

STAAR SURGICAL CO
Form 10-Q
August 03, 2016

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
p ACT OF 1934**

For the quarterly period ended: July 1, 2016

Or

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE
o 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 40,431,411 shares of common stock, par value \$0.01 per share, issued and outstanding as of July 29, 2016.

STAAR SURGICAL COMPANY

INDEX

	PAGE NUMBER
<u>PART I – FINANCIAL INFORMATION</u>	
Item 1. <u>Financial Statements.</u>	1
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations.</u>	14
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk.</u>	20
Item 4. <u>Controls and Procedures.</u>	20
<u>PART II – OTHER INFORMATION</u>	
Item 1. <u>Legal Proceedings.</u>	21
Item 1A. <u>Risk Factors.</u>	21
Item 4. <u>Mine Safety Disclosures.</u>	21
Item 5. <u>Other Information.</u>	21
Item 6. <u>Exhibits.</u>	21

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

	July 1, 2016	January 1, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 12,688	\$ 13,402
Accounts receivable trade, net of allowance for doubtful accounts of \$2,023 and \$1,877, respectively	16,112	15,675
Inventories, net	15,692	15,921
Prepayments, deposits and other current assets	3,938	3,636
Deferred income taxes	510	439
Total current assets	48,940	49,073
Property, plant and equipment, net	11,424	10,095
Intangible assets, net	659	666
Goodwill	1,786	1,786
Deferred income taxes	1,664	717
Other assets	828	617
Total assets	\$65,301	\$ 62,954
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Line of credit	\$4,866	\$4,159
Accounts payable	8,725	6,691
Deferred income taxes	370	370
Obligations under capital leases	346	362
Other current liabilities	6,078	6,305
Total current liabilities	20,385	17,887

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

Obligations under capital leases	1,384	204
Deferred income taxes	1,006	1,888
Asset retirement obligations	222	156
Deferred Rent	77	87
Pension liability	4,240	3,886
Total liabilities	27,314	24,108

Commitments and contingencies (Note 12)

Stockholders' equity:

Common stock, \$0.01 par value; 60,000 shares authorized; 40,433 and 39,887 shares issued and outstanding at July 1, 2016 and January 1, 2016, respectively	404	399
Additional paid-in capital	195,073	187,007
Accumulated other comprehensive loss	(326)	(1,580)
Accumulated deficit	(157,164)	(146,980)
Total stockholders' equity	37,987	38,846
Total liabilities and stockholders' equity	\$65,301	\$62,954

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 1, 2016	July 3, 2015	July 1, 2016	July 3, 2015
Net sales	\$20,974	\$18,657	\$40,243	\$37,514
Cost of sales	6,348	6,296	12,624	12,254
Gross profit	14,626	12,361	27,619	25,260
General and administrative	4,928	4,736	13,393	9,896
Marketing and selling	7,181	5,832	14,856	11,500
Research and development	4,659	3,536	11,565	7,116
Total selling, general and administrative expenses	16,768	14,104	39,814	28,512
Operating loss	(2,142)	(1,743)	(12,195)	(3,252)
Other income (expense):				
Interest income	—	49	—	49
Interest expense	(29)	(33)	(57)	(68)
Gain (loss) on foreign currency transactions	(416)	180	42	(711)
Royalty income	351	106	373	151
Other income, net	(38)	(5)	(82)	19
Other income (expense), net	(132)	297	276	(560)
Loss before provision for income taxes	(2,274)	(1,446)	(11,919)	(3,812)
Provision (benefit) for income taxes	(131)	153	(1,735)	126
Net loss	\$(2,143)	\$(1,599)	\$(10,184)	\$(3,938)
Net loss per share – basic and diluted	\$(0.05)	\$(0.04)	\$(0.25)	\$(0.10)
Weighted average shares outstanding – basic and diluted	40,210	39,066	40,097	38,769

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 1, 2016	July 3, 2015	July 1, 2016	July 3, 2015
Net loss	\$(2,143)	\$(1,599)	\$(10,184)	\$(3,938)
Other comprehensive income (loss):				
Defined benefit pension plans:				
Net change in plan assets	(12)	(9)	(23)	(18)
Reclassification into earnings	26	15	53	30
Foreign currency translation gain (loss)	1,036	(302)	1,768	(234)
Tax effect	(316)	107	(544)	81
Other comprehensive income (loss), net of tax	734	(189)	1,254	(141)
Comprehensive loss	\$(1,409)	\$(1,788)	\$(8,930)	\$(4,079)

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 1, 2016	July 3, 2015
Cash flows from operating activities:		
Net loss	\$(10,184)	\$(3,938)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property, plant and equipment	1,237	996
Amortization of intangibles	111	103
Deferred income taxes	(1,802)	(35)
Change in net pension liability	220	95
Stock-based compensation expense	7,758	1,823
Provision for sales returns and bad debts	89	243
Changes in working capital:		
Accounts receivable trade	(65)	(1,732)
Inventories, net	1,613	1,669
Prepayments, deposits and other current assets	(418)	606
Accounts payable	1,280	(1,994)
Other current liabilities	(324)	759
Net cash used in operating activities	(485)	(1,405)
Cash flows from investing activities:		
Acquisition of property, plant and equipment	(1,991)	(701)
Cash proceeds from sale of property, plant and equipment	17	2
Net cash used in investing activities	(1,974)	(699)
Cash flows from financing activities:		
Repayment of capital lease obligations	(184)	(210)
Proceeds from sale leaseback transactions	1,154	—
Taxes paid related to net share settlement of equity awards	(611)	—
Proceeds from exercise of stock options	737	1,896
Proceeds from exercise of warrants	—	2,800
Net cash provided by financing activities	1,096	4,486
Effect of exchange rate changes on cash and cash equivalents	649	(60)
Increase (decrease) in cash and cash equivalents	(714)	2,322
Cash and cash equivalents, at beginning of the period	13,402	13,013

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

Cash and cash equivalents, at end of the period	\$12,688	\$15,335
---	----------	----------

See accompanying notes to the condensed consolidated financial statements.

STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1 — Basis of Presentation and Significant Accounting Policies

The condensed 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 1, 2016 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 1, 2016.

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 fiscal 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 May 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2016-12, “Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients” (“ASU 2016-12”). The amendments in ASU 2016-12 provide clarifying guidance in certain narrow areas and add some practical expedients. Specifically, the amendments in this update (1) clarify the objective of the collectability criterion in step 1, and provides additional clarification for when to recognize revenue for a contract that fails step 1, (2) permit an entity, as an accounting policy election, to exclude amounts collected from customers for all

sales (and other similar) taxes from the transaction price, (3) specify that the measurement date for noncash consideration is contract inception, and clarifies that the variable consideration guidance applies only to variability resulting from reasons other than the form of the consideration, (4) provide a practical expedient that permits an entity to reflect the aggregate effect of all modifications that occur before the beginning of the earliest period presented when identifying the satisfied and unsatisfied performance obligations, determining the transaction price, and allocating the transaction price to the satisfied and unsatisfied performance obligations, and (5) clarifies that a completed contract for purposes of transition is a contract for which all (or substantially all) of the revenue was recognized under legacy GAAP before the date of initial application. Further, accounting for elements of a contract that do not affect revenue under legacy GAAP are irrelevant to the assessment of whether a contract is complete. In addition, the amendments permit an entity to apply the modified retrospective transition method either to all contracts or only to contracts that are not completed contracts, and clarifies that an entity that retrospectively applies the guidance in Topic 606 to each prior reporting period is not required to disclose the effect of the accounting change for the period of adoption. However, an entity is still required to disclose the effect of the changes on any prior periods retrospectively adjusted. The effective date and transition requirements for the amendments are the same as the effective date and transition requirements in Topic 606. The guidance is effective for the Company beginning January 1, 2018, although early adoption is permitted beginning January 1, 2017. The Company is currently evaluating the effects of ASU 2016-12 on its consolidated financial statements.

In April 2016, the FASB issued ASU 2016-10, “Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing.” The amendments clarify two aspects of Topic 606: (a) identifying performance obligations; and (b) the licensing implementation guidance. The update is effective for annual periods beginning after December 15, 2017 including interim reporting periods therein. The Company is currently evaluating the impact the adoption of ASU 2016-10 will have on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, “Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting”, which simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, forfeitures, classification of awards as either equity or liabilities, and classification of awards on the statement of cash flows. The update is effective for fiscal years beginning after December 15, 2016. The Company is currently evaluating the impact of the adoption of ASU 2016-09 will have on its consolidated financial statements.

STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

In February 2016, the FASB issued ASU 2016-02, "Leases (Topic 842)", which requires lessees to recognize assets and liabilities for leases with lease terms greater than twelve months in the statement of financial position. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2016-02 also requires improved disclosures to help users of financial statements better understand the amount, timing and uncertainty of cash flows arising from leases. The update is effective for fiscal years beginning after December 15, 2018, including interim reporting periods within that reporting period. Early adoption is permitted. The Company is currently evaluating the impact the adoption of ASU 2016-02 will have on its consolidated financial statements.

In January 2016, the FASB issued ASU 2016-01, "Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities", which changes how entities measure certain equity investments and how entities present changes in the fair value of financial liabilities measured under the fair value option that are attributable to instrument-specific credit risk. ASU 2016-01 is effective for annual reporting periods beginning after December 15, 2017, including interim periods within those fiscal years. The Company is currently assessing the impact of the adoption of ASU 2016-01 will have on its consolidated financial statements.

In November 2015, the FASB issued ASU 2015-17, "Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes", which changes how deferred taxes are classified on company's balance sheets. The ASU eliminates the current requirement to present deferred tax liabilities and assets as current and noncurrent on the balance sheet. Instead, companies will be required to classify all deferred tax assets and liabilities as noncurrent. The amendments are effective for annual financial statements beginning after December 15, 2016, and interim periods within those annual periods. The Company is currently evaluating the impact the adoption of ASU 2015-17 will have on its consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, "Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern". ASU No. 2014-15 defines management's responsibility to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. It is effective for annual reporting periods ending after December 15, 2016, and for annual and interim reporting periods thereafter. Early adoption is permitted. The Company has not elected to early adopt, and will apply the provisions of ASU No. 2014-15 when assessing going concern upon adoption.

In May 2014, the FASB issued ASU 2014-09, “Revenue from Contracts with Customers (Topic 606)”, which supersedes nearly all existing revenue recognition guidance under GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five-step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing GAAP. The revised revenue standard is effective for public entities for annual periods beginning after December 15, 2017, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients; or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). The Company is currently evaluating the impact of the Company’s pending adoption of ASU 2014-09 on the Company’s financial statements and has not yet determined the method by which it will adopt the standard in fiscal 2018.

Prior Year Reclassifications

For the three-month and six-month periods ended July 3, 2015, the Company reclassified \$106,000 and \$151,000 from other income, net to royalty income, respectively, in the condensed consolidated statements of operations.

STAAR SURGICAL COMPANY**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)****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 1, 2016	January 1, 2016
Raw materials and purchased parts	\$2,344	\$2,317
Work-in-process	1,971	1,995
Finished goods	15,614	15,058
	19,929	19,370
Less: inventory reserves	4,237	3,449
	\$15,692	\$15,921

Note 3 — Prepayments, Deposits, and Other Current Assets

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

	July 1, 2016	January 1, 2016
Prepayments and deposits	\$1,493	\$1,386
Income tax receivable	651	597
Value added tax (VAT) receivable	538	724
Royalties receivable	129	65
Deferred charges for foreign profits	182	182
Other current assets	945	682
	\$3,938	\$3,636

Note 4 — Property, Plant and Equipment

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

	July 1, 2016	January 1, 2016
Machinery and equipment	\$17,832	\$17,094
Furniture and fixtures	8,387	6,980
Leasehold improvements	9,208	8,611
	35,427	32,685
Less: accumulated depreciation	24,003	22,590
	\$11,424	\$10,095

Note 5 –Intangible Assets

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

	July 1, 2016			January 1, 2016		
	Gross			Gross		
	Carrying	Accumulated	Net	Carrying	Accumulated	Net
	Amount	Amortization		Amount	Amortization	
Long-lived intangible assets:						
Patents and licenses	\$9,303	\$ (8,951	) \$352	\$9,207	\$ (8,891	) \$316
Customer relationships	1,526	(1,297	) 229	1,305	(1,044	) 261
Developed technology	970	(892	) 78	829	(740	) 89
Total	\$11,799	\$ (11,140	) \$659	\$11,341	\$ (10,675	) \$666

STAAR SURGICAL COMPANY**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)****Note 6 – Other Current Liabilities**

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

	July 1, 2016	January 1, 2016
Accrued salaries and wages	\$2,092	\$ 1,909
Accrued bonuses	1,395	2,114
Accrued severance	136	133
Accrued insurance	426	540
Customer credit balances	292	203
Accrued income taxes	83	217
Accrued audit fees	295	314
Other ⁽¹⁾	1,359	875
	\$6,078	\$ 6,305

⁽¹⁾ 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.

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 Six Months Ended

	July 1,	July 3,	July 1,	July 3,
	2016	2015	2016	2015
Service cost	\$ 155	\$ 107	\$ 309	\$ 214
Interest cost	18	19	36	38
Expected return on plan assets	(23)	(21)	(45)	(42)
Net amortization of transitional obligation (a)	3	3	6	5
Actuarial loss recognized in current period (a)	23	12	47	25
Total	\$ 176	\$ 120	\$ 353	\$ 240

(a) Amounts reclassified from accumulated other comprehensive loss.

During the six months ended July 1, 2016 and July 3, 2015, the Company made cash contributions of approximately \$419,000 and \$400,000, respectively, to its Swiss pension plan and the Company is not required to make additional cash contributions during the remainder of 2016. The Company currently is not required to and does not make contributions to its Japan pension plan.

STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

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 1,	July 3,	July 1,	July 3,
	2016	2015	2016	2015
Numerator:				
Net loss	\$(2,143)	\$(1,599)	\$(10,184)	\$(3,938)
Denominator:				
Weighted average common shares and denominator for basic and diluted calculation:				
Weighted average common shares outstanding	40,225	39,173	40,112	38,876
Less: Unvested restricted stock	15	107	15	107
Denominator for basic and diluted calculation	40,210	39,066	40,097	38,769
Net loss per share – basic and diluted	\$(0.05)	\$(0.04)	\$(0.25)	\$(0.10)

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

	Three Months Ended		Six Months Ended	
	July 1,	July 3,	July 1,	July 3,
	2016	2015	2016	2015
Options	3,199	1,561	2,994	1,396
Restricted stock and units	258	137	188	211

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

Warrants	—	385	—	345
Total	3,457	2,083	3,182	1,952

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. Other than Japan, China, the United States, Korea, Spain, France and Germany, the Company does not conduct business in any country in which its sales exceed 5% of worldwide 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 1, 2016	July 3, 2015	July 1, 2016	July 3, 2015
Japan	\$3,989	\$3,980	\$8,229	\$8,267
China	4,417	3,327	7,495	5,698
United States	2,420	2,723	4,936	5,589
Korea	1,665	1,269	3,687	3,612
Spain	1,528	1,486	2,980	2,964
France	1,103	888	2,230	2,039
Germany	1,153	694	2,120	1,190
Other	4,699	4,290	8,566	8,155
Total	\$20,974	\$18,657	\$40,243	\$37,514

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):

STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

	Three Months Ended		Six Months Ended	
	July 1, 2016	July 3, 2015	July 1, 2016	July 3, 2015
ICLs	\$15,408	\$12,236	\$28,588	\$24,490
IOLs	5,068	5,204	10,134	10,562
Core products	20,476	17,440	38,722	35,052
Other surgical products	498	1,217	1,521	2,462
Total	\$20,974	\$18,657	\$40,243	\$37,514

One customer, our distributor in China, accounted for 21% and 19% of net sales for the three and six months ended July 1, 2016, respectively, and one customer accounted for 16% and 14% of net sales for the three and six months ended July 3, 2015, respectively. As of July 1, 2016, two customers, our distributors in China and Korea, accounted for 23% and 10%, respectively of consolidated trade receivables. As of January 1, 2016, there was one customer, our distributor in China, which accounted for 24% of consolidated trade receivables.

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 1, 2016	July 3, 2015	July 1, 2016	July 3, 2015
Employee stock options	\$153	\$555	\$5,049	\$1,193
Restricted stock	2	63	227	307
Restricted stock units	145	154	2,423	274
Nonemployee stock options		57	59	49
Total	\$300	\$829	\$7,758	\$1,823

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

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

	Three Months Ended		Six Months Ended	
	July 1,	July 3,	July 1,	July 3,
	2016	2015	2016	2015
Cost of sales	\$	\$6	\$560	\$23
General and administrative	167	548	3,688	1,124
Marketing and selling	68	104	1,471	355
Research and development	65	171	2,039	321
Total stock compensation expense	300	829	7,758	1,823
Amounts capitalized as part of inventory	36	129	188	251
Total	\$336	\$958	\$7,946	\$2,074

Stock Option Plan

Our Amended and Restated 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 (“RSUs”), 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 our 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 under certain circumstances in the event of a change in control (as defined in the Plan). Pursuant to the Plan, options for 3,785,537 shares were outstanding at July 1, 2016 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 15,379 shares of restricted stock and 260,425 RSUs outstanding at July 1, 2016. As of July 1, 2016, there were 2,223,858 shares authorized and available for grants under the Plan.

STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

Immediate Vesting of All Unvested Equity Awards

On February 11, 2016, one of our shareholders increased its beneficial ownership of the Company's common stock to approximately 26% of all shares outstanding. This triggered the "Change in Control" provision in the Plan, which resulted in the immediate vesting of all unvested equity awards outstanding under the Plan ("Acceleration Event") and us recording an aggregate \$6.9 million non-cash charge to stock-based compensation in the condensed consolidated statements of operations on that date (\$4.6 million for stock options and \$2.3 million for restricted stock and RSUs). This charge was recorded and included in the following categories of the condensed consolidated statements of operations for the six months ended July 1, 2016: \$2.9 million in general and administrative expenses, \$1.5 million in marketing and selling expenses, \$1.9 million in research and development expenses and \$0.6 million in manufacturing costs. Approximately \$3.7 million of the \$6.9 million of accelerated charges would have been recognized for stock-compensation by the Company during fiscal year 2016 after the Change in Control provision was triggered.

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 9% 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 July 1,		Six Months Ended July 3,	
	2016	2015	2016	2015
Expected dividend yield	0 %	0 %	0 %	0 %
Expected volatility	45 %	57 %	53 %	57 %
Risk-free interest rate	1.01 %	1.42 %	1.27 %	1.61 %
Expected term (in years)	4.40	5.54	5.19	5.61

A summary of option activity under the Plan for the six-month period ended July 1, 2016 is presented below:

	Options
	Shares
	(000's)
Outstanding at January 1, 2016	3,623
Granted	725
Exercised	(265)
Forfeited or expired	(298)
Outstanding at July 1, 2016	3,785
Exercisable at July 1, 2016	3,176

A summary of restricted stock and RSU activity under the Plan for the six-month period ended July 1, 2016 is presented below:

	Restricted	RSUs
	Shares	(000's)
	(000's)	
Outstanding at January 1, 2016	124	339
Granted	15	307
Vested	(124)	(379)
Forfeited		(6)
Outstanding at July 1, 2016	15	261

Note 11 — Income Taxes

The Company's quarterly provision for income taxes is determined by estimating an annual effective tax rate. This estimate may fluctuate throughout the year as new information becomes available affecting its underlying assumptions. The tax effect of unusual or infrequent transactions that occurred during the reporting period is calculated separately and added to the amount of tax estimated using the annual effective tax rate discussed above. All earnings from the Company's subsidiaries are not considered to be permanently reinvested. Accordingly, the Company provides withholding and U.S. taxes on all unremitted foreign earnings.

STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

The \$1.7 million income tax benefit recorded during the first six months of 2016, was attributable to 1) the Company's net operating losses reported by its foreign operations principally due to an acceleration of stock-based compensation during the first quarter of 2016 and 2) a reduction in its foreign withholding taxes in connection with the dissolution of one of its foreign subsidiaries effective April 1, 2016. During the six months ended July 3, 2015, the Company recorded an income tax provision of \$126,000, primarily benefiting from the mix of pre-tax earnings in lower- and zero- rate foreign jurisdictions. There are no unrecognized tax benefits related to uncertain tax positions taken by the Company.

Note 12 - Commitments and Contingencies

Lines of Credit and Guarantee

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 1, 2016), at an interest rate equal to the Tokyo short-term prime interest rate (approximately 1.475% as of July 1, 2016). The line of credit expires on September 30, 2016 and is renewable annually. The Company had 500,000,000 Yen outstanding on the line of credit as of July 1, 2016 and January 1, 2016 (approximately \$4.9 million and \$4.2 million based on the foreign currency exchange rates on July 1, 2016 and January 1, 2016, respectively). As of July 1, 2016 there was no available credit 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 borrowing of up to 1,000,000 CHF (Swiss Francs) (approximately \$1.0 million at the rate of exchange on July 1, 2016), to be used for working capital purposes. Accrued interest and 0.25% commissions on average outstanding borrowings is payable quarterly and the interest rate will be determined by the Bank based on the then prevailing market conditions at the time of borrowing. The credit agreement is automatically renewed on an annual basis based on the same terms assuming there is no default. The credit agreement may be terminated by either party at any time in accordance with its general terms and conditions. The credit facility is not collateralized and contains certain conditions such as providing the Bank with audited financial statements annually and notice of significant events or conditions, as defined in the credit agreement. The Bank may also declare all amounts outstanding to be immediately due and payable upon a change of control or a material qualification as defined in the credit agreement. There were no borrowings outstanding as of July 1, 2016 and January 1, 2016.

On May 1, 2015, STAAR Surgical AG entered into a guarantee agreement with Bankinter. The agreement, as amended, provides Bankinter with a guarantee of up to EUR 200,000 (approximately \$222,000 at the rate of exchange on July 1, 2016) 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 up to approximately 783,000 Swiss francs (approximately up to \$803,000 at the rate of exchange on July 1, 2016). 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 matters. Legal proceedings can extend for several years, and the matters described below concerning the Company are at 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.

STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

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 U.S. District Court for the Central District of 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 October 20, 2014, plaintiff amended its complaint, dismissed two Company officers, added one other officer, reduced the alleged Class Period to November 1, 2013 through June 30, 2014, and demanded compensatory damages and attorneys' fees. On September 21, 2015, the Company filed a motion to dismiss the amended complaint. On April 12, 2016, the court denied the motion to dismiss. 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 itself against this lawsuit. The Company has not recorded any loss or accrual in the accompanying condensed consolidated financial statements at July 1, 2016 and January 1, 2016 for this matter as the likelihood and amount of loss, if any, has not been determined and is not currently estimable.

Stockholder Derivative Litigation: Forestal Action

On June 22, 2016, Kevin Forestal filed a stockholder derivative complaint against our then-current Board of Directors, which included Caren Mason, Mark B. Logan, Stephen C. Farrell, Richard A. Meier, John C. Moore, J. Steven Roush, Louis E. Silverman, and William P. Wall, and STAAR as well as Barry G. Caldwell and John S. Santos in the U.S. District Court for the Central District of California. The plaintiff alleges breaches of fiduciary duties by, among other things, allowing STAAR to disseminate misleading statements to investors regarding the condition of the Company's Quality System, failing to properly oversee the Company, and unjust enrichment. The complaint seeks damages, restitution and governance reforms, attorneys' fees and costs. 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 has not recorded any loss or accrual in the accompanying condensed consolidated financial statements at July 1, 2016 for this matter as the likelihood and amount of loss, if any, has not been determined and is not currently estimable.

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.

Note 13. Sale-Leaseback Transactions

On June 7, 2016, the Company entered into a new schedule of an existing master agreement with Farnam Street Financial, Inc. of \$1.3 million of which \$1.2 million was a sale-leaseback agreement pursuant to which the Company sold production equipment and received net proceeds of \$1.2 million, which represented the net book value of the equipment as of that date. The lease line of credit provides for borrowings up to \$2.0 million for an initial term of 24 months, at an annual rate of 3.94% for hardware equipment and 4.75% for non-hardware equipment of the purchase price. As of July 1, 2016, there was \$0.7 million available for future transactions.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The matters addressed in this Item 2 that are not historical information constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Readers can recognize forward-looking statements by the use of words like "anticipate," "estimate," "expect," "intend," "plan," "believe," "will," "forecast" and similar expressions in connection with any discussion of future operating or financial performance. In particular, these include 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; statements regarding new, existing, or improved products, including but not limited to, expectations for success of new, existing, and improved products in the U.S. or international markets or government approval of a new or improved products (including the Toric ICL in the U.S.); or commercialization of new or improved products; the nature, timing and likelihood of resolving issues cited in the FDA's 2014 Warning Letter or 2015 FDA-483; future economic conditions or size of market opportunities; expected costs of quality system remediation efforts; statements of belief, including as to achieving 2016 business plans; expected regulatory activities and approvals, product launches, and any statements of assumptions underlying any of the foregoing.

Although we believe that the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risks and we can give no assurance that our expectations will prove to be correct. Actual results could differ from those described in this report because of numerous factors, many of which are beyond our control. These factors include, without limitation, those described in our Annual Report on Form 10-K in "Item 1A. Risk Factors" filed on March 11, 2016. We undertake no obligation to update these forward-looking statements after the date of this report to reflect future events or circumstances or to reflect actual outcomes.

The following discussion should be read in conjunction with the unaudited consolidated financial statements of STAAR, including the related notes, provided in this report.

Overview

STAAR Surgical Company designs, develops, manufactures and sells implantable lenses for the eye and companion delivery systems used to deliver the lenses into the eye. We are the leading maker of lenses used worldwide in corrective or "refractive" surgery. Our goal is to position our refractive lenses throughout the world as primary and premium solutions for patients seeking visual freedom from wearing glasses or contact lenses while achieving excellent visual acuity through refractive vision correction. We also make lenses for use in surgery that treats

cataracts. Unless the context indicates otherwise, “we,” “us,” the “Company,” and “STAAR” refer to STAAR Surgical Company and its consolidated subsidiaries.

STAAR has significant operations globally. Activities outside the United States (“U.S.”) accounted for 88% of our total sales in second quarter of 2016, 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 U.S., Canada, Japan, Spain, Germany, and the U.K. and independent distribution in the remainder of the world. STAAR maintains operational and administrative facilities in the U.S., Switzerland and Japan.

Recent Developments and Strategic Priorities for 2016

In the second quarter of 2016, worldwide ICL revenues increased 25.9% compared to the prior year quarter. In the regional markets, Asia Pacific ICL revenues increased 40.0% and units increased 38.0%; Europe, Middle East and Africa ICL revenues increased 16.4% and units decreased 2.2%; and North America ICL revenues increased 0.6% and units decreased 9.3%. Worldwide ICL units grew 17.6% compared to the prior year quarter. In the regional markets, compared to the prior year quarter, Asia Pacific IOL revenues decreased 0.8% and units decreased 22.1%; Europe, Middle East and Africa IOL revenues increased 15.5% and units increased 7.4%; and North America IOL revenues decreased 23.5% and units decreased 28.2%. Worldwide IOL units declined 14.8%, driven by decreased U.S. IOL sales and the planned phase-out of IOL sales in China, partially offset by continued unit growth in Japan. Overall, second quarter of 2016 net sales were \$21.0 million, a 12.4% increase over the second quarter of 2015.

We continue to enter into new cooperation agreements with strategic accounts. Generally, under these strategic agreements we will provide additional training, marketing and pricing support to these accounts in exchange for unit growth of our products and participation in our patient registry, marketing, generating clinical data, and new product development efforts.

During the quarter, the third party manufacturer of injectors used in our pre-loaded hydrophobic acrylic lens systems notified us it may not produce the quantity of injectors previously agreed-upon by the parties. We remain in discussions with the manufacturer to resolve this matter. Also, sales of our injectors to Nidek Co., Ltd (“Nidek”) declined 73.3% compared to the prior year quarter as a result of settlements with our third party manufacturer and Nidek whereby our third party manufacturer agreed to repair or replace allegedly defective injectors previously sold to Nidek without additional charge. We expect modest injector sales to Nidek through 2016. Effective December 31, 2016, we will cease selling silicone IOLs, AquaFlow, and related accessories in North America. We launched a sales campaign offering existing North American customers of the silicone IOL attractive terms to switch to our NanoFLEX IOL. Included in cost of sales during the quarter were \$426,000 in inventory reserves of silicone IOLs and related accessories. The Company expects to sell the remaining finished goods inventory of silicone IOLs through the end of the year. During the second quarter of 2016, we launched our new corporate website in languages suitable for Germany, Spain, France, Sweden, the U.K., Norway, Italy, Belgium, Switzerland, The Netherlands, the Middle East, Canada, India, and Latin America. These websites feature, where permitted, the EVO Visian ICL and our “Evolution in Visual Freedom” messaging.

On May 12, 2016, we were notified that the Medical Devices Bureau of Health Canada approved for distribution in Canada our EVO Visian ICL, which is the ICL with a central port.

For the rest of 2016, our four strategic priorities remain as follows:

1. FDA Remediation and Continuation of Quality Systems Overhaul: We expect to achieve our internal remediation and quality system plan commitments while also maintaining our global quality certifications, continuing to hire employees in the Quality and Regulatory departments, and qualifying equipment such as a Master Control Quality Management System;
2. Create the Visual Freedom Market for Implantable Lenses: Position the ICL as a primary and premium refractive procedure with clinical validation, new corporate and product branding, new digital and social media marketing, and by entering into strategic partnerships with large refractive surgical providers operating eye hospitals and clinics;
3. Begin our Clinical Validation and Regulatory Rebirth: The expanded Global Clinical and Medical Affairs teams will assist in supporting submissions to and responding to queries from regulatory agencies and will monitor clinical data, conduct clinical studies, begin building patient registries and enhance medical communications protocol; and
4. Innovating and Developing New Products, Materials and Delivery Systems: Expanding our R&D team, upgrading our labs and testing apparatus, and focusing on our research and development priorities.

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 provided in this report, 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 1, 2016 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 1, 2016.

Immediate Vesting of All Unvested Equity Awards

On February 11, 2016, one of our shareholders increased its beneficial ownership of the Company's common stock to approximately 26% of all shares outstanding. This triggered the "Change in Control" provision in our Amended and Restated Omnibus Equity Incentive Plan ("Plan"), which resulted in the immediate vesting of all unvested equity awards outstanding under the Plan and the recording of an aggregate \$6.9 million non-cash charge to stock-based compensation in the condensed consolidated statements of operations on that date (\$4.6 million for stock options and \$2.3 million for restricted stock and restricted stock units). This charge was recorded and included in the following categories of the condensed consolidated statements of operations for the six months ended July 1, 2016: \$2.9 million in general and administrative expenses, \$1.5 million in marketing and selling expenses, \$1.9 million in research and development expenses and \$0.6 million in manufacturing costs. Approximately \$3.7 million of the \$6.9 million of accelerated charges would have been recognized for stock-compensation by the Company during fiscal year 2016 after the Change in Control provision was triggered.

Results of Operations

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

	Percentage of Net Sales for Three Months		Percentage of Net Sales for Six Months			
	July 1, 2016	July 3, 2015	July 1, 2016		July 3, 2015	
Net sales	100.0 %	100.0 %	100.0	%	100.0	%
Cost of sales	30.3	33.7	31.4		32.7	
Gross profit	69.7	66.3	68.6		67.3	
General and administrative	23.5	25.4	33.3		26.4	
Marketing and selling	34.2	31.3	36.9		30.7	
Research and development	22.2	19.0	28.7		19.0	
	79.9	75.7	98.9		76.0	
Operating loss	(10.2)	(9.4)	(30.3)		(8.7)	
Other income (expense), net	(0.6)	1.7	0.7		(1.5)	
Loss before provision for income taxes	(10.8)	(7.7)	(29.6)		(10.2)	
Provision (benefit) for income taxes	(0.6)	0.8	(4.3)		0.3	
Net loss	(10.2)%	(8.5)%	(25.3)%		(10.5)%	

Net Sales

	Three Months Ended		Percentage		Six Months Ended		Percentage	
	July 1,	July 3,	Change		July 1,	July 3,	Change	
	2016	2015	2016		2016	2015	2016	
			vs. 2015				vs. 2015	
Net sales	\$ 20,974	\$ 18,657	12.4	%	\$ 40,243	\$ 37,514	7.3	%
ICL	15,408	12,236	25.9		28,588	24,490	16.7	
IOL	5,068	5,204	(2.6	)	10,134	10,562	(4.1	)
Other	498	1,217	(59.1	)	1,521	2,462	(38.2	)

Net sales for the three months ended July 1, 2016 were \$21.0 million, an increase of 12.4% compared with \$18.7 million reported during the same period of 2015. Total sales for the six months ended July 1, 2016 were \$40.2 million, an increase of 7.3% compared with \$37.5 million reported during the same period of 2015. The effect of exchange rate changes had a favorable impact on net sales of \$0.5 million and \$0.6 million, respectively, during the three and six months ended July 1, 2016

Total ICL sales for the three months ended July 1, 2016 were \$15.4 million, an increase of 25.9% compared with \$12.2 million reported during the same period of 2015. EMEA ICL sales were \$5.5 million during the second quarter, an increase of 16.4% compared to the prior year period, with a decrease of 2.2% in units. Additionally, the increase in sales was driven by a 132.4% increase in sales in Germany, due to the transition to a direct sales model as well as the impact of increased pricing which occurred in most markets beginning in the fourth quarter of 2015. APAC ICL sales were \$8.4 million during the second quarter of 2016, an increase of 40.0% compared to the prior year period, which was comprised of a 38.0% increase in units and a 1.4% increase in average selling prices, driven by strong double-digit growth in all markets. North America ICL sales were \$1.6 million during the second quarter, an increase of 0.6% and a decrease of 9.3% in units compared to the prior year period.

Total ICL sales for the six months ended July 1, 2016 were \$28.6 million, a 16.7% increase compared with \$24.5 million reported during the same period of 2015. EMEA ICL sales were \$10.4 million for the six months ended July 1, 2016, a 12.6% increase compared to \$9.2 million reported in the same period in 2015 with 2.7% decrease in units sold. Additionally, the increase in sales was driven by 120.1% increase in Germany sales, due to the transition of a direct sales model as well as the impact of increased pricing with occurred in most markets in the fourth quarter of 2015. APAC ICL sales were \$15.0 million for the six months ended July 1, 2016, a 25.1% increase compared to \$12.0 million reported during the same period of 2015. The increase was comprised of 20.5% increase in units and an average 6% increase in average selling prices. The increase was also driven by a 47.4% increase in China sales. North America ICL sales were \$3.2 million during the six months ended July 1, 2016, a 2.5% decrease in sales and a 12.0% decrease in units compared to the same period in 2015.

Total IOL sales for the three months ended July 1, 2016 were \$5.1 million, a decrease of 2.6% compared with \$5.2 million reported during the same period of 2015. Total IOL sales for the six months ended July 1, 2016 were \$10.1 million, a 4.1% decrease compared with \$10.6 million reported during the same period in 2015. The decline for both the three and six-month periods was due to a planned phase-out of sales in China, and decreased IOL sales in the U.S., partially offset by the favorable impact of foreign exchange on sales which was \$0.3 million and \$0.5 million, respectively. The Company expects U.S. silicone IOL sales will continue to decline in the second half of 2016, at which point, we will cease selling them. Although programs are in place to convert silicone IOL accounts to our NanoFLEX IOL, we can give no assurance these programs will be successful. U.S. silicone IOL sales were \$0.7 million in the first half of 2016 and \$2.1 million in fiscal 2015. The Company will continue to sell pre-loaded silicone IOLs internationally. Preloaded IOL sales represented 81% of the Company's IOL sales in the first half of 2016.

Other product sales for the three months ended July 1, 2016, were \$0.5 million, a decrease of 59.1% compared with the \$1.2 million reported during the same period of 2015. Total other product sales for the six months ended July 1, 2016 were \$1.5 million, a 38.2% decrease compared with \$2.5 million reported during the same period in 2015. The decrease in other product sales is due to a decrease in injector part sales. The Company expects continued soft injector part sales during the remainder of fiscal 2016.

Gross Profit

	Three Months Ended		Percentage Change 2016 vs. 2015	Six Months Ended		Percentage Change 2016 vs. 2015	
	July 1, 2016	July 3, 2015		July 1, 2016	July 3, 2015		
Gross Profit	\$ 14,626	\$ 12,361	18.3	% \$ 27,619	\$ 25,260	9.3	%
Gross Profit Margin	69.7	% 66.3	%	68.6	% 67.3	%	

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

Gross profit for the second quarter of 2016 was \$14.6 million, or 69.7% of revenue, compared with \$12.4 million, or 66.3% of revenue, in the prior year period. The increase in gross margin for the quarter is due to an increased mix of higher margin ICL units, higher average selling prices, and lower ICL unit costs, partially offset by higher IOL unit costs and other cost of sales and inventory reserves recorded against silicone IOL inventory as a result of the Company's decision to cease selling this product by the end of fiscal 2016.

Gross profit for the six months ended July 1, 2016 was \$27.6 million, or 68.6% of revenue, compared with \$25.3 million, or 67.3% of revenue, in the prior year period. The increase in gross margin for the first six months of 2016 is due to an increased mix of higher margin ICL units, higher average selling prices, and lower ICL unit costs, partially offset by higher IOL unit costs and other cost of sales and the \$0.6 million non-cash charge related to the immediate vesting of all unvested equity awards as a result of the triggering of the "Change of Control" provision of the Company's equity incentive plan.

General and Administrative

	Three Months Ended		Percentage Change 2016		Six Months Ended		Percentage Change 2016	
	July 1, 2016	July 3, 2015	vs. 2015		July 1, 2016	July 3, 2015	vs. 2015	
General and Administrative	\$ 4,928	\$ 4,736	4.1	%	\$ 13,393	\$ 9,896	35.3	%
Percentage of Net Sales	23.5	% 25.4	%		33.3	% 26.4	%	

General and administrative expenses for this quarter were \$4.9 million, an increase of 4.1% when compared with \$4.7 million reported for the same period last year. The increase was primarily due to an increase in compensation and travel and the unfavorable impact of the Japanese yen on expenses, partially offset by decreased stock-based compensation and local taxes.

General and administrative expenses for the six months ended July 1, 2016 were \$13.4 million, an increase of 35.3% when compared with \$9.9 million reported for the same period last year. The increase was primarily due to a \$2.9 million non-cash charge related to the immediate vesting of all unvested equity awards as a result of the triggering of the "Change of Control" provision of the Company's equity incentive plan and increased compensation and travel.

Marketing and Selling

	Three Months Ended		Percentage Change		Six Months Ended		Percentage Change	
	July 1, 2016	July 3, 2015	2016		July 1, 2016	July 3, 2015	2016	
			vs. 2015				vs. 2015	
Marketing and Selling	\$ 7,181	\$ 5,832	23.1	%	\$ 14,856	\$ 11,500	29.2	%
Percentage of Net Sales	34.2 %	31.3 %			36.9 %	30.7 %		

Marketing and selling expenses for this quarter were \$7.2 million, an increase of 23.1% when compared with \$5.8 million reported for the same period last year. The increase was primarily due to increased marketing costs related to our rebranding efforts, increased international selling and promotional costs, increased trade show costs, and the unfavorable impact of the Japanese yen on expenses.

Marketing and selling expenses for the six months ended July 1, 2016 were \$14.9 million, an increase of 29.2% when compared with \$11.5 million reported for the same period last year. The increase is primarily due to a \$1.5 million non-cash charge related to the immediate vesting of all unvested equity awards as a result of the triggering of the “Change of Control” provision of the Company’s equity incentive plan and increased marketing costs related to our rebranding efforts, increased trade show costs, increased international selling and promotional costs, and the unfavorable impact of the Japanese yen on expenses.

Research and Development

	Three Months Ended		Percentage Change		Six Months Ended		Percentage Change	
	July 1, 2016	July 3, 2015	2016		July 1, 2016	July 3, 2015	2016	
			vs. 2015				vs. 2015	
Research and Development	\$ 4,659	\$ 3,536	31.8	%	\$ 11,565	\$ 7,116	62.5	%
Percentage of Net Sales	22.2 %	19.0 %			28.7 %	19.0 %		

Research and development expenses for this quarter were \$4.7 million, an increase of 31.8% when compared with \$3.5 million reported for the prior year quarter. The increase was primarily due to increased costs related to quality system improvements, including increased headcount, and investments in clinical affairs, partially offset by a decrease in FDA remediation expenses.

Research and development expenses for the six months ended July 1, 2016 were \$11.6 million, a 62.5% increase compared to \$7.1 million for the same prior year period. The increase was primarily due to a \$1.9 million non-cash charge related to the immediate vesting of all unvested equity awards as a result of the triggering of the “Change of Control” provision of the Company’s equity incentive plan, increased costs related to quality system improvements, including increased headcount, and investments in clinical affairs, partially offset by a decrease in FDA remediation expenses.

Research and development expense consists primarily of compensation and related costs for personnel responsible for the research and development of new and existing products and the regulatory and clinical activities required to acquire and maintain product approvals globally. These costs are expensed as incurred.

Other Income (Expense), Net

	Three Months Ended		Percentage Change	Six Months Ended		Percentage Change
	July 1, 2016	July 3, 2015	2016 vs. 2015	July 1, 2016	July 3, 2015	2016 vs. 2015
Other income (expense), net	\$(132)	\$297	—*	\$276	\$(560)	—*

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

The change in other income (expense), net for this quarter is primarily due to increased foreign currency losses, partially offset by an increase in royalty income.

The change in other income (expense), net for the first six months of 2016 is primarily due to an increase in foreign currency gains and royalty income.

Income Taxes

	Three Months Ended		Percentage Change	Six Months Ended	Percentage Change
	July 1, 2016	July 3, 2015	2016 vs. 2015	July 1, 2016	July 3, 2015
					2016 vs. 2015
Provision (benefit) for income taxes	\$(131)	\$ 153	—*	\$(1,735)	\$ 126

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

The \$1.7 million income tax benefit recorded during the first six months of 2016 was attributable to 1) the Company's net operating losses reported by its foreign operations principally due to the acceleration of stock-based compensation during the first quarter of 2016 and 2) a reduction in its foreign withholding taxes in connection with the dissolution of one of its foreign subsidiaries effective April 1, 2016. There are no unrecognized tax benefits related to uncertain tax positions taken by the Company.

Based on current information and subject to future events and circumstances, we expect the estimated annual effective tax rate for 2016 to be approximately 32%.

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 and lease lines of credit. 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 estimated \$2.2 million cost in 2016 associated with our FDA remediation efforts of which \$1.0 million was incurred in the first six months of 2016. We cannot currently estimate the amount of remediation expense which may be required beyond 2016 but will update as more information becomes available. We continue to expect our investments to outpace revenue and gross margin expansion for the remainder of the year. 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. and STAAR Japan's line of credit is currently fully drawn.

To the extent STAAR's cash balances exceed levels needed for working capital and as a cushion for unforeseen demand, STAAR intends to invest its cash in expanding and improving its business. It does not anticipate paying dividends from its earnings for the foreseeable future.

Overview of Changes in Cash and Cash Equivalents and Other Working Capital Accounts.

As of July 1, 2016 and January 1, 2016, respectively, STAAR had \$12.7 million and \$13.4 million, of cash and cash equivalents, respectively.

Net cash used in operating activities was \$0.5 million and \$1.4 million for the six months ended July 1, 2016 and July 3, 2015, respectively. The net cash used in operating activities for the six months ended July 1, 2016, resulted from a net loss of \$10.2 million, partially offset by \$7.6 million in non-cash items and \$2.1 million increase in net working capital.

Net cash used in investing activities was \$2.0 million for the six months ended July 1, 2016, compared to \$0.7 million in net cash used in investing activities for the six months ended July 3, 2015. Net cash used in investing activities for both periods was primarily due to the acquisition of property, plant and equipment.

Net cash provided by financing activities was \$1.1 million for the six months ended July 1, 2016; compared with \$4.5 million in net cash provided by financing activities for the six months ended July 3, 2015. Net cash provided by financing activities during the first six months of 2016 resulted from the proceeds of sale-leaseback transactions and exercises of stock options, partially offset by taxes paid related to net share settlement of equity awards and repayment of capital lease obligations.

Credit Facilities and Commitments

Lines of Credit, Guarantee, and Sale-Leaseback

See Notes 12 and 13 of the accompanying Condensed Consolidated Financial Statements.

Covenant Compliance

The Company is in compliance with the covenants of its credit facilities as of July 1, 2016.

Employment Agreements

The Company's Chief Executive Officer entered into an employment agreement with the Company, effective March 1, 2015. She 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.

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

During the six months ended July 1, 2016, 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 1, 2016.

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 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 Securities and Exchange 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 the Company in the reports that it files or submits under the Act is accumulated and communicated to the Company'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 1, 2016 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 is involved in various legal proceedings and other matters arising in the normal course of business. Certain legal proceedings in which we are currently involved are discussed under “Litigation and Claims” in Note 12, “Commitments and Contingencies,” to our Condensed Consolidated Financial Statements provided in this report, and such discussions are hereby incorporated by reference.

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 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 1, 2016. Such risks and uncertainties could materially adversely affect our business, financial condition or operating results.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

On June 7, 2016, the Company entered into a new schedule of an existing master agreement with Farnam Street Financial, Inc. for \$1.3 million of which \$1.2 million was a sale-leaseback agreement, pursuant to which the Company sold production equipment and received net proceeds of \$1.2 million, which represented the net book value of the equipment as of that date. The lease line of credit provides for borrowings up to \$2.0 million for an initial term of 24

months, at an annual rate of 3.94% for hardware equipment and 4.75% for non-hardware equipment of the purchase price. As of July 1, 2016, there was \$0.7 million available for future transactions.

ITEM 6. EXHIBITS

- 3.1 Restated Certificate of Incorporation.(1)
 - 3.2 Amended and Restated By-laws.(4)
 - 4.4 Form of Certificate for Common Stock, par value \$0.01 per share.(2)
 - †4.5 Amended and Restated Omnibus Equity Incentive Plan.(3)
 - 10.35 Lease Schedule No. 009 and Purchase Option dated June 7, 2016, of Lease Agreement dated May 30, 2006 by and between the Company and Farnam Street Financial, Inc.*
 - 31.1 Certifications 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 Certifications 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 1, 2016, formatted in Extensible Business Reporting Language (XBRL), are filed herewith and include: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed 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 Exhibit 5.03A of 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 of Amendment No. 1 to the Company's Registration Statement on Form 8-A/A, filed with the Commission on April 18, 2003.
- (3) Incorporated by reference to Exhibit 10.1 of the Company's Proxy Statement on Form 8-K, filed with the Commission on March 1, 2016.
- (4) Incorporated by reference to Exhibit 5.03 of the Company's Form 8-K filed with the Commission on June 27, 2016.

* Filed herewith.

** Furnished herewith.

† Management contract or compensatory plan.

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 3, 2016 By: /s/ STEPHEN P. BROWN
Stephen P. Brown

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