

STAAR SURGICAL CO  
Form 10-Q  
July 31, 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: July 4, 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):

Non-accelerated filer

Large accelerated filer  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 38,593,330 shares of common stock, par value \$0.01 per share, issued and outstanding as of July 24, 2014.

**STAAR SURGICAL COMPANY**

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

	July 4, 2014	January 3, 2014
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$19,186	\$22,954
Accounts receivable trade, net of allowance for doubtful accounts of \$1,461 and \$1,449, respectively	12,700	10,731
Inventories, net	14,932	12,514
Prepays, deposits and other current assets	3,539	3,503
Deferred income taxes	384	373
Total current assets	50,741	50,075
Property, plant and equipment, net	9,320	7,405
Intangible assets, net	1,206	1,380
Goodwill	1,786	1,786
Deferred income taxes	647	626
Other assets	672	659
Total assets	\$64,372	\$61,931
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Line of credit	\$4,900	\$4,750
Accounts payable	5,269	6,263
Deferred income taxes	738	739
Obligations under capital leases	445	288
Other current liabilities	5,833	6,372
Total current liabilities	17,185	18,412
Obligations under capital leases	629	141
Deferred income taxes	1,735	1,654
Asset retirement obligations	134	157
Pension liability	2,858	2,715
Total liabilities	22,541	23,079
Commitments and contingencies (Note 12)		
Stockholders' equity:	384	379

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Common stock, \$0.01 par value; 60,000 shares authorized; 38,361 and 37,911 shares issued and outstanding at July 4, 2014 and January 3, 2014

Additional paid-in capital	176,204	170,246
Accumulated other comprehensive income	446	282
Accumulated deficit	(135,203)	(132,055)
Total stockholders' equity	41,831	38,852
Total liabilities and stockholders' equity	\$64,372	\$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		Six Months Ended	
	July 4, 2014	June 28, 2013	July 4, 2014	June 28, 2013
Net sales	\$ 20,048	\$ 18,164	\$ 40,226	\$ 36,165
Cost of sales	6,381	5,544	12,675	10,891
Gross profit	13,667	12,620	27,551	25,274
General and administrative	5,321	3,923	10,717	7,881
Marketing and selling	7,026	5,659	13,164	10,945
Research and development	2,498	1,686	5,981	3,052
Medical device tax	47	45	87	104
Other general and administrative expenses	165	613	334	1,514
Operating income (loss)	(1,390 )	694	(2,732 )	1,778
Other income (expense):				
Interest income	10	8	18	15
Interest expense	(34 )	(41 )	(67 )	(96 )
Gain (loss) on foreign currency transactions	(134 )	77	(68 )	(264 )
Other income, net	126	139	287	230
Other income (expense), net	(32 )	183	170	(115 )
Income (loss) before provision for income taxes	(1,422 )	877	(2,562 )	1,663
Provision for income taxes	367	599	586	914
Net income (loss)	\$(1,789 )	\$ 278	\$(3,148 )	\$ 749
Net income (loss) per share - basic	\$(0.05 )	\$ 0.01	\$(0.08 )	\$ 0.02
Net income (loss) per share - diluted	\$(0.05 )	\$ 0.01	\$(0.08 )	\$ 0.02
Weighted average shares outstanding - basic	38,168	36,496	37,970	36,461
Weighted average shares outstanding - diluted	38,168	38,342	37,970	37,887

*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		Six Months Ended	
	July 4, 2014	June 28, 2013	July 4, 2014	June 28, 2013
Net income (loss)	\$ (1,789 )	\$ 278	\$ (3,148 )	\$ 749
Other comprehensive income (loss):				
Defined benefit pension plans:				
Net change in plan assets	(11 )	(18 )	(23 )	(30 )
Reclassification into earnings	6	14	12	19
Impact of change in discount rate	(558 )	—	(558 )	—
Curtailment gain	537	—	537	—
Foreign currency translation gain (loss)	291	(230 )	302	(894 )
Tax effect	(103 )	(1 )	(106 )	(5 )
Other comprehensive income (loss), net of tax	162	(235 )	164	(910 )
Comprehensive income (loss), net of tax	\$ (1,627 )	\$ 43	\$ (2,984 )	\$ (161 )

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



## STAAR SURGICAL COMPANY

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Six Months Ended	
	July 4, 2014	June 28, 2013
Cash flows from operating activities:		
Net income (loss)	\$(3,148 )	\$ 749
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:		
Depreciation of property and equipment	981	840
Amortization of intangibles	213	225
Deferred income taxes	57	129
Fair value adjustment of warrant	—	(27 )
Loss on disposal of property and equipment	—	59
Change in net pension liability	83	57
Stock-based compensation expense	3,183	2,019
Accretion of asset retirement obligation	2	7
Provision for sales returns and bad debts	1	111
Changes in working capital:		
Accounts receivable	(1,895 )	(2,229 )
Inventories	(2,093 )	71
Prepays, deposits and other current assets	(20 )	(507 )
Accounts payable	(874 )	(1,123 )
Other current liabilities	(554 )	(25 )
Net cash (used in) provided by operating activities	(4,064 )	356
Cash flows from investing activities:		
Cash proceeds from sale of equipment	68	—
Acquisition of property and equipment	(2,269 )	(2,017 )
Net cash used in investing activities	(2,201 )	(2,017 )
Cash flows from financing activities:		
Repayment of capital lease obligations	(251 )	(478 )
Proceeds from exercise of stock options	2,632	952
Net cash provided by financing activities	2,381	474
Effect of exchange rate changes on cash and cash equivalents	116	(763 )
Decrease in cash and cash equivalents	(3,768 )	(1,950 )

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Cash and cash equivalents, at beginning of the period	22,954	21,675
Cash and cash equivalents, at end of the period	\$19,186	\$ 19,725

*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 six months ended July 4, 2014 and June 28, 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 six months ended July 4, 2014 and June 28, 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 and disclosures to conform to the current period’s presentation.

*New 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.

## Note 2 — Inventories

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

	July 4, 2014	January 3, 2014
Raw materials and purchased parts	\$1,867	\$ 1,367
Work-in-process	1,769	913
Finished goods	12,463	11,029
	16,099	13,309
Less: inventory reserves	1,167	795
	\$14,932	\$ 12,514

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

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

	July 4, 2014	January 3, 2014
Prepaid and deposits	\$1,990	\$2,157
Value added tax (VAT) receivable	631	618
Deferred charges for foreign profits	340	362
Other current assets	578	366
	<b>\$3,539</b>	<b>\$3,503</b>

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

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

	July 4, 2014	January 3, 2014
Machinery and equipment	\$16,670	\$16,225
Furniture and fixtures	5,455	4,837
Leasehold improvements	7,573	6,552
	29,698	27,614
Less: accumulated depreciation	20,378	20,209
	<b>\$9,320</b>	<b>\$7,405</b>

**Note 5 – Amortizable Intangible Assets**

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

July 4, 2014			January 3, 2014		
Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net

## Amortized intangible assets:

Patents and licenses	\$10,657	\$ (10,173	) \$484	\$10,637	\$ (10,057	) \$580
Customer relationships	1,537	(999	) 538	1,490	(894	) 596
Developed technology	977	(793	) 184	947	(743	) 204
Total	\$13,171	\$ (11,965	) \$1,206	\$13,074	\$ (11,694	) \$1,380

**Note 6 – Other Current Liabilities**

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

	July 4, 2014	January 3, 2014
Accrued salaries and wages	\$1,770	\$ 1,630
Accrued bonuses	1,107	935
Accrued severance	350	731
Accrued income taxes	317	485
Accrued audit fees	310	328
Accrued commissions	296	528
Accrued insurance	154	551
Other <sup>(1)</sup>	1529	1,184
	\$5,833	\$ 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. However, since the Swiss pension plan's accumulated other comprehensive loss, immediately preceding the curtailment exceeded the curtailment gain, the curtailment gain was 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.

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 July 4, 2014	Three Months Ended June 28, 2013	Six Months Ended July 4, 2014	Six Months Ended June 28, 2013
Service cost	\$ 117	\$ 80	\$ 233	\$ 204
Interest cost	36	25	71	52
Expected return on plan assets	(28 )	(24 )	(55 )	(48 )
Net amortization of transitional obligation	—	—	—	3
Actuarial loss recognized in current period	6	14	12	19
	\$ 131	\$ 95	\$ 261	\$ 230

During the six months ended July 4, 2014 and June 28, 2013, the Company made cash contributions totaling approximately \$276,000 and \$115,000 to its Swiss pension plan and does not expect to make any additional cash 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**

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

	Three Months Ended		Six Months Ended	
	July 4, 2014	June 28, 2013	July 4, 2014	June 28, 2013
Numerator:				
Net income (loss)	\$ (1,789 )	\$ 278	\$ (3,148 )	\$ 749
Denominator:				
Weighted average common shares and denominator for basic calculation:				
Weighted average common shares outstanding	38,400	36,830	38,247	36,745
Less: Unvested restricted stock	(232 )	(334 )	(277 )	(284 )
Denominator for basic calculation	38,168	36,496	37,970	36,461
Weighted average effects of dilutive equity-based compensation awards:				
Stock options	—	999	—	746
Restricted stock	—	139	—	94
Warrants	—	708	—	586
Denominator for diluted calculation	38,168	38,342	37,970	37,887
Net income (loss) per share – basic	\$ (0.05 )	\$ 0.01	\$ (0.08 )	\$ 0.02
Net income (loss) per share - diluted	\$ (0.05 )	\$ 0.01	\$ (0.08 )	\$ 0.02



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		Six Months Ended	
	July 4, 2014	June 28, 2013	July 4, 2014	June 28, 2013
Options	2,216	1,262	2,117	1,428
Restricted stock and units	195	25	280	110
Warrants	526	—	527	—
Total	2,937	1,287	2,924	1,538

### Note 9 — Geographic and Product Data

The Company markets and sells its products in over 60 countries and has two manufacturing sites in the United States. During the quarter ended July 4, 2014, the Company completed the consolidation of its Swiss manufacturing facility to the U.S. Other than the United States, Japan, Korea, China, Spain, France and Germany, 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		Six Months Ended	
	July 4, 2014	June 28, 2013	July 4, 2014	June 28, 2013
Japan	\$ 4,549	\$ 4,648	\$ 9,557	\$ 9,387
United States	2,926	3,154	5,801	6,394
China	2,535	2,230	4,759	4,301
Korea	1,952	1,834	4,573	3,869
Spain	1,474	1,163	3,092	2,454
France	1,190	595	2,136	1,127
Germany	1,015	611	1,912	1,126
Other	4,407	3,929	8,396	7,507
Total	\$ 20,048	\$ 18,164	\$ 40,226	\$ 36,165

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):

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	Three Months Ended		Six Months Ended	
	July 4, 2014	June 28, 2013	July 4, 2014	June 28, 2013
ICLs	\$ 12,172	\$ 11,261	\$24,413	\$21,892
IOLs	6,428	5,863	13,041	12,211
Core products	18,600	17,124	37,454	34,103
Other surgical products	1,448	1,040	2,772	2,062
Total	\$ 20,048	\$ 18,164	\$40,226	\$36,165

One customer accounted for 11% of net sales for the three and six months ended July 4, 2014. This customer accounted for 11% and 10% of net sales for the three and six months ended June 28, 2013. One customer accounted for 12% of net sales for the six months ended July 4, 2014. This customer accounted for 10% and 11% of net sales for the three and six months ended June 28, 2013, respectively.

The Company sells its products internationally, which subjects the Company to several potential risks including 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		Six Months Ended	
	July 4, 2014	June 28, 2013	July 4, 2014	June 28, 2013
Employee stock options	\$ 675	\$ 666	\$ 1,472	\$ 1,492
Restricted stock	232	252	525	435
Restricted stock units	764	—	1,152	—
Nonemployee stock options	12	66	34	92
Total	\$ 1,683	\$ 984	\$ 3,183	\$ 2,019

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

	Three Months Ended		Six Months Ended	
	July 4, 2014	June 28, 2013	July 4, 2014	June 28, 2013
Cost of sales	\$ 39	\$ 25	\$ 77	\$ 50
General and administrative	1,033	646	1,970	1,357
Marketing and selling	306	212	580	382
Research and development	305	101	556	230
Total	\$ 1,683	\$ 984	\$ 3,183	\$ 2,019

#### 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 stock options, restricted stock, unrestricted stock 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 options and stock awards provide for accelerated vesting if there is a change in control or certain pre-established financial metrics are met. Pursuant to the Plan, options for 3,276,770 shares were outstanding at July 4, 2014 with exercise prices ranging between \$0.95 and \$17.62 per share. Restricted stock grants under the Plan generally vest over a period of between one to three years. There were 229,500 shares of restricted stock and 299,000 RSUs outstanding at July 4, 2014. As of July 4, 2014, there were 1,998,046 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		Six Months Ended	
	July 4,	June 28,	July 4,	June 28,
	2014	2013	2014	2013
Expected dividend yield	0 %	0 %	0 %	0 %
Expected volatility	56 %	72 %	55 %	73 %
Risk-free interest rate	1.30 %	0.70 %	1.29 %	0.62 %
Expected term (in years)	4.12	4.12	4.12	4.12

A summary of option activity under the Plan as of July 4, 2014 is presented below:

	Options Shares (000's)
Outstanding at January 3, 2014	3,299
Granted	576
Exercised	(564 )
Forfeited or expired	(34 )
Outstanding at July 4, 2014	3,277
Exercisable at July 4, 2014	2,082

Warrants outstanding and exercisable as of July 4, 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 July 4, 2014 is presented below:

	Restricted Shares (000's)	Restricted Units (000's)
Outstanding at January 3, 2014	341	135
Granted	29	304
Exercised	(140 )	(135 )
Forfeited	—	(5 )
Outstanding at July 4, 2014	230	299

#### 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 Company recorded an income tax provision of \$586,000 and \$914,000 for the six months ended July 4, 2014 and June 28, 2013, respectively, primarily benefiting in the current six-month period from the mix of pre-tax earnings in lower- and zero- rate foreign jurisdictions. There are no unrecognized tax benefits as of any period presented.

## **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.

**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 in the middle of 2015.

The Company has invested approximately \$6.3 million since inception of these initiatives, including \$334,000 incurred during the six months ended July 4, 2014, and future expenses, if any, are not expected to be material. These consolidation expenses are included in the other general and administrative expenses in the consolidated statements of operations. Expenditures to date 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 six-month period ended July 4, 2014 (in thousands):

	Termination Benefits	Other Associated Costs	Total
Liability at January 3, 2014	\$ 731	\$ 28	\$759
Costs incurred and charged to expense	212	122	334
Cash payments	(593	) (150	) (743)

Liability at July 4, 2014	\$ 350	\$ —	\$350
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## **ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

This information should be read in conjunction with the condensed consolidated financial statements and the notes thereto included in Part I, Item 1 of this Quarterly Report and with Management's Discussion and Analysis of Financial Condition and Results of Operations for the year ended January 3, 2014 contained in our 2013 Annual Report on Form 10-K.

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 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 (including approval of the Toric ICL in the U.S.); future economic conditions or size of market opportunities; expected IOL backorder position; expected costs of Monrovia facility expansion; expected costs and savings from the business consolidation plans and the timetable for those plans; statements of belief, including as to achieving 2014 growth plans or metrics; expected regulatory activities (including any costs or activities related thereto) 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. 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.

### **Overview**

STAAR Surgical Company ("we," "us," the "Company," and "STAAR") designs, develops, manufactures and sells implantable lenses and delivery systems for the eye. We are the world's leading manufacturer of intraocular lenses used in "refractive" surgery, and we also make lenses for use in surgery to treat cataracts. All of the lenses we make are foldable, which allows the surgeon to insert them into the eye through a small incision during minimally invasive surgery. Refractive surgery is performed to treat the type of visual disorders that have traditionally been corrected using eyeglasses or contact lenses. We refer to our lenses used in refractive surgery as "implantable Collamer® lenses" or "ICLs" and market them under the Visian® brand name. The field of refractive surgery includes both lens-based procedures, using products like the Visian ICL®, and laser-based procedures like LASIK. Successful refractive surgery can correct common vision disorders such as myopia, hyperopia and astigmatism. 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®, Elastimide®, nanoFLEX®, nanoPOINT™, CentraFLOW® AquaPORT®, Epiphany® and AquaFlow™ are trademarks or registered trademarks of STAAR in the U.S. and other countries.

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

### ***Products***

A detailed description of STAAR's business appears in our Annual Report on Form 10-K for the fiscal year ended 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 sixty (60%) percent 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 TICL, treats myopic and hyperopic patients with astigmatism. Astigmatism is a condition that causes blurred vision when an irregular shape of the cornea prevents light from focusing properly on the retina. 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 Submissions.”

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 range (from -3.0 to +3.0), and the V4c, which includes the proprietary CentraFLOW technology (a port in the center of the myopic ICL and TICL) that eliminates the need for a peripheral iridectomy or iridotomy procedure prior to implanting the ICL.

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

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

Aspheric IOLs, available in single-piece and three-piece designs made (i) from 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 three piece aspheric silicone is sold preloaded in certain markets outside of the U.S. The Collamer three piece lens is only marketed and sold in the U.S.

The nanoFLEX IOL, a single-piece Collamer aspheric IOL that can be implanted through a micro-incision with a single-use disposable nanoPOINT injector system, is available in the U.S and territories that accept the CE Mark.

The Preloaded IOL line consists of a three-piece silicone and a three piece and single piece acrylic IOL preloaded into a single-use disposable injector which is currently available outside the U.S. The acrylic IOL Preloaded line utilizes an acrylic lens sourced from another manufacturer. The KS-SP is a single-piece preloaded acrylic IOL and the KS-X(s) is a three piece preloaded acrylic IOL. The KS IOL line is available in Japan and on a limited basis in Europe.

The 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.

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

*Other Surgical Products.* We also sell other instruments, devices, and injector parts. Although we have been deemphasizing these products since 2009 because of their lower overall gross profit margins, we expect that sales of these products will continue to increase due to an increase in the demand of injector parts.

### *Operations*

STAAR operates its global administrative headquarters and a manufacturing facility in Monrovia, California, conducts materials manufacturing in Aliso Viejo, California and also maintains products manufacturing capabilities in Nidau, Switzerland. STAAR operates administrative and distribution facilities in Nidau, Switzerland through its wholly owned subsidiary STAAR Surgical AG, and in Chiba Prefecture, Japan through its wholly owned subsidiary STAAR Japan Inc.

STAAR has completed a project to consolidate its international manufacturing into a single site at its Monrovia, California location as of July 4, 2014, which we expect to yield significant savings in cost of goods, lower our global administrative and regulatory costs and reduce income taxes. As of the end of the second quarter of 2014, all IOLs and ICLs were manufactured in the U.S. 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 objectives for 2014 are guided by two principal strategic goals: to achieve profitability and to lay the groundwork for future profitable growth. In pursuit of these goals, STAAR has aligned its business initiatives during 2014 along five objectives it uses to gauge its success for the year. Those objectives are as follows:

Increase total revenue by 8% to 10%.

- As discussed below in "*Results of Operations*," our total revenue increased by 10% in the second quarter of 2014. Total revenue increased by 11% in the first half of 2014.

Increase ICL sales by 20% for the full year.

- As discussed below in "*Results of Operations*," ICL sales grew by 8% in the second quarter of 2014. ICL sales grew by 12% for the first half of 2014.

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 130 basis points to 68.2% in the second quarter of 2014, compared to 69.5% in the second quarter of 2013, and decreased to 68.5% for the first half of 2014, compared to 69.9% during the first half of 2013. While the Company expects to increase gross profit margins during the second half of 2014, we do not expect to achieve 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 \$1.8 million in the second quarter of 2014 and a net loss of \$3.1 million for the first half of 2014.

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

- As of the end of the second quarter of 2014, we completed the transfer of manufacturing from our Nidau, Switzerland location, completing the consolidation of our international manufacturing sites.

## Other Highlights

Gross profit margin for the second quarter of 2014 was 68.2% compared to 69.5% in the second quarter of 2013. Our gross margin expansion was limited during the quarter primarily due to the geographic mix of increased KS-10L sales, manufacturing transition of our ICLs from Switzerland to the U.S. and a higher mix of low margin injector part sales. We continue to experience downward pressure on gross margin driven by the increased supply of preloaded injectors to our third party vendor for their preloaded acrylic IOL products. We expect this to expand during the second half of 2014 as their demand for the product increases. Our costing for ICLs manufactured in the U.S. continues to improve and we expect it to continue through the second half of 2014. We expect gross margins to improve during the second half of 2014 based upon increased rate of growth in ICL products, customer adoption of new products, combined with improved ICL manufacturing costs and higher selling prices. Our net loss for the second quarter of 2014 was primarily driven by the increased investments in R&D and Sales and Marketing, as well as additional costs in General and Administrative.

In the second quarter of 2014, ICL revenue grew in Europe, Middle East, Latin America and Africa (EMEA) region by 22%, in Asia Pacific (APAC) region by 2% and declined in North America by 1%. Sales were particularly strong, compared to the second quarter of 2013, in France (47% growth), Germany (21% growth), and Spain (26% growth). Further market penetration of the ICL with CentraFLOW technology contributed to the sales growth. ICL revenue in Japan declined 32% as refractive procedures in Japan continued to experience downward pressure.

IOL revenue in the second quarter of 2014 increased 10% primarily due to increased sales of KS-IOL products in the European markets and increased sales in China. Sales were particularly strong, compared to the second quarter of 2013, in EMEA (117% growth) and China (65% growth). Sales in Japan, which represents 46% of the Company's total IOL sales, declined 10% in the second quarter of 2014. Our third party supplier of components for the KS-IOL product line increased the quantity of KS-IOL products delivered to us during the second quarter of 2014, and we expect the supply of KS-IOL products from our supplier to continue to increase throughout 2014.

As of the end of the second quarter of 2014, we ceased manufacturing products in our Nidau, Switzerland location, thus completing the transfer of manufacturing to the U.S. In the second quarter of 2014, we incurred approximately \$0.2 million in consolidation-related cost.

On June 30, 2014, we received CE Market approval for our Preloaded ICL with enhanced optics. We also continue our development efforts for an ICL with an enhanced optic to add near-vision enhancement of up to two diopters which could address early onset of presbyopia. We are targeting availability in the EU for this product in first half of 2015.

#### *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). 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: designs 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. The FDA has not provided us with a timeline for 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, and it is unclear whether the Warning Letter will ultimately impact the timing of a potential approval. 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.

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). We expect to appropriately and promptly revise the software fields and provide the requested data regarding software anomalies.

On May 15, 2014, the China Food and Drug Administration (CFDA) conducted an expert panel meeting regarding the Visian ICL with CentraFLOW technology. The CFDA sent the Company questions after the meeting to which the Company has prepared a response and expects to hear from CFDA within 105 working days.

On October 9, 2012, 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 six months ended July 4, 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.



## 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 Six Months	
	July 4, 2014	June 28, 2013	July 4, 2014	June 28, 2013
Net sales	100.0 %	100.0 %	100.0 %	100.0 %
Cost of sales	31.8	30.5	31.5	30.1
Gross profit	68.2	69.5	68.5	69.9
General and administrative	26.5	21.6	26.6	21.8
Marketing and selling	35.0	31.2	32.7	30.3
Research and development	12.5	9.3	14.9	8.4
Medical device tax	0.3	0.2	0.3	0.3
Other general and administrative expenses	0.8	3.4	0.8	4.2
	75.1	65.7	75.3	65.0
Operating income (loss)	(6.9 )	3.8	(6.8 )	4.9
Other income (loss), net	(0.2 )	1.0	0.4	(0.3 )
Income (loss) before provision for income taxes	(7.1 )	4.8	(6.4 )	4.6
Provision for income taxes	1.8	3.3	1.4	2.5
Net income (loss)	(8.9 )%	1.5 %	(7.8 )%	2.1 %

## Net Sales

	Three Months Ended		Fav/ (Unfav) % Change 2014 vs. 2013	Six Months Ended		Fav/ (Unfav) % Change 2014 vs. 2013
	July 4, 2014	June 28, 2013		July 4, 2014	June 28, 2013	
Net sales	\$ 20,048	\$ 18,164	10.4 %	\$ 40,226	\$ 36,165	11.2 %
ICL	12,172	11,261	8.1	24,413	21,892	11.5
IOL	6,428	5,863	9.6	13,041	12,211	6.8
Other	1,448	1,040	39.2	2,772	2,062	34.4

Net sales for the three months ended July 4, 2014 were \$20.0 million, an increase of 10.4% compared to the \$18.2 million reported during the three months ended June 28, 2013. Net sales for the six months ended July 4, 2014 were \$40.2 million, an 11.2% increase compared with \$36.2 million reported during the six months ended June 28, 2013. The effect of exchange rates had a negative impact on sales of \$0.1 million and \$0.7 million, respectively, for the three and six months ended July 4, 2014.

Total ICL sales for the three months ended July 4, 2014 were \$12.2 million, an increase of 8.1% compared with \$11.3 million reported during the three months ended June 28, 2013. The increase in ICL sales for the quarter is due to increased sales in Europe, Middle East, Africa and Latin America (EMEA) +22%, and Asia Pacific +2%, partially offset by a 1% decline in North America sales. Total ICL sales for the six months ended July 4, 2014 were \$24.4 million, an increase of 11.5% compared with \$21.9 million reported during the six months ended June 28, 2013. The increase in ICL sales for the six month period is due to increased sales in Europe, Middle East, Africa and Latin America (EMEA) +24%, and Asia Pacific +9%, partially offset by an 8% decline in North America sales. ICL sales represented 60.7% of our total sales for the three and six months ended July 4, 2014, compared to 62.0% and 60.5% for the three and six month periods ended June 28, 2013.

Total IOL sales for the three months ended July 4, 2014 were \$6.4 million, an increase of 9.6%, when compared with \$5.9 million for the three months ended June 28, 2013. Total IOL sales for the six months ended July 4, 2014 were \$13.0 million, an increase of 6.8%, when compared with \$12.2 million for the six months ended June 28, 2013. The increase in IOL sales for the three and six month periods ended July 4, 2014, is due to increased sales of our acrylic preloaded IOL, particularly in Europe, which grew 117% and 92% new during the same periods, respectively. The increase in acrylic preloaded IOL sales for the three and six month periods ended July 4, 2014, was partially offset by a 19% and 5%, respective decrease in other IOL sales. IOL sales represent 32.1% and 32.4% of sales for the three and six months ended July 4, 2014, compared to 32.3% and 33.8% for the three and six month periods ended June 28, 2013.

Other product sales for the three and six months ended July 4, 2014 were \$1.4 million and \$2.8 million, an increase of 39.2% and 34.4%, respectively, when compared with \$1.0 million and \$2.1 million for the three and six months ended June 28, 2013. The increase in other product sales was due to the increase in injector part sales to a third party supplier.

**Gross Profit**

	Three Months Ended		Fav/ (Unfav) % Change	Six Months Ended		Fav/ (Unfav) % Change	
	July 4, 2014	June 28, 2013	2014 vs. 2013	July 4, 2014	June 28, 2013	2014 vs. 2013	
Gross Profit	\$ 13,667	\$ 12,620	8.3	% \$ 27,551	\$ 25,274	9.0	%
Gross Profit Margin	68.2 %	69.5 %		68.5 %	69.9 %		

Gross profit for the second quarter was \$13.7 million, or 68.2% of net sales, compared with \$12.6 million, or 69.5% of net sales, in the prior year period. Three key factors drove a 450 basis point negative impact on the gross margin during the quarter; two of which should improve and one remain negative during the second half. The increased geographical sales mix of KS-IOL products had a negative impact of approximately 230 basis points. This should improve with the increasing growth rate of KS-IOL sales within our higher margin markets. Secondly, the increase of lower margin IOL injectors to a third party drove a negative impact of 80 basis points. This factor should continue to be a headwind during the second half. Finally, the transition of ICL production to the U.S. had a negative impact of 140 basis points. This should improve the second half, as it has in the first half, with increased manufacturing experience in the U.S. and the transfer of management from Switzerland. An increase of 3% in the average prices on ICLs had a positive impact on gross margin during the second quarter. The Company expects higher average prices for both ICLs and IOLs will have a positive impact during the second half of the year.

During the first six months of 2014, gross profit was \$27.6 million, or 68.5% of revenue, compared with \$25.3 million, or 69.9% of revenue, in the prior year period. Three key factors drove a 290 basis point negative impact on the gross margin during the first six months of 2014. The increased geographical sales mix of KS-IOL products had a negative impact of approximately 110 basis points. Secondly, the increase of lower margin IOL injectors to a third party drove a negative impact of 60 basis points. Finally, the transition of ICL production of ICLs to the U.S. had a negative impact of 120 basis points. An increase of 2% in the average prices on ICLs had a positive impact on gross margin.

**General and Administrative**

Three Months Ended	Fav/ (Unfav)	Six Months Ended	Fav/ (Unfav)
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	July 4, 2014	June 28, 2013	% Change 2014 vs. 2013	July 4, 2014	June 28, 2013	% Change 2014 vs. 2013
General and Administrative	\$ 5,321	\$ 3,923	(35.6 )%	\$ 10,717	\$ 7,881	(36.0 )%
Percentage of Net Sales	26.5 %	21.6 %		26.6 %	21.8 %	

General and administrative expenses increased by 35.6% to \$5.3 million in the second quarter of 2014 from the \$3.9 million reported in the second quarter of 2013. General and administrative expenses for the six months ended July 4, 2014 were \$10.7 million, an increase of 36.0% when compared with \$7.9 million reported last year. The increase is due to an increase in compensation expenses, including stock based compensation and bonuses and increased tax consulting expenses.

***Marketing and Selling***

	Three Months Ended			Six Months Ended		
	July 4, 2014	June 28, 2013	Fav/ (Unfav) % Change 2014 vs. 2013	July 4, 2014	June 28, 2013	Fav/ (Unfav) % Change 2014 vs. 2013
Marketing and Selling	\$ 7,026	\$ 5,659	(24.2 )%	\$ 13,164	\$ 10,945	(20.3 )%
Percentage of Net Sales	35.0 %	31.2 %		32.7 %	30.3 %	

Marketing and selling expenses increased 24.2% to \$7.0 million in the second quarter of 2014, compared with \$5.7 million in the second quarter of 2013. Marketing and selling expenses for the six months ended July 4, 2014 were \$13.2 million, an increase of 20.3% when compared with \$11.0 million reported last year. The increase is due to an increase in compensation expense, including stock based compensation and an increase in trade show and promotional expense.

### ***Research and Development***

	Three Months Ended		Fav/ (Unfav) % Change	Six Months Ended		Fav/ (Unfav) % Change
	July 4, 2014	June 28, 2013	2014 vs. 2013	July 4, 2014	June 28, 2013	2014 vs. 2013
Research and Development	\$ 2,498	\$ 1,686	(48.2 )%	\$ 5,981	\$ 3,052	(96.0 )%
Percentage of Net Sales	12.5 %	9.3 %		14.9 %	8.4 %	

Research and development expense increased in the second quarter of 2014, by 48.2% to \$2.5 million, compared with \$1.7 million in the second quarter of 2013. Research and development expense for the six months ended July 4, 2014 was \$6.0 million, an increase of 96.0%, when compared with \$3.1 million reported last year. The increase for the quarter is due to increased compensation expense, including stock based compensation, increased consulting expenses associated with the recent FDA warning letter, and increased development costs of the Preloaded ICL and the V6a ICL. The increase in expense for the six month period is for the same reasons noted above but also due to the FDA panel costs of the first quarter.

### ***Other General and Administrative Expenses***

	Three Months Ended		Fav/ (Unfav) % Change	Six Months Ended		Fav/ (Unfav) % Change
	July 4, 2014	June 28, 2013	2014 vs. 2013	July 4, 2014	June 28, 2013	2014 vs. 2013
Other General and Administrative Expenses	\$ 0.165	\$ 0.613	73.1 %	\$ 0.334	\$ 1,514	77.9 %
Percentage of Net Sales	0.8 %	3.4 %		0.8 %	4.2 %	

Other general and administrative expenses for the quarter were \$0.2 million, compared with \$0.6 million in the second quarter of 2013. Other general and administrative expenses for the six months ended July 4, 2014 were \$0.3 million, compared with \$1.5 million, during the first six months of 2013. The Company has completed the transfer of its

international manufacturing to the U.S. and does not anticipate reporting material additional expenses during the remainder of 2014.

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

	Three Months Ended	Fav/ (Unfav) % Change	Six Months Ended	Fav/ (Unfav) % Change
	July 4, 2014	June 28, 2014 vs. 2013	July 4, 2014	June 28, 2014 vs. 2013
Other Income (Expense), Net	\$ (0.032 )	\$ 0.183	—*	\$ 0.170 \$ (0.115 ) —*

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

The year over year change in other income (expense), net for both periods is due to changes in foreign currency gains and losses, decreased interest expense, and fluctuations in royalty income.

### ***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.

Income tax provision for the quarter ended July 4, 2014 was \$0.4 million, compared to \$0.6 million reported in the comparative period last year. During the six months ended July 4, 2014 and June 28, 2013, the tax provision was \$0.6 million and \$0.9 million, respectively. The current year provisions principally benefitted from the mix of pre-tax earnings in the Company's lower- and zero- rate foreign jurisdictions. There are no unrecognized tax benefits as of any period presented.

Tax benefits from manufacturing consolidation are being partially realized during the year with greater realization anticipated in 2015.

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

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 July 4, 2014 and January, 2014, respectively, STAAR had \$19.2 million and \$23.0 million, of cash and cash equivalents.

Net cash used in operating activities for the six months ended July 4, 2014 and June 28, 2013, respectively, was \$4.1 million, compared to cash used in operating activities of \$0.4 million for the six months ended June 28, 2013. Net cash provided by operations for the six months ended July 4, 2014 consisted of net loss of \$3.1 million and a decrease in working capital of \$5.4 million, offset by \$4.5 million in non-cash items.

Net cash used in investing activities for the six months ended July 4, 2014 and June 28, 2013, respectively, was \$2.2 million and \$2.0 million. Net cash used in investing activities was due to acquisition of property, plant and equipment.

Net cash provided by financing activities was \$2.4 million and \$0.5 million for the six months ended July 4, 2014 and June 28, 2013, respectively. Net cash provided by financing activities for the six months ended July 4, 2014 consisted of \$2.6 million in proceeds from stock options, partially offset by \$0.3 million in capital lease repayments.



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

#### *Accrued Termination Benefits for Manufacturing Consolidations Project*

The Company has accrued \$0.4 million as of July 4, 2014 in termination benefit costs, in connection with its manufacturing consolidation project. The accrual represents STAAR's current best estimate of the termination benefits that will be paid to the eligible employees.

#### *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 \$4.9 million based on the rate of exchange on July 4, 2014), at an interest rate equal to the Tokyo short-term prime interest rate (approximately 1.475% as of July 4, 2014). The Company had 500,000,000 Yen outstanding on the line of credit as of July 4, 2014 and January 3, 2014 (approximately \$4.9 million and \$4.8 million based on the foreign currency exchange rates on July 4, 2014 and January 3, 2014). As of July 4, 2014 there were no available borrowings under the line.

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 July 4, 2014), to be used for working capital purposes. There were no borrowings outstanding as of July 4, 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	July 4, 2014	January 3, 2014
2014	\$ 270	\$ 303
2015	432	142
2016	335	6
2017	133	—
Thereafter	—	—
Total minimum lease payments	\$ 1,170	\$ 451
Less: interest	(96 )	(22 )
Total lease obligation	\$ 1,074	\$ 429
Current	\$ 445	\$ 288
Long-term	\$ 629	\$ 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 July 4, 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 intends to fully cooperate with this informal inquiry. On July 25, 2014, the Company sent the SEC documents responsive to the request.

*Todd v. STAAR*

On July 8, 2014, a punitive 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.

**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. Such risks and uncertainties could materially adversely affect our business, financial condition or operating results.

***FDA compliance issues at our manufacturing facilities may impact the timeline for review and approval of our products and we expect to devote significant resources to maintaining compliance in the future.***

The FDA's Center for Devices and Radiological Health regularly inspects our facilities to determine whether we are in compliance with the FDA Quality System Regulation, which governs such things as manufacturing practices, validation, testing, quality control, product labeling and complaint handling, and our compliance with FDA Medical Device Reporting regulations and other FDA regulations. The FDA also regularly inspects for compliance with regulations governing advertising and promotional activities as well as clinical investigations.

While we believe that we are substantially in compliance with the FDA's Quality System Regulations, past quality system deficiencies observed at certain of our facilities have led to FDA Warning Letters and the issuance of such Warning Letters may delay our efforts to obtain new product approvals while we resolve the deficiencies cited therein. For example, on May 27, 2014, we received a Warning Letter from the FDA citing violations of current good manufacturing practice ("cGMP") regulations that were identified by FDA during an inspection of the Company's manufacturing facility in Monrovia, California between February 10, 2014 and March 21, 2014. The violations set forth in the Warning Letter principally relate to inadequate documentation and procedures at the facility. The Warning Letter does not restrict production or shipment of the Company's commercialized devices from this facility, but does

confirm 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. The FDA has not provided us with a timeline for follow-up after the advisory panel meeting regarding the TICL and it therefore remains unclear whether the Warning Letter applies to the PMA Supplement and whether it will independently impact the timing of a potential approval of this PMA Supplement, which has been pending since 2006. While the PMA supplement remains pending, we cannot provide any assurance that we will ultimately obtain approval in a timely fashion, or at all.

Our ability to continue our U.S. business depends on vigilance in our compliance with FDA regulations. Accordingly, our management expects to continue to devote significant resources and attention to those efforts for the foreseeable future. We cannot ensure that our efforts will be successful. Any failure to demonstrate substantial compliance with FDA regulations can result in enforcement actions that terminate, suspend or severely restrict our ability to continue manufacturing and selling medical devices. Please see the related risks discussed in "Part I-Item 1A-Risk Factors" of the Company's Form 10-K for the fiscal year ended January 3, 2014 under the headings "*—We are subject to extensive government regulation, which increases our costs and could prevent us from selling our products*" and "*— We are subject to federal and state regulatory investigations.*"

***If we suffer loss to our facilities due to catastrophe, or if our manufacturing site fails to be in compliance with regulatory approvals, our operations could be seriously harmed.***

Following consolidation of international manufacturing to our facilities in California, we manufacture our principal products at a single approved site (though we maintain manufacturing capability in Switzerland). Our facilities could suffer catastrophic loss due to fire, flood, earthquake, terrorism or other natural or man-made disasters and we would need to obtain additional regulatory approvals in order to manufacture our product at any new manufacturing site. Our California facilities are in an area where earthquakes could cause catastrophic loss. If our facilities were to experience a catastrophic loss, or found not to be in substantial compliance with regulatory requirements, it could disrupt our operations, delay production, shipments and revenue and result in large expenses to repair or replace the facility, as well as lost customers or sales. Our insurance for property damage and business interruption may not be sufficient to cover any particular loss. We do not carry insurance or reserve funds for interruptions or potential losses arising from earthquakes, terrorism or regulatory actions.

**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.(1)

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

†4.5 Amended and Restated 2003 Omnibus Equity Incentive Plan, and form of Option Grant and Stock Option Agreement.\*

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 July 4, 2014, 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 (Loss), (iv) the Condensed Consolidated Statements of Cash Flows, and (v) the Notes to Condensed Consolidated Financial Statements tagged as blocks of text. \*

(1)





**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: July 31, 2014 By: /s/ STEPHEN P. BROWN  
**Stephen P. Brown**

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