

STAAR SURGICAL CO  
Form 10-Q  
November 07, 2014

**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: October 3, 2014**

**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):

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

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

The registrant has 38,653,734 shares of common stock, par value \$0.01 per share, issued and outstanding as of October 26, 2014.

**STAAR SURGICAL COMPANY**

**INDEX**

	PAGE NUMBER
<u>PART I – FINANCIAL INFORMATION</u>	
Item 1. <u>Financial Statements (Unaudited)</u>	1
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	12
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	20
Item 4. <u>Controls and Procedures</u>	20
<u>PART II – OTHER INFORMATION</u>	
Item 1. <u>Legal Proceedings</u>	21
Item 1A. <u>Risk Factors</u>	21
Item 4. <u>Mine Safety Disclosures</u>	21
Item 5. <u>Other Information</u>	22
Item 6. <u>Exhibits</u>	22

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

	October 3, 2014	January 3, 2014
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$18,359	\$22,954
Accounts receivable trade, net of allowance for doubtful accounts of \$1,517 and \$1,449, respectively	11,666	10,731
Inventories, net	15,731	12,514
Prepays, deposits and other current assets	3,293	3,503
Deferred income taxes	361	373
Total current assets	49,410	50,075
Property, plant and equipment, net	9,339	7,405
Intangible assets, net	1,033	1,380
Goodwill	1,786	1,786
Deferred income taxes	586	626
Other assets	640	659
Total assets	\$62,794	\$61,931
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Line of credit	\$4,600	\$4,750
Accounts payable	6,259	6,263
Deferred income taxes	738	739
Obligations under capital leases	419	288
Other current liabilities	4,989	6,372
Total current liabilities	17,005	18,412
Obligations under capital leases	538	141
Deferred income taxes	1,773	1,654
Asset retirement obligations	127	157
Pension liability	2,708	2,715
Total liabilities	22,151	23,079

Commitments and contingencies (Note 12)

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

Stockholders' equity:

Common stock, \$0.01 par value; 60,000 shares authorized; 38,390 and 37,911 shares issued and outstanding at October 3, 2014 and January 3, 2014	384	379
Additional paid-in capital	178,049	170,246
Accumulated other comprehensive income	119	282
Accumulated deficit	(137,909)	(132,055)
Total stockholders' equity	40,643	38,852
Total liabilities and stockholders' equity	\$62,794	\$61,931

*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	
	October	September	October	September
	3,	27,	3,	27,
	2014	2013	2014	2013
Net sales	\$18,188	\$ 17,106	\$58,414	\$ 53,271
Cost of sales	6,319	5,047	18,995	15,939
Gross profit	11,869	12,059	39,419	37,332
General and administrative	3,250	4,140	13,968	12,021
Marketing and selling	7,026	5,527	20,189	16,471
Research and development	3,137	1,684	9,118	4,736
Medical device tax	9	45	96	149
Other general and administrative expenses	—	490	334	2,004
Operating income (loss)	(1,553 )	173	(4,286 )	1,951
Other income (expense):				
Interest income	7	9	26	23
Interest expense	(35 )	(38 )	(102 )	(134 )
Gain (loss) on foreign currency transactions	(628 )	226	(696 )	(38 )
Other income, net	51	130	338	360
Other income (expense), net	(605 )	327	(434 )	211
Income (loss) before provision (benefit) for income taxes	(2,158 )	500	(4,720 )	2,162
Provision (benefit) for income taxes	548	(25 )	1,134	888
Net income (loss)	\$(2,706 )	\$ 525	\$(5,854 )	\$ 1,274
Net income (loss) per share - basic	\$(0.07 )	\$ 0.01	\$(0.15 )	\$ 0.03
Net income (loss) per share - diluted	\$(0.07 )	\$ 0.01	\$(0.15 )	\$ 0.03
Weighted average shares outstanding - basic	38,369	36,750	38,044	36,552
Weighted average shares outstanding - diluted	38,369	39,284	38,044	38,482

*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	
	October 3, 2014	September 27, 2013	October 3, 2014	September 27, 2013
Net income (loss)	\$(2,706)	\$ 525	\$(5,854)	\$ 1,274
Other comprehensive loss:				
Defined benefit pension plans:				
Net change in plan assets	(9 )	65	(32 )	35
Reclassification into earnings	6	(69 )	18	(50 )
Impact for change in discount rate	—	—	(558 )	—
Curtailment gain	150	—	687	—
Foreign currency translation loss	(704 )	(92 )	(402 )	(986 )
Tax effect	231	(1 )	124	(6 )
Other comprehensive loss	(326 )	(97 )	(163 )	(1,007 )
Comprehensive income (loss)	\$(3,032)	\$ 428	\$(6,017)	\$ 267

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



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

	Nine Months Ended	
	October	September
	3,	27,
	2014	2013
Cash flows from operating activities:		
Net income (loss)	\$(5,854 )	\$ 1,274
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:		
Depreciation of property and equipment	1,520	1,325
Amortization of intangibles	317	334
Deferred income taxes	161	(220 )
Fair value adjustment of warrant	—	(27 )
Loss on disposal of property and equipment	—	172
Change in net pension liability	118	124
Stock-based compensation expense	4,736	2,924
Accretion of asset retirement obligation	3	9
Other	—	157
Changes in working capital:		
Accounts receivable, net	(1,064 )	(1,423 )
Inventories, net	(3,191 )	(707 )
Prepays, deposits and other current assets	207	(614 )
Accounts payable	(17 )	(389 )
Other current liabilities	(1,364 )	489
Net cash (used in) provided by operating activities	(4,428 )	3,428
Cash flows from investing activities:		
Disposal of property and equipment	68	—
Acquisition of property and equipment	(2,517 )	(2,984 )
Net cash used in investing activities	(2,449 )	(2,984 )
Cash flows from financing activities:		
Repayment of capital lease obligations	(372 )	(675 )
Proceeds from exercise of stock options	2,793	2,723
Net cash provided by financing activities	2,421	2,048
Effect of exchange rate changes on cash and cash equivalents	(139 )	(816 )

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

Increase (decrease) in cash and cash equivalents	(4,595 )	1,676
Cash and cash equivalents, at beginning of the period	22,954	21,675
Cash and cash equivalents, at end of the period	\$18,359	\$ 23,351

*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 January 3, 2014.

The condensed consolidated financial statements for the nine months ended October 3, 2014 and September 27, 2013, 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 October 3, 2014 and September 27, 2013 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.

*Prior Year Reclassifications*

Certain reclassifications have been made to the prior periods’ unaudited condensed financial statements to conform to the current period’s presentation.

*Recent Accounting Pronouncements*

In June 2014, the FASB issued ASU 2014-12, “Compensation – Stock Compensation (Topic 718): Accounting for Shared Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved After the Requisite Service Period (a consensus of the FASB Emerging Issues Task Force)”. ASU 2014-12 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2015. The Company is assessing

the impact, if any, to the consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09, “Revenue from Contracts with Customers (Topic 606)”. This guidance includes the required steps to achieve the core principle that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This guidance is effective for fiscal years and interim periods beginning after December 15, 2016. Early adoption is not permitted. The Company expects to adopt this guidance when effective, and the impact on its consolidated financial statements is not currently estimable.

In August 2014, the FASB issued ASU 2014-15, “Presentation of Financial Statements Going Concern (Subtopic 205-40) – Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern”. Currently there is no guidance in U.S. GAAP about management’s responsibility to evaluate whether there is substantial doubt about the entity’s ability to continue as a going concern. This amends that guidance requiring management to assess the entity’s ability to continue as a going concern. This guidance is effective for fiscal years ending after December 15, 2016. Early adoption is permitted. The Company expects to adopt this guidance when effective, and is not expected to have an impact on the consolidated financial statements.

## Note 2 — Inventories, Net

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

	October 3, 2014	January 3, 2014
Raw materials and purchased parts	\$2,077	\$1,367
Work-in-process	2,147	913
Finished goods	12,861	11,029
	17,085	13,309
Less: inventory reserves	1,354	795
	\$15,731	\$12,514

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

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

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

	October	January
	3,	3,
	2014	2014
Prepaid and deposits	\$ 1,740	\$ 2,157
Value added tax (VAT) receivable	800	618
Deferred charges for foreign profits	378	362
Other current assets	375	366
	\$ 3,293	\$ 3,503

**Note 4 — Property, Plant and Equipment, Net**

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

	October 3, 2014	January 3, 2014
Machinery and equipment	\$16,473	\$16,225
Furniture and fixtures	5,291	4,837
Leasehold improvements	7,662	6,552
	29,426	27,614
Less: accumulated depreciation	20,087	20,209
	\$9,339	\$7,405

**Note 5 – Amortizable Intangible Assets**

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

	October 3, 2014			January 3, 2014		
	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Net</b>	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Net</b>
Amortized intangible assets:						
Patents and licenses	\$10,617	\$(10,213	) \$404	\$10,637	\$(10,057	) \$580
Customer relationships	1,443	(974	) 469	1,490	(894	) 596
Developed technology	917	(757	) 160	947	(743	) 204
Total	\$12,977	\$(11,944	) \$1,033	\$13,074	\$(11,694	) \$1,380

**Note 6 – Other Current Liabilities**

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

	October 3, 2013	January 3, 2014
Accrued salaries and wages	\$ 1,936	\$ 1,630
Accrued income taxes	523	485
Accrued audit fees	426	328
Accrued commissions	360	528
A/R credit balances	252	153
Accrued severance	245	731
Accrued insurance	39	551
Accrued bonuses	-	935
Other <sup>(1)</sup>	1,208	1,031
	\$ 4,989	\$ 6,372

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

**Note 7 – Pension Plans**

During the three months ended July 4, 2014, pursuant to the Manufacturing Consolidation Project, the Company terminated certain employees in its Swiss subsidiary resulting in a Swiss pension plan curtailment as defined by ASC 715-30-35, *Defined Benefit Plans – Pensions, Settlements, Curtailments, and Certain Termination Benefits*. The curtailment resulted in a decrease of \$1.2 million in the Swiss pension plan’s projected benefit obligation, of which \$0.7 million was used to distribute cash payments to employees resulting in a decrease in plan assets. The remaining \$0.5 million was recorded as a curtailment gain measured in accordance with ASC 715-30-35-93.

For the three month period ended October 3, 2014, the Company recorded an additional curtailment in its Swiss pension plan, resulting in an decrease of \$0.4 million in the Swiss pension plan’s projected benefit obligation, of which \$0.2 million was used to distribute cash payments to employees from plan assets. The remaining \$0.2 million was recorded as a curtailment gain measured in accordance with ASC 715-30-35-93.

However, since the Swiss pension plan’s accumulated other comprehensive loss, immediately preceding the curtailments exceeded the curtailment gains, the curtailment gains were fully offset against the loss and no gain was recognized in earnings.

As of July 4, 2014, the discount rate, one of the key assumptions used to calculate the Swiss pension plan’s projected benefit obligation, was reduced from 2.5% to 2%, resulting in an increase to the projected benefit obligation of \$0.6 million recorded through an offsetting increase in the accumulated other comprehensive loss account of the Swiss pension plan. As of October 3, 2014, no significant changes to any key assumptions were made.

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 October 3, 2014	Three Months Ended September 27, 2013	Nine Months Ended October 3, 2014	Nine Months Ended September 27, 2013
Service cost	\$ 116	\$ 81	\$ 349	\$ 284
Interest cost	30	—	102	52
Expected return on plan assets	(22 )	(25 )	(76 )	(73 )
Amortization of unrecognized transitional obligation	—	—	—	4



Edgar Filing: STAAR SURGICAL CO - Form 10-Q

Amortization of prior service cost	—	—	—	—
Recognized actuarial gain	6	(69 )	18	(50 )
	\$ 130	\$ (13 )	\$ 393	\$ 217

During the nine months ended October 3, 2014 and September 27, 2013, the Company made employer contributions totaling approximately \$279,000 and \$175,000 to its Swiss pension plan and does not expect to make any additional contributions during the remainder of 2014, as the Company has met the annual contribution requirement. 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	
	October 3, 2014	September 27, 2013	October 3, 2014	September 27, 2013
Numerator:				
Net income (loss)	\$(2,706 )	\$ 525	\$(5,854 )	\$ 1,274
Denominator:				
Weighted average common shares and denominator for basic calculation:				
Weighted average common shares outstanding	38,618	37,108	38,311	36,860
Less: Unvested restricted stock	249	358	267	308
Denominator for basic calculation	38,369	36,750	38,044	36,552
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	38,369	39,284	38,044	38,482
Net income (loss) per share – basic	\$(0.07 )	\$ 0.01	\$(0.15 )	\$ 0.03
Net income (loss) per share - diluted	\$(0.07 )	\$ 0.01	\$(0.15 )	\$ 0.03

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		Nine Months	
	Ended		Ended	
	October	September	October	September
	3,	27,	3,	27,
	2014	2013	2014	2013
Options	2,198	1,001	2,067	1,091
Restricted stock and units	312	—	244	—
Warrants	460	—	509	—
Total	2,970	1,001	2,820	1,091

**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, Spain, and France, 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	
	October 3, 2014	September 27, 2013	October 3, 2014	September 27, 2013
Japan	\$4,792	\$ 4,040	\$14,349	\$ 13,427
United States	2,875	2,993	8,676	9,388
China	2,915	2,275	7,675	6,575
Korea	1,098	1,982	5,671	5,851
Spain	1,178	1,012	4,270	3,466
France	820	595	2,956	1,722
Other	4,510	4,209	14,817	12,842
Total	\$18,188	\$ 17,106	\$58,414	\$ 53,271

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	
	October 3, 2014	September 27, 2013	October 3, 2014	September 27, 2013
ICLs	\$10,640	\$ 10,725	\$35,052	\$ 32,616
IOLs	5,763	5,322	18,804	17,533
Core products	16,403	16,047	53,856	50,149
Other Surgical Products	1,785	1,059	4,558	3,122
Total	\$18,188	\$ 17,106	\$58,414	\$ 53,271

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, the 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		Nine Months	
	Ended		Ended	
	October	September	October	September
	3,	27,	3,	27,
	2014	2013	2014	2013
Employee stock options	\$666	\$ 576	\$2,138	\$ 2,068
Restricted stock	141	283	666	718
Restricted stock units	705	—	1,857	—
Nonemployee stock options	41	47	75	138
Total	\$1,553	\$ 906	\$4,736	\$ 2,924

The Company recorded stock-based compensation expense in the following categories on the accompanying condensed consolidated statements of operations (in thousands):

	Three Months		Nine Months	
	Ended		Ended	
	October	September	October	September
	3,	27,	3,	27,
	2014	2013	2014	2013
General and administrative	\$869	\$ 506	\$2,925	\$ 1,912
Marketing and selling	326	211	906	593
Research and development	358	189	905	419
Total	\$1,553	\$ 906	\$4,736	\$ 2,924

#### 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 restricted stock units (RSUs). 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 3,227,435 shares were outstanding as of October 3, 2014 with exercise prices ranging between \$0.95 and \$17.62 per share. Grant of restricted stock outstanding under the Plan generally vest over periods of one to three years. Grant of RSUs outstanding under the Plan generally vest based on time, performance or a combination of both. There were 246,763 shares of restricted stock and 289,000 shares of RSUs outstanding as of October 3, 2014. As of October 3, 2014 there were 2,006,452 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 weighted-average assumptions noted in the following table. Expected volatilities are based on historical volatility of the Company’s stock. The expected term of options granted is derived from the historical exercises and post-vesting cancellations, and represents the period of time that options granted are expected to be outstanding. The Company has calculated a 7% estimated forfeiture rate 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			
	October 3, 2014	September 27, 2013	October 3, 2014	September 27, 2013	October 3, 2014	September 27, 2013
Expected dividend yield	0 %	0 %	0 %	0 %	0 %	0 %
Expected volatility	56.24 %	58.43 %	55.47 %	71.69 %		
Risk-free interest rate	1.36 %	1.32 %	1.29 %	0.69 %		
Expected term (in years)	4.12	4.12	4.12	4.12		

A summary of option activity under the Plan as of October 3, 2014 is presented below:

	Options Shares (000's)
Outstanding as of January 3, 2014	3,299
Granted	614
Exercised	(593 )
Forfeited or expired	(93 )
Outstanding as of October 3, 2014	3,227
Exercisable as of October 3, 2014	2,098

Warrants outstanding and exercisable as of October 3, 2014 and January 3, 2014 were 700,000.

A summary of restricted stock and restricted stock units activity under the Plan for the period ending October 3, 2014 is presented below:

	Restricted Shares (000's)	Restricted Units (000's)
Outstanding as of January 3, 2014	341	135
Granted	65	304
Vested	(140 )	(135 )
Forfeited or expired	(19 )	(15 )
Outstanding as of October 3, 2014	247	289

#### **Note 11 — Income Taxes**

The provision for income taxes is determined using an estimated annual effective tax rate. The effective tax rate may be subject to fluctuations during the year as new information is obtained, which may affect the assumptions used to estimate the annual effective tax rate, including factors such as the mix of pre-tax earnings in the various tax jurisdictions applicable to the Company, valuation allowances against deferred tax assets, the recognition or de-recognition of tax benefits related to uncertain tax positions, if any, and changes in or the interpretation of tax laws in jurisdictions where the Company conducts business.

The income tax provision for the quarter ended October 3, 2014 was \$0.5 million, compared to a small net income tax benefit of \$0.03 million reported for the quarter ended September 27, 2013. The income tax benefit recorded in the prior year quarter is due to the release of a valuation allowance at STAAR Japan. The income tax provision for the nine months ended October 3, 2014 and September 27, 2013 was \$1.1 million and \$0.9 million, respectively.

#### **Note 12 — Commitments and Contingencies**

##### *Litigation and Claims*

From time to time the Company may be subject to various claims and legal proceedings arising out of the normal course of our business. The Company expenses legal costs as incurred. These claims and legal proceedings may relate to contractual rights and obligations, securities or employment matters, or claims of product liability. The most

significant of these actions, and proceedings is described below. STAAR maintains insurance coverage for product liability and certain securities claims. Legal proceedings can extend for several years, and the matter described below concerning the Company is at very early stages of the legal process. As a result, this matter has not yet progressed sufficiently through discovery and/or development of important factual information and legal issues to enable the Company to determine whether the proceeding is material to the Company or to estimate a range of possible loss, if any. Unless otherwise disclosed, the Company is unable to estimate the possible loss or range of loss for the legal proceedings described below. While it is not possible to accurately predict or determine the eventual outcomes of this matter, an adverse determination in one or more of these items currently pending could have a material adverse effect on the Company's consolidated results of operations, financial position or cash flows.

*Todd v. STAAR*

On July 8, 2014, a putative securities class action lawsuit was filed by Edward Todd against the Company and three officers in federal court located in Los Angeles, California. The plaintiff claims that STAAR made misleading statements to and omitted material information from the Company's investors between February 27, 2013 and June 30, 2014 about alleged regulatory violations at the Company's Monrovia manufacturing facility. The Company was served with the Complaint on July 21, 2014. Although the ultimate outcome of this action cannot be determined with certainty, the Company believes that the allegations in the Complaint are without merit. The Company intends to vigorously defend against this lawsuit. The Company intends to file a motion to dismiss the complaint, when appropriate, in the ongoing proceeding. On October 20, 2014, plaintiff amended its complaint, dismissed two Company officers, added one other officer, and reduced the alleged Class Period to November 1, 2013 to June 30, 2014.

**Note 13 — Manufacturing Consolidation Project and Tax Strategy**

From fiscal 2011 through June 2014, the Company has devoted significant resources to two initiatives: a project to consolidate global manufacturing and development of a strategy to optimize its global organization for tax purposes. The goal of these initiatives is to further improve upon gross profit margin by streamlining operations, thereby reducing costs and increasing profits in the U.S., to enable the Company to utilize its approximately \$122 million in net operating loss carryforwards and at the same time, reduce income taxes in foreign jurisdictions where it pays tax. STAAR had manufactured its products in four facilities worldwide (Monrovia, Ca., Aliso Viejo, Ca., Nidau, Switzerland, and Ichikawa City, Japan). As of June 2014, all international production has been consolidated into the Monrovia site. Aliso Viejo is expected to integrate into Monrovia by the end of 2015.



The Company has invested approximately \$6.3 million since inception of these initiatives, including \$334,000 incurred during the nine months ended October 3, 2014, and future expenses, if any, are not expected to be material. These expenses are included in the other general and administrative expenses in the condensed consolidated statements of operations. Expenditures have largely consisted of severance, employee costs, professional fees to advisors and consultants.

A summary of the activity for these initiatives is presented below for the nine-month period ended October 3, 2014 (in thousands):

	Termination Benefits	Other Associated Costs	Total
Liability as of January 3, 2014	\$ 731	\$ 28	\$759
Costs incurred and charged to expense	212	122	334
Cash payments	(698 )	(150 )	(848)
Liability as of October 3, 2014	\$ 245	\$ —	\$245

## **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 2014; statements regarding new or improved products, including but not limited to, expectations for success of new and improved products in the U.S. or international markets or government approval of a new or improved products (including the Toric ICL in the U.S.); or commercialization of new or improved products; the nature, timing and likelihood of resolving issues cited in the FDA’s Warning Letter; future economic conditions or size of market opportunities; expected costs of quality system remediation efforts; expected costs and savings from business consolidation plans and the timetable for those plans; statements of belief, including as to achieving 2014 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 January 3, 2014, under the caption “Risk Factors: and also in our quarterly report on Form 10-Q for the period ended July 4, 2014, under the caption “Risk Factors.” 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 January 3, 2014, 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.

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.

*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.

## ***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 has substantially completed 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 and Switzerland to the U.S. is complete, though we maintain manufacturing capabilities in Switzerland. This project, which is subject to significant risks, is further described under Note 13, “*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 2014 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 2014 along four key operational metrics used to gauge its success during the year. Those metrics are as follows:

Increase total revenue by 8% to 10%.

As discussed below in “*Results of Operations*,” our total revenue increased by 6% in the third quarter of 2014. Year to date total revenue increased by 10%.

Increase ICL Sales by 20% for the full year

As discussed below in “*Results of Operations*,” ICL sales declined by 1% in the third quarter of 2014. Year to date total ICL sales grew by 8%. We do not expect to meet this metric for the full year.

Increase gross profit margins by 300 basis points to 72.7% for the full year.

As discussed below in “*Results of Operations*,” our gross profit decreased by 520 basis points to 65.3% in the third quarter of 2014, compared to 70.5% in the third quarter 2013. We do not expect to meet this metric for the full year.

Achieve profitability on a GAAP basis for the full year.

As discussed below in “*Results of Operations*,” we reported a net loss of \$2.7 million in the third quarter of 2014, and a net loss of \$5.9 million year to date. We do not expect to meet this metric for the full year.

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

We completed the planned transfer of manufacturing from our Nidau, Switzerland location, completing the consolidation of our international manufacturing sites. We maintain manufacturing capability at that location.

## **Other Highlights**

In the third quarter of 2014, ICL revenue grew in Europe, Middle East, Latin America and Africa (EMEA) region by 11%, declined in Asia Pacific (APAC) by 8% and declined in North America by 1%. In the third quarter 2014, ICL revenue in Korea declined by 45% and in Japan declined by 30%. We believe these declines were driven by negative LASIK press in Korea (for example, an investigative journalism program aired by the Moonhwa Broadcasting Company network in July 2014) and negative pressure on refractive procedures in Japan. We have seen negative LASIK press impact other markets in the past and it is difficult to predict a market’s recovery. Our Korean distributor plans to launch in December a direct-to-consumer marketing campaign with a Korean actress who has had ICL’s for the past eight years.

Sales were particularly strong in the third quarter of 2014, compared to the third quarter of 2013, in China (27% growth), Spain (19% growth), and Middle East (24% growth). Further market penetration of the ICL with CentraFLOW technology continues to contribute to sales growth where the product is available.

IOL revenue in the third quarter 2014 increased 8% primarily due to increased sales of KS-IOL products in the European markets (40% growth). Sales in Japan, which represents 51% the Company's total IOL sales, increased 7% in the third quarter of 2014. Our third party supplier of components for the KS-IOL product line continues to increase the quantity of KS-IOL products available and we plan on expanding its sale to new markets.

Our preloaded ICL with enhanced optics, which received CE Mark approval in the second quarter of 2014, is not yet ready for full commercial release as we experience challenges in reliably manufacturing it in large quantities, which may require minor design modifications. We also continue our development efforts for an ICL with an enhanced optic to add near-vision enhancement of up to two diopters that could address early onset presbyopia.

Gross margin for the third quarter of 2014 was 65.3% compared to 70.5% in the third quarter of 2013. Our gross margin expansion was limited by the geographic mix of IOL sales, continued higher ICL start up manufacturing costs in our Monrovia facility as compared to the Nidau facility, and increased sales of lower margin IOL injectors to our third party vendor for their preloaded acrylic IOL products. We expect their demand for IOL injectors to continue, and expand during the fourth quarter of 2014 as their demand for the product increases. We expect our costing for ICLs manufactured in the U.S. to improve in the fourth quarter 2014. Gross profit margin will continue to experience challenges from higher injector sales.

Operating expenses during the third quarter of 2014, increased 13% over the third quarter of 2013, due primarily to: 1) the timing of \$1.2 million of expenses associated with the European Society of Cataract & Refractive Surgeons (ESCRS) tradeshow which was held during the third quarter of 2014, compared to the fourth quarter of 2013; 2) the FDA Warning Letter remediation expenses of \$0.6 million; and 3) V5 and V6a ICL development activities. These expenses were partially offset by a decrease in bonus accruals and a decrease in manufacturing consolidation expenses.

Other expense increased \$0.9 million due to losses on foreign currency transactions and income taxes were \$0.5 million.

As a result of these factors, we reported a net loss for the quarter of \$2.7 million or \$0.07 per share.

#### *Status of Regulatory Submissions*

Regarding our PMA Supplement submission to the FDA seeking approval of the TICL, on March 14, 2014, a FDA Ophthalmic Devices Panel of the Medical Devices Advisory Committee voted favorably in response to the three questions posed to it by the FDA's Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices (regarding the TICL's safety and effectiveness as well as whether the TICL's benefits outweigh its risks). The FDA has not provided us with a timeline for a follow-up after the advisory panel meeting regarding a timeline for a decision on the PMA Supplement for the TICL, which has remained pending for over eight years. While the PMA Supplement remains pending, we cannot predict when, or if, the FDA will grant approval of the TICL for use in the United States.

As discussed in our "Risk Factors" contained in our Form 10-K filed on March 12, 2014 – "*FDA compliance issues have delayed approvals and we expect to devote significant resources to maintaining compliance in the future,*" on May 27, 2014, we received a Warning Letter from the FDA citing alleged violations of current good manufacturing practice ("cGMP") regulations that were identified by the FDA during an inspection of the Company's manufacturing facility in Monrovia, California between February 10, 2014 and March 21, 2014. To summarize, the Warning Letter observations require remedial action in four general areas: design control documentation; validation of software for an



on-line calculator; data collection and trending of ICL vault complaints; and shelf life data on the ICL product. The Warning Letter provides that, until the Company addresses the deficiencies to the FDA's satisfaction, the FDA will not approve premarket applications ("PMAs") for the Company's Class III devices where the applications are reasonably related to the cGMP violations cited in the Warning Letter. On October 15, we responded to questions from the FDA regarding the method used to select ICL power and length. It is unclear whether the Warning Letter will ultimately impact the timing of a potential TICL approval.

On April 14, 2014, STAAR submitted a PMA Supplement seeking approval of calculator software for the ICL. On July 16, 2014, we received a deficiency letter requesting that we revise the acceptable range of data for the corneal thickness and contact lens sphere fields, clarify that the anterior chamber depth field should include corneal thickness, and provide a list of any known software anomalies (i.e., bugs). On September 25, 2014, we revised the software fields and provided the requested data regarding software anomalies.

On November 3, 2014, the China Food and Drug Administration (CFDA) issued an Approved Certification, which finalized the approval process for our Visian ICL with CentraFLOW technology for marketing and sale in China.

On October 9, 2013, STAAR submitted a clinical study protocol regarding the ICL with CentraFLOW technology. On December 12, 2013, we met with the FDA in Washington D.C. to discuss the protocol and we remain in dialogue with the FDA regarding a revised proposed protocol.

### **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 October 3, 2014 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

January 3, 2014.

15

## 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		
	October 3, 2014	September 27, 2013	October 3, 2014	September 27, 2013	
Net sales	100.0%	100.0	% 100.0%	100.0	%
Cost of sales	34.7	29.5	32.5	29.9	
Gross profit	65.3	70.5	67.5	70.1	
General and administrative	17.9	24.2	23.9	22.5	
Marketing and selling	38.6	32.3	34.6	30.9	
Research and development	17.2	9.8	15.6	8.9	
Medical device tax	0.1	0.3	0.1	0.3	
Other general and administrative expenses	0.0	2.9	0.6	3.8	
	73.8	69.6	74.8	66.4	
Operating income (expense)	(8.5 )	1.0	(7.3 )	3.7	
Other income (expense), net	(3.4 )	1.9	(0.8 )	0.4	
Income before provision (benefit) for income taxes	(11.9 )	2.9	(8.1 )	4.1	
Provision (benefit) for income taxes	3.0	(0.1 )	1.9	1.7	
Net income (loss)	(14.9 )%	3.0	% (10.0 )%	2.4	%

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

### Net Sales

Three Months Ended		Fav/ (Unfav) %	Nine Months Ended		Fav/ (Unfav) %
October 3,	September 27,	Change 2014 vs. 2013	October 3,	September 27,	Change 2014 vs. 2013

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

	2014	2013		2014	2013		
Net sales	\$18,188	\$17,106	6.3	% \$58,414	\$53,271	9.7	%
ICL	10,640	10,725	(0.8	)	35,052	32,616	7.5
IOL	5,763	5,322	8.3		18,804	17,533	7.2
Other	1,785	1,059	68.6		4,558	3,122	46.0

Net sales for the three months ended October 3, 2014 were \$18.2 million, an increase of 6.3% compared to the \$17.1 million reported during three months ended September 27, 2013. Net sales for the nine months ended October 3, 2014 were \$58.4 million, a 9.7% increase compared with \$53.3 million reported during the nine months ended September 27, 2013. The effect of foreign exchange had a negative impact on sales of \$0.4 million and \$1.1 million, respectively, for the three and nine months ended October 3, 2014.

Total ICL sales for the three months ended October 3, 2014 were \$10.6 million, a decrease of 0.8% compared with \$10.7 million reported during the three months ended September 27, 2013. Total ICL sales for the nine months ended October 3, 2014 were \$35.1 million, an increase of 7.5% compared with \$32.6 million reported during the nine months ended September 27, 2013. ICL sales decreased 1% and increased 8%, respectively, in the Company's top 12 markets during the three and nine months ended October 3, 2014. The decrease during the quarter was due to a 45% decrease in sales in Korea due to negative publicity surrounding LASIK and a 30% decrease in sales in Japan due to decreased demand for refractive procedures. These decreases were partially offset by increased sales in China, up 27%, Spain, up 19%, and the Middle East, up 24%. ICL sales represented 58.5% and 60.0%, respectively, of our total sales for the three and nine months ended October 3, 2014, compared to 62.7% and 61.2% for the three and nine month periods ended September 27, 2013.

Total IOL sales for the three months ended October 3, 2014 were \$5.8 million, an increase of 8.3%, when compared with \$5.3 million for the three months ended September 27, 2013. Total IOL sales for the nine months ended October 3, 2014 were \$18.8 million, an increase of 7.2%, when compared with \$17.5 million for the nine months ended September 27, 2013. IOL sales represent 31.7% and 32.2% of sales for the three and nine months ended October 3, 2014, respectively, compared to 31.1% and 32.9% for the three and nine month periods ended September 27, 2013, respectively. The increase in IOL sales was due to increased KS-IOL sales in Japan and Europe. The effect of foreign exchange reduced IOL sales by \$0.2 million and \$0.7 million, respectively, for the three and nine months ended October 3, 2014.

Other product sales for the three and nine months ended October 3, 2014 were \$1.8 million and \$4.6 million, an increase of 68.6% and 46.0%, respectively, when compared with \$1.1 million and \$3.1 million for the three and nine months ended September 27, 2013. 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)	Nine Months Ended		Fav/ (Unfav)
	October 3, 2014	September 27, 2013	% Change 2014 vs. 2013	October 3, 2014	September 27, 2013	% Change 2014 vs. 2013
Gross Profit	\$11,869	\$12,059	(1.6)%	\$39,419	\$37,332	5.6%
Gross Profit Margin	65.3%	70.5%		67.5%	70.1%	

Gross profit for the third quarter was \$11.9 million, or 65.3% of revenue, compared with \$12.1 million, or 70.5% of revenue, in the prior year period. During the first nine months of 2014, gross profit was \$39.4 million, or 67.5% of revenue, compared with \$37.3 million, or 70.1% of revenue, in the prior year period. Gross profit margin for the three and nine month periods was negatively impacted by increased ICL costs, the increased mix of low margin injector system sales, the increased mix of preloaded acrylic sales, and increased inventory reserves.

**General and Administrative**

	Three Months Ended		Fav/ (Unfav)	Nine Months Ended		Fav/ (Unfav)
	October 3, 2014	September 27, 2013	% Change 2014 vs. 2013	October 3, 2014	September 27, 2013	% Change 2014 vs. 2013
General and Administrative Percentage of Sales	\$3,250 17.9%	\$4,140 24.2%	21.5%	\$13,968 23.9%	\$12,021 22.5%	(16.2)%

General and administrative expenses decreased 21.5% to \$3.3 million in the third quarter of 2014 from the \$4.1 million reported in the third quarter of 2013. General and administrative expenses for the nine months ended October 3, 2014 were \$14.0 million, an increase of 16.2% when compared with \$12.0 million reported last year. The decrease for the quarter is due to a decrease in bonus accruals based upon performance to date. The increase for the year to date period is due to increased stock compensation, travel, facility, tax consulting and legal expenses.

**Marketing and Selling**

	Three Months Ended		Fav/ (Unfav)	Nine Months Ended		Fav/ (Unfav)
	October 3, 2014	September 27, 2013	% Change 2014 vs. 2013	October 3, 2014	September 27, 2013	% Change 2014 vs. 2013
Marketing and Selling	\$7,026	\$ 5,527	(27.1 )%	\$20,189	\$ 16,471	(22.6 )%
Percentage of Sales	38.6 %	32.3 %		34.6 %	30.9 %	

Marketing and selling expenses were \$7.0 million for the third quarter of 2014, an increase of 27.1% compared to \$5.5 or 32.3% for the third quarter of 2013. Marketing and selling expenses for the nine months ended October 3, 2014 were \$20.2 million compared to \$16.5 million reported last year. The increase for the quarter is due to the timing of ESCRS tradeshow expense, which was held in the third quarter of 2014, compared to the fourth quarter of 2013. Marketing and selling expense for the three and nine month periods also increased due to increased headcount, travel and promotional activities to support the increased level of sales, and increased trade show spending.

**Research and Development**

	Three Months Ended		Fav/ (Unfav)	Nine Months Ended		Fav/ (Unfav)
	October 3, 2014	September 27, 2013	% Change 2014 vs. 2013	October 3, 2014	September 27, 2013	% Change 2014 vs. 2013
Research and Development	\$3,137	\$ 1,684	(86.3 )%	\$9,118	\$ 4,736	(92.5 )%
Percentage of Sales	17.2 %	9.8 %		15.6 %	8.9 %	

Research and development expense increased in the third quarter of 2014, by 86.3% to \$3.1 million, compared with \$1.7 million in the third quarter of 2013. Research and development expense for the nine months ended October 3, 2014 was \$9.1 million, an increase of 92.5% when compared with \$4.7 million reported last year. The increase for the quarter and year to date periods is due to FDA warning letter remediation expenses which totaled approximately \$0.6 million for the quarter, increased V5 and V6 ICL development activities and increased headcount and stock compensation. We believe fourth quarter FDA warning letter remediation expenses will be similar to the amount for the third quarter. In addition, for the year to date period, expense increased due to the FDA panel meeting held during Q1 of this year.

### *Other General and Administrative Expenses*

	Three Months Ended	Fav/ (Unfav) % Change	Nine Months Ended	Fav/ (Unfav) % Change		
	October 3, 2014	September 27, 2014 vs. 2013	October 3, 2014	September 27, 2013 vs. 2013		
Other General and Administrative Expenses	\$—	\$ 490	100 %	\$ 334	\$ 2,004	83.3 %
Percentage of Sales	<del>%</del>	2.9 %		0.6 %	3.8 %	

Other general and administrative expenses for the quarter were \$0.0 million, compared with \$0.5 million in the third quarter of 2013. Other general and administrative expenses for the nine months ended October 3, 2014 were \$0.3 million, compared to \$2.0 million from the first nine months of 2013. This expense was associated with the consolidation of the Company's manufacturing facilities that was completed by the end of the second quarter of 2014.

### *Other Income, (Expense) Net*

Three Months Ended	Fav/ (Unfav) % Change	Nine months Ended	Fav/ (Unfav) % Change
October 3, 2014	September 27, 2014 vs. 2013	October 3, 2014	September 27, 2013 vs. 2013

## Edgar Filing: STAAR SURGICAL CO - Form 10-Q

	2014	2013		2014	2013	
Other Income (expense), Net	\$(605)	\$ 327	—%	\$(434)	\$ 211	—%

The year over year change in other income (expense), net for both periods is due to losses on foreign currency realized during the periods.

### *Income Taxes*

The provision for income taxes is determined using an estimated annual effective tax rate. The effective tax rate may be subject to fluctuations during the year as new information is obtained, which may affect the assumptions used to estimate the annual effective tax rate, including factors such as the mix of pre-tax earnings in the various jurisdictions applicable to the Company, valuation allowances against deferred tax assets, the recognition or de-recognition of tax benefits related to uncertain tax positions, if any, and change in or the interpretation of tax laws in jurisdictions where the Company conducts business.

The income tax provision for the quarter ended October 3, 2014 was \$0.5 million, compared to a small net income tax benefit of \$0.03 million reported for the quarter ended September 27, 2013. The income tax benefit recorded in the prior year quarter is due to the release of a valuation allowance at STAAR Japan. The income tax provision for the nine months ended October 3, 2014 and September 27, 2013 was \$1.1 million and \$0.9 million, respectively.

### *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 costs associated with the FDA Warning Letter remediation. 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 increased in 2012 and 2013 but have decreased during the first nine months of 2014 due to investments in inventory and other changes in working capital. To the extent STAAR's cash balances exceed levels needed for working capital and as a cushion for unforeseen demand, 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 October 3, 2014 and January 3, 2014, respectively, STAAR had \$18.4 million and \$23.0 million, of cash and cash equivalents.

Net cash used in operating activities for the nine months ended October 3, 2014 was \$4.4 million and net cash provided by operating activities for the nine months ended September 27, 2013 was \$3.4 million. Net cash used in operations for the nine months ended October 3, 2014 consisted of net loss of \$5.9 million plus \$5.4 million used for working capital, offset by \$6.9 million in non-cash items.

Net cash used in investing activities for the nine months ended October 3, 2014 and September 27, 2013, respectively, was \$2.4 million and \$3.0 million. Net cash used in investing activities for the nine months ended October 3, 2014 was due to acquisition of property, plant and equipment.

Net cash provided by financing activities for the nine months ended October 3, 2014 and September 27, 2013, respectively, was \$2.4 million and \$2.0 million. Net cash provided by financing activities for the nine months ended October 3, 2014 consisted of \$2.8 million in proceeds from stock options, partially offset by \$0.4 million in capital lease repayments.

*Credit Facilities, Contractual Obligations and Commitments*

*Accrued Termination Benefits for Manufacturing Consolidations Project*

The Company has \$0.2 million in accrued termination benefit costs as of October 3, 2014, in connection with its manufacturing consolidation project. The accrual represents STAAR's current best estimate of the remaining

termination benefits that will be paid to eligible employees.

*Lines of Credit*

The Company's wholly owned Japanese subsidiary, STAAR Japan, has an agreement, as amended on October 3, 2014, with Mizuho Bank, which provides for borrowings of up to 500,000,000 Yen (approximately \$4.6 million based on the rate of exchange on October 3, 2014), at an interest rate equal to the Tokyo short-term prime interest rate (approximately 1.475% as of October 3, 2014). As of October 3, 2014 and January 3, 2014, there were no available borrowings under the line. The bank line is renewed every three months and the next renewal date is December 26, 2014.

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 October 3, 2014), to be used for working capital purposes. There were no borrowings outstanding as of October 3, 2014 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	October 3, 2014	January 3, 2014
2014	\$ 134	\$ 303
2015	433	142
2016	338	6
2017	133	—
Thereafter	—	—
Total minimum lease payments	1,038	451
Less: interest	81	22
Total lease obligation	\$ 957	\$ 429
Current	\$ 419	\$ 288
Long-term	\$ 538	\$ 141

### **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 January 3, 2014.

### **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 October 3, 2014 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, securities or employment matters, or claims of product liability or regulatory actions. The most significant of these actions, proceedings and investigations are described below. STAAR maintains insurance coverage for product liability and certain securities claims. Legal proceedings can extend for several years, and the matters described below concerning the Company are at very early stages of the legal and administrative process. As a result, these matters have not yet progressed sufficiently through discovery and/or development of important factual information and legal issues to enable the Company to determine whether the proceedings are material to the Company or to estimate a range of possible loss, if any. Unless otherwise disclosed, the Company is unable to estimate the possible loss or range of loss for the legal proceedings described below. While it is not possible to accurately predict or determine the eventual outcomes of these items, an adverse determination in one or more of these items currently pending could have a material adverse effect on the Company's consolidated results of operations, financial position or cash flows.

#### *Securities and Exchange Commission Informal Inquiry*

In a letter dated July 3, 2014, the United States Securities and Exchange Commission (“SEC”) advised STAAR that it is conducting an informal inquiry into compliance with U.S. securities laws. The letter requested documents concerning any FDA inspections, investigations, observations, noted violations, or warnings since January 1, 2014. The Company is cooperating with this informal inquiry.

#### *Todd v. STAAR*

On July 8, 2014, a putative securities class action lawsuit was filed by Edward Todd against STAAR and three officers in the federal court located in Los Angeles, California. The plaintiff claims that STAAR made misleading statements to and omitted material information from our investors between February 27, 2013 and June 30, 2014 about alleged regulatory violations at STAAR's Monrovia manufacturing facility. On July 21, 2014, the Company was served with the Complaint. Although the ultimate outcome of this action cannot be determined with certainty, the Company believes that the allegations in the Complaint are without merit. The Company intends to vigorously defend against this lawsuit. The Company intends to file a motion to dismiss the complaint, when appropriate, in the ongoing proceeding. On October 20, 2014, plaintiff amended its complaint, dismissed two Company officers, added one other officer, and reduced the alleged Class Period to November 1, 2013 to June 30, 2014.

***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 January 3, 2014 and Form 10-Q for the quarterly period ended July 4, 2014. 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**

On October 3, 2014, we announced that Barry Caldwell, President and CEO, would retire on March 1, 2015. The Board of Directors has initiated a search for his successor. After his retirement, Mr. Caldwell will become a consultant to STAAR through March 2016.

**ITEM 6. EXHIBITS**

3.1 Certificate of Incorporation, as amended to date.(1)

3.2 Amended and Restated By-laws. (1)

4.4 Form of Certificate for Common Stock, par value \$0.01 per share.(2)

31.1 Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, Adopted Pursuant to Section 302 of the S

31.2 Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, Adopted Pursuant to Section 302 of the S

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 October  
filed herewith and include: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of  
Statements of Comprehensive Income, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) the Notes to C  
Statements tagged as blocks of text. \*

---

(1) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Commission on June 11, 2014.

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

\* Filed herewith.



**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

Dated: November 7, 2014 By: /s/ STEPHEN P. BROWN  
**Stephen P. Brown**

**Chief Financial Officer**

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