

STAAR SURGICAL CO  
Form 10-Q  
August 07, 2015

**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 3, 2015**

**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 39,804,516 shares of common stock, par value \$0.01 per share, issued and outstanding as of July 24, 2015.

**STAAR SURGICAL COMPANY**

**INDEX**

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

**PART 1 – FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****STAAR SURGICAL COMPANY****CONDENSED CONSOLIDATED BALANCE SHEETS****(In thousands, except par value amounts)****(Unaudited)**

	<b>July 3,</b>	January 2,
	<b>2015</b>	2015
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 15,335	\$ 13,013
Accounts receivable trade, net of allowance for doubtful accounts of \$1,824 and \$1,589, respectively	12,478	11,054
Inventories, net	14,153	15,717
Prepays, deposits and other current assets	4,017	4,517
Deferred income taxes	582	596
Total current assets	46,565	44,897
Property, plant and equipment, net	9,931	10,066
Intangible assets, net	750	870
Goodwill	1,786	1,786
Deferred income taxes	685	695
Other assets	580	597
Total assets	\$ 60,297	\$ 58,911
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Line of credit	\$ 4,055	\$ 4,150
Accounts payable	4,761	6,620
Deferred income taxes	301	301
Obligations under capital leases	349	399
Other current liabilities	5,580	4,901
Total current liabilities	15,046	16,371

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

Obligations under capital leases	305	468
Deferred income taxes	1,813	1,704
Asset retirement obligations	112	115
Pension liability	3,140	3,079
Other long-term liabilities	89	75
Total liabilities	20,505	21,812
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Common stock, \$0.01 par value; 60,000 shares authorized; 39,795 and 38,429 shares issued and outstanding at July 3, 2015 and January 2, 2015, respectively	398	384
Additional paid-in capital	184,990	178,232
Accumulated other comprehensive loss	(1,211 )	(1,070 )
Accumulated deficit	(144,385)	(140,447)
Total stockholders' equity	39,792	37,099
Total liabilities and stockholders' equity	\$60,297	\$58,911

*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 3, 2015	July 4, 2014	July 3, 2015	July 4, 2014
Net sales	\$ 18,657	\$ 20,048	\$ 37,514	\$ 40,226
Cost of sales	6,296	6,381	12,254	12,675
Gross profit	12,361	13,667	25,260	27,551
General and administrative	4,736	5,368	9,896	10,804
Marketing and selling	5,832	7,026	11,500	13,164
Research and development	3,536	2,498	7,116	5,981
Other general and administrative expenses	—	165	—	334
Operating loss	(1,743 )	(1,390 )	(3,252 )	(2,732 )
Other income (expense):				
Interest income	49	10	49	18
Interest expense	(33 )	(34 )	(68 )	(67 )
Gain (loss) on foreign currency transactions	180	(134 )	(711 )	(68 )
Other income, net	101	126	170	287
Other income (expense), net	297	(32 )	(560 )	170
Loss before provision for income taxes	(1,446 )	(1,422 )	(3,812 )	(2,562 )
Provision for income taxes	153	367	126	586
Net loss	\$(1,599 )	\$(1,789 )	\$(3,938 )	\$(3,148 )
Net loss per share – basic and diluted	\$(0.04 )	\$(0.05 )	\$(0.10 )	\$(0.08 )
Weighted average shares outstanding – basic and diluted	39,066	38,168	38,769	37,970

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



**STAAR SURGICAL COMPANY****CONDENSED CONSOLIDATED STATEMENTS****OF COMPREHENSIVE LOSS****(In thousands)****(Unaudited)**

	Three Months Ended		Six Months Ended	
	July 3, 2015	July 4, 2014	July 3, 2015	July 4, 2014
Net loss	\$(1,599)	\$(1,789)	\$(3,938)	\$(3,148)
Other comprehensive income (loss):				
Defined benefit pension plans:				
Net change in plan assets	(9 )	(11 )	(18 )	(23 )
Reclassification into earnings	15	6	30	12
Impact of change in discount rate	—	(558 )	—	(558 )
Curtailment gain	—	537	—	537
Foreign currency translation gain (loss)	(302 )	291	(234 )	302
Tax effect	107	(103 )	81	(106 )
Other comprehensive income (loss), net of tax	(189 )	162	(141 )	164
Comprehensive loss	\$(1,788)	\$(1,627)	\$(4,079)	\$(2,984)

*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 3, 2015	July 4, 2014
Cash flows from operating activities:		
Net loss	\$(3,938 )	\$(3,148 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property, plant and equipment	996	981
Amortization of intangibles	103	213
Deferred income taxes	(35 )	57
Change in net pension liability	95	83
Stock-based compensation expense	1,823	3,183
Accretion of asset retirement obligation	—	2
Provision for sales returns and bad debts	243	1
Changes in working capital:		
Accounts receivable	(1,732 )	(1,895 )
Inventories	1,669	(2,093 )
Prepays, deposits and other current assets	606	(20 )
Accounts payable	(1,994 )	(874 )
Other current liabilities	759	(554 )
Net cash used in operating activities	(1,405 )	(4,064 )
Cash flows from investing activities:		
Acquisition of property, plant, and equipment	(701 )	(2,269 )
Cash proceeds from sale of property and equipment	2	68
Net cash used in investing activities	(699 )	(2,201 )
Cash flows from financing activities:		
Repayment of capital lease obligations	(210 )	(251 )
Proceeds from exercise of stock options	1,896	2,632
Proceeds from exercise of warrants	2,800	—
Net cash provided by financing activities	4,486	2,381
Effect of exchange rate changes on cash and cash equivalents	(60 )	116
Increase (decrease) in cash and cash equivalents	2,322	(3,768 )
Cash and cash equivalents, at beginning of the period	13,013	22,954
Cash and cash equivalents, at end of the period	\$15,335	\$19,186

*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. In accordance with those rules and regulations certain information and footnote disclosures normally included in comprehensive financial statements have been condensed or omitted pursuant to such rules and regulations. The consolidated balance sheet as of January 2, 2015 was derived from the audited financial statements at that date, but does not include all the information and footnotes required by GAAP. These financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the year ended January 2, 2015.

The accompanying interim condensed consolidated financial statements, 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 condensed consolidated results of operations are not necessarily indicative of the results to be expected for any other interim period or for the entire year.

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

### *Recent Accounting Pronouncements*

In July 2015, the Financial Accounting Standards Board (“FASB”) postponed the effective date of the new revenue standard, Accounting Standards Update (“ASU”) 2014-09, “Revenue from Contracts with Customers (Topic 606)”, by one year. The new effective date is for fiscal years and interim periods beginning after December 15, 2017. The Company expects to adopt this guidance when effective and the impact, if any, on its consolidated financial statements is not currently estimable.

In July 2015, the FASB issued ASU 2015-11, “Simplifying the Measurement of Inventory” that replaces the existing accounting standards for the measurement of inventory. ASU 2015-11 requires a company to measure inventory at the lower of cost and net realizable value. Net realizable value is defined as the “estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation”. The effective date of ASU 2015-11 is for annual reporting periods beginning after December 15, 2016, including interim periods within

those annual reporting periods. The Company does not expect ASU 2015-11 will have a material effect on its consolidated financial statements.

*Prior Year Reclassifications*

During the quarter ended July 3, 2015, the Company reclassified \$75,000 from Other Current Liabilities to Other Long-Term Liabilities in the condensed consolidated balance sheet as of January 2, 2015 and related note disclosures to conform to current period's presentation.

**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 3, 2015	January 2, 2015
Raw materials and purchased parts	\$2,287	\$2,146
Work-in-process	1,857	1,781
Finished goods	12,872	14,504
	17,016	18,431
Less: inventory reserves	2,863	2,714
	\$14,153	\$15,717

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

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

	July 3, 2015	January 2, 2015
Prepaid and deposits	\$2,310	\$1,991
Income tax receivable	323	1,084
Value added tax (VAT) receivable	654	721
Deferred charges for foreign profits	518	338
Other current assets	212	383
	\$4,017	\$4,517

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

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

	July 3, 2015	January 2, 2015
Machinery and equipment	\$16,388	\$15,674
Furniture and fixtures	6,589	6,535
Leasehold improvements	8,420	8,400
	31,397	30,609
Less: accumulated depreciation	21,466	20,543
	\$9,931	\$10,066

**Note 5 –Intangible Assets**

Intangible assets, net consisted of the following (in thousands):

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

	July 3, 2015			January 2, 2015		
	<b>Gross</b>		<b>Net</b>	<b>Gross</b>		<b>Net</b>
	<b>Carrying</b>	<b>Accumulated</b>		<b>Carrying</b>	<b>Accumulated</b>	
		<b>Amortization</b>			<b>Amortization</b>	
	<b>Amount</b>			<b>Amount</b>		
Intangible assets:						
Patents and licenses	\$9,193	(8,869	) \$324	\$9,205	\$ (8,859	) \$346
Customer relationships	1,272	(954	) 318	1,302	(911	) 391
Developed technology	808	(700	) 108	827	(694	) 133
Total	\$11,273	\$ (10,523	) \$750	\$11,334	\$ (10,464	) \$870

**Note 6 – Other Current Liabilities**

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

	July 3,	January
	2015	2,
	2015	2015
Accrued salaries and wages	\$1,743	\$1,647
Accrued insurance	429	550
Accrued bonuses	1,089	75
Customer credit balances	212	186
Accrued income taxes	352	867
Accrued audit fees	293	352
Accrued commissions	155	309
Other <sup>(1)</sup>	1,307	915
	\$5,580	\$4,901

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

**Note 7 – Defined Benefit Pension Plans**

The Company has defined benefit plans covering employees of its Switzerland and Japan operations.

During the year ended January 2, 2015, 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 \$1.6 million in the Swiss pension plan's projected benefit obligation, of which \$0.9 million was used to distribute cash payments to employees resulting in a decrease in plan assets. The remaining \$0.7 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 January 2, 2015, 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 1.4%, resulting in an increase to the projected benefit obligation of \$0.7 million recorded through an offsetting increase in the accumulated other comprehensive loss account of the Swiss pension plan. There were no changes in key assumptions as of July 3, 2015.

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

	<b>Three Months Ended</b>	<b>Three Months Ended</b>	<b>Six Months Ended</b>	<b>Six Months Ended</b>
	<b>July 3, 2015</b>	<b>July 4, 2014</b>	<b>July 3, 2015</b>	<b>July 4, 2014</b>
Service cost	\$ 107	\$ 117	\$ 214	\$ 233
Interest cost	19	36	38	71
Expected return on plan assets	(21 )	(28 )	(42 )	(55 )
Net amortization of transitional obligation (a)	3	—	5	—
Actuarial loss recognized in current period (a)	12	6	25	12
	<b>\$ 120</b>	<b>\$ 131</b>	<b>\$ 240</b>	<b>\$ 261</b>

(a) Amounts reclassified from accumulated other comprehensive income.

During the six months ended July 3, 2015 and July 4, 2014, the Company made cash contributions totaling approximately \$400,000 and \$558,000, respectively, to its Swiss pension plan and does not expect to make any additional cash contributions during the remainder of 2015, 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 Loss Per Share**

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

	Three Months Ended		Six Months Ended	
	July 3, 2015	July 4, 2014	July 3, 2015	July 4, 2014
Numerator:				
Net loss	\$(1,599 )	\$(1,789 )	\$(3,938 )	\$(3,148 )
Denominator:				
Weighted average common shares and denominator for basic and diluted calculation:				
Weighted average common shares outstanding	39,173	38,400	38,876	38,247
Less: Unvested restricted stock	(107 )	(232 )	(107 )	(277 )
Denominator for basic and diluted calculation	39,066	38,168	38,769	37,970
Net loss per share – basic and diluted	\$(0.04 )	\$(0.05 )	\$(0.10 )	\$(0.08 )

The following table 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 3, 2015	July 4, 2014	July 3, 2015	July 4, 2014
Options	1,561	2,216	1,396	2,117
Restricted stock and units	137	195	211	280
Warrants	385	526	345	527
Total	2,083	2,937	1,952	2,924





**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 Japan, China, United States, Korea, 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 3,	July 4,	July 3,	July 4,
	2015	2014	2015	2014
Japan	\$3,980	\$4,549	\$8,267	\$9,557
China	3,327	2,535	5,698	4,759
United States	2,723	2,926	5,589	5,801
Korea	1,269	1,952	3,612	4,573
Spain	1,486	1,474	2,964	3,092
France	888	1,190	2,039	2,136
Germany	694	1,015	1,190	1,912
Other	4,290	4,407	8,155	8,396
Total	\$18,657	\$20,048	\$37,514	\$40,226

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		Six Months Ended	
	July 3,	July 4,	July 3,	July 4,
	2015	2014	2015	2014
ICLs	\$12,236	\$12,172	\$24,490	\$24,413
IOLs	5,204	6,428	10,562	13,041
Core products	17,440	18,600	35,052	37,454
Other surgical products	1,217	1,448	2,462	2,772
Total	\$18,657	\$20,048	\$37,514	\$40,226

One customer accounted for 16% and 14% of net sales for the three and six months ended July 3, 2015 and 11% and 12% of net sales for the three and six months ended July 4, 2014, respectively. As of July 3, 2015, one customer accounted for 17% of consolidated trade receivables. As of January 2, 2015, there were two customers with trade

receivable balances of 10% and 11% of consolidated trade receivables, 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 <b>July 3,</b>		Six Months Ended <b>July 3, July 4,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Employee stock options	\$555	\$675	\$1,193	\$1,472
Restricted stock	63	232	307	525
Restricted stock units	154	764	274	1,152
Nonemployee stock options	57	12	49	34
Total	\$829	\$1,683	\$1,823	\$3,183

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

	Three Months Ended <b>July 3,</b>		Six Months Ended <b>July 3, July 4,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Cost of sales	\$6	\$39	\$23	\$77
General and administrative	548	1,033	1,124	1,970
Marketing and selling	104	306	355	580
Research and development	171	305	321	556
Total stock compensation expense	829	1,683	1,823	3,183
Amounts capitalized as part of inventory	129	71	251	149
Total	\$958	\$1,754	\$2,074	\$3,332

### 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, restricted stock units, and performance contingent stock units. Options under the plan are granted at fair market value on the date of grant, become exercisable over a three year period, or as determined by the Board of Directors, and expire over periods not exceeding 10 years from the date of grant. Certain option and share awards provide for accelerated vesting if there is a change in control (as defined in the Plan). Pursuant to the Plan, options for 3,463,744 shares were outstanding at July 3, 2015 with exercise prices ranging between \$0.95 and \$17.62 per share. Restricted stock grants under the Plan generally vest over a period between one to four years. There were 107,500 shares of restricted stock and 220,212 restricted stock units (RSUs) outstanding at July 3, 2015. As of July 3, 2015, there were 1,429,890 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	
	<b>July 3,</b>	<b>July 4,</b>	<b>July 3,</b>	<b>July 4,</b>
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Expected dividend yield	0 %	0 %	0 %	0 %
Expected volatility	57 %	56 %	57 %	55 %
Risk-free interest rate	1.42 %	1.30 %	1.61 %	1.29 %
Expected term (in years)	5.54	4.12	5.61	4.12

A summary of option activity under the Plan for the period ended July 3, 2015 is presented below:

	<b>Options Shares (000's)</b>
Outstanding at January 2, 2015	3,175
Granted	814
Exercised	(424 )
Forfeited or expired	(101 )
Outstanding at July 3, 2015	3,464
Exercisable at July 3, 2015	2,144

On June 1, 2009, the Company issued warrants to Broadwood Partners, L.P. (“Broadwood”), pursuant to a Warrant Agreement granting the right to purchase 700,000 shares of the Company’s common stock at a strike price of \$4.00 per share. On May 27, 2015, Broadwood gave notice to exercise the 700,000 warrants and paid the \$2.8 million exercise price in cash. On July 27, 2015, the Company issued 700,000 shares of Common Stock to Broadwood pursuant to exercise of the Warrant Agreement dated June 1, 2009, and warrants were no longer outstanding.

A summary of restricted stock and restricted stock unit’s activity under the Plan for the period ended July 3, 2015 is presented below:

	<b>Restricted</b>	<b>Restricted</b>
	<b>Shares</b>	<b>Units</b>
	<b>(000’s)</b>	<b>(000’s)</b>
Outstanding at January 2, 2015	247	156
Granted	—	101
Exercised	(125 )	(10 )
Forfeited	(15 )	(27 )
Outstanding at July 3, 2015	107	220

**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 \$126,000 and \$586,000 for the six months ended July 3, 2015 and July 4, 2014, 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**

*Lines of Credit and Guarantee*

The Company's wholly owned Japanese subsidiary, STAAR Japan, entered into an agreement on December 28, 2012, as amended, with Mizuho Bank, which provides for borrowings of up to 500,000,000 Yen (approximately \$4.1 million based on the rate of exchange on July 3, 2015), at an interest rate equal to the Tokyo short-term prime interest rate (approximately 1.475% as of July 3, 2015). The line of credit expires September 30, 2015 and is renewable quarterly. The Company had 500,000,000 Yen outstanding on the line of credit as of July 3, 2015 and January 2, 2015 (approximately \$4.1 million and \$4.2 million based on the foreign currency exchange rates on July 3, 2015 and January 2, 2015, respectively). As of July 3, 2015 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 ("Credit Suisse"). 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 3, 2015), to be used for working capital purposes. Borrowings, if any, on the credit line are due in one year from the borrowing date. The credit agreement is renewable every three years with a current expiration date of September 1, 2016. There were no borrowings outstanding as of July 3, 2015 and January 2, 2015, and the full amount of the line, reduced by any guarantees made to Bankinter Spain (described below), was available for borrowing.

On May 1, 2015, STAAR Surgical AG entered into a guarantee agreement with Bankinter Spain ("Bankinter"). The agreement provides Bankinter with a guarantee of up to EUR 400,000 (approximately \$443,000 at the rate of exchange on July 3, 2015) for trade receivables from the Company's Spanish customers. The total guarantee amount is offset against the credit agreement in place with Credit Suisse and therefore reduces the credit line available to STAAR Surgical AG for working capital requirements to up to 581,000 Swiss Francs (approximately up to \$614,000 at the rate of exchange on July 3, 2015). Unless terminated sooner by Bankinter, the guarantee agreement expires on May 1, 2017.

*Covenant Compliance*

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

### *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. These claims and legal proceedings may relate to contractual rights and obligations, employment matters, and claims of product liability. The most significant of these actions, proceedings and investigations are described below. STAAR maintains insurance coverage for product liability and certain securities. 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 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.

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. 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. 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.

### *Employment Agreements*

The Company's Chief Executive Officer and certain officers have as provisions of their agreements certain rights, including continuance of cash compensation and benefits, upon a "change in control," which may include an acquisition of substantially all of its assets, or termination "without cause or for good reason" as defined in the employment agreements.



## **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, 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, and any statements of assumptions underlying any of the foregoing. Any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words “believes,” “anticipates,” “plans,” “expects,” “seeks,” “estimates,” and similar expressions are intended to identify forward-looking statements. While the Company may elect to update forward-looking statements in the future, it specifically disclaims any obligation to do so, even if the Company’s estimates change and readers should not rely on those forward-looking statements as representing the Company’s views as of any date subsequent to the date of the filing of this Quarterly Report. 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. A number of important factors could cause the results of the company to differ materially from those indicated by such forward-looking statements, including those detailed under the heading “Risk Factors” in Part I, Item 1A of the Company’s Form 10-K for the fiscal year ended January 2, 2015.

The following discussion should be read in conjunction with STAAR’s interim condensed consolidated 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 and delivery systems for the eye. We are the world’s leading manufacturer of phakic 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®, STAARVISC®, Elastimide®, nanoFLEX®, nanoPOINT®, CentraFLOW®, AquaPORT®, Epiphany® and AquaFlow are trademarks or registered trademarks of STAAR in the U.S. and other countries.

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

### ***Products***

A detailed description of STAAR's business appears in our Annual Report on Form 10-K for the fiscal year ended January 2, 2015, 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 (65%) 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 inside the U.S. in 2006.

The Visian Toric ICL, or TICL, treats myopic and hyperopic patients with astigmatism. Astigmatism is a condition that causes blurred vision when an irregular shape of the cornea or defects in the natural lens prevents light from coming to a single focus 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 Submission."

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

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

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

Aspheric IOLs, available in single-piece and three-piece designs made from (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 three-piece aspheric silicone IOL is sold preloaded in certain markets outside of the U.S. The three piece Collamer IOL 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 Preloaded IOL line utilizes an acrylic lens sourced from another manufacturer. The KS-SP is the single-piece preloaded acrylic IOL and the KS-X is the three-piece preloaded acrylic IOL. The KS IOL line is available in Japan and parts of 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.

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 certain instruments, devices, and injector systems. Although we have been deemphasizing these products because of their lower overall gross profit margins, we expect that sales of injector systems will continue. .

*Operations*

STAAR is a global company. Activities outside the U.S. accounted for approximately 85% of our total sales during the first half of 2015, primarily due to the pacing of product approvals and commercialization that tend to occur first outside the U.S. STAAR sells its products in more than 60 countries, with direct distribution in the United States, Canada, Japan, Spain, and Germany, and independent distribution in the remainder of the world.

STAAR maintains operational and administrative facilities in the United States, Switzerland and Japan. In June 2014, STAAR completed a project to consolidate substantially all of its manufacturing in its Monrovia, California facility. Its current global operations are as follows:

*United States.* STAAR operates its global administrative headquarters and a manufacturing facility in Monrovia, California. The Monrovia manufacturing facility principally makes Collamer and silicone intraocular lenses (IOLs), and injector systems for its IOLs. We also manufacture the Visian implantable Collamer lenses (ICLs) and preloaded IOL injectors. STAAR manufactures the raw material for Collamer lenses (both IOLs and ICLs) and the AquaFlow Device (for the treatment of glaucoma) in a facility in Aliso Viejo, California.

*Switzerland.* STAAR operates an administrative, packaging and distribution facility in Nidau, Switzerland under its wholly owned subsidiary, STAAR Surgical AG. The Nidau facility also maintains manufacturing capabilities, if needed for STAAR's ICL products and the AquaFlow Device.

*Japan.* STAAR operates administrative and distribution facilities in Japan under its wholly owned subsidiary, STAAR Japan Inc. STAAR Japan's administrative facility is located in Shin-Urayasu and its distribution facility is located in Ichikawa City. STAAR final packages its silicone preloaded IOL injectors at the Ichikawa City facility.

The global nature of STAAR's business operations subjects it to risks due to many factors some of which are beyond our control. As noted above, investors and prospective investors should consider carefully, in addition to other information contained in this report, 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 2, 2015. Such risks and uncertainties could materially adversely affect our business, financial condition or operating results.

### ***Recent Developments***

Backlog of ICLs decreased to approximately \$100,000 during the second quarter of 2015 from a \$3.3 million peak during the first quarter of 2015, in part due to improved ICL manufacturing production. Also, we returned to customary order fulfillment levels for the TICL during the second quarter of 2015. After the transfer of ICL production to Monrovia, based upon the current level of U.S. income, we currently do not expect to achieve the level of U.S. income required to use all of our net operating loss (NOL) tax credits in the U.S. prior to their expiration. In July 2015, we began our direct sales efforts in Germany. The KS-IOL production challenges experienced by our third party supplier of components for the KS-IOL product line ended during the second quarter of 2015. We continue to devote significant effort towards improving our quality system and our remediation efforts. For the next eighteen months to two years, we expect that we will continue to focus on improving our quality system and business processing as well as investing in infrastructure. In addition, the Company's three other current strategic initiatives are: (i) further developing global clinical validation and clinical utility excellence; (ii) building or improving our vision correction solutions for myopia, presbyopia and cataract care; and (iii) enhancing the performance value of the ICL and the related services that will improve the surgeon and patient experience. We expect to increase prices on our ICL products globally, on average by 5% to 7%, with most price increases taking effect on or about October 1, 2015.

### ***Status of Regulatory Submission***

As previously disclosed, STAAR received an FDA Warning Letter, dated May 21, 2014, regarding compliance with current Good Manufacturing Practices at the Monrovia facility. Upon receipt of this letter, STAAR initiated development and subsequent implementation of corrective action plans related to this letter. Beginning on November 14, 2014 and continuing through February 4, 2015, the U.S. Food and Drug Administration (FDA) inspected the Company's Monrovia facility as a follow-up to the 2014 Warning Letter and also as a post-approval inspection

regarding the approved PMA supplement that added the Monrovia facility as an alternate manufacturing facility for the ICL. On February 4, 2015, at the conclusion of the inspections, the FDA issued a Form 483 with ten inspectional observations (2015 FDA-483). The observations focus primarily on the need for adherence to and improved procedures, processes and documentation relating to design change, design transfer into specifications and production, verification and validation associated with device design and production, improvement in Good Documentation Practices, and broader environmental monitoring.

STAAR responded to the 2015 FDA-483 and continues to develop and implement its corrective action plans relating to the 2014 Warning Letter and the 2015 FDA-483. STAAR takes the matters identified by the FDA seriously and will continue to work diligently to address the observations identified. STAAR has enhanced and continues to enhance its overall quality program as we focus on remediating all elements identified. We expect that it will take more than a year to fully complete all of the activities contained in our corrective action plans. We provide monthly updates to the FDA regarding our status on completing the deliverables contained in our corrective action plans.

There can be no assurance that the FDA will be satisfied with our response. Unless and until STAAR is able to correct outstanding issues to the FDA's satisfaction, the FDA may withhold approval of new products such as the Toric ICL (TICL) or take additional regulatory or legal action against the Company. Any such further action could have a material and negative impact on the Company's ongoing business and operations.

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). Once again, STAAR cannot predict when, or if, the FDA will grant approval of the TICL for use in the United States. We do not expect a decision from the FDA regarding the TICL's PMA Supplement until the FDA determines that we have resolved or made sufficient progress in addressing the issues raised in the 2014 Warning Letter and 2015 FDA-483.

## 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 3, 2015 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 2, 2015.

## 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 3, 2015	July 4, 2014	July 3, 2015	July 4, 2014
Net sales	100.0%	100.0%	100.0%	100.0%
Cost of sales	33.7	31.8	32.7	31.5
Gross profit	66.3	68.2	67.3	68.5
General and administrative	25.4	26.8	26.4	26.9
Marketing and selling	31.3	35.0	30.7	32.7
Research and development	19.0	12.5	19.0	14.9

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

Other general and administrative expenses	0.0	0.8	0.0	0.8
	75.6	75.1	76.0	75.3
Operating loss	(9.3 )	(6.9 )	(8.7 )	(6.8 )
Other income (expense), net	1.6	(0.2 )	(1.5 )	0.4
Loss before provision for income taxes	(7.8 )	(7.1 )	(10.2 )	(6.4 )
Provision for income taxes	0.8	1.8	0.3	1.4
Net loss	(8.6 )%	(8.9 )%	(10.5 )%	(7.8 )%

*Net Sales*

	Three Months Ended		Fav/(Unfav) % Change	Six Months Ended		Fav/ (Unfav) % Change
	July 3, 2015	July 4, 2014		July 3, 2015	July 4, 2014	
Net sales	\$18,657	\$20,048	(7 )%	\$37,514	\$40,226	(7 )%
ICL	12,236	12,172	1	24,490	24,413	0
IOL	5,204	6,428	(19 )	10,562	13,041	(19 )
Other	1,217	1,448	(16 )	2,462	2,772	(11 )



Net sales for the three months ended July 3, 2015 were \$18.7 million, a decrease of 7% compared to the \$20.0 million reported during the three months ended July 4, 2014. Net sales for the six months ended July 3, 2015 were \$37.5 million, a decrease of 7% compared to the \$40.2 million reported during the six months ended July 4, 2014. The effect of changes in currency exchange rates had a negative impact on net sales of \$2.1 million and \$3.4 million, respectively, for the three and six months ended July 3, 2015 when compared to their respective prior year periods.

Total ICL sales for the three months ended July 3, 2015 and July 4, 2014 were \$12.2 million. Although second quarter ICL unit sales in Europe, Middle East, Africa and Latin America (EMEA) increased 24%, EMEA ICL sales increased only 3% due to a weakening euro against the U.S. dollar and its impact on average selling prices. ICL sales in Asia Pacific decreased 1% due to a 35% decrease in Korea sales as a result of the MERS scare, partially offset by a 33% increase in China sales. ICL sales in North America decreased 3%.

Total ICL sales for the six months ended July 3, 2015 and July 4, 2014 were \$24.5 million and \$24.4 million, respectively. Although ICL unit sales in EMEA increased 16%, EMEA ICL sales only increased 1% due to a weakening euro against the U.S. dollar. ICL sales in Asia Pacific decreased 2% due to a 21% decrease in Korea sales, partially offset by a 22% increase in China sales. ICL sales in North America decreased 7%.

Total IOL sales for the three months ended July 3, 2015 were \$5.2 million, a decrease of 19% compared with \$6.4 million for the three months ended July 4, 2014. Total IOL sales for the six months ended July 3, 2015 were \$10.6 million, a decrease of 19% compared with \$13.0 million for the six months ended July 4, 2014. The effect of changes in currency exchange rates had a negative impact on IOL sales of \$0.8 million and \$1.4 million, respectively, for the three and six months ended July 3, 2015. IOL sales for both periods of 2015 were negatively impacted by the discontinuation of IOL sales to our former German distributor and higher than usual distributor stocking of the KS IOL preloaded acrylic product in the second quarter of 2014 following an extended period of backorders.

Other product sales for the three and six months ended July 3, 2015 were \$1.2 million and \$2.5 million, a decrease of 16% and 11%, respectively, compared with \$1.4 million and \$2.8 million for the three and six months ended July 4, 2014, respectively. The effect of changes in currency exchange rates had a negative impact on other product sales of \$0.2 million and \$0.4 million, respectively, for the three and six months ended July 3, 2015.

### ***Gross Profit***

Three Months Ended	Fav/ (Unfav) %	Six Months Ended	Fav/ (Unfav) %
	Change		Change

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

	July 3, 2015	July 4, 2014	vs. 2014	July 3, 2015	July 4, 2014	vs. 2014
Gross Profit	\$12,361	\$13,667	(10 )%	\$25,260	\$27,551	(8 )%
Gross Profit Margin	66.3 %	68.2 %		67.3 %	68.5 %	

Gross profit for the second quarter was \$12.4 million, or 66.3% of net sales, compared with \$13.7 million, or 68.2% of net sales, in the prior year period. During the first six months of 2015, gross profit was \$25.3 million, or 67.3% of net sales, compared with \$27.6 million, or 68.5% of net sales, in the prior year period. The decrease in gross profit and gross profit margin for both periods primarily relates to lower euro-denominated sales as a result of the weakening euro while cost of sales is U.S. dollar denominated.

*General and Administrative*

	Three Months Ended			Six Months Ended		
	July 3, 2015	July 4, 2014	Fav/ (Unfav) % Change 2015	July 3, 2015	July 4, 2014	Fav/ (Unfav) % Change 2015
General and Administrative	\$4,736	\$5,368	12 %	\$9,896	\$10,804	8 %
Percentage of Net Sales	25.4 %	26.8 %		26.4 %	26.9 %	

General and administrative expenses decreased by 12% to \$4.7 million in the second quarter of 2015 from the \$5.4 million reported in the second quarter of 2014. General and administrative expenses for the six months ended July 3, 2015 were \$9.9 million, a decrease of 8% when compared with \$10.8 million reported last year. The decrease for both periods is due to a reduction in stock-based compensation expense due to fewer grants of performance-based restricted stock and restricted stock units and the forfeiture of unvested restricted stock and stock options of a former executive. Travel and tax consulting expenses also decreased during the quarter.

*Marketing and Selling*

	Three Months Ended		Fav/ (Unfav) % Change 2015	Six Months Ended		Fav/ (Unfav) % Change 2015
	July 3, 2015	July 4, 2014		July 3, 2015	July 4, 2014	
Marketing and Selling	\$5,832	\$7,026	17 %	\$11,500	\$13,164	13 %
Percentage of Net Sales	31.3 %	35.0 %		30.7 %	32.7 %	

Marketing and selling expenses decreased 17% to \$5.8 million in the second quarter of 2015, compared with \$7.0 million in the second quarter of 2014. Marketing and selling expenses for the six months ended July 3, 2015 were \$11.5 million, a decrease of 13% when compared with \$13.2 million reported last year. The decrease for both periods is due to a reduction in stock-based compensation expense, travel, promotions and international marketing expenses. Compensation and travel decreased due to headcount reduction within the U.S. sales force, promotions decreased due to more focused spending during the quarter and international marketing expenses decreased as a result of moving to direct distribution in Spain.

*Research and Development*

	Three Months Ended		Fav/ (Unfav) % Change 2015	Six Months Ended		Fav/ (Unfav) % Change 2015
	July 3, 2015	July 4, 2014		July 3, 2015	July 4, 2014	
Research and Development	\$3,536	\$2,498	(42) %	\$7,116	\$5,981	(19) %
Percentage of Net Sales	19.0 %	12.5 %		19.0 %	14.9 %	

Research and development expense increased in the second quarter of 2015, by 42% to \$3.5 million, compared with \$2.5 million in the second quarter of 2014. Research and development expense for the six months ended July 3, 2015 was \$7.1 million, an increase of 19%, when compared with \$6.0 million reported last year. The increase for both 2015 periods is due to quality system remediation expenses.

*Other General and Administrative Expenses*

	Three Months Ended	July 3, July 4,	Fav/ (Unfav) % Change	2015	vs. 2014	Six Months Ended	July 3, July 4,	Fav/ (Unfav) % Change	2015	vs. 2014
Other General and Administrative Expenses	\$—	\$165	100 %			\$—	\$334	100 %		
Percentage of Net Sales	<del>%</del>	0.8 %				<del>%</del>	0.8 %			

Other general and administrative expenses for the three and six months ended July 4, 2014 related to the Company's manufacturing consolidation project which was completed in June 2014.

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

	Three Months Ended	July 3, July 4,	Fav/ (Unfav) % Change	2015	vs. 2014	Six Months Ended	July 3, July 4,	Fav/ (Unfav) % Change	2015	vs. 2014
Other Income (Expense), Net	\$297	\$(32)	—*	\$(560)	\$170	—*				

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

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

***Income Taxes***

Three Months Ended	July 3, July 4,	Fav/ (Unfav) % Change	2015	Six Months Ended	July 3, July 4,	Fav/ (Unfav) % Change	2015
--------------------------	--------------------	--------------------------------	------	---------------------	--------------------	--------------------------------	------

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

	2015	2014	vs. 2014	2015	2014	vs. 2014	
Provision for Income Taxes	\$153	\$367	58	%	\$126	\$586	79 %

The provision for income taxes is determined using an estimated annual effective tax rate. The income tax provision for the three and six months ended July 3, 2015 was \$0.2 million and \$0.1 million, compared to \$0.4 million and \$0.6 million reported for the three and six months ended July 4, 2014. The income tax provision primarily benefited from the mix of pretax earnings in lower- and zero- rate foreign jurisdictions and includes pre-tax losses generated in certain foreign jurisdictions which are consolidated for Swiss income tax purposes. There are no unrecognized tax benefits as of any period presented.

Based on current year projections, we currently expect the estimated annual effective tax rate to be 67%.

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.

### *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 or warrants, 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. We may, in the future elect to supplement this with further debt or commercial borrowing.

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 approximate \$4 million cost in 2015 associated with our quality system remediation efforts of which \$2.6 million was incurred during the first six months of 2015. Although we anticipate these costs will continue into 2016, we cannot currently estimate the amount but will update as more information becomes available. If the need for financing arises, which we cannot rule out, STAAR cannot assure that it will be available on acceptable terms, or 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 Japan's line of credit is currently fully drawn (renewable quarterly) and the total amount available under the Swiss credit line is reduced by the guarantee issued by Bankinter Spain described below.

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 3, 2015 and January 2, 2015, respectively, STAAR had \$15.3 million and \$13.0 million, of cash and cash equivalents.

Net cash used in operating activities for the six months ended July 3, 2015 and July 4, 2014, respectively, was \$1.4 million and \$4.1 million, respectively. Net cash used in operating activities for the six months ended July 3, 2015 consisted of net loss of \$3.9 million and an increase in net working capital of \$0.7 million, offset by \$3.2 million in non-cash items.

Net cash used in investing activities for the six months ended July 3, 2015 and July 4, 2014, respectively, was \$0.7 million and \$2.2 million, primarily due to acquisition of property, plant and equipment.

Net cash provided by financing activities was \$4.5 million and \$2.4 million for the six months ended July 3, 2015 and July 4, 2014, respectively. Net cash provided by financing activities for the six months ended July 3, 2015 consisted of \$2.8 million in proceeds from the exercise of warrants, \$1.9 million in proceeds from the exercise of stock options, partially offset by \$0.2 million in capital lease repayments.

## *Credit Facilities, Contractual Obligations and Commitments*

### *Lines of Credit and Guarantee*

The Company's wholly owned Japanese subsidiary, STAAR Japan, entered into an agreement on December 28, 2012, as amended, with Mizuho Bank, which provides for borrowings of up to 500,000,000 Yen (approximately \$4.1 million based on the rate of exchange on July 3, 2015), at an interest rate equal to the Tokyo short-term prime interest rate (approximately 1.475% as of July 3, 2015). The line of credit expires September 30, 2015 and is renewable quarterly. The Company had 500,000,000 Yen outstanding on the line of credit as of July 3, 2015 and January 2, 2015 (approximately \$4.1 million and \$4.2 million based on the foreign currency exchange rates on July 3, 2015 and January 2, 2015, respectively). As of July 3, 2015 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 ("Credit Suisse"). 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 3, 2015), to be used for working capital purposes. Borrowings, if any, on the credit line are due in one year from the borrowing date. The credit agreement is renewable every three years with a current expiration date of September 1, 2016. There were no borrowings outstanding as of July 3, 2015 and January 2, 2015, and the full amount of the line, reduced by any guarantees made to Bankinter Spain (described below), was available for borrowing.

On May 1, 2015, STAAR Surgical AG entered into a guarantee agreement with Bankinter Spain ("Bankinter"). The agreement provides Bankinter with a guarantee of up to EUR 400,000 (approximately \$443,000 at the rate of exchange on July 3, 2015) for trade receivables from the Company's Spanish customers. The total guarantee amount is offset against the credit agreement in place with Credit Suisse and therefore reduces the credit line available to STAAR Surgical AG for working capital requirements to up to 581,000 Swiss Francs (approximately up to \$614,000 at the rate of exchange on July 3, 2015). Unless terminated sooner by Bankinter, the guarantee agreement expires on May 1, 2017.

### *Covenant Compliance*

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

### *Employment Agreements*



The Company's Chief Executive Officer and certain officers have as provisions of their agreements certain rights, including continuance of cash compensation and benefits, upon a "change in control," which may include an acquisition of substantially all of its assets, or termination "without cause or for good reason" as defined in the employment agreements.

*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):

	July
Fiscal Year	3,
	2015
2015	\$ 381
2016	297
2017	19
Total minimum lease payments	\$ 697
Less: interest	(43 )
Total lease obligation	\$ 654
Current	\$ 349
Long-term	\$ 305

### **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 2, 2015.

### **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 3, 2015 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***

#### ***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. These claims and legal proceedings may relate to contractual rights and obligations, employment matters, and claims of product liability. 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 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.

***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. 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. 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 2, 2015. Such risks and uncertainties could materially adversely affect our business, financial condition or operating results.

***ITEM 4. MINE SAFETY DISCLOSURES***

Not Applicable.

***ITEM 5. OTHER INFORMATION***

Not Applicable.

***ITEM 6. EXHIBITS***

- 3.1 Certificate of Incorporation, as amended to date.(1)
- 3.2 Amended and Restated By-laws.(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.(4)
- 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.\*  
Financial statements from the quarterly report on Form 10-Q of STAAR Surgical Company for the quarter ended July 3, 2015, formatted in XBRL, are filed herewith and include: (i) the Condensed Consolidated Balance Sheets, 101 (ii) the Condensed Consolidated Statements of Operations, (iii) the Consolidated Statements of Comprehensive Loss, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) the Notes to Condensed Consolidated Financial 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.
  - (3) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the period ended July 4, 2014, as filed on July 31, 2014.

\*Filed herewith.

†Management contract or compensatory plan or arrangement.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

STAAR SURGICAL COMPANY

Date: August 7, 2015 By: /s/ STEPHEN P. BROWN  
**Stephen P. Brown**

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