

STAAR SURGICAL CO
Form 10-Q
November 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
ACT OF 1934**

For the quarterly period ended: September 30, 2016

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 40,609,093 shares of common stock, par value \$0.01 per share, issued and outstanding as of October 24, 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>	20
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)**

	September 30,	January 1,
	2016	2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 14,284	\$ 13,402
Accounts receivable trade, net of allowance for doubtful accounts of \$2,039 and \$1,877, respectively	14,372	15,675
Inventories, net	15,895	15,921
Prepayments, deposits and other current assets	4,649	3,636
Deferred income taxes	518	439
Total current assets	49,718	49,073
Property, plant and equipment, net	11,718	10,095
Intangible assets, net	607	666
Goodwill	1,786	1,786
Deferred income taxes	1,670	717
Other assets	835	617
Total assets	\$ 66,334	\$ 62,954
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Line of credit	\$ 4,941	\$ 4,159
Accounts payable	7,973	6,691
Deferred income taxes	370	370
Obligations under capital leases	398	362
Other current liabilities	7,568	6,305
Total current liabilities	21,250	17,887

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

Obligations under capital leases	1,676	204
Deferred income taxes	1,005	1,888
Asset retirement obligations	225	156
Deferred rent	68	87
Pension liability	4,380	3,886
Total liabilities	28,604	24,108
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Common stock, \$0.01 par value; 60,000 shares authorized; 40,607 and 39,887 shares issued and outstanding at September 30, 2016 and January 1, 2016, respectively	406	399
Additional paid-in capital	196,411	187,007
Accumulated other comprehensive loss	(145) (1,580)
Accumulated deficit	(158,942) (146,980)
Total stockholders' equity	37,730	38,846
Total liabilities and stockholders' equity	\$ 66,334	\$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		Nine Months Ended	
	September 30, 2016	October 2, 2015	September 30, 2016	October 2, 2015
Net sales	\$ 20,052	\$ 18,750	\$ 60,295	\$ 56,264
Cost of sales	5,180	5,951	17,804	18,206
Gross profit	14,872	12,799	42,491	38,058
General and administrative	4,985	4,853	18,378	14,748
Marketing and selling	7,149	6,284	22,006	17,784
Research and development	4,453	3,684	16,018	10,800
Total selling, general and administrative expenses	16,587	14,821	56,402	43,332
Operating loss	(1,715)	(2,022)	(13,911)	(5,274)
Other income (expense):				
Interest income		1	1	50
Interest expense	(29)	(29)	(86)	(97)
Gain (loss) on foreign currency transactions	(29)	20	13	(692)
Royalty income	134	224	507	375
Other income, net	(68)	43	(150)	62
Other income (expense), net	8	259	285	(302)
Loss before provision for income taxes	(1,707)	(1,763)	(13,626)	(5,576)
Provision (benefit) for income taxes	71	(11)	(1,664)	114
Net loss	\$(1,778)	\$(1,752)	\$(11,962)	\$(5,690)
Net loss per share – basic and diluted	\$(0.04)	\$(0.04)	\$(0.30)	\$(0.14)
Weighted average shares outstanding – basic and diluted	40,486	39,727	40,227	39,409

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended		Nine Months Ended	
	September	October	September	October
	30, 2016	2, 2015	30, 2016	2, 2015
Net loss	\$ (1,778)	\$ (1,752)	\$ (11,962)	\$ (5,690)
Other comprehensive income (loss):				
Defined benefit pension plans:				
Net change in plan assets	(11)	(9)	(34)	(27)
Reclassification into earnings	27	14	80	44
Foreign currency translation gain	232	288	2,000	54
Tax effect	(67)	(99)	(611)	(18)
Other comprehensive income, net of tax	181	194	1,435	53
Comprehensive loss	\$ (1,597)	\$ (1,558)	\$ (10,527)	\$ (5,637)

See accompanying notes to the condensed consolidated financial statements.

STAAR SURGICAL COMPANY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended	
	September 30, 2016	October 2, 2015
Cash flows from operating activities:		
Net loss	\$(11,962)	\$ (5,690)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation of property, plant and equipment	1,933	1,563
Amortization of intangibles	171	154
Deferred income taxes	(1,806)	(148)
Change in net pension liability	390	136
Stock-based compensation expense	8,143	2,747
Provision for sales returns and bad debts	99	331
Changes in working capital:		
Accounts receivable	1,707	(2,040)
Inventories, net	1,601	1,497
Prepayments, deposits and other current assets	(1,118)	737
Accounts payable	594	(991)
Other current liabilities	1,104	1,387
Net cash provided by (used in) operating activities	856	(317)
Cash flows from investing activities:		
Acquisition of property, plant and equipment	(2,709)	(1,283)
Cash proceeds from sale of property, plant and equipment	65	2
Net cash used in investing activities	(2,644)	(1,281)
Cash flows from financing activities:		
Repayment of capital lease obligations	(302)	(306)
Proceeds from sale-leaseback transactions	1,154	—
Repurchase of employee common stock for taxes withheld	(611)	—
Proceeds from exercise of stock options	1,652	2,149
Proceeds from exercise of warrants	—	2,800
Net cash provided by financing activities	1,893	4,643
Effect of exchange rate changes on cash and cash equivalents	777	23

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

Increase in cash and cash equivalents	882	3,068
Cash and cash equivalents, at beginning of the period	13,402	13,013
Cash and cash equivalents, at end of the period	\$ 14,284	\$ 16,081

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 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 August of 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2016-15, “Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments” (“ASU 2016-15”), which clarifies how companies present and classify certain cash receipts and cash payments in the statement of cash flows. ASU 2016-15 is effective for fiscal years beginning after December 15, 2017 and early adoption is permitted. The Company is currently evaluating the impact ASU 2016-15 will have on its consolidated financial statements.

In May 2016, the FASB issued 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.

STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

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.

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 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 does not expect the adoption of ASU 2015-17 will have a material impact on its consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, "Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern". ASU 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 does not expect the adoption of ASU 2014-15 will have a material impact on its financial statements.

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

During the three-month and nine-month periods ended October 2, 2015 the Company reclassified \$224,000 and \$375,000, respectively, from other income, net to royalty income 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):

	September 30, 2016	January 1, 2016
Raw materials and purchased parts	\$ 2,177	\$ 2,317
Work-in-process	2,099	1,995
Finished goods	15,714	15,058
	19,990	19,370
Less: inventory reserves	4,095	3,449
	\$ 15,895	\$ 15,921

Note 3 — Prepayments, Deposits, and Other Current Assets

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

	September 30, 2016	January 1, 2016
Prepayments and deposits	\$ 2,052	\$ 1,386
Income tax receivable	626	597
Consumption tax receivable	507	—
Value added tax (VAT) receivable	658	724
Deferred charges for foreign profits	182	182
Other current assets	624	747
	\$ 4,649	\$ 3,636

Note 4 — Property, Plant and Equipment

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

	September 30, 2016	January 1, 2016
Machinery and equipment	\$ 18,934	\$ 17,094
Furniture and fixtures	8,255	6,980
Leasehold improvements	9,238	8,611
	36,427	32,685
Less: accumulated depreciation	24,709	22,590
	\$ 11,718	\$ 10,095

Note 5 –Intangible Assets

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

	September 30, 2016			January 1, 2016		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Intangible assets:						
Patents and licenses	\$9,312	\$ (8,965) \$347	\$9,207	\$ (8,891) \$316
Customer relationships	1,550	(1,356) 194	1,305	(1,044) 261
Developed technology	985	(919) 66	829	(740) 89
Total	\$11,847	\$ (11,240) \$607	\$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):

	September 30, 2016	January 1, 2016
Accrued salaries and wages	\$ 2,452	\$ 1,909
Accrued bonuses	2,027	2,114
Consumption tax	482	157
Accrued insurance	144	540
Accrued audit fees	412	314
Other ⁽¹⁾	2,051	1,271
	\$ 7,568	\$ 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		Nine Months Ended	
	September 30, 2016	October 2, 2015	September 30, 2016	October 2, 2015
Service cost	\$ 155	\$ 108	\$ 466	\$ 322
Interest cost	19	19	54	57

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

Expected return on plan assets	(24)	(22)	(69)	(64)
Net amortization of transitional obligation (a)	3	3	10	8
Actuarial loss recognized in current period (a)	24	11	70	36
Total	\$ 177	\$ 119	\$ 531	\$ 359

(a) Amounts reclassified from accumulated other comprehensive loss.

During the nine months ended September 30, 2016 and October 2, 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 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		Nine Months Ended	
	September 30, 2016	October 2, 2015	September 30, 2016	October 2, 2015
Numerator:				
Net loss	\$(1,778)	\$(1,752)	\$(11,962)	\$(5,690)
Denominator:				
Weighted average common shares and denominator for basic and diluted calculation:				
Weighted average common shares outstanding	40,501	39,851	40,242	39,533
Less: Unvested restricted stock	(15)	(124)	(15)	(124)
Denominator for basic and diluted calculation	40,486	39,727	40,227	39,409
Net loss per share – basic and diluted	\$(0.04)	\$(0.04)	\$(0.30)	\$(0.14)

STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

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		Nine Months Ended	
	September 30, 2016	October 2, 2015	September 30, 2016	October 2, 2015
Options	2,134	2,615	2,937	2,446
Restricted stock and units	60	124	48	193
Warrants	—	—	—	345
Total	2,194	2,739	2,985	2,984

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, and the United States, the Company does not conduct business in any country in which its sales exceed 10% of consolidated sales. Sales are attributed to countries based on location of customers. The composition of the Company's net sales to unaffiliated customers is set forth below (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30, 2016	October 2, 2015	September 30, 2016	October 2, 2015
Japan	\$ 4,029	\$ 4,249	\$ 12,258	\$ 12,514
China	4,254	3,095	11,749	8,794
United States	2,419	2,873	7,355	8,464
Other	9,350	8,533	28,933	26,492
Total	\$ 20,052	\$ 18,750	\$ 60,295	\$ 56,264

Because 100% of the Company's sales are generated from the ophthalmic surgical product segment and the chief operating decision maker makes operating decisions and allocates resources based on consolidated operating results, the Company operates as one operating segment for financial reporting purposes. The Company's principal products are implantable Collamer lenses ("ICLs") used in refractive surgery and intraocular lenses ("IOLs") used in cataract

surgery. The composition of the Company's net sales by product line is as follows (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30, 2016	October 2, 2015	September 30, 2016	October 2, 2015
ICLs	\$ 14,801	\$ 12,907	\$ 43,389	\$ 37,396
IOLs	4,649	4,390	14,783	14,952
Other surgical products	602	1,453	2,123	3,916
Total	\$ 20,052	\$ 18,750	\$ 60,295	\$ 56,264

One customer, our distributor in China, accounted for 21% and 19%, of net sales for the three and nine months ended September 30, 2016, respectively, and 16% and 14% of net sales for the three and nine months ended October 2, 2015, respectively.

As of September 30, 2016, two customers, our distributors in China and Korea, accounted for 20% and 11% 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.

The Company sells its products internationally, which subjects the Company to several potential risks, including regional/country economic conditions and regulatory requirements, 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.

STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

Note 10 — Stock-Based Compensation

The cost that has been charged against income for stock-based compensation is set forth below (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30, 2016	October 2, 2015	September 30, 2016	October 2, 2015
Employee stock options	\$ 208	\$ 625	\$ 5,257	\$ 1,818
Restricted stock	32	88	259	396
Restricted stock units	146	210	2,569	484
Nonemployee stock options	—	—	58	49
Total	\$ 386	\$ 923	\$ 8,143	\$ 2,747

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

	Three Months Ended		Nine Months Ended	
	September 30, 2016	October 2, 2015	September 30, 2016	October 2, 2015
Cost of sales	\$ —	\$ 9	\$ 560	\$ 33
General and administrative	248	543	3,936	1,667
Marketing and selling	72	184	1,544	539
Research and development	66	187	2,103	508
Total stock compensation expense	386	923	8,143	2,747
Amounts capitalized as part of inventory	39	130	227	258
Total	\$ 425	\$ 1,053	\$ 8,370	\$ 3,005

Stock Option Plan

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 3,614,370 shares were outstanding at September 30, 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 23,140 shares of restricted stock and 266,050 restricted stock units (RSUs) outstanding at September 30, 2016. As of September 30, 2016, there were 2,222,972 shares authorized and available for grants under the Plan.

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 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 RSUs). This charge was recorded and included in the following categories of the condensed consolidated statements of operations for the nine months ended September 30, 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-based compensation by the Company during fiscal year 2016 after the Change in Control provision was triggered.

STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

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				Nine Months Ended			
	September 30, 2016		October 2, 2015		September 30, 2016		October 2, 2015	
Expected dividend yield	0	%	0	%	0	%	0	%
Expected volatility	57	%	58	%	57	%	57	%
Risk-free interest rate	1.19	%	1.60	%	1.34	%	1.61	%
Expected term (in years)	5.57		5.62		5.57		5.61	

A summary of option activity under the Plan for the nine-month period ended September 30, 2016 is presented below:

	Options Shares (000's)
Outstanding at January 1, 2016	3,623
Granted	761
Exercised	(424)
Forfeited or expired	(346)
Outstanding at September 30, 2016	3,614
Exercisable at September 30, 2016	2,968

A summary of restricted stock and restricted stock unit's activity under the Plan for the nine-month period ended September 30, 2016 is presented below:

	Restricted Shares (000's)	Restricted Units (000's)
Outstanding at January 1, 2016	124	339
Granted	23	313
Exercised	(124)	(380)
Forfeited	—	(6)
Outstanding at September 30, 2016	23	266

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.

The \$1.7 million income tax benefit recorded during the first nine 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 nine months ended October 2, 2015, the Company recorded an income tax provision of \$114,000, 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.

STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

Note 12 - Commitments and Contingencies

Lines of Credit and Guarantee

The Company's wholly owned Japanese subsidiary, STAAR Japan, has an agreement, dated 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 September 30, 2016), at an interest rate equal to the Tokyo short-term prime interest rate (approximately 1.475% as of September 30, 2016). The line of credit, as most recently amended, expires September 30, 2017 and is renewable annually. The Company had 500,000,000 Yen outstanding on the line of credit as of September 30, 2016 and January 1, 2016 (approximately \$4.9 million and \$4.2 million based on the foreign currency exchange rates on September 30, 2016 and January 1, 2016, respectively). As of September 30, 2016, there were no available borrowings under the line.

In August 2010, the Company's wholly owned Swiss subsidiary, STAAR Surgical AG, entered into a credit agreement with Credit Suisse (the "Bank"). The credit agreement provides for borrowing of up to 1,000,000 CHF (Swiss Francs) (approximately \$1.0 million at the rate of exchange on September 30, 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 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 agreement. There were no borrowings outstanding as of September 30, 2016 and January 1, 2016.

On June 7, 2016, the Company entered into a schedule of an existing master lease agreement with Farnam Street Financial, Inc. that 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 September 30, 2016, approximately \$1.4 million of the line was used including a sale-leaseback transaction resulting in net proceeds to the Company of \$1.2 million. Approximately \$0.6 million of the line is available for future transactions.

Covenant Compliance

The Company believes it 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 claims. 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 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.

Stockholder Securities Litigation: Todd Action

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 August 19, 2016, plaintiff filed a Motion for Class Certification, which the court scheduled for hearing on December 12, 2016. 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 September 30, 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.

STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

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. On August 15, 2016, the Company as nominal defendant filed a Motion to Dismiss, which the court scheduled for hearing on December 5, 2016. 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 September 30, 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 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, 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 condensed 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 the third 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, Germany, the U.K. and Spain, and independent distribution in the remainder of the world. STAAR maintains operational and administrative facilities in the U.S., Switzerland and Japan. We also maintain offices in Germany, Spain, and China.

Recent Developments and Strategic Priorities for 2016

In the third quarter of 2016, worldwide ICL revenues increased 14.7% compared to the prior year quarter. In the regional markets, Asia Pacific ICL revenues increased 28.5% and units increased 29.5%; Europe, Middle East and Africa ICL revenues increased 6.2% and units increased 4.4%; and North America ICL revenues decreased 13.0% and units decreased 19.5%. Worldwide ICL units grew 15.3% compared to the prior year quarter. In regional markets, compared to the prior year quarter, Asia Pacific IOL revenues increased 11.8% and units decreased by 7.4%; and North America IOL revenues decreased 18.5% and units decreased by 16.6%. Worldwide IOL units declined 2.6% compared to prior year quarter driven by decreased U.S. sales. Overall third quarter of 2016 net sales were \$20.1 million, a 6.9% increase over the third quarter of 2015.

During the third quarter, we entered into new strategic cooperation agreements with leading providers in South East Europe and India. 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.

On September 21, 2016, we were notified that the Medical Devices Bureau of Health Canada approved for distribution in Canada the toric version of 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 MasterControl Quality Management System;

2. **Creating the Visual Freedom Market for Implantable Lenses:** We seek to 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. During the third quarter, we reported record global ICL unit sales;

3. **Beginning 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:** We are expanding our R&D team, upgrading our labs and testing apparatus, and focusing on our research and development priorities. During the third quarter and continuing in the fourth quarter, we are implanting EVO+ Visian ICLs with EDOF (extended depth of field), in the first human subjects. The initial results are positive and the clinical study for these lenses continues.

Immediate Vesting of All Unvested Equity Awards

See Note 10 of the Condensed Consolidated Financial Statements.

Critical Accounting Policies

This Management's Discussion and Analysis of Financial Condition and Results of Operations discusses and analyzes data in our unaudited Condensed Consolidated Financial Statements, which we have prepared in accordance with U.S.

generally accepted accounting principles. Preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. Management bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Senior management has discussed the development, selection and disclosure of these estimates with the Audit Committee of our Board of Directors. Actual conditions may differ from our assumptions and actual results may differ from our estimates.

An accounting policy is deemed critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, if different estimates reasonably could have been used, or if changes in the estimate that are reasonably likely to occur could materially impact the financial statements. Management believes that there have been no significant changes during the nine months ended September 30, 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.

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 Nine Months			
	September 30, 2016		October 2, 2015		September 30, 2016		October 2, 2015	
Net sales	100.0	%	100.0	%	100.0	%	100.0	%
Cost of sales	25.8		31.7		29.5		32.4	
Gross profit	74.2		68.3		70.5		67.6	
General and administrative	24.9		25.9		30.5		26.2	
Marketing and selling	35.7		33.5		36.5		31.6	
Research and development	22.2		19.6		26.6		19.2	
	82.8		79.0		93.6		77.0	
Operating loss	(8.6)	(10.7)	(23.1)	(9.4)
Other income (expense), net	0.2		1.3		0.5		(0.5)
Loss before provision (benefit) for income taxes	(8.4)	(9.4)	(22.6)	(9.9)
Provision (benefit) for income taxes	0.4		(0.1)	(2.8)	0.2	
Net loss	(8.8)%	(9.3)%	(19.8)%	(10.1)%

Net Sales

	Three Months Ended		Percentage Change	Nine Months Ended		Percentage Change		
	September 30, 2016	October 2, 2015		September 30, 2016	October 2, 2015			
Net sales	\$ 20,052	\$ 18,750	6.9	%	\$ 60,295	\$ 56,264	7.2	%
ICL	14,801	12,907	14.7		43,389	37,396	16.0	
IOL	4,649	4,390	5.9		14,783	14,952	(1.1)
Other	602	1,453	(58.6)	2,123	3,916	(45.8)

Net sales for the three months ended September 30, 2016 were \$20.1 million, an increase of 6.9% compared with \$18.8 million reported during the same period of 2015. Net sales for the nine months ended September 30, 2016 were \$60.3 million, an increase of 7.2% compared with \$56.3 million reported during the same period of 2015. The effect of exchange rate changes of the Japanese Yen had a favorable impact on net sales of \$0.6 million and \$1.2 million,

respectively, during the three and nine months ended September 30, 2016.

Total ICL sales for the three months ended September 30, 2016 were \$14.8 million, an increase of 14.7% compared with \$12.9 million reported during the same period of 2015. APAC ICL sales were \$8.2 million during the third quarter, an increase of 28.5% compared to the prior year period, due to a 29.5% increase in units, driven by a 42.2% increase in China sales. EMEA ICL sales were \$5.1 million during the third quarter, an increase of 6.2% compared to the prior year period, with an increase of 4.4% in units. North America ICL sales were \$1.5 million during the third quarter, a decrease of 13.0% and a decrease of 19.5% in units compared to the prior year period.

Total ICL sales for the nine months ended September 30, 2016 and October 2, 2015 were \$43.4 million and \$37.4 million, respectively, an increase of 16.0%. The sales increase was driven by higher ICL unit sales in APAC and EMEA, partially offset by a decrease in NA sales.

Total IOL sales for the three months ended September 30, 2016 were \$4.6 million, an increase of 5.9% compared with \$4.4 million reported during the same period of 2015. Total IOL sales for the nine months ended September 30, 2016 were \$14.8 million, a 1.1% decrease compared with \$15.0 million reported during the same period in 2015. The decline for both the three and nine-month periods was due to a planned phase-out of IOL sales in China, and decreased IOL sales in the U.S. due to the discontinuance of the silicone IOL product line, partially offset by the favorable impact of foreign exchange on sales of \$0.5 million and \$0.9 million, respectively, for the three and nine months ended September 30, 2016. The Company expects U.S. silicone IOL sales will continue to decline in the fourth quarter of 2016, and we plan to cease selling them at the end of the fourth quarter of 2016. Although programs are in place to convert silicone IOL accounts to our NanoFLEX IOL, we can give no assurance these programs will be successful. The Company will continue to sell pre-loaded silicone IOLs internationally. Preloaded IOL sales represented 80% of the Company's IOL sales in the first nine months of 2016, compared to 77% in the first nine months of 2015.

Other product sales for the three and nine months ended September 30, 2016 were \$0.6 million and \$2.1, respectively, a decrease of 58.6% and 45.8%, respectively, compared with the \$1.5 million and \$3.9 million, respectively, reported during the same period of 2015. The decrease in other product sales is due to a decrease in injector part sales largely related to the repair and replacement at no charge to STAAR of allegedly defective injectors manufactured by our third-party manufacturer and previously sold by STAAR.

Gross Profit

	Three Months Ended		Percentage Change vs. 2015	Nine Months Ended		Percentage Change vs. 2015	
	September 30, 2016	October 2, 2015		September 30, 2016	October 2, 2015		
Gross Profit	\$14,872	\$12,799	16.2	% \$42,491	\$38,058	11.6	%
Gross Profit Margin	74.2	% 68.3	%	70.5	% 67.6	%	

Gross profit for the third quarter was \$14.9 million, or 74.2% of revenue, compared with \$12.8 million, or 68.3% of revenue, in the prior year period. We attribute improved margins to an increased mix of higher margin ICL units, lower ICL unit costs, partially offset by higher IOL unit costs and other cost of sales and lower inventory reserves.

During the first nine months of 2016, gross profit was \$42.5 million, or 70.5% of net sales, compared with \$38.1 million, or 67.6% of net sales, in the prior year period. The increase in gross margin for the first nine months of 2016 is due to an increased mix of higher margin ICL units, higher average selling prices, and partially offset by the \$0.6 million non-cash charge related to the immediate vesting of all unvested equity awards because of the triggering of "Change of Control" provision of the Company's equity incentive plan.

General and Administrative

	Three Months Ended		Percentage Change 2016 vs. 2015	Nine Months Ended		Percentage Change 2016 vs. 2015	
	September 30, 2016	October 2, 2015		September 30, 2016	October 2, 2015		
General and Administrative	\$ 4,985	\$ 4,853	2.7	% \$18,378	\$ 14,748	24.6	%
Percentage of Net Sales	24.9	% 25.9	%	30.5	% 26.2	%	

General and administrative expenses for the quarter ended September 30, 2016 were \$5.0 million, an increase of 2.7% when compared with \$4.9 million reported for the same period last year. The increase was primarily due to the unfavorable impact of the Japanese yen on expenses.

General and administrative expenses for the nine months ended September 30, 2016 were \$18.4 million, an increase of 24.6% when compared with \$14.7 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 because of the triggering of the “Change of Control” provision of the Company’s equity incentive plan, local taxes in Japan, and the unfavorable impact of the Japanese yen on expenses.

Marketing and Selling

	Three Months Ended		Percentage Change 2016 vs. 2015	Nine Months Ended		Percentage Change 2016 vs. 2015	
	September 30, 2016	October 2, 2015		September 30, 2016	October 2, 2015		
Marketing and Selling	\$ 7,149	\$ 6,284	13.8	% \$22,006	\$ 17,784	23.7	%
Percentage of Net Sales	35.7	% 33.5	%	36.5	% 31.6	%	

Marketing and selling expenses for the quarter ended September 30, 2016 were \$7.1 million, an increase of 13.8% when compared with \$6.3 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 nine months ended September 30, 2016 were \$22.0 million, an increase of 23.7% when compared with \$17.8 million reported for the same period last year. The increase was primarily due to a \$1.5 million non-cash charge related to the immediate vesting of all unvested equity awards because 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 and increased international selling and promotional costs, partially offset by the optimization of North American selling costs.

Research and Development

	Three Months Ended		Percentage Change 2016 vs. 2015	Nine Months Ended		Percentage Change 2016 vs. 2015
	September 30, 2016	October 2, 2015		September 30, 2016	October 2, 2015	
Research and Development	\$ 4,453	\$ 3,684	20.9	\$ 16,018	\$ 10,800	48.3
Percentage of Net Sales	22.2	% 19.6	%	26.6	% 19.2	%

Research and development expenses for the quarter ended September 30, 2016 were \$4.5 million, an increase of 20.9% when compared with \$3.7 million reported last year. The increase was primarily due to increased costs related to quality system improvements, including increased headcount, and investments in clinical affairs and product development, partially offset by a decrease in FDA remediation expenses.

Research and development expense for the nine months ended September 30, 2016 were \$16.0 million, an increase of 48.3%, when compared with \$10.8 million reported in the same period last year. The increase was 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 and increased costs related to quality system improvements including increased headcount, and investments in clinical affairs and product development, 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, costs of intellectual property protection and the regulatory, quality, 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	Nine Months Ended	Percentage Change
--	--------------------	----------------------	-------------------	----------------------

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

	September 30, 2016	October 2, 2015	2016 vs. 2015	September 30, 2016	October 2, 2015	2016 vs. 2015	
Other Income (Expense), Net	\$ 8	\$ 259	(96.9)%	\$ 285	\$ (302)		—*

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

The year over year change in other income (expense), net for the three and nine-month period is primarily due to changes in foreign currency gains and losses and royalty income.

Income Taxes

	Three Months Ended		Percentage Change	Nine Months Ended		Percentage Change
	September 30, 2016	October 2, 2015	2016 vs. 2015	September 30, 2016	October 2, 2015	2016 vs. 2015
Provision (benefit) for income taxes	\$ 71	\$ (11)	—*	\$ (1,664)	\$ 114	—*

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

We recorded an income tax benefit of \$1.7 million and a provision for income taxes of \$114,000, respectively, for the nine months ended September 30, 2016 and October 2, 2015. The income tax benefit for the nine months ended September 30, 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.

The provision (benefit) for income taxes is determined using an estimated annual effective tax rate. 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. 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 flows from operating activities will be sufficient to meet its working capital requirements for the foreseeable future, including the approximate \$2 million cost in 2016 associated with our FDA remediation efforts, of which \$1.5 million was incurred in the first nine months of 2016. Although we anticipate these costs will continue, we cannot currently estimate the amount but will provide an 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.

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 September 30, 2016, and January 1, 2016, respectively, STAAR had \$14.3 million and \$13.4 million, of cash and cash equivalents, respectively.

Net cash provided by operating activities was \$0.9 million for the nine months ended September 30, 2016 and net cash used by operating activities was \$0.3 million for the nine months ended October 2, 2015. The net cash provided by operating activities for the nine months ended September 30, 2016, consisted of the net loss of \$12.0 million, plus \$8.9 million in non-cash items and \$3.9 million increase in net working capital.

Net cash used in investing activities was \$2.6 million for the nine months ended September 30, 2016, compared to \$1.3 million in net cash used in investing activities for the nine months ended October 2, 2015. Net cash used in investing activities was primarily due to the acquisition of property, plant and equipment.

Net cash provided by financing activities was \$1.9 million for the nine months ended September 30, 2016, compared with \$4.6 million in net cash provided by financing activities for the nine months ended October 2, 2015. Cash provided by financing activities resulted from the proceeds of sale-leaseback transactions of \$1.2 million and exercises of stock options of \$1.7 million, partially offset by the repurchase of employee common stock for taxes withheld of \$0.6 million and repayment of capital lease obligations of \$0.3 million.

Credit Facilities and Commitments

Lines of Credit and Guarantee

See Note 12 of the accompanying Condensed Consolidated Financial Statements.

Covenant Compliance

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

Employment Agreements

See Note 12 of the accompanying Condensed Consolidated Financial Statements.

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 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 STAAR Surgical Company and its subsidiaries (the "Company"). Based on that evaluation, our CEO and CFO concluded, as of the end of the period covered by this quarterly report on Form 10-Q, that our disclosure controls and procedures were effective. For purposes of this statement, the term "disclosure controls and procedures" means controls and other procedures of the Company that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act (15 U.S.C. 78a et seq.) is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Our management, including the CEO and the CFO, do not expect that our disclosure controls and procedures or our internal control over financial reporting will necessarily prevent all fraud or material errors. An internal control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are

resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations on all internal control systems, our internal control system can provide only reasonable assurance of achieving its objectives and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of internal control is also based in part upon certain assumptions about the likelihood of future events, and can provide only reasonable, not absolute, assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in circumstances, or the degree of compliance with the policies and procedures may deteriorate.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 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

Litigation and Claims

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

None.

ITEM 6. EXHIBITS

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

3.2 Amended and Restated By-laws. (2)

4.4 Form of Certificate for Common Stock, par value \$0.01 per share. (3)

†4.5 Amended and Restated STAAR Surgical Company Omnibus Equity Incentive Plan, effective February 25, 2016.
(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

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

Certification Pursuant to 18 U.S.C. Section 1350, Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. **

101 Financial statements from the quarterly report on Form 10-Q of STAAR Surgical Company for the quarter ended September 30, 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 the Company's Current Report on Form 8-K filed with the Commission on June 11, 2014.

(2) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Commission on June 27, 2016.

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

(4) Incorporated by reference to Appendix 1 of the Company's Proxy Statement filed on May 2, 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: November 3, 2016 By: /s/ STEPHEN P. BROWN

Stephen P. Brown

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