

STAAR SURGICAL CO
Form 10-Q
August 02, 2017

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: June 30, 2017

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

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

(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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

<input type="checkbox"/> Large accelerated filer	<input checked="" type="checkbox"/> Accelerated filer	<input type="checkbox"/> Non-accelerated filer (Do not check if a smaller reporting company)	<input type="checkbox"/> Smaller reporting company
<input type="checkbox"/> Emerging growth company			

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

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 41,108,776 shares of common stock, par value \$0.01 per share, issued and outstanding as of July 24, 2017.

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>	20
Item 4. <u>Mine Safety Disclosures.</u>	20
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)**

	June 30, 2017	December 30, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$13,438	\$ 13,999
Accounts receivable trade, net of allowance for doubtful accounts of \$2,136 and \$2,056, respectively	16,426	16,344
Inventories, net	13,458	14,825
Prepayments, deposits and other current assets	4,474	4,349
Total current assets	47,796	49,517
Property, plant and equipment, net	11,619	11,790
Intangible assets, net	383	473
Goodwill	1,786	1,786
Deferred income taxes	1,104	1,105
Other assets	948	772
Total assets	\$63,636	\$ 65,443
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Line of credit	\$4,460	\$ 4,283
Accounts payable	6,917	8,311
Obligations under capital leases	1,252	1,198
Other current liabilities	6,353	7,275
Total current liabilities	18,982	21,067
Obligations under capital leases	1,128	1,339
Deferred income taxes	889	881
Asset retirement obligations	203	195

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

Deferred rent	61	59
Pension liability	4,080	3,997
Total liabilities	25,343	27,538

Commitments and contingencies (Note 12)

Stockholders' equity:

Common stock, \$0.01 par value; 60,000 shares authorized; 41,109 and 40,732 shares issued and outstanding at June 30, 2017 and December 30, 2016, respectively	411	407
Additional paid-in capital	200,921	197,657
Accumulated other comprehensive loss	(756)	(1,050)
Accumulated deficit	(162,283)	(159,109)
Total stockholders' equity	38,293	37,905
Total liabilities and stockholders' equity	\$63,636	\$ 65,443

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	
	June 30,	July 1,	June 30,	July 1,
	2017	2016	2017	2016
Net sales	\$ 21,936	\$ 20,974	\$42,286	\$40,243
Cost of sales	6,462	6,348	12,235	12,624
Gross profit	15,474	14,626	30,051	27,619
General and administrative	4,761	4,928	10,120	13,393
Marketing and selling	7,321	7,181	13,851	14,856
Research and development	4,712	4,659	9,495	11,565
Total selling, general and administrative expenses	16,794	16,768	33,466	39,814
Operating loss	(1,320)	(2,142)	(3,415)	(12,195)
Other income (expense):				
Interest expense, net	(32)	(29)	(61)	(57)
Gain (loss) on foreign currency transactions	380	(416)	294	42
Royalty income	128	351	259	373
Other income (expense), net	19	(38)	36	(82)
Other income (expense), net	495	(132)	528	276
Loss before provision (benefit) for income taxes	(825)	(2,274)	(2,887)	(11,919)
Provision (benefit) for income taxes	146	(131)	287	(1,735)
Net loss	\$(971)	\$(2,143)	\$(3,174)	\$(10,184)
Net loss per share – basic and diluted	\$(0.02)	\$(0.05)	\$(0.08)	\$(0.25)
Weighted average shares outstanding – basic and diluted	40,933	40,210	40,841	40,097

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	
	June 30, 2017	July 1, 2016	June 30, 2017	July 1, 2016
Net loss	\$ (971)	\$ (2,143)	\$ (3,174)	\$ (10,184)
Other comprehensive income (loss):				
Defined benefit pension plans:				
Net change in plan assets	(14)	(12)	(28)	(23)
Reclassification into earnings	20	26	40	53
Foreign currency translation gain (loss)	(37)	1,036	411	1,768
Tax effect	12	(316)	(123)	(544)
Other comprehensive income (loss), net of tax	(19)	734	300	1,254
Comprehensive loss	\$ (990)	\$ (1,409)	\$ (2,874)	\$ (8,930)

See accompanying notes to the condensed consolidated financial statements.

STAAR SURGICAL COMPANY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Six Months Ended	
	June 30, 2017	July 1, 2016
Cash flows from operating activities:		
Net loss	\$(3,174)	\$ (10,184)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property, plant and equipment	1,548	1,237
Amortization of long-lived intangibles	110	111
Deferred income taxes	9	(1,802)
Change in net pension liability	30	220
Loss on disposal of property and equipment	72	17
Stock-based compensation expense	1,378	7,758
Provision for sales returns and bad debts	66	89
Inventory provision	789	1,182
Changes in working capital:		
Accounts receivable trade	(21)	(65)
Inventories	908	431
Prepayments, deposits and other current assets	(278)	(418)
Accounts payable	(1,767)	1,280
Other current liabilities	(961)	(324)
Net cash used in operating activities	(1,291)	(468)
Cash flows from investing activities:		
Acquisition of property and equipment	(696)	(1,991)
Net cash used in investing activities	(696)	(1,991)
Cash flows from financing activities:		
Repayment of capital lease obligations	(661)	(184)
Proceeds from sale leaseback transactions		1,154
Repurchase of employee common stock for taxes withheld	(234)	(611)
Proceeds from vested restricted stock and exercise of stock options	1,963	737
Net cash provided by financing activities	1,068	1,096
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	359	649

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

Decrease in cash, cash equivalents, and restricted cash	(560)	(714)
Cash, cash equivalents, and restricted cash, at beginning of the period	14,118	13,521
Cash, cash equivalents, and restricted cash, at end of the period	\$13,558	\$ 12,807

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 December 30, 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 December 30, 2016.

The condensed consolidated financial statements for the three and six months ended June 30, 2017 and July 1, 2016, in the opinion of management, include all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the Company’s financial condition and results of operations. The results of operations for the three and six months ended June 30, 2017 and July 1, 2016, 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.

Recently Adopted Accounting Pronouncements

During the quarter ended March 31, 2017, the Company adopted Financial Accounting Standards Board (“FASB”) Accounting Standards Update (“ASU”) 2015-11, “Simplifying the Measurement of Inventory”. ASU 2015-11 requires a company to measure inventory at the lower of cost and net realizable value. Net realizable value is defined as the “estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation”. We adopted this standard as of December 31, 2016 (beginning of FY 2017). The adoption of ASU

2015-11 did not have a material effect on the consolidated financial statements.

During the quarter ended March 31, 2017, the Company adopted ASU 2016-09, “Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting”, which simplified 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. We adopted this standard as of December 31, 2016 (beginning of FY 2017). The adoption of ASU 2016-09 did not have a material effect on the consolidated financial statements and prior periods were not restated.

During the quarter ended March 31, 2017, the Company adopted ASU 2015-17, “Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes”, on a retrospective basis, which changes how deferred taxes are classified on the Company’s balance sheets. Accordingly, the Company adjusted the December 30, 2016 balance sheet for current and noncurrent deferred tax assets to conform to the presentation for the current quarter due to the adoption of ASU 2015-17. The ASU eliminates the requirement to present deferred tax liabilities and assets as current and noncurrent on the balance sheet. Instead, companies are required to classify all deferred tax assets and liabilities as noncurrent. We adopted this standard as of December 31, 2016 (beginning of FY 2017). The adoption of ASU 2015-17 did not have a material effect on the consolidated financial statements.

During the quarter ended March 31, 2017, the Company adopted ASU 2016-18, “Statement of Cash Flows (Topic 230): Restricted Cash”, that requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents, and restricted cash and that restricted cash be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. We early adopted this standard as of December 31, 2016 (beginning of FY 2017). The adoption of ASU 2016-18 did not have a material effect on the consolidated financial statements, however, prior period restricted cash was added to beginning and ending cash and cash equivalents in the statement of cash flows to conform to the current presentation.

STAAR SURGICAL COMPANY**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the condensed consolidated balance sheets that sum to the total of the same such amounts shown in the condensed consolidated statement of cash flows (in 000's):

	June 30, 2017	December 30, 2016	July 1, 2016	January 1, 2016
Cash and cash equivalents	\$ 13,438	\$ 13,999	\$ 12,688	\$ 13,402
Restricted cash included in other long-term assets	120	119	119	119
Total cash, cash equivalents, and restricted cash as shown in the statement of cash flows	\$ 13,558	\$ 14,118	\$ 12,807	\$ 13,521

The Company has restricted cash of approximately \$120,000 set aside as collateral for a standby letter of credit required by the California Department of Public Health for unforeseen future regulatory costs related to the decommissioning of certain manufacturing equipment.

Recent Accounting Pronouncements Not Yet Adopted

In May 2017, the FASB issued ASU 2017-09 "Scope of Modification Accounting," which amends the scope of modification accounting for share-based payment arrangements, provides guidance on the types of changes to the terms or conditions of share-based payment awards to which an entity would be required to apply modification accounting under ASC 718. For all entities, the ASU is effective for annual reporting periods, including interim periods within those annual reporting periods, beginning after December 15, 2017, and thereafter. Early adoption is permitted, including adoption in any interim period. We will adopt this standard as of December 30, 2017 (beginning of FY 2018) and do not expect the adoption of the standard will have a material impact on our consolidated financial statements.

In 2017, the FASB issued ASU No. 2017-07, "Compensation-Retirement Benefits (Topic 715), Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost." The standard requires that an

employer report the service cost component in the same line items as other compensation costs arising from services rendered by the pertinent employees during the period. The other components of net benefit cost are required to be presented in the income statement separately from the service cost component and outside of operating profit. The standard is effective for public companies for annual periods beginning after December 15, 2017, including interim periods within those annual periods. Prior periods are required to be recast. We will adopt this standard as of December 30, 2017 (beginning of FY 2018) and are currently evaluating the impact ASU 2017-07 may have on our consolidated financial statements.

In 2016, the FASB issued ASU No. 2016-16, “Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory”, which removes the prohibition in ASC 740 against the immediate recognition of the current and deferred income tax effects of intra-entity transfers of assets other than inventory. The ASU is effective for public companies for fiscal years beginning after December 15, 2017, and interim periods within those annual periods. The ASU should be applied on a modified retrospective basis, recognizing the effects in retained earnings as of the beginning of the year of adoption. We will adopt this standard as of December 30, 2017 (beginning of FY 2018) and are currently evaluating the impact ASU 2016-16 may have on our consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04, “Intangibles—Goodwill and Other (Topic 350)”, which simplifies the test for goodwill impairment. ASU 2017-04 is effective for annual or any interim goodwill impairment tests in fiscal years beginning after December 15, 2019. The Company does not expect ASU 2017-04 to have a material effect on the consolidated financial statements.

In August 2016, the FASB issued 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 may 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 gathering data to evaluate the impact the adoption of ASU 2016-02 may have on its consolidated financial statements and expects to complete the evaluation by the third quarter of 2018.

STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

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).

In August 2015, ASU 2014-09 was amended by ASU No. 2015-14, “Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date”, which defers the effective date of ASU 2014-09 by one year for all entities and permits early adoption on a limited basis. ASU 2014-09 was subsequently amended by four additional pronouncements: (i) ASU No. 2016-10, “Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing;” (ii) ASU No. 2016-11, “Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815): Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting”; (iii) ASU No. 2016-12, “Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients”; and (iv) ASU No. 2016-20, “Revenue from Contracts with Customers (Topic 606): Technical Corrections and Improvements to Topic 606”.

The Company commenced an assessment of the standard during the second quarter of 2016. The assessment included analyzing the standard’s impact on the Company’s contract portfolio, comparing its historical accounting policies and practices to the requirements of the new standard, and identifying potential differences in the application of the new standard to its contracts. Based on its initial analysis, the adoption of ASU 2014-09 is not anticipated to have a material impact on the Company’s consolidated financial position, results of operations, equity or cash flows. The Company expects to complete its assessment by the end of the third quarter of 2017, and expects to apply the Modified Retrospective transition method.

Note 2 — Inventories

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

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

	June 30, 2017	December 30, 2016
Raw materials and purchased parts	\$2,210	\$ 2,264
Work-in-process	2,139	1,924
Finished goods	11,611	14,268
	15,960	18,456
Less: inventory reserves	2,502	3,631
	\$13,458	\$ 14,825

Note 3 — Prepayments, Deposits, and Other Current Assets

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

	June 30, 2017	December 30, 2016
Prepayments and deposits	\$ 1,366	\$ 1,003
Prepaid insurance	901	935
Income tax receivable	388	686
Consumption tax receivable	192	573
Value added tax (VAT) receivable	796	668
Pension benefit prepayment	226	
Other current assets ⁽¹⁾	605	484
	\$ 4,474	\$ 4,349

⁽¹⁾ No individual item in “Other current assets” above exceeds 5% of the total prepayments, deposits, and other current assets.

STAAR SURGICAL COMPANY**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)****Note 4 — Property, Plant and Equipment**

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

	June 30, 2017	December 30, 2016
Machinery and equipment	\$ 18,881	\$ 19,807
Furniture and fixtures	9,676	8,025
Leasehold improvements	9,611	9,179
	38,168	37,011
Less: accumulated depreciation	26,549	25,221
	\$ 11,619	\$ 11,790

Note 5 — Intangible Assets

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

	June 30, 2017			December 30, 2016		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Long-lived intangible assets:						
Patents and licenses	\$ 9,248	\$ (8,959)) \$ 289	\$ 9,224	\$ (8,930)) \$ 294
Customer relationships	1,399	(1,329)) 70	1,343	(1,209)) 134
Developed technology	889	(865)) 24	854	(809)) 45
Total	\$ 11,536	\$ (11,153)) \$ 383	\$ 11,421	\$ (10,948)) \$ 473

Note 6 — Other Current Liabilities

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

	June 30, 2017	December 30, 2016
Accrued salaries and wages	\$ 2,757	\$ 2,334
Accrued bonuses	1,173	1,414
Accrued consumption tax	218	424
Accrued insurance	429	501
Accrued income taxes	353	1,095
Other ⁽¹⁾	1,423	1,507
	\$ 6,353	\$ 7,275

⁽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.

STAAR SURGICAL COMPANY**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

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	
	June 30, 2017	July 1, 2016	June 30, 2017	July 1, 2016
Service cost	\$ 127	\$ 155	\$ 254	\$ 309
Interest cost	14	18	28	36
Expected return on plan assets	(24)	(23)	(47)	(45)
Net amortization of transitional obligation (a)	3	3	6	6
Actuarial loss recognized in current period (a)	17	23	34	47
Total	\$ 137	\$ 176	\$ 275	\$ 353

(a) Amounts reclassified from accumulated other comprehensive loss.

During the six months ended June 30, 2017 and July 1, 2016, the Company made cash contributions of approximately \$501,000 and \$419,000, respectively, to its Swiss pension plan and the Company is not required to make additional cash contributions during the remainder of 2017. The Company currently is not required to and does not make contributions to its Japan pension plan.

Note 8 — Basic and Diluted Loss Per Share

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

Three Months Ended		Six Months Ended	
June 30, 2017	July 1, 2016	June 30, 2017	July 1, 2016

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

Numerator:				
Net loss				
Denominator:				
Weighted average common shares outstanding	40,954	40,225	40,862	40,112
Less: Unvested restricted stock	21	15	21	15
Denominator for basic and diluted calculation	40,933	40,210	40,841	40,097
Net loss per share – basic and diluted				

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	
	June 30, 2017	July 1, 2016	June 30, 2017	July 1, 2016
Options	3,225	3,199	2,953	2,994
Restricted stock and units	111	258	144	188
Total	3,336	3,457	3,097	3,182

Note 9 — Geographic and Product Data

The Company markets and sells its products in over 60 countries and conducts its manufacturing 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 worldwide consolidated sales. Sales are generally 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	
	June 30, 2017	July 1, 2016	June 30, 2017	July 1, 2016
China	\$ 5,862	\$ 4,417	\$ 10,325	\$ 7,495
Japan	4,417	3,989	8,216	8,229
United States	2,092	2,420	4,050	4,936
Other	9,565	10,148	19,695	19,583
Total	\$ 21,936	\$ 20,974	\$ 42,286	\$ 40,243

STAAR SURGICAL COMPANY**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

100% of the Company's sales are generated from the ophthalmic surgical product segment, and therefore the Company operates as one operating segment for financial reporting purposes. The Company's principal products are implantable Collamer lenses ("ICLs") used in refractive surgery and intraocular lenses ("IOLs") used in cataract surgery. The composition of the Company's net sales by product line is as follows (in thousands):

	Three Months Ended		Six Months Ended	
	June 30, 2017	July 1, 2016	June 30, 2017	July 1, 2016
ICLs	\$ 16,317	\$ 15,408	\$ 31,588	\$ 28,588
IOLs	4,377	5,068	8,983	10,134
Other surgical products	1,242	498	1,715	1,521
Total	\$ 21,936	\$ 20,974	\$ 42,286	\$ 40,243

One customer, our distributor in China, accounted for 27% and 24% of net sales for the three and six months ended June 30, 2017, respectively, and the same customer accounted for 21% and 19% of net sales for the three and six months ended July 1, 2016, respectively. As of June 30, 2017 and December 30, 2016, respectively, one customer, our distributor in China, accounted for 30% and 22% 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	
	June 30, 2017	July 1, 2016	June 30, 2017	July 1, 2016
Employee stock options	\$ 493	\$ 153	\$ 761	\$ 5,049
Restricted stock	46	2	86	227
Restricted stock units	329	145	531	2,423
Nonemployee stock options				59
Total	\$ 868	\$ 300	\$ 1,378	\$ 7,758

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	
	June 30, 2017	July 1, 2016	June 30, 2017	July 1, 2016
Cost of sales	\$2	\$	\$4	\$560
General and administrative	394	167	658	3,688
Marketing and selling	228	68	344	1,471
Research and development	244	65	372	2,039
Total stock compensation expense	868	300	1,378	7,758
Amounts capitalized as part of inventory	109	36	162	188
Total	\$977	\$336	\$1,540	\$7,946

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 3,934,517 shares were outstanding at June 30, 2017 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 20,833 shares of restricted stock and 431,120 RSUs outstanding at June 30, 2017. As of June 30, 2017, there were 1,220,418 shares authorized and available for grants under the Plan.

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 5.4% estimated forfeiture rate based on historical forfeiture experience. The risk-free rate is based on the U.S. Treasury yield curve corresponding to the expected term at the time of the grant.

	Three Months Ended		Six Months Ended	
	June 30, 2017	July 1, 2016	June 30, 2017	July 1, 2016
Expected dividend yield	0 %	0 %	0 %	0 %
Expected volatility	57 %	45 %	57 %	53 %
Risk-free interest rate	1.81 %	1.01 %	1.95 %	1.27 %
Expected term (in years)	5.67	4.40	5.67	5.19

A summary of option activity under the Plan for the six-month period ended June 30, 2017 is presented below:

	Options Shares (000's)
Outstanding at December 30, 2016	3,502
Granted	794
Exercised	(288)
Forfeited or expired	(73)
Outstanding at June 30, 2017	3,935
Exercisable at June 30, 2017	2,819

A summary of restricted stock and RSU activity under the Plan for the six-month period ended June 30, 2017 is presented below:

	Restricted Shares (000's)	RSUs (000's)
Outstanding at December 30, 2016	23	274
Granted	21	269
Vested	(23)	(91)
Forfeited		(21)
Outstanding at June 30, 2017	21	431

Note 11 — Income Taxes

As discussed in Note 1 of the notes to the condensed consolidated financial statements, the Company adopted an accounting standard update regarding the recognition of excess tax benefits through the income statement upon settlement of share-based compensation awards. As the Company has a full valuation allowance, any realized benefits would be offset by the valuation allowance with no impact to the tax provision. Accordingly, there is no benefit reflected in the current tax provision and no restatement of the prior period.

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.

STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

The Company recorded an income tax provision of \$0.1 million and \$0.3 million for the three and six months ended June 30, 2017 primarily due to pre-tax income generated in certain foreign jurisdictions. There are no unrecognized tax benefits related to uncertain tax positions taken by the Company.

The income tax benefit of \$0.1 million and \$1.7 million for the three and six months ended July 1, 2016 was primarily due to net operating losses from our foreign operations, primarily due to the acceleration of stock compensation and tax benefits related to the dissolution of one of our foreign subsidiaries.

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 Company reduced its deferred tax liability in 2016 related to withholding taxes from unremitted foreign earnings by the accumulated deficit of one of its foreign subsidiaries dissolved as of April 1, 2016.

Note 12 — Commitments and Contingencies

Lines of Credit

Since 1988, the Company's wholly owned Japanese subsidiary, STAAR Japan, has had an agreement, as amended on or about November 21, 2016, with Mizuho Bank which provides for borrowings of up to 500,000,000 Yen, at an interest rate equal to the uncollateralized overnight call rate (approximately 0.12% as of June 30, 2017) plus a 0.50% spread, and may be renewed annually (the current line expires on November 21, 2017). The credit facility is not collateralized. The Company had 500,000,000 Yen outstanding on the line of credit as of June 30, 2017 and December 30, 2016 (approximately \$4.5 million and \$4.3 million based on the foreign exchange rates on June 30, 2017 and December 30, 2016, respectively), which approximates fair value due to the short-term maturity and market interest rates of the line of credit. In case of default, the interest rate will be increased to 14% per annum. As of June 30, 2017, there were no available borrowings under the line.

In August 2010, the Company's wholly owned Swiss subsidiary, STAAR Surgical AG, entered into a credit agreement with Credit Suisse (the Bank). The credit agreement provides for borrowings of up to 1,000,000 CHF (Swiss Francs)

(\$1.0 million at the rate of exchange on June 30, 2017), 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” in STAAR Surgical independent auditors’ report, as defined. There were no borrowings outstanding as of June 30, 2017 and December 30, 2016.

Covenant Compliance

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

Lease Line of Credit (Capital Leases)

On January 30, 2017, the Company entered into lease schedule 010 with Farnam Street Financial, Inc (“Farnam”). The line of credit provides for borrowings of up to \$2.0 million at a lease rate factor of 3.94% per \$1 for hardware equipment and 4.75% per \$1 for non-hardware equipment. Interim rent is paid until the full amount of the line is used at which time the lease commences. As of June 30, 2017, approximately \$894,539 of the line was available for borrowing.

On January 31, 2017, the Company entered into lease schedule 009R with Farnam. Under 009R, equipment with a cost of \$1,957,000 was financed over a period of 24 months at a lease rate factor of 3.94% per \$1 for hardware equipment and 4.75% per \$1 for non-hardware equipment. At the end of the lease the Company can opt to continue to rent the equipment, return the equipment, or exercise a fair market value purchase option. As of June 30, 2017, approximately \$1,553,697 was outstanding.

STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

On June 12, 2014, the Company entered into lease schedule 008R with Farnam. Under the agreement, hardware and non-hardware with a cost of \$964,612 was financed over a period of 36 months at a lease rate factor of 2.81% per \$1 for hardware equipment and 3.12% per \$1 for non-hardware equipment. At the end of the lease the Company could opt to continue to rent the equipment, return the equipment, or exercise a fair market value purchase option. The lease schedule was paid off in May 2017 and the Company is renting the equipment on a month to month basis temporarily until it decides to either return the equipment or exercise the fair market value purchase option.

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 most of the matters 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.

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 January 5, 2017, the court granted plaintiff's Motion for Class Certification. On July 10, 2017, the court granted plaintiff's application for preliminary approval of a class action settlement in the amount of \$7,000,000. If finally approved, the Company's insurance carriers will fund the entire settlement. The court scheduled a final approval hearing regarding

the settlement for October 16, 2017. The Company has not recorded any loss or accrual in the accompanying condensed consolidated financial statements at June 30, 2017 and December 30, 2016 for this matter.

Stockholder Derivative Litigation: Forestal Action

On June 21, 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 January 31, 2017, the court granted the Company's Motion to Dismiss. On February 6, 2017, plaintiff filed a Notice of Appeal, and on July 17, 2017 plaintiff filed his appellate brief. 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 June 30, 2017 and December 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 of its assets, or termination "without cause or for good reason" as defined in the employment agreements.

Note 13 — Reclassifications

The Company reclassified inventory reserves from Changes in Working Capital - Inventory in the Statement of Cash Flows to the non-cash section of the Statement for both the six months ended June 30, 2017 and July 1, 2016. The Company also reclassified \$17,000 from Cash Proceeds from Sale of Property and Equipment to Loss on Disposal of Property and Equipment for the six months ended July 1, 2016.

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 or guidance as to earnings, revenue, sales, profit margins, expense rate, cash, effective tax rate remediation expense or capital expense 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 new or improved products (including the Toric ICL in the U.S.); 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 and completion of FDA remediation efforts; statements of belief, including as to achieving 2017 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 in “Item 1A. Risk Factors” filed on March 2, 2017. 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 believe we are the world’s leading manufacturer of intraocular lenses for patients seeking refractive vision correction, and we also make lenses for use in surgery to treat cataracts. All the lenses we make are foldable, which allows the surgeon to insert them into the eye through a small incision during minimally invasive surgery. Refractive surgery is performed to treat the type of visual disorders that have traditionally been corrected using eyeglasses or contact lenses. We refer to our lenses used in refractive surgery

as “implantable Collamer® lenses” or “ICLs,” which includes the EVO Visian ICL™ product line. The field of refractive surgery includes both lens-based procedures, using products like our ICL family of products, and laser-based procedures like LASIK. Successful refractive surgery can correct common vision disorders such as myopia, hyperopia, and astigmatism. Cataract surgery is a common outpatient procedure where the eye’s natural lens that has become cloudy with age is removed and replaced with an artificial lens called an intraocular lens (IOL) to restore the patient’s vision. STAAR employs a commercialization strategy that strives for sustainable profitable growth. 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 position our IOL lenses used in cataract surgery in standard and premium value segments.

STAAR has significant operations globally. Activities outside the United States (“U.S.”) accounted for 90% of our total sales in the second quarter of 2017, 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 Japan, North America, Spain, Germany, Singapore, 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 2017

In the second quarter of 2017, quarterly net sales increased 5% from prior year quarter to \$21.9 million. Worldwide ICL sales increased 6% and units increased 11% from prior year quarter. In the quarter, ICL sales grew 140% in Canada, 14% in Japan and 32% in China. In regional markets, compared to the prior year quarter, ICL units increased 15% in North America, 4% in Europe, Middle East and Africa, and 15% in Asia Pacific, in spite of planned challenges in Korea. The Asia Pacific growth included a 52% unit decrease in India due to larger than normal orders from distributors in the first quarter of 2017 to compensate for a delay in a registration renewal, which impacted normal import timing in the second quarter of 2017. Global Toric ICL shipments continue to account for a growing percentage of the ICL product mix. For the second quarter of 2017, injector part sales were significantly higher than prior year second quarter. We are continuing to experience challenges with one of the materials used in our silicone IOL preloaded injectors. We are addressing the matter. With the discontinuation of our U.S. silicone IOL business and materials challenges, we expect that IOL sales will decrease in 2017 compared to 2016. We expect sales of injector parts to continue to increase compared to prior year in the remainder of 2017. In May, our EVO+ Visian ICL with Aspheric (EDOF) Optic, received CE Mark for commercialization in the European Union from our Notified Body, DEKRA. Our goal remains to introduce this upgraded lens, to select surgeons, in 2017. Our first-in-man clinical trial for the next generation ICL with EDOF continued in the second quarter and the results continue to be positive. With regard to FDA remediation, we completed our internal work in the first quarter of 2017 and have notified the FDA that we are ready for inspection. In July, DEKRA re-certified our facilities as compliant with ISO 13485, the quality standard applicable for medical devices, and re-certified the CE marking for all our currently certified and commercially available medical devices.

For 2017, our strategic priorities are as follows:

1. Complete Remediation Plan and Quality Systems Overhaul: We expect to complete our internal remediation and quality system rebuild commitments while also maintaining our global quality certifications;
2. Continue to Build the *Visual Freedom* Market for Implantable Lenses: We will continue our activities to position the ICL as a primary and premium refractive procedure with clinical validation, new digital and social media marketing, product branding launched in 2016, and enhanced surgeon training and practice development programs;
3. Build Go-to-Market Strategy to Expand Market Share Globally: We are planning for double digit ICL growth through a refreshed sales strategy and by entering into additional strategic business relationships with growth-oriented refractive surgical providers operating eye hospitals and clinics;

4. Deliver Global Clinical Validation & Clinical Utility Excellence: The expanded Global Clinical and Medical Affairs teams will continue to assist in supporting submissions to and responding to queries from regulatory agencies and will monitor clinical data, conduct and monitor clinical studies and patient registries established in 2016 and enhance our medical communications protocol; and

5. Innovate, Develop and Release to Market Premium Collamer Lenses and Delivery Systems: We plan to complete research and development efforts relating to EVO (spherical) with EDOF lens design and meet internal commitments regarding other research and development priorities.

We continue to expect double-digit ICL unit growth in 2017 driven primarily by increasing market acceptance of the EVO Visian ICL in established markets with the exception of the U.S. and Korea. We continue to anticipate gross profit as a percentage of sales for full year 2017 to be higher than 2016. We expect operating expenses for 2017 will be below operating expenses in 2016. Finally, we will continue to evaluate opportunities to acquire new product lines, technologies, and companies.

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 June 30, 2017 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 December 30, 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 Six Months			
	June 30, 2017	July 1, 2016	June 30, 2017		July 1, 2016	
Net sales	100.0 %	100.0 %	100.0	%	100.0	%
Cost of sales	29.5	30.3	28.9		31.4	
Gross profit	70.5	69.7	71.1		68.6	
General and administrative	21.7	23.5	23.9		33.3	
Marketing and selling	33.4	34.2	32.8		36.9	
Research and development	21.5	22.2	22.5		28.7	
	76.6	79.9	79.2		98.9	
Operating loss	(6.1)	(10.2)	(8.1))	(30.3))
Other income (expense), net	2.3	(0.6)	1.3		0.7	
Loss before provision for income taxes	(3.8)	(10.8)	(6.8))	(29.6))
Provision (benefit) for income taxes	0.7	(0.6)	0.7		(4.3))
Net loss	(4.5)%	(10.2)%	(7.5)%)%	(25.3)%)%

Net Sales

	Three Months Ended			Percentage Change	Six Months Ended		Percentage Change
	June 30, 2017	July 1, 2016	vs. 2016		June 30, 2017	July 1, 2016	
Net sales	\$ 21,936	\$ 20,974	4.6	%	\$ 42,286	\$ 40,243	5.1 %
ICL	16,317	15,408	5.9		31,588	28,588	10.5
IOL	4,377	5,068	(13.6))	8,983	10,134	(11.4)
Other	1,242	498	149.4		1,715	1,521	12.8

Net sales for the three months ended June 30, 2017 were \$21.9 million, an increase of 4.6% compared with \$21.0 million reported during the same period of 2016. Total sales for the six months ended June 30, 2017 were \$42.3 million, an increase of 5.1% compared with \$40.2 million reported during the same period of 2016. The effect of exchange rate changes had an unfavorable impact on net sales of \$0.1 million, during the three and six months ended June 30, 2017.

Total ICL sales for the three months ended June 30, 2017 were \$16.3 million, an increase of 5.9% compared with \$15.4 million reported during the same period of 2016. North America ICL sales were \$1.8 million during the second quarter, an increase of 15.2% in both sales and units compared to the prior year period. The increase in North America ICL sales was driven by a 140% increase in Canada sales as a result of the successful commercialization of the EVO Toric ICL which was introduced late in the third quarter of 2016. APAC ICL sales were \$9.0 million during the second quarter of 2017, an increase of 7% compared to the prior year period, which was comprised of a 15% increase in units and a 6.8% decrease in average selling prices, driven by strong double-digit growth in China. EMEA ICL sales were \$5.6 million during the second quarter, an increase of 1.6% compared to the prior year period, which was comprised of a 4.2% increase in units and a 2.5% decrease in average selling prices.

Total ICL sales for the six months ended June 30, 2017 were \$31.6 million, a 10.5% increase compared with \$28.6 million reported during the same period of 2016. Total ICL units increased 15.2% and average selling prices decreased 4.1%. EMEA ICL sales were \$10.9 million for the six months ended June 30, 2017, a 5% increase compared to \$10.4 million reported in the same period in 2016 which was comprised of a 7.2% increase in units and a 2.0% decrease in average selling prices. APAC ICL sales were \$17.2 million for the six months ended June 30, 2017, a 14.2% increase compared to \$15.0 million reported during the same period of 2016. The increase was comprised of 20.7% increase in units and a 5.4% decrease in average selling prices. The increase was driven by a 37.5% increase in China sales, partially offset by lower sales in India and Korea. North America ICL sales were \$3.5 million during the six months ended June 30, 2017, an 11.2% increase in sales and a 10.7% increase in units compared to the same period in 2016.

Total IOL sales for the three months ended June 30, 2017 were \$4.4 million, a decrease of 13.6% compared with \$5.1 million reported during the same period of 2016. Total IOL sales for the six months ended June 30, 2017 were \$9.0 million, an 11.4% decrease compared with \$10.1 million reported during the same period in 2016. The decline for both the three and six-month periods was due to the discontinuance of the silicone IOL product line in the U.S. during 2016 and due to production issues with one of the materials used in our silicone IOL preloaded injectors which has resulted in lower than planned IOL sales in Japan.

Other product sales for the three months ended June 30, 2017, were \$1.2 million, an increase of 149.4% compared with the \$0.5 million reported during the same period of 2016. Total other product sales for the six months ended June 30, 2017 were \$1.7 million, a 12.8% increase compared with \$1.5 million reported during the same period in 2016. The increase in other product sales is due to an increase in injector part sales as expected.

Gross Profit

	Three Months Ended		Percentage Change 2017 vs. 2016	Six Months Ended		Percentage Change 2017 vs. 2016
	June 30, 2017	July 1, 2016		June 30, 2017	July 1, 2016	
Gross Profit	\$ 15,474	\$ 14,626	5.8	% \$30,051	\$ 27,619	8.8
Gross Profit Margin	70.5	% 69.7	%	71.1	% 68.6	%

Gross profit for the three months ended June 30, 2017 was \$15.5 million, or 70.5% of revenue, compared with \$14.6 million, or 69.7% of revenue, in the prior year period. The increase in gross margin for the quarter is due to increased Toric ICL sales, a reduction in inventory provisions and improved unit costs, partially offset by lower average selling prices and unfavorable product mix due to increased sales of low margin injector parts. Inventory provisions in 2016 were unfavorably impacted by the discontinuance of silicone IOL sales in the U.S. and V4b ICL sales internationally.

Gross profit for the six months ended June 30, 2017 was \$30.1 million, or 71.1% of revenue, compared with \$27.6 million, or 68.6% of revenue, in the prior year period. The increase in gross margin for the first six months of 2017 is due to cost of sales related to 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 recorded in the first six months of 2016 which was not repeated in 2017, lower inventory provisions, improved product and country mix, and lower unit costs, partially offset by lower average selling prices.

General and Administrative

	Three Months Ended		Percentage Change 2017 vs. 2016	Six Months Ended		Percentage Change 2017 vs. 2016		
	June 30, 2017	July 1, 2016		June 30, 2017	July 1, 2016			
General and Administrative	\$ 4,761	\$ 4,928	(3.4)%	\$ 10,120	\$ 13,393	(24.4)%
Percentage of Net Sales	21.7	% 23.5	%		23.9	% 33.3	%	

General and administrative expenses for the three months ended June 30, 2017 were \$4.8 million, a decrease of 3.4% when compared with \$4.9 million reported for the same period last year. The decrease was primarily due to lower compensation expenses.

General and administrative expenses for the six months ended June 30, 2017 were \$10.1 million, a decrease of 24.4% when compared with \$13.4 million reported for the same period last year. The decrease was primarily due to lower stock based compensation expenses due to the \$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 lower local taxes in Japan recorded during the first six months of 2016 which were not repeated in the first six months of 2017. General and administrative expenses for the first six months of 2017 were also lower due to decreased compensation expenses.

Marketing and Selling

	Three Months Ended		Percentage Change 2017 vs. 2016	Six Months Ended		Percentage Change 2017 vs. 2016		
	June 30, 2017	July 1, 2016		June 30, 2017	July 1, 2016			
Marketing and Selling	\$ 7,321	\$ 7,181	1.9	%	\$ 13,851	\$ 14,856	(6.8)%
Percentage of Net Sales	33.4	% 34.2	%		32.8	% 36.9	%	

Marketing and selling expenses for the three months ended June 30, 2017 were \$7.3 million, an increase of 1.9% when compared with \$7.2 million reported for the same period last year. The increase was primarily due to increased headcount in China and a trade show in Germany.

Marketing and selling expenses for the six months ended June 30, 2017 were \$13.9 million, a decrease of 6.8% when compared with \$14.9 million reported for the same period last year. The decrease is primarily due to lower stock based compensation expenses due to the \$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 recorded during the first six months of 2016 which was not repeated in the first six months of 2017.

Research and Development

	Three Months Ended		Percentage Change 2017 vs. 2016	Six Months Ended		Percentage Change 2017 vs. 2016
	June 30, 2017	July 1, 2016		June 30, 2017	July 1, 2016	
Research and Development	\$ 4,712	\$ 4,659	1.1	% \$9,495	\$ 11,565	(17.9)%
Percentage of Net Sales	21.5 %	22.2 %		22.5 %	28.7 %	

Research and development expenses for the three months ended June 30, 2017 were \$4.7 million, an increase of 1.1% when compared with \$4.7 million reported for the prior year quarter. The increase was primarily due to increased costs for product development and quality and regulatory costs related to quality system improvements, including increased headcount, largely offset by a decrease in FDA remediation expenses.

Research and development expenses for the six months ended June 30, 2017 were \$9.5 million, a 17.9% decrease compared to \$11.6 million for the same prior year period. The decrease is primarily due to lower stock based compensation expenses due to the \$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 recorded during the first six months of 2016 which was not repeated in the first six months of 2017.

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 2017 vs. 2016	Six Months Ended		Percentage Change 2017 vs. 2016	
	June 30, 2017	July 1, 2016		June 30, 2017	July 1, 2016		
Other income (expense), net	\$ 495	\$ (132)	—*	\$ 528	\$ 276	91.3	%

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

The change in other income (expense), net for the three and six months ended June 30, 2017 is primarily due to increased foreign currency transaction gains.

Income Taxes

	Three Months Ended		Percentage Change 2017 vs. 2016	Six Months Ended		Percentage Change 2017 vs. 2016	
	June 30, 2017	July 1, 2016		June 30, 2017	July 1, 2016		
Provision (benefit) for income taxes	\$ 146	\$ (131)	—*	\$ 287	\$ (1,735)	—*	

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

The provision for income taxes is determined using an estimated annual effective tax rate. We recorded an income tax provision of \$0.1 million and \$0.3 million, respectively, for the three and six months ended June 30, 2017. The income tax provision for the three and six months ended June 30, 2017 is due primarily to pre-tax income generated in certain higher rate foreign jurisdictions. The income tax benefit for the three and six months ended July 1, 2016 was primarily due to net operating losses from our foreign operations, primarily due to the acceleration of stock compensation, and tax benefits related to the dissolution of one of our foreign subsidiaries. We have no unrecognized tax benefits pertaining to any uncertain tax positions as of any period presented.

Liquidity and Capital Resources

We have historically financed our operations primarily through operating cash flows, the issuance of common stock and proceeds from stock option exercises, borrowings under lines of credit and by relying on equipment and other commercial financing. During 2017, and for the foreseeable future, we will be highly dependent on our operating cash flows to supplement our current liquidity and funding of our operations. We may in the future supplement our working capital.

With continued expanding ICL sales and gross margins, the Company has been able to invest in its operations while maintaining its cash balances. Since 2014, we have maintained an average cash balance of approximately \$13.5 million and went from using approximately \$8.0 million in cash for operating activities in 2014 to generating \$1 million from operating activities in 2016 and we expect similar improved results in 2017. As we shift from remediation to commercialization, we expect to invest more in sales and marketing while maintaining quality. We believe these investments will accelerate high margin sales which should result in a significantly improved cash position and profitability.

We believe our current cash balances coupled with cash flow from operating activities will be sufficient to meet our working capital requirements for the foreseeable future. Our need for working capital, and the terms on which financing may be available, will depend in part on our degree of success in maintaining positive cash flow through the strategies described above under the caption “*Recent Developments and Strategic Priorities for 2017.*”

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

As of June 30, 2017 and December 30, 2016, respectively, STAAR had \$13.6 million and \$14.1 million, of cash, cash equivalents and restricted cash.

Net cash used in operating activities was \$1.3 million and \$0.5 million for the six months ended June 30, 2017 and July 1, 2016, respectively. The net cash used in operating activities for the six months ended June 30, 2017, resulted from a net loss of \$3.2 million, offset by \$4.0 million in non-cash items and increased by a \$2.1 million decrease in net working capital.

Net cash used in investing activities was \$0.7 million for the six months ended June 30, 2017, compared to \$2.0 million in net cash used in investing activities for the six months ended July 1, 2016. Net cash used in investing

activities for both periods was due to the acquisition of property, plant and equipment.

Net cash provided by financing activities was \$1.1 million for both the six months ended June 30, 2017 and the six months ended July 1, 2016. Net cash provided by financing activities during the first six months of 2017 resulted primarily from the proceeds from vested restricted stock and exercises of stock options, partially offset by repayment of capital lease obligations.

Credit Facilities and Commitments

Lines of Credit and Lease Line of Credit (Capital Leases)

See Note 12 of the accompanying Condensed Consolidated Financial Statements.

Covenant Compliance

The Company is in compliance with the covenants of its credit facilities as of June 30, 2017.

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 June 30, 2017, 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 December 30, 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 Interim 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 Interim 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 Interim 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 June 30, 2017 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 December 30, 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

The Company's proposal to amend its Bylaws at the Company's 2016 annual meeting of stockholders to remove the provision that the exact number of directors constituting the entire Board of Directors is presently fixed at seven did not attain the requisite affirmative vote of holders of at least two-thirds of the outstanding shares of common stock entitled to vote on the proposal. The Company has refiled the corrected Bylaws with this quarterly report to include the statement. No other changes have been made to the Bylaws.

ITEM 6. EXHIBITS

3.1 Restated Certificate of Incorporation.(1)

3.2 Amended and Restated Bylaws.*

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

†4.5 Amended and Restated 2003 Omnibus Equity Incentive Plan, effective February 25, 2016.(2)

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 June 30, 2017, 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 as filed with the Commission on June 11, 2014.

(2) Incorporated by reference to Appendix 1 of the Company's Proxy Statement on Form DEF 14A as filed with the Commission on May 2, 2016.

(3)

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

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

- * Filed herewith.
- ** 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 2, 2017 By: /s/ DEBORAH J. ANDREWS
Deborah J. Andrews

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