
Accounts payable	4,536	5,129
Deferred income taxes	439	439
Obligations under capital leases	393	829
Other current liabilities	6,052	5,702
Total current liabilities	16,470	17,949
Obligations under capital leases	211	488
Deferred income taxes	1,690	885
Asset retirement obligations	374	707
Pension liability	2,971	2,988
Total liabilities	21,716	23,017
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Common stock, \$0.01 par value; 60,000 shares authorized; 36,955 and 36,423 shares issued and outstanding at September 27, 2013 and December 28, 2012	370	364
Additional paid-in capital	168,056	162,251
Accumulated other comprehensive income	574	1,580
Accumulated deficit	(131,179)	(132,453)
Total stockholders' equity	37,821	31,742
Total liabilities and stockholders' equity	\$59,537	\$54,759

*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 27, 2013	September 28, 2012	September 27, 2013	September 28, 2012
Net sales	\$ 17,106	\$ 15,866	\$ 53,271	\$ 47,316
Cost of sales	5,047	4,690	15,939	14,194
Gross profit	12,059	11,176	37,332	33,122
General and administrative	4,140	3,450	12,021	10,942
Marketing and selling	5,527	5,507	16,471	15,536
Research and development	1,684	1,582	4,736	4,640
Medical device tax	45		149	
Other general and administrative expenses	490	728	2,004	1,980
Operating income (loss)	173	(91)	1,951	24
Other income (expense):				
Interest income	9	7	23	14
Interest expense	(38)	(65)	(134)	(227)
Gain (loss) on foreign currency transactions	226	191	(38)	9
Other income, net	130	87	360	610
Other income, net	327	220	211	406
Income before provision (benefit) for income taxes	500	129	2,162	430
Provision (benefit) for income taxes	(25)	219	888	779
Net income (loss)	\$ 525	\$ (90)	\$ 1,274	\$ (349)
Net income (loss) per share - basic	\$ 0.01	\$ (0.00)	\$ 0.03	\$ (0.01)
Net income (loss) per share - diluted	\$ 0.01	\$ (0.00)	\$ 0.03	\$ (0.01)
Weighted average shares outstanding - basic	36,750	36,292	36,552	36,206
Weighted average shares outstanding - diluted	39,284	36,292	38,482	36,206

*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 27, 2013	September 28, 2012	September 27, 2013	September 28, 2012
Net income (loss)	\$ 525	\$ (90)	\$ 1,274	\$ (349)
Other comprehensive income (loss), net of tax:				
Foreign currency translation	(92)	201	(986)	15
Pension liability adjustment, net of tax	(5)	(12)	(21)	(36)
Other comprehensive income (loss)	(97)	189	(1,007)	(21)
Comprehensive income (loss)	\$ 428	\$ 99	\$ 267	\$ (370)

*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 27, 2013	September 28, 2012
Cash flows from operating activities:		
Net income (loss)	\$ 1,274	\$ (349)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation of property and equipment	1,325	989
Amortization of intangibles	334	525
Deferred income taxes	(220)	114
Fair value adjustment of warrant	(27)	(217)
Loss on disposal of property and equipment	172	47
Change in net pension liability	124	187
Stock-based compensation expense	2,924	2,317
Accretion of asset retirement obligation	9	
Other	157	40
Changes in working capital:		
Accounts receivable	(1,423)	910
Inventories	(707)	(734)
Prepays, deposits and other current assets	(614)	85
Accounts payable	(389)	(444)
Other current liabilities	489	236
Net cash provided by operating activities	3,428	3,706
Cash flows from investing activities:		
Release of restricted cash		129
Acquisition of property and equipment	(2,984)	(1,161)
Net cash used in investing activities	(2,984)	(1,032)
Cash flows from financing activities:		
Repayment of capital lease obligations	(675)	(619)
Proceeds from exercise of stock options	2,723	1,102
Net cash provided by financing activities	2,048	483
Effect of exchange rate changes on cash and cash equivalents	(816)	14
Increase in cash and cash equivalents	1,676	3,171
Cash and cash equivalents, at beginning of the period	21,675	16,582
Cash and cash equivalents, at end of the period	\$ 23,351	\$ 19,753

*See accompanying notes to the condensed consolidated financial statements.*





## **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. Certain information and footnote disclosures normally included in comprehensive financial statements have been condensed or omitted pursuant to such rules and regulations, although the Company believes that the disclosures made are adequate to make the information not misleading. 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 28, 2012.

The condensed consolidated financial statements for the nine months ended September 27, 2013 and September 28, 2012, 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 nine months ended September 27, 2013 and September 28, 2012 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.

### *Recent Accounting Pronouncements*

In July 2013, the FASB issued ASU 2013-11, “Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists (Topic 740)” (ASU 2013-11), which states that an unrecognized tax benefit, or a portion of an unrecognized tax benefit, should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward. To the extent a net operating loss carryforward, a similar tax loss, or a tax credit carryforward is not available at the reporting date under the tax law of the applicable jurisdiction to settle any additional income taxes that would result from the disallowance of a tax position or the tax law of the applicable jurisdiction does not require the entity to use, and the entity does not intend to use, the deferred tax asset for such purpose, the unrecognized tax benefit should be presented in the financial statements as a liability and should not be combined with deferred tax assets. The assessment of whether a deferred tax asset is available is based on the unrecognized tax benefit and deferred tax asset that exist at the reporting date and should be made presuming disallowance of the tax position at the reporting date. ASU 2013-11 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. The Company plans to adopt this guidance during its quarter ending March 28, 2014 and is assessing the impact, if any, to the consolidated financial statements.

In March 2013, the FASB issued ASU 2013-05, “Parent’s Accounting for the Cumulative Translation Adjustment upon Derecognition of Certain Subsidiaries or Groups of Assets within a Foreign Entity or an investment in a Foreign Entity (Topic 830)” (ASU 2013-05), which provides guidance on releasing cumulative translation adjustments when a reporting entity (parent) ceases to have a controlling financial interest in a subsidiary or group of assets that is a nonprofit activity or a business within a foreign entity. In addition, these amendments provide guidance on the release of cumulative translation adjustments in partial sales of equity method investments and in step acquisitions. This new guidance is effective on a prospective basis for fiscal years and interim reporting periods beginning after December 15, 2013. The amendments should be applied prospectively to derecognition events occurring after the effective date. Prior periods should not be adjusted and early adoption is permitted. The Company plans to adopt this guidance during its quarter ending March 28, 2014 and does not expect the adoption to have any significant impact to

its consolidated financial statements.

In February 2013, the FASB issued ASU 2013-02, “Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income (Topic 220)” (ASU 2013-02), that expanded disclosures for items reclassified out of accumulated other comprehensive income. The standard requires presentation of information about reclassification adjustments from accumulated other comprehensive income in a single note or on the face of the financial statements. ASU 2013-02 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2012. The Company adopted ASU 2013-02 during the quarter ended March 29, 2013, which did not have any effect on its consolidated financial position or results of operations.

In July 2012, the FASB issued ASU 2012-02, “Goodwill and Other - Testing Indefinite-Lived Intangible Assets for Impairment” (ASU 2012-02), which provides companies the option to perform a qualitative assessment to determine whether further impairment testing of indefinite-lived intangible assets is necessary. ASU 2012-02 prescribes an entity to perform a quantitative impairment test if qualitative factors indicate that it is more likely than not that its indefinite-lived intangible assets are impaired. The qualitative factors are similar to the guidance established for goodwill impairment testing and include identifying and assessing events and circumstances that would most significantly impact, individually or in the aggregate, the carrying value of the indefinite-lived intangible assets. ASU 2012-02 is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012. The Company adopted this new standard on December 29, 2012, which did not have a material effect on its consolidated financial position or results of operations.

## Note 2 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 27, 2013	December 28, 2012
Raw materials and purchased parts	\$1,647	\$1,946
Work-in-process	2,999	1,318
Finished goods	7,968	8,945
	12,614	12,209
Less: inventory reserves	734	536
	\$11,880	\$11,673

## Note 3 Prepaids, Deposits, and Other Current Assets

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

	September 27, 2013	December 28, 2012
Prepaid vendors	\$1,522	\$1,044
Prepaid insurance	361	628
Value added tax (VAT) receivable	402	307
Other current assets	418	204
	\$2,703	\$2,183

## Note 4 Property, Plant and Equipment

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

	September 27, 2013	December 28, 2012
Machinery and equipment	\$15,825	\$14,734
Furniture and fixtures	3,384	3,483
Leasehold improvements	6,585	5,281
	25,794	23,498
Less: accumulated depreciation	19,282	18,059

\$6,512                  \$5,439

**Note 5 Amortizable Intangible Assets**

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

	September 27, 2013			December 28, 2012		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Amortized intangible assets:						
Patents and licenses	\$ 10,678	\$ (10,014)	\$664	\$10,786	\$ (9,875)	\$ 911
Customer relationships	1,584	(911)	673	1,835	(917)	918
Developed technology	1,007	(777)	230	1,166	(853)	313
Total	\$ 13,269	\$ (11,702)	\$1,567	\$13,787	\$ (11,645)	\$ 2,142

**Note 6 Other Current Liabilities**

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

	September 27, 2013	December 28, 2012
Accrued salaries and wages	\$1,962	\$1,950
Accrued bonuses	985	500
Accrued severance	776	499
Customer credit balances	190	324
Accrued insurance	196	515
Accrued audit fees	384	396
Accrued tax preparation fees	343	119
Accrued income taxes	411	451
Other <sup>(1)</sup>	805	948
	\$6,052	\$5,702

<sup>(1)</sup>No item in "Other" above exceeds 5% of the total other current liabilities

**Note 7 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 27, 2013	Three Months Ended September 28, 2012	Nine Months Ended September 27, 2013	Nine Months Ended September 28, 2012
Service cost	\$81	\$122	\$284	\$364
Interest cost		34	52	102
Expected return on plan assets	(25)	(28)	(73)	(81)
Amortization of unrecognized transitional obligation		4	4	12
Amortization of prior service cost				(1)
Recognized actuarial gain	(69)	(1)	(50)	(4)
	\$(13)	\$131	\$217	\$392

During the nine months ended September 27, 2013 and September 28, 2012, the Company made cash contributions totaling approximately \$175,000 and \$176,000 to its Swiss pension plan and expects to make additional cash contributions totaling approximately \$58,000 during the remainder of 2013. The Company is not required to and does not make contributions to its Japan pension plan.

**Note 8 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	September	September	September
	27,	28,	27,	28,
	2013	2012	2013	2012
Numerator:				
Net income (loss)	\$525	\$ (90)	\$1,274	\$ (349)
Denominator:				
Weighted average common shares and denominator for basic calculation:				
Weighted average common shares outstanding	37,108	36,495	36,860	36,378
Less: Unvested restricted stock	358	203	308	172
Denominator for basic calculation	36,750	36,292	36,552	36,206
Weighted average effects of dilutive equity-based compensation awards:				
Employee stock options and restricted stock	1,612		1,188	
Warrants	922		742	
Denominator for diluted calculation	39,284	36,292	38,482	36,206
Net income (loss) per share basic	\$0.01	\$ (0.00)	\$0.03	\$ (0.01)
Net income (loss) per share - diluted	\$0.01	\$ (0.00)	\$0.03	\$ (0.01)

The following tables sets forth (in thousands) the weighted average number of options and warrants to purchase shares of common stock and restricted 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	September	September	September
	27,	28,	27,	28,
	2013	2012	2013	2012
Options and restricted stock	1,001	3,183	1,091	1,813
Warrants		605		806
Total	1,001	3,788	1,091	2,619

**Note 9 Geographic and Product Data**

The Company markets and sells its products in over 60 countries and has manufacturing sites in the United States and Switzerland. Other than the United States, Japan, Korea, China, and Spain, 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 27,	September 28,	September 27,	September 28,

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

	2013	2012	2013	2012
United States	\$ 2,993	\$ 3,038	\$ 9,388	\$ 9,428
Japan	4,040	4,237	13,427	12,187
China	2,275	2,444	6,575	6,691
Korea	1,982	1,755	5,851	5,379
Spain	1,012	808	3,466	1,850
Other	4,804	3,584	14,564	11,781
Total	\$ 17,106	\$ 15,866	\$ 53,271	\$ 47,316



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 27, 2013	September 28, 2012	September 27, 2013	September 28, 2012
ICLs	\$ 10,725	\$ 9,111	\$ 32,616	\$ 26,321
IOLs	5,322	6,052	17,533	19,185
Core products	16,047	15,163	50,149	45,506
Other Surgical Products	1,059	703	3,122	1,810
Total	\$ 17,106	\$ 15,866	\$ 53,271	\$ 47,316

The Company sells its products internationally, which subjects the Company to several potential risks, regional/country economic conditions and regulatory requirements, 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 10 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 27, 2013	September 28, 2012	September 27, 2013	September 28, 2012
Employee stock options	\$576	\$ 660	\$2,068	\$ 1,850
Restricted stock expense	283	170	718	433
Consultant compensation	47	8	138	34
Total	\$906	\$ 838	\$2,924	\$ 2,317

#### 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 performance contingent restricted stock units. 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 and pre-established financial metrics are met (as defined in the Plan). Pursuant to the Plan, options for 3,390,915 shares were outstanding at September 27, 2013 with exercise prices ranging between \$0.95 and \$12.87 per share. Restricted stock grants under the Plan generally vest over a period of one, three or four years. There were 341,100 shares of restricted stock outstanding at September 27, 2013. As of September 27, 2013, there were 1,400,270 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 2013 option grants based on historical forfeiture experience. The risk-free rate is based on the U.S. Treasury yield curve corresponding to the expected term at the time of the grant.

	Three Months Ended		Nine Months Ended				
	September 27, 2013		September 28, 2012	September 27, 2013		September 28, 2012	
Expected dividend yield	0	%	0	%0	%	0	%
Expected volatility	58.43	%	80.28	%71.69	%	79.48	%
Risk-free interest rate	1.32	%	0.63	%0.69	%	0.82	%
Expected term (in years)	4.12		5.21	4.12		5.21	

A summary of option activity under the Plan as of September 27, 2013 is presented below:

	Options Shares (000's)	Restricted Shares (000's)	Warrants Shares (000's)
Outstanding at December 28, 2012	3,376	205	1,470
Granted	560	153	
Exercised	(515)	(17)	
Forfeited or expired	(30)		(70)
Outstanding at September 27, 2013	3,391	341	1,400
Exercisable at September 27, 2013	2,198		1,400

#### Note 11 Income Taxes

STAAR is subject to income taxes in the U.S. and numerous foreign jurisdictions. In evaluating STAAR's ability to recover the deferred tax assets within a jurisdiction from which they arise, management considers all available positive and negative evidence, including scheduled reversals of deferred tax liabilities, projected future taxable income, tax-planning strategies and results of recent operations. In projecting future taxable income, STAAR begins with historical results and incorporates assumptions including overall current and projected business and industry conditions, the amount of future federal, state, and foreign pretax operating income, the reversal of temporary differences and the successful implementation of feasible and prudent tax-planning strategies. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates STAAR uses to manage the underlying businesses. In evaluating the objective evidence that historical results provide, STAAR considers three years of cumulative operating results. Valuation allowances, or reductions to deferred tax assets, are recognized if, based on the weight of all the available evidence, it is more likely than not that some portion or all of the deferred tax asset may not be realized.

STAAR Surgical Company acquired its remaining ownership interest in STAAR Japan in 2008. Based on management's assessment of all available evidence at the time, including STAAR Japan's history of cumulative losses, STAAR concluded it was more likely than not that the net deferred tax assets would not be realized, and accordingly, a full valuation allowance was established. As of December 28, 2012, STAAR Japan's valuation allowance was approximately \$1.0 million.

During 2011 and 2012, STAAR was engaged in a global restructuring strategy to consolidate global manufacturing into the U.S. to reduce costs, improve gross profit, enable use of \$122.5 million in net operating loss carryforwards in the U.S., and reduce income taxes in foreign jurisdictions. At the time, STAAR manufactured its products in three facilities one of each located in the U.S., Switzerland and Japan. Since that time, STAAR has developed and begun implementing a plan to consolidate its manufacturing into a single site at its Monrovia, California location, to be completed by the middle of 2014. During 2013, STAAR completed the transfer of the manufacturing operations in Japan to the U.S.

An important change in connection with this global restructuring strategy was the conversion of STAAR Japan from a traditional principal manufacturer with unlimited manufacturing and inventory risk to a limited-risk distributor, or LRD. As an LRD, STAAR Japan has no risks of manufacturing and very limited risk of maintaining inventory. This conversion was accomplished by contractually shifting these risks from STAAR Japan to STAAR AG, another wholly owned subsidiary of STAAR, as part of this global restructuring strategy.

STAAR Japan, although legally converted to an LRD at the end of 2012, continued to sell off its on-hand inventory from the end of 2012 through the first six months of 2013; consequently, it retained that inventory risk and functioned substantively as a principal entrepreneur during that period. Beginning in the third quarter of 2013, STAAR Japan began to operate as an LRD, both legally and economically, for STAAR AG. STAAR AG contractually assumed full principal manufacturing responsibility for its LRD (STAAR Japan), thereby allowing STAAR Japan to completely transfer the risks of being a principal manufacturer to STAAR AG. As a result of this change to an LRD, in the normal course of business, STAAR Japan no longer bears the risks of manufacturing its inventory and operates as a limited-risk distributor for STAAR AG. STAAR AG has engaged STAAR U.S. as its contract manufacturer for all of STAAR AG's territory, including for Japan and China. Also, beginning in the third quarter of 2013, STAAR AG began selling inventory to STAAR Japan in order for STAAR Japan to market and distribute the products in its territory, principally in Japan and China, as an LRD. As a limited-risk distributor, STAAR Japan is contractually guaranteed to earn a fixed return on its net sales. The rate of return is consistent with what a limited-risk distributor would earn in a distribution agreement of similar risks and responsibilities with an unrelated party as determined by formal transfer price studies conducted by STAAR in connection with its global manufacturing consolidation strategy.

As a result of this change from a principal manufacturer to a limited-risk distributor with a guaranteed return, STAAR Japan has achieved a three-year cumulative pretax income in the third quarter of 2013, as measured from the beginning of the fourth quarter of 2010 through the end of the third quarter of 2013. Based on these results and management's consideration of all available positive and negative evidence, including the projected pretax income that STAAR Japan is contractually guaranteed to earn as an LRD, management concluded that, at September 27, 2013, it is more likely than not that STAAR Japan's deferred tax assets would be realized. Accordingly, STAAR Japan fully released its remaining valuation allowance against net deferred tax assets based on the weight of positive evidence that existed at September 27, 2013. This release amounted to approximately \$433,000 of income tax benefit recorded in the consolidated financial statements for the three and nine months ended September 27, 2013 (as translated using the Japanese Yen exchange rate on September 27, 2013). The valuation allowance as of December 28, 2012 of \$1.0 million was reduced to \$433,000 primarily due to the utilization of STAAR Japan's net operating loss carryover during the nine months ended September 27, 2013.

## Note 12 Manufacturing Consolidation Project and Tax Strategy

Since 2011 the Company has been engaged in a restructuring initiative to consolidate global manufacturing into the U.S. to reduce costs, improve gross profit, enable the use of \$122.5 million in net operating loss carryforwards in the U.S., and reduce income taxes in foreign jurisdictions. At the time, the Company manufactured its products in four facilities located in the U.S., Switzerland and Japan. Since that time, the Company has developed and began implementing a plan to consolidate its manufacturing into a single site at its Monrovia, California location, to be largely completed by the middle of 2014. During 2013, STAAR completed the transfer of manufacturing operations from Japan to the U.S.

The Company expects the initiative to cost approximately \$6.2 million over a three and a half year period, of which approximately \$5.7 million has been spent to date. The Company estimates that the cost for 2013 is approximately \$2.3 million. Total costs during the nine months ended September 27, 2013 are approximately \$2.0 million. These expenses are included in "other general and administrative expenses" in the consolidated statement of income for the period ended September 27, 2013. The expenses generally consist of professional fees to advisors and consultants, travel, salaries and severance accruals.

A summary of the costs associated with this initiative is presented below as of September 27, 2013 (in thousands):

	Termination Benefits	Other Associated Costs	Total
Liability at December 28, 2012	\$ 504	\$ 293	\$ 797
Costs incurred and charged to expense	\$ 376	\$ 1,629	\$ 2,005
Cash payments	\$ (105)	\$ (1,867)	\$ (1,972)
Liability at September 27, 2013	\$ 775	\$ 55	\$ 830
Total costs incurred to date	\$ 1,276	\$ 4,425	\$ 5,701
Total costs expected to be incurred	\$ 1,592	\$ 4,608	\$ 6,200

## **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, including statements about any of the following: any projections of earnings, revenue, sales, profit margins, cash, effective tax rate or any other financial items; the plans, strategies, and objectives of management for future operations or prospects for achieving such plans; metrics for 2013; statements regarding new products, including but not limited to, expectations for success of new products in the U.S. or international markets or government approval or commercialization of new products; future economic conditions or size of market opportunities; expected IOL backorder position; expected costs of Monrovia facility expansion; expected costs and savings from business consolidation plans and the timetable for those plans; statements of belief, including as to achieving 2013 growth plans or metrics; expected regulatory activities and approvals, product launches, and any statements of assumptions underlying any of the foregoing. 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 28, 2012. 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 (near-sightedness), hyperopia (far-sightedness) and astigmatism (irregular shape of cornea causing blurred vision). 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®, Visian®, Collamer®, STAARVISC®, Elastimide®, nanoFLEX® nanoPOINT®, CentraFLOW®, AquaPORT®, Epiphany® and AquaFlow® are trademarks or registered trademarks of STAAR Surgical Company 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 28, 2012, 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 - Implantable Collamer Lenses for Refractive Surgery.* Sales of refractive lenses make up over half of our total sales. Made from our proprietary biocompatible Collamer material, highlights of STAAR's family of Visian ICL products are as follows:

- 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 in the U.S. in 2006.
- The Visian Toric ICL or TICL, treats myopic and hyperopic patients with astigmatism. STAAR has been selling the Visian TICL outside the U.S. since 2002. STAAR remains in dialogue with the FDA regarding its PMA Supplement submission seeking approval to sell the TICL in the U.S. This matter is further discussed below under, "Status of Regulatory Submission."
- STAAR currently sells several versions of the Visian ICL and Visian TICL globally; the V4, the V4b, which expands the population of eligible patients to individuals in the lower diopter ranges for both myopia and hyperopia, and the V4c, which includes the proprietary CentraFLOW technology (a port, KS-AquaPORT, in the center of the myopic Visian ICL and TICL) that eliminates the need for a peripheral iridectomy or iridotomy procedure prior to implanting the Visian ICL or TICL.

· 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 (i) Collamer, STAAR's proprietary biocompatible collagen copolymer lens material and (ii) from silicone. Aspheric IOLs are designed to improve the patient's quality of vision when compared to earlier spherical IOL designs. The aspheric silicone lenses are available in the U.S. and are sold preloaded in certain markets outside of the U.S., predominately in Japan. 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 primarily marketed and sold in the U.S.

· The Preloaded Injector, a silicone or acrylic IOL preloaded into a single-use disposable injector is currently available outside the U.S. The acrylic IOL Preloaded Injector uses an acrylic lens sourced from a third party manufacturer. The KS-SP (single-piece) and KS-Xs (three piece) preloaded acrylic IOLs that can be implanted through a micro-incision with a single-use disposable injector system is available in Japan and on a limited basis in Europe. The third party supplier of these acrylic lenses is currently unable to meet STAAR's demand for the new KS IOL products, thus the company experienced approximately \$800,000 in backorders from its European customers at the end of the third quarter of 2013. We are seeking alternative suppliers but cannot predict whether our efforts will prove successful.

· 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. A Collamer version of our toric IOL nanoFLEX Toric has CE mark approval and initial shipments began to Europe late in the second quarter.

*Other Surgical Products.* We also sell other instruments and devices 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. In addition, we report sales of low margin injectors to our third party supplier of IOLs under this category. In recent periods, these sales have increased due to the parties' launch of their respective pre-loaded IOL systems, which are currently experiencing backorder due to high demand and the limited supply of third party IOLs.

### ***Operations***

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

STAAR is implementing a project to consolidate its manufacturing into a single site at its Monrovia, California location, which we expect to yield significant savings in cost of goods, lower our global administrative and regulatory costs and reduce income taxes. The transition of manufacturing from Japan to the U.S. is complete. The expected completion date for the consolidation of our Swiss manufacturing facility is the middle of 2014. This project, which is subject to significant risks, is further described under Note 12, "*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 employs a commercialization strategy that focuses on achieving sustainable profitable growth.

STAAR's key operational metrics for 2013 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 aligned its business initiatives during 2013 along four key operational metrics used to gauge its success during the year. Those metrics are as follows:

- Increase total revenue by 12% to 14% (increased on July 31, 2013 from the previous 8% to 10% metric).
- As discussed below in "*Results of Operations*," our total revenue increased by 8% in the third quarter of 2013. Total revenue increased by 13% in the first nine months of 2013.
- Increase gross profit margins by 250 basis points for the full year.

- As discussed below in “*Results of Operations*,” our gross profit was 70.5% in the third quarter of 2013 compared to 70.4% in the third quarter of 2012, and increased to 70.1% for the first nine months of 2013, compared to 70.0% for the first nine months of 2012.

- Achieve profitability in each quarter of 2013.

- As discussed below in “*Results of Operations*,” we achieved net income of \$0.5 million in the third quarter of 2013 and \$1.3 million for the first nine months of 2013.

- Manage the manufacturing consolidation with no material disruption to customer supply requirements or quality.

- The Company’s consolidation efforts are proceeding substantially according to plans. On July 31, 2013, we revised this metric by extending the transfer of Swiss operations until the middle of 2014 to assure that we can meet higher than anticipated demand for the Visian ICL. By the end of 2013, we expect to have 100% of all IOL production, two thirds of ICL’s and one third of TICL’s manufactured in the U.S.

### **Other Highlights**

In the third quarter of 2013, Visian ICLs grew in Europe, Middle East and Africa (EMEA) by 40% in revenue while units increased 30% and price 8%; in Asia Pacific (APAC) an increase of 10% in revenue, while units increased 10% and price was unchanged; in North America (NA) an increase of 9% in revenue, while units increased 10% and price declined 2%. We experienced growth in ten of our eleven target markets including growth in our top three markets as follows: Korea +13%; China + 22%;, and the U.S. +7%. Spain grew 23% and the third quarter was the first quarter that reflected a true direct to direct distribution model comparison. Other notable markets experiencing growth were: India +18%; the Middle East + 39%; Latin America + 30%; Germany +154%; and Italy +53%. Japan decreased 24% due to a significant decline in Lasik procedures that impacted refractive procedures in general. We believe growth in EMEA is due to growing acceptance of the CentraFLOW technology and new sales personnel hired in 2012. Regarding China, we believe we will continue to see growth during the remainder of the year, followed by the anticipated approval of the Visian ICL with CentraFLOW technology during the first half of 2014.

Backorders of our preloaded acrylic IOLs in Europe were approximately \$800,000 at the end of the third quarter, due to demand for our KS-SP and KS-Xs products and the supply constraints we continue to experience from a third party supplier. This backorder position is expected to continue to limit IOL sales for the entire year and we are evaluating potential options to meet this demand. Our overall gross margins were limited by the weakened value of the Japanese yen and by an increased mix of low margin IOL injector system sales. IOL units sold in Japan increased 6%, although average selling prices decreased 16% driven by the weakened value of the yen. IOL sales in Japan represented 52% of worldwide IOL sales. IOL sales in China declined by \$503,000 during the third quarter due to our need to suspend allocation of KS IOL products available for sale due to the supply constraints.

STAAR continued its manufacturing consolidation efforts in the third quarter of 2013 in preparation of transferring Swiss manufacturing activities to our Monrovia facility. In the third quarter of 2013, the Company spent \$490,000 in consolidation costs and expects to spend an additional \$260,000 during the remainder of 2013. At the end of the third quarter the Company has approximately 11,400 ICLs in inventory in both Europe and the U.S. This inventory build is consistent with management’s plan to assure adequate supply and quality of product throughout this consolidation project.

*Status of Regulatory Submissions.* The Company received regulatory approval to sell and market the Visian ICL with CentraFLOW technology in India during the third quarter of 2013. The Company currently anticipates approval of the Visian ICL with CentraFLOW for China and Japan during the first half of 2014. In addition, the Company expects to receive CE Mark approval for the Visian ICL V5, which is preloaded and offers a larger optical zone, before the end

of 2013 and to begin commercialization in the first quarter 2014.

Regarding our PMA Supplement submission to the FDA seeking approval for the TICL, on November 15, 2012, STAAR submitted to the FDA (1) clinical data showing no statistical difference in the clinical outcomes with or without the patient data that was obtained outside the study windows, (2) engineering data regarding the lens design, and (3) a validation report for the Toric ICL power calculation software. STAAR remains in dialogue with the agency regarding our PMA Supplement, and hosted inspection visits from the FDA, which included reviewers of the TICL submission at our Nidau, Switzerland and Monrovia, California facilities during the third quarter of 2013. The Company has been told by the FDA that the current intent is to take the TICL submission to the Advisory Panel. On October 30, 2013, the Company received a technical question from the FDA with a response due date of November 6, 2013. The Company expects to respond prior to that due date. There are no other pending questions. A date for the advisory panel has not been established and the Company is preparing the information needed for the Panel Package. 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. On February 12, 2013, in response to a request by the FDA, we submitted a Pre-Submission for the PMA Supplement. On June 17, 2013, the FDA responded to our proposal with suggestions for revision. During the third quarter of 2013, we submitted our revised proposed protocol and the FDA scheduled a face-to-face meeting with the Company for December 12, 2013 in Washington, D.C.

### 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 27, 2013 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 28, 2012.

### 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.

	Percentage of Net Sales for Three Months		Percentage of Net Sales for Nine Months					
	September 27, 2013	%	September 28, 2012	September 27, 2013	%	September 28, 2012	%	
Net sales	100.0	%	100.0	%	100.0	%	100.0	%
Cost of sales	29.5		29.6		29.9		30.0	
Gross profit	70.5		70.4		70.1		70.0	
General and administrative	24.2		21.7		22.5		23.1	
Marketing and selling	32.3		34.7		30.9		32.8	
Research and development	9.8		10.0		8.9		9.8	
Medical device tax	0.3				0.3			
Other general and administrative expenses	2.9		4.6		3.8		4.2	
	69.5		71.0		66.4		69.9	
Operating income (loss)	1.0		(0.6)		3.7		0.1	
Other income, net	1.9		1.4		0.4		0.9	
	2.9		0.8		4.1		0.9	

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

Income before provision (benefit) for income taxes

Provision (benefit) for income taxes	(0.1)		1.4	1.7		1.6	
Net income (loss)	3.0	%	(0.6)	%2.4	%	(0.7)	%

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

**Net Sales**

	Three Months Ended		Fav/ (Unfav) % Change	Nine Months Ended		Fav/ (Unfav) % Change	
	September 27, 2013	September 28, 2012	2013 vs. 2012	September 27, 2013	September 28, 2012	2013 vs. 2012	
Net sales	\$ 17,106	\$ 15,866	7.8	%\$53,271	47,316	12.6	%
ICL	10,725	9,111	17.7	32,616	26,321	23.9	
IOL	5,322	6,052	(12.1)	17,533	19,185	(8.6)	
Other	1,059	703	50.8	3,122	1,810	72.5	

Net sales for the three months ended September 27, 2013 were \$17.1 million, an increase of 7.8% compared to the \$15.9 million reported during three months ended September 28, 2012. Net sales for the nine months ended September 27, 2013 were \$53.3 million, a 12.6% increase compared with \$47.3 million reported during the nine months ended September 27, 2012. The increase in net sales for the three and nine month periods was due to increased sales of ICLs and Other surgical products, partially offset by a decrease in IOL sales. The effect of foreign exchange had a negative impact on sales of \$1.0 million and \$2.7 million, respectively, for the three and nine months ended September 27, 2013.

Total ICL sales for the three months ended September 27, 2013 were \$10.7 million, an increase of 17.7% compared with \$9.1 million reported during the three months ended September 28, 2012. Total ICL sales for the nine months ended September 27, 2013 were \$32.6 million, an increase of 23.9% compared with \$26.3 million reported during the nine months ended September 28, 2012. ICL sales increased 16% and 24%, respectively, in the Company's top 11 markets during the three and nine months ended September 27, 2013. ICL sales represented 62.7% and 61.2%, respectively, of our total sales for the three and nine months ended September 27, 2013, compared to 57.4% and 55.6% for the three and nine month periods ended September 28, 2012.

Total IOL sales for the three months ended September 27, 2013 were \$5.3 million, a decrease of 12.1%, when compared with \$6.1 million for the three months ended September 28, 2012. Total IOL sales for the nine months ended September 27, 2013 were \$17.5 million, a decrease of 8.6%, when compared with \$19.2 million for the nine months ended September 28, 2012. IOL sales represent 31.1% and 32.9% of sales for the three and nine months ended September 27, 2013, compared to 38.1% and 40.5% for the three and nine month periods ended September 28, 2012. The decrease in IOL sales was due to the effect of foreign exchange which reduced IOL sales by \$0.8 million and \$2.2 million, respectively, for the three and nine months ended September 27, 2013.

Other product sales for the three and nine months ended September 27, 2013 were \$1.1 million and \$3.1 million, an increase of 50.8% and 72.5%, respectively, when compared with \$0.7 million and \$1.8 million for the three and nine months ended September 28, 2012. The increase in other product sales was due to an increase in injector part sales to a third party supplier.

**Gross Profit**

	Three Months Ended		Fav/ (Unfav) % Change	Nine Months Ended		Fav/ (Unfav) % Change	
	September 27, 2013	September 28, 2012	2013 vs. 2012	September 27, 2013	September 28, 2012	2013 vs. 2012	
Gross Profit	\$ 12,059	\$ 11,176	7.9	%\$37,332	\$ 33,122	12.7	%

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

Gross Profit Margin	70.5	%	70.4	%	70.1	%	70.0	%
---------------------	------	---	------	---	------	---	------	---

Gross profit for the third quarter was \$12.1 million, or 70.5% of revenue, compared with \$11.2 million, or 70.4% of revenue, in the prior year period. During the first nine months of 2013, gross profit was \$37.3 million, or 70.1% of revenue, compared with \$33.1 million, or 70.0% of revenue, in the prior year period. Gross profit margin for the three and nine month periods was negatively impacted by foreign exchange rates and the increased sales mix of low margin injector system sales. These factors negatively impacted margins by 290 basis points for the quarter and 250 basis points year to date in 2013.

**General and Administrative**

	Three Months Ended		Fav/ (Unfav)	Nine Months Ended		Fav/ (Unfav)	
	September 27, 2013	September 28, 2012	% Change 2013 vs. 2012	September 27, 2013	September 28, 2012	% Change 2013 vs. 2012	
General and Administrative	\$4,140	\$3,450	(20.0)	22.5	\$10,942	(9.9)	%
Percentage of Sales	24.2	% 21.7	%	22.5	% 23.1	%	

General and administrative expenses increased by 20.0% to \$4.1 million in the third quarter of 2013 from the \$3.5 million reported in the third quarter of 2012. General and administrative expenses for the nine months ended September 27, 2013 were \$12.0 million, an increase of 10% when compared with \$10.9 million reported last year. The increase is due to an increase in bonus accruals based upon performance to date and the incremental cost associated with the expanded facility in Monrovia. General and administrative expenses were favorably impacted by foreign currency exchange by approximately \$0.1 million during the quarter and by approximately \$0.3 million for the nine month period.

### *Marketing and Selling*

	Three Months Ended				Fav/ (Unfav) % Change		Nine Months Ended				Fav/ (Unfav) % Change	
	September 27, 2013		September 28, 2012		2013 vs. 2012		September 27, 2013		September 28, 2012		2013 vs. 2012	
Marketing and Selling	\$5,527		\$ 5,507		(0.4)		16,471		\$ 15,536		(6.0)	%
Percentage of Sales	32.3	%	34.7	%			30.9	%	32.8	%		

Marketing and selling expenses were \$5.5 million in the third quarter of 2013, flat when compared with the third quarter of 2012. Marketing and selling expenses for the nine months ended September 27, 2013 were \$16.5 million, an increase of 6% when compared with \$15.5 million reported last year. The increase is due to increased headcount and promotional activities to support the increased level of sales, partially offset by the timing of ESCRS which was held in the third quarter of 2013, and in the third quarter of 2012. Marketing and selling expenses were favorably impacted by foreign currency exchange by approximately \$0.4 million during the quarter and by approximately \$0.9 million for the nine month period.

### *Research and Development*

	Three Months Ended				Fav/ (Unfav) % Change		Nine Months Ended				Fav/ (Unfav) % Change	
	September 27, 2013		September 28, 2012		2013 vs. 2012		September 27, 2013		September 28, 2012		2013 vs. 2012	
Research and Development	\$1,684		\$ 1,582		(6.4)		4,736		\$ 4,640		(2.1)	%
Percentage of Sales	9.8	%	10.0	%			8.9	%	9.8	%		

Research and development expense increased in the third quarter of 2013, by 6.4% to \$1.7 million, compared with \$1.6 million in the third quarter of 2012. Research and development expense for the nine months ended September 27, 2013 was \$3.1 million, an increase of 2.1% when compared with \$4.6 million reported last year. The increase is due to increased costs of gaining regulatory approvals for new products in various markets around the world and development costs of the V5 Preloaded ICL. Research and development expenses were favorably impacted by foreign currency exchange by approximately \$0.08 million during the quarter and by approximately \$0.2 million for the nine month period.

### *Other General and Administrative Expenses*



Edgar Filing: STAAR SURGICAL CO - Form 10-Q

	Three Months Ended		Fav/ (Unfav) % Change	Nine Months Ended		Fav/ (Unfav) % Change
	September 27, 2013	September 28, 2012	2013 vs. 2013	September 27, 2013	September 28, 2012	2013 vs. 2012
Other General and Administrative Expenses	\$490	\$728	32.7	2,004	\$1,980	(1.2)
Percentage of Sales	2.9	4.6	%	3.8	4.2	%

Other general and administrative expenses for the quarter were \$0.5 million, compared with \$0.7 million in the third quarter of 2012. Other general and administrative expenses for the nine months ended September 27, 2013 were \$2.0, unchanged from the first nine months of 2012. These expenses generally relate to accrued severance, salaries, travel, consulting fees and other expenses associated with the consolidation of the Company's manufacturing facilities. The Company expects these costs to continue to decrease in the fourth quarter of 2013. Other general and administrative expenses were favorably impacted by foreign currency exchange by approximately \$0.05 million during the quarter and by approximately \$0.1 million for the nine month period.

**Other Income, (Expense) Net**

	Three Months Ended		Fav/ (Unfav) % Change	Nine months Ended		Fav/ (Unfav) % Change
	September 27, 2013	September 28, 2012	2013 vs. 2012	September 27, 2013	September 28, 2012	2013 vs. 2012
Other Income, Net	\$327	\$ 220	48.6	¥\$211	\$ 406	(48.0) %

The year over year change in other income (expense), net for both periods is due to decreased interest expense, changes in foreign currency exchange, increased royalty income, offset by a decrease in gains from the fair valuation of warrants which expired during 2013 and a decrease in other income resulting from the release of escrow funds in 2012 associated with the sale of our former German distributor.

**Income Taxes**

The Company recorded a small net income tax benefit during the quarter ended September 27, 2013 as compared to a provision for income taxes of \$0.2 million during the quarter ended September 28, 2012. The Company also recorded a provision for income taxes of \$0.9 million and \$0.8 million for the nine months ended September 27, 2013 and September 28, 2012, respectively. The income tax benefit for the three months ended September 27, 2013 is primarily due to the release of STAAR Japan's valuation allowance of \$0.4 million while the Company maintained a full valuation allowance for STAAR Japan in the comparative prior year period. The valuation allowance was released in the third quarter of 2013 after management concluded that, based on the weight of the positive evidence available at September 27, 2013 it is more likely than not that STAAR Japan's net deferred tax assets would be realized. The Company determines its provision for income taxes for interim reporting purposes by applying an estimated annual effective income tax rate. Certain jurisdictions where the Company anticipates reporting losses in 2013 are not included in the effective tax rate calculation for interim reporting purposes.

**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 cost associated with the manufacturing consolidation plan previously discussed by us and further described in Note 12, "*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 purposes, 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 27, 2013 and December 28, 2012, respectively, STAAR had \$23.4 million and \$21.7 million, of cash and cash equivalents.

Net cash provided by operating activities for the nine months ended September 27, 2013 and September 28, 2012, respectively, was \$3.4 and \$3.7 million. Net cash provided by operations for the nine months ended September 27, 2013 consisted of net income of \$1.3 million plus \$4.8 million in non-cash items, offset by \$2.7 decrease in working capital.

Net cash used in investing activities for the nine months ended September 27, 2013 and September 28, 2012, respectively, was \$3.0 million and \$1.0 million. Net cash used in investing activities for the nine months ended September 27, 2013 was due to acquisition of property, plant and equipment primarily related to the manufacturing consolidation project and the new facility expansion.

Net cash provided by financing activities for the nine months ended September 27, 2013 and September 28, 2012, respectively, was \$2.0 million and \$0.5 million. Net cash provided by financing activities for the nine months ended September 27, 2013 consisted of \$2.7 million in proceeds from stock options, partially offset by \$0.7 million in capital lease repayments.

***Credit Facilities, Contractual Obligations and Commitments***

*Accrued Termination Benefits for Manufacturing Consolidations Project*

The Company has \$0.8 million in accrued termination benefit costs as of September 27, 2013, in connection with its manufacturing consolidation project and anticipates accruing another \$316,000 through the end of the project. The accrual represents STAAR’s current best estimate of the termination benefits that will be paid to the eligible employees.

*Lines of Credit*

The Company’s wholly owned Japanese subsidiary, STAAR Japan, has an agreement, as amended on December 28, 2012, with Mizuho Bank, which provides for borrowings of up to 500,000,000 Yen (approximately \$5.1 million based on the rate of exchange on September 27, 2013), at an interest rate equal to the Tokyo short-term prime interest rate (approximately 1.475% as of September 27, 2013). The Company had 500,000,000 Yen outstanding on the line of credit as of September 27, 2013 and December 28, 2012 (approximately \$5.1 million and \$5.8 million based on the foreign currency exchange rates on September 27, 2013 and December 28, 2012). As of September 27, 2013 there were no available borrowings under the line. The bank line is renewed every three months and the next renewal date is December 27, 2013.

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 \$1.1 million at the rate of exchange on September 27, 2013), to be used for working capital purposes. There were no borrowings outstanding as of September 27, 2013 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 27, 2013	December 28, 2012
2013	\$167	\$916

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

2014	312	318
2015	145	152
2016	7	8
Total minimum lease payments	\$631	\$1,394
Less: interest	27	77
Total lease obligation	\$604	\$1,317
Current	\$393	\$829
Long-term	\$211	\$488

### **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 28, 2012.

### **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 27, 2013 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 28, 2012. 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 Amended and Restated By-laws. (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)
- 10.96 Letter of the Company dated August 7, 2013 to Stephen Brown, Vice President of Finance, and Chief Financial Officer, regarding compensation.(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 27, 2013, formatted in XBRL, are filed herewith and include: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Consolidated Statements of Comprehensive Income, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) the Notes to Condensed Consolidated Financial Statements tagged as blocks of text. \*

---

(1)



Edgar Filing: STAAR SURGICAL CO - Form 10-Q

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 15, 2013.
- (3) Incorporated by reference to the Company's Proxy Statement for its Annual Meeting of Stockholders held on May 13, 2013, filed with the Commission on March 26, 2013.
- (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.
- (7) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Commission on September 9, 2013.
- \* 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 1, 2013

By:

/s/ STEPHEN P. BROWN

**Stephen P. Brown**

**Chief Financial Officer**

**(on behalf of the Registrant and as it's  
principal financial officer)**