

STAAR SURGICAL CO
Form 10-Q
May 11, 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: April 1, 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 40,186,856 shares of common stock, par value \$0.01 per share, issued and outstanding as of May 4, 2016.

STAAR SURGICAL COMPANY

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

	April 1, 2016	January 1, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$8,968	\$13,402
Accounts receivable trade, net of allowance for doubtful accounts of \$1,877 and \$1,877, respectively	16,227	15,675
Inventories, net	16,019	15,921
Prepayments, deposits and other current assets	4,558	3,636
Deferred income taxes	468	439
Total current assets	46,240	49,073
Property, plant and equipment, net	10,982	10,095
Intangible assets, net	658	666
Goodwill	1,786	1,786
Deferred income taxes	1,568	717
Other assets	646	617
Total assets	\$61,880	\$62,954
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Line of credit	\$4,457	\$4,159
Accounts payable	6,852	6,691
Deferred income taxes	370	370
Obligations under capital leases	368	362
Other current liabilities	5,955	6,305
Total current liabilities	18,002	17,887
Obligations under capital leases	118	204
Deferred income taxes	1,086	1,888
Asset retirement obligations	203	156

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Deferred rent	76	87
Pension liability	4,064	3,886
Total liabilities	23,549	24,108

Commitments and contingencies (Note 12)

Stockholders' equity:

Common stock, \$0.01 par value; 60,000 shares authorized; 40,169 and 39,887 shares issued and outstanding at April 1, 2016 and January 1, 2016, respectively	402	399
Additional paid-in capital	194,010	187,007
Accumulated other comprehensive loss	(1,060)	(1,580)
Accumulated deficit	(155,021)	(146,980)
Total stockholders' equity	38,331	38,846
Total liabilities and stockholders' equity	\$61,880	\$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	
	April 1, 2016	April 3, 2015
Net sales	\$ 19,269	\$ 18,858
Cost of sales	6,276	5,959
Gross profit	12,993	12,899
General and administrative	8,465	5,162
Marketing and selling	7,675	5,668
Research and development	6,906	3,579
Operating loss	(10,053)	(1,510)
Other income (expense):		
Interest expense	(28)	(36)
Gain (loss) on foreign currency transactions	458	(892)
Royalty income	22	45
Other income (expense), net	(44)	25
Total other income (expense), net	408	(858)
Loss before income tax benefit	(9,645)	(2,368)
Income tax benefit	(1,604)	(28)
Net loss	\$(8,041)	\$(2,340)
Net loss per share – basic and diluted	\$(0.20)	\$(0.06)
Weighted average shares outstanding – basic and diluted	39,983	38,481

See accompanying notes to the condensed consolidated financial statements.

STAAR SURGICAL COMPANY

CONDENSED CONSOLIDATED STATEMENTS

OF COMPREHENSIVE LOSS

(In thousands)

(Unaudited)

	Three Months Ended	
	April 1, 2014	April 3, 2015
Net loss	\$ (8,041)	\$ (2,340)
Other comprehensive income (loss):		
Defined Benefit Pension Plans:		
Net change in plan assets	(11)	(8)
Reclassification into earnings	27	15
Foreign currency translation	732	79
Tax effect	(228)	(24)
Other comprehensive income, net of tax	520	62
Comprehensive loss	\$ (7,521)	\$ (2,278)

See accompanying notes to the condensed consolidated financial statements.

STAAR SURGICAL COMPANY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Three Months Ended	
	April 1, 2016	April 3, 2015
Cash flows from operating activities:		
Net loss	\$ (8,041)	\$ (2,340)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	591	497
Amortization of long-lived intangibles	54	52
Deferred income taxes	(1,639)	(118)
Change in net pension liability	118	50
Stock-based compensation expense	7,458	994
Accretion of asset retirement obligation	—	1
Provision for sales return and bad debt expense	(22)	99
Changes in working capital:		
Accounts receivable trade, net	(317)	(56)
Inventories	564	617
Prepayments, deposits and other current assets	(912)	(573)
Accounts payable	(435)	(1,741)
Other current liabilities	(398)	309
Net cash used in operating activities	(2,979)	(2,209)
Cash flows from investing activities:		
Acquisition of property and equipment	(1,006)	(328)
Sale of property and equipment	—	2
Net cash used in investing activities	(1,006)	(326)
Cash flows from financing activities:		
Repayment of capital lease obligations	(92)	(115)
Repurchase of employee common stock for taxes withheld	(611)	—
Proceeds from vested restricted stock and exercise of stock options	7	421
Net cash provided by (used in) financing activities	(696)	306
Effect of exchange rate changes on cash and cash equivalents	247	25
Decrease in cash and cash equivalents	(4,434)	(2,204)
Cash and cash equivalents, at beginning of the period	13,402	13,013

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Cash and cash equivalents, at end of the period	\$ 8,968	\$ 10,809
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See accompanying notes to the 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 condensed 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 condensed consolidated financial statements for the three months ended April 1, 2016 and April 3, 2015, 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 months ended April 1, 2016 and April 3, 2015 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 April 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2016-10, “Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing.” The amendments clarify two aspects of Topic 606: (a) identifying performance obligations; and (b) the licensing implementation guidance. The update is effective for annual periods beginning after December 15, 2017 including interim reporting periods therein. The Company is currently evaluating the impact the adoption of ASU 2016-10 will have on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, “Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting”, which simplifies several aspects of the accounting for share-based

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

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

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

In April 2015, the FASB issued ASU No. 2015-04, Compensation—Retirement Benefits (Topic 715): Practical Expedient for the Measurement Date of an Employer’s Defined Benefit Obligation and Plan Assets. ASU 2015-04 permits an entity to measure defined benefit plan assets and obligations using the month-end that is closest to the entity’s fiscal year-end and apply that practical expedient consistently from year to year. ASU 2015-04 is effective for public business entities for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early application is permitted. The adoption of ASU 2015-04 in the first quarter of 2016 did not have a material impact on the Company’s consolidated financial statements.

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

In May 2014, the FASB issued ASU 2014-09, “Revenue from Contracts with Customers (Topic 606)”, which supersedes nearly all existing revenue recognition guidance under GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five-step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing GAAP.

The revised revenue standard is effective for public entities for annual periods beginning after December 15, 2017, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). The Company is currently evaluating the impact of the Company’s pending adoption of ASU 2014-09 on the Company’s financial statements and has not yet determined the method by which it will adopt the standard in fiscal 2018.

Prior Year Reclassifications

During the quarter ended April 1, 2016 the Company reclassified \$48,000 from medical device tax to general and administrative expenses and \$45,000 from other income, net to royalty income in the condensed consolidated statement of operations.

Note 2 – Inventories, Net

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

	April 1, 2016	January 1, 2016
Raw materials and purchased parts	\$2,190	\$ 2,317
Work-in-process	2,292	1,995
Finished goods	15,116	15,058
	19,598	19,370
Less: inventory reserves	3,579	3,449
	\$16,019	\$ 15,921

Note 3 - Prepayments, Deposits, and Other Current Assets

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

	April 1, 2016	January 1, 2016
Prepayments and deposits	\$2,636	\$ 1,386
Income tax receivable	597	597
Value added tax (VAT) receivable	620	724
Deferred charge for foreign profits	182	182
Pension plan	307	—
Other current assets	216	747
	\$4,558	\$ 3,636

Note 4 - Property, Plant and Equipment, Net

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

	April 1, 2016	January 1, 2016
Machinery and equipment	\$18,081	\$17,094
Furniture and fixtures	7,281	6,980
Leasehold improvements	8,875	8,611
	34,237	32,685
Less: accumulated depreciation	23,255	22,590
	\$10,982	\$10,095

Note 5 – Intangible Assets, Net

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

	April 1, 2016			January 1, 2016		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Long-lived intangible assets:						
Patents and licenses	\$9,247	(8,917)) \$330	\$9,207	\$ (8,891)) \$316
Customer relationships	1,398	(1,153)) 245	1,305	(1,044)) 261
Developed technology	888	(805)) 83	829	(740)) 89
Total	\$11,533	\$ (10,875)) \$658	\$11,341	\$ (10,675)) \$666

Note 6 - Other Current Liabilities

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

	April 1, 2016	January 1, 2016
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Accrued salaries and wages	\$ 2,482	\$ 1,909
Accrued bonuses	736	2,114
Accrued severance	139	133
Accrued insurance	707	540
Customer credit balances	267	203
Accrued income taxes	28	217
Accrued audit fees	162	314
Other ⁽¹⁾	1,434	875
	\$ 5,955	\$ 6,305

⁽¹⁾No item in "Other" above exceeds 5% of the total other current liabilities

Note 7 - Pension Plans

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 April 1, 2016	Three Months Ended April 3, 2015
Service cost	\$ 151	\$ 107
Interest cost	17	19
Expected return on plan assets	(22) (21
Net amortization of transitional obligation (a)	3	3
Actuarial loss, recognized in current period (a)	24	12
	\$ 173	\$ 120

(a) Amounts reclassified from accumulated other comprehensive loss.

During the three months ended April 1, 2016 and April 3, 2015, the Company made cash contributions of approximately \$419,000 and 400,000, respectively, to its Swiss pension plan and the Company is not required to make additional cash contributions during the remainder of 2016. The Company 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 April 1, 2016	Three Months Ended April 3, 2015
Numerator:		
Net loss	\$ (8,041)	\$ (2,340)
Denominator:		
Weighted average common shares and denominator for basic calculation:		
Weighted average common shares outstanding	39,983	38,638

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Less: Unvested restricted stock	—	157
Denominator for basic and diluted calculation	39,983	38,481
Net loss per share – basic and diluted	\$ (0.20)	\$ (0.06)

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

	Three Months Ended	
	April 1, 2016	April 3, 2015
Options	2,730	1,187
Restricted stock and units	116	237
Warrants	—	316
Total	2,846	1,740

Note 9 - Geographic and Product Data

The Company markets and sells its products in over 60 countries and does its manufacturing in the United States. Other than Japan, China, United States, Korea, Spain, France and Germany the Company does not conduct business in any country in which its sales exceed 5% of consolidated net 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	
	April 1, 2016	April 3, 2015
Japan	\$ 4,240	\$ 4,286
China	3,078	2,371
United States	2,516	2,867
Korea	2,023	2,343
Spain	1,453	1,478
France	1,127	1,150
Germany	967	495
Other	3,865	3,868
Total	\$ 19,269	\$ 18,858

100% of the Company's net 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	
	April 1, 2016	April 3, 2015
ICLs	\$ 13,180	\$ 12,255
IOLs	5,067	5,358
Core products	18,247	17,613
Other Surgical Products	1,022	1,245
Total	\$ 19,269	\$ 18,858

The Company sells its products internationally, which subjects the Company to several financial risks, including fluctuating foreign currency exchange rates (to the extent the Company's transactions are not in U.S. dollars), regulation of fund transfers by foreign governments, United States and foreign export and import duties and tariffs, and political instability.

Two customers, our distributors in Korea and China, accounted for 11% and 16% of net sales for the three months ended April 1, 2016 and 12% and 11% of net sales for the three months ended April 3, 2015, respectively. As of April 1, 2016, one customer, our distributor in China, accounted for 21% of consolidated trade receivables. As of April 3, 2015, two customers, our distributors in China and France, accounted for 10% and 11% of consolidated trade receivables, respectively.

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	
	April 1, 2016	April 3, 2015
Employee stock options	\$ 4,896	\$ 638
Restricted stock	225	244
Restricted stock units	2,280	119
Nonemployee stock options	57	(7)
Total	\$ 7,458	\$ 994

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

	Three Months Ended	
	April 1, 2016	April 3, 2015
Cost of sales	\$ 560	\$ 10
General and administrative	3,394	583
Marketing and selling	1,531	251
Research and development	1,973	150
Total stock compensation expense	7,458	994
Amounts capitalized as part of inventory	152	122
Total	\$ 7,610	\$ 1,116

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, and restricted stock units (RSUs). Options under the plan are granted at fair market value on the date of grant, become exercisable generally 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 and pre-established financial metrics are met (as defined in the Plan). Grants of restricted stock outstanding under the Plan generally vest over periods of one to three years. Grants of RSUs outstanding under the Plan generally vest based on service, performance or a combination of both. As of April 1, 2016, there were 413,513 shares authorized and available for grant 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 our Amended and Restated 2003 Omnibus Equity Incentive Plan (“Plan”). As a result, all unvested equity awards outstanding under the Plan immediately vested. Consequently, we recorded an aggregate \$6.9 million non-cash charge to stock-based compensation in the condensed consolidated statements of operations on that date (\$4.6 million for stock options and \$2.3 million for restricted stock and restricted stock units). This charge was recorded and included in the following categories of the condensed consolidated statements of operations for the three months ended April 1, 2016: \$2.9 million in general and administrative expenses, \$1.5 million in marketing and selling expenses, \$1.9 million in research and development expenses and \$0.6 million in manufacturing costs. Approximately \$3.7 million of the \$6.9

million of accelerated charges would have been recognized for stock-based compensation by the Company during fiscal year 2016 after the Change in Control provision was triggered.

Assumptions

The fair value of each option award is estimated on the date of grant using a Black-Scholes option valuation model applying the 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			
	April 1, 2016		April 3, 2015	
Expected dividend yield	0	%	0	%
Expected volatility	57	%	57	%
Risk-free interest rate	1.40	%	1.70	%
Expected term (in years)	5.57		5.64	

A summary of option activity under the Plan for the period ended April 1, 2016 is presented below:

	Options Shares (000's)
Outstanding at January 1, 2016	3,623
Granted	486
Exercised	(1)
Forfeited or expired	(61)
Outstanding at April 1, 2016	4,047
Exercisable at April 1, 2016	3,674

A summary of restricted stock and restricted stock units activity under the Plan for the period ended April 1, 2016 is presented below:

	Restricted Shares (000's)	Restricted Units (000's)
Outstanding at January 1, 2016	124	339
Granted	—	233
Vested	(124)	(380)
Forfeited	—	(4)
Outstanding at April 1, 2016	—	188

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 \$1.6 million income tax benefit recorded during the first quarter of 2016 was largely attributable to the Company's net operating losses in its foreign operations and a reduction in its foreign withholding taxes in connection with the dissolution of one of its foreign subsidiaries effective April 1, 2016. The Company recorded an income tax benefit of \$28,000 for the three months ended April 3, 2015 primarily due to pre-tax losses generated in certain foreign jurisdictions the Company consolidates for Swiss income tax purposes. There are no unrecognized tax benefits related to uncertain tax positions taken by the Company.

The first quarter 2016 foreign operating losses and the resulting tax benefits were principally due to an allocation of the stock-based compensation recorded during the quarter resulting from the immediate vesting of all unvested equity grants outstanding under the Company's Equity Incentive Plan as of February 11, 2016.

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 related to withholding taxes from unremitted foreign earnings by the accumulated deficit of one of its foreign subsidiaries dissolved as of April 1, 2016.

The Company considers these two transactions to be nonrecurring due to the significant and unusual nature of the transaction and, in accordance with Accounting Standards Codification ("ASC 740"), has reported their tax benefits as discrete events.

Note 12 - Commitments and Contingencies

Lines of Credit and Guarantee

The Company's wholly owned Japanese subsidiary, STAAR Japan, has an agreement, as amended on December 28, 2012, with Mizuho Bank, which provides for borrowings of up to 500,000,000 Yen (approximately \$4.5 million based on the rate of exchange on April 1, 2016), at an interest rate equal to the Tokyo short-term prime interest rate (approximately 1.475% as of April 1, 2016). The line of credit expires September 30, 2016 and is renewable annually. The Company had 500,000,000 Yen outstanding on the line of credit as of April 1, 2016 and January 1, 2016 (approximately \$4.5 million and \$4.2 million based on the foreign currency exchange rates on April 1, 2016 and January 1, 2016, respectively). As of April 1, 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 April 1, 2016), to be used for working capital purposes. Accrued interest and 0.25% commissions on average outstanding borrowings is payable quarterly and the interest rate will be determined by the Bank based on the then prevailing market conditions at the time of borrowing. The credit agreement is automatically renewed on an annual basis based on the same terms assuming there is no default. The credit agreement may be terminated by either party at any time in accordance with its general terms and conditions. The credit facility is not collateralized and contains certain conditions such as providing the Bank with audited financial statements annually and notice of significant events or conditions, as defined in the credit agreement. The Bank may also declare all amounts outstanding to be immediately due and payable upon a change of control or a material qualification as defined in the agreement. There were no borrowings outstanding as of April 1, 2016 and January 1, 2016.

On May 1, 2015, STAAR Surgical AG entered into a guarantee agreement with Bankinter. The agreement, as amended, provides Bankinter with a guarantee of up to EUR 200,000 (approximately \$228,000 at the rate of exchange on April 1, 2016) for trade receivables from the Company's Spanish customers. The total guarantee amount is offset against the credit agreement in place with Credit Suisse and therefore reduces the credit line available to STAAR Surgical AG for working capital requirements to up to 781,000 Swiss francs (approximately up to \$814,000 at the rate of exchange on April 1, 2016). Unless terminated sooner by Bankinter, the guarantee agreement expires on May 1, 2017.

Covenant Compliance

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

Litigation and Claims

From time to time the Company may be subject to various claims and legal proceedings arising out of the normal course of our business. These claims and legal proceedings may relate to contractual rights and obligations, employment matters, and claims of product liability. The most significant of these actions, proceedings and investigations are described below. STAAR maintains insurance coverage for product liability and certain securities. Legal proceedings can extend for several years, and the matters described below concerning the Company are at very early stages of the legal and administrative process. As a result, these matters have not yet progressed sufficiently through discovery and/or development of important factual information and legal issues to enable the Company to determine whether the proceedings are material to the Company or to estimate a range of possible loss, if any. Unless otherwise disclosed, the Company is unable to estimate the possible loss or range of loss for the legal proceedings described below. While it is not possible to accurately predict or determine outcomes of these items, an adverse

determination in one or more of these items currently pending could have a material adverse effect on the Company's consolidated results of operations, financial position or cash flows.

Todd v. STAAR

On July 8, 2014, a putative securities class action lawsuit was filed by Edward Todd against STAAR and three officers in the federal court located in Los Angeles, California. The plaintiff claims that STAAR made misleading statements to and omitted material information from our investors between February 27, 2013 and June 30, 2014 about alleged regulatory violations at STAAR's Monrovia manufacturing facility. On 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 fees. On September 21, 2015, the Company filed a motion to dismiss the amended complaint. On April 12, 2016, the court denied the motion to dismiss. Although the ultimate outcome of this action cannot be determined with certainty, the Company believes that the allegations in the Complaint are without merit. The Company intends to vigorously defend itself against this lawsuit. The Company has not recorded any loss or accrual in the accompanying condensed consolidated financial statements 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.

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, including those relating to working capital requirements, effective tax rate or any other financial items; the plans, strategies, and objectives of management for future operations or prospects for achieving such plans; statements regarding new, existing, or improved products, including but not limited to, expectations for success of new, existing, and improved products in the U.S. or international markets or government approval of a new or improved products (including the Toric ICL in the U.S.); or commercialization of new or improved products; the nature, timing and likelihood of resolving issues cited in the FDA’s 2014 Warning Letter or 2015 FDA-483; future economic conditions or size of market opportunities; expected costs of quality system remediation efforts; statements of belief, including as to achieving 2016 business plans; expected regulatory activities and approvals, product launches, and any statements of assumptions underlying any of the foregoing.

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

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

Overview

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

Company and its consolidated subsidiaries.

STAAR has significant operations globally. Activities outside the United States (“U.S.”) accounted for 87% of our total sales in first 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.

Recent Developments and Strategic Priorities for 2016

In the first quarter of 2016, worldwide ICL sales increased 8% compared to the prior year quarter on the strength of continued unit growth in China and increased average selling prices worldwide. As compared to the prior year quarter, China ICL unit sales grew 40%; Korea ICL unit sales decreased 19% after two consecutive quarters of unit growth. Germany ICL sales increased 108% due to our conversion to a direct sales structure on unit growth of 2%. The increased sales in Germany for the quarter were largely due to the increased average selling prices after the conversion and partially offset by additional expenses attributable to the new direct sales structure. Worldwide IOL sales declined 5% compared to the prior year quarter, driven by soft U.S. sales and the planned phase-out of IOL sales in China, partially offset by continued unit growth in Japan. U.S. IOL sales declined 19% compared to the prior year quarter, 70% of which was due to an IOL product placed on hold until qualification of equipment and inspection methods are completed. Overall, first quarter of 2016 net sales were \$19.3 million, a 2% increase over the first quarter of 2015.

As previously disclosed, effective January 1, 2016, we entered into cooperation agreements with Aier Eye Hospital Group in China and Memira Eye Clinics in Sweden. Generally, under these agreements we will provide additional training, marketing and pricing support to these accounts in exchange for greater consideration of our products and participation in our patient registry, marketing, generating clinical data, and new product development efforts.

In the first quarter of 2016 we resolved a dispute that arose with Nidek Co., Ltd and our third party manufacturer regarding allegedly defective injectors. Our third party manufacturer will repair or replace allegedly defective injectors without financial expense to us. Nidek and STAAR extended the term of our business relationship, whereby we sell Nidek injectors and Nidek sells us pre-loaded hydrophobic acrylic lens systems, to December 31, 2019.

In May 2016, we voluntarily initiated a recall of two lots of Class I injector cartridges shipped to the U.S. and Canada in the fourth quarter of 2013. The cartridges were not performing as expected. We provide these cartridges free of charge to customers for use with our IOLs. We estimate there are less than 500 units remaining in the field. We do not expect the cost of this recall to be material.

For 2016, our four strategic priorities are as follows:

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

Critical Accounting Policies

This Management's Discussion and Analysis of Financial Condition and Results of Operations discusses and analyzes data in our unaudited Condensed Consolidated Financial Statements, 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 three months ended April 1, 2016 to the items that we disclosed as our critical accounting policies and estimates in Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the fiscal year ended January 1, 2016.

Immediate Vesting of All Unvested Equity Awards

On February 11, 2016, one of our shareholders increased its beneficial ownership of the Company's common stock to approximately 26% of all shares outstanding. This triggered the "Change in Control" provision in our Amended and Restated 2003 Omnibus Equity Incentive Plan ("Plan"), which resulted in the immediate vesting of all unvested equity awards outstanding under the Plan ("Acceleration Event") and our recording an aggregate \$6.9 million non-cash charge to stock-based compensation in the condensed consolidated statements of operations on that date (\$4.6 million for stock options and \$2.3 million for restricted stock and restricted stock units). This \$6.9 million charge was recorded and included in the following categories of the condensed consolidated statements of operations for the three months ended April 1, 2016: \$2.9 million in general and administrative expenses, \$1.5 million in marketing and selling expenses, \$1.9 million in research and development expenses and \$0.6 million in manufacturing costs. Approximately \$3.7 million of the \$6.9 million of accelerated charges would have been recognized for stock-based compensation by the Company during fiscal year 2016 after the Change in Control provision was triggered.

Results of Operations

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

	Percentage of Net Sales for Three Months			
	April 1, 2016		April 3, 2015	
		%		%
Net sales	100.0	%	100.0	%
Cost of sales	32.6		31.6	
Gross profit	67.4		68.4	
General and administrative	43.9		27.4	
Marketing and selling	39.8		30.1	
Research and development	35.8		19.0	
	119.5		76.5	
Operating loss	(52.2)	(8.0)
Other income (expense), net	2.1		(4.5)
Loss before provision (benefit) for income taxes	(50.1)	(12.6)
Provision (benefit) for income taxes	(8.3)	(0.1)
Net loss	(41.8)%	(12.5)%

Net Sales

	Three Months Ended		Percentage Change for Three Months	
	April 1, 2016	April 3, 2015	2016 vs. 2015	
Net sales	\$ 19,269	\$ 18,858	2.2	%
ICL	13,180	12,255	7.5	
IOL	5,067	5,358	(5.4)
Other	1,022	1,245	(17.9)

Net sales for the three months ended April 1, 2016 were \$19.3 million, an increase of 2.2% compared with \$18.9 million reported during the same period of 2015.

Total ICL sales for the three months ended April 1, 2016 were \$13.2 million, an increase of 7.5% compared with \$12.3 million reported during the same period of 2015. Europe, Middle East and Africa ICL sales were \$4.9 million during the first quarter, an increase of 8.7% compared to the prior year period, with a decrease of 3.2% in units. Additionally, the increase in sales was driven by a 108% increase in sales in Germany, due to the transition to a direct sales model as well as the impact of increased pricing which occurred in most markets in the fourth quarter of 2015. These sales were partially offset by lower IOL sales and injector parts sold to a third-party. Asia Pacific ICL sales were \$6.7 million during the first quarter, an increase of 10.3% compared to the prior year period, which was comprised of a 4.0% increase in units and an average 6% increase in average selling prices, and also driven by a 46% increase in China sales. North America ICL sales were \$1.6 million during the first quarter, a decrease of 5.4% and a decrease of 14.4% in units compared to the prior year period.

Total IOL sales for the three months ended April 1, 2016 were \$5.1 million, a decrease of 5.4% compared with \$5.4 million reported during the same period of 2015. The decline was due to a planned phase-out of sales in China, continued softness in the U.S., partially offset by the impact of the weakening euro against the U.S. dollar.

Other product sales for the three months ended April 1, 2016 were \$1.0 million, a decrease of 17.9% compared with the \$1.2 million reported during the same period of 2015. The decrease in other product sales is due to a decrease in injector part sales.

Gross Profit

	Three Months Ended		Percentage Change for Three Months	
	April 1, 2016	April 3, 2015	2016	vs. 2015
Gross Profit	\$ 12,993	\$ 12,889	0.8	%
Gross Profit Margin	67.4 %	68.4 %		

Gross profit for the quarter ended April 1, 2016 was \$13.0 million, or 67.4% of revenue, compared with \$12.9 million, or 68.4% of revenue, in the prior year quarter. A non-cash charge of \$0.6 million was recorded to cost of goods sold in the quarter ending April 1, 2016 due to the immediate vesting of all unvested equity awards as a result of the triggering of the “Change in Control” provision of the Company’s equity incentive plan. This charge decreased the gross profit margin by 290 basis points. This impact was partially offset by a 190 basis point improvement from higher average selling prices net of currency impacts, lower ICL unit costs, an increased mix of higher margin ICL units, lower other costs, and higher IOL unit costs.

General and Administrative

	Three Months Ended		Percentage Change for Three Months	
	April 1, 2016	April 3, 2015	2016	vs. 2015
General and Administrative	\$ 8,465	\$ 5,162	64.0	%
Percentage of Sales	43.9 %	27.1 %		

General and administrative expenses for the quarter were \$8.5 million, an increase of 64.0% when compared with \$5.2 million reported for the same period last year. The increase was primarily due to a \$2.9 million non-cash charge

related to the immediate vesting of all unvested equity awards as a result of the triggering of the “Change of Control” provision of the Company’s equity incentive plan and local taxes in Japan.

Marketing and Selling

	Three Months Ended		2016 vs. 2015	Percentage Change for Three Months
	April 1, 2016	April 3, 2015		
Marketing and Selling	\$ 7,675	\$ 5,668	35.4	%
Percentage of Sales	39.8 %	30.1 %		

Marketing and selling expenses for the quarter were \$7.7 million, an increase of 35.4% when compared with \$5.7 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 as a result of the triggering of the “Change of Control” provision of the Company’s equity incentive plan, and increased marketing costs related to our rebranding efforts and increased international selling and promotional costs of \$1.0 million partially offset by \$0.5 million in optimization of North American selling and promotional costs.

Research and Development

	Three Months Ended		Percentage Change for Three Months	
	April 1, 2016	April 3, 2015	2016 vs. 2015	%
Research and Development	\$ 6,906	\$ 3,579	93.0	%
Percentage of Sales	35.8 %	19.0 %		

Research and development expenses for the quarter were \$6.9 million, an increase of 93.0% when compared with \$3.6 million reported last year. The increase was primarily due to a \$1.9 million non-cash charge related to the immediate vesting of all unvested equity awards as a result of the triggering of the “Change of Control” provision of the Company’s equity incentive plan and increased costs related to quality system improvements of \$0.6 million as well as \$0.9 million for investments in clinical affairs.

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 for Three Months	
	April 1, 2016	April 3, 2015	2016 vs. 2015	%
Other Income (Expense), Net	\$ 408	\$ (858)	—*	

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

Other income for the quarter was \$0.4 million compared to other expense of \$0.9 million in the first quarter of 2015. The increase in other income is due to foreign currency transaction gains recorded in the first quarter of 2016, compared to foreign currency transaction losses recorded during the first quarter of 2015. Foreign currency gains and

losses result from transactions primarily denominated in currencies other than the U.S. dollar.

Income taxes

	Three Months Ended		Percentage Change for Three Months 2016 vs. 2015
	April 1, 2016	April 3, 2015	
Income tax benefit	\$ 1,604	\$ 28	—*

* 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 benefit of \$1.6 million and \$28,000 for the three months ended April 1, 2016 and April 3, 2015, respectively. The income tax benefit for the three months ended April 1, 2016 was primarily due to our net operating losses from our foreign operations 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.

Based on current year projections, we expect the estimated annual effective tax rate to be approximately 30%.

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 flow 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 \$0.5 million was incurred in the first quarter of 2016. Although we anticipate these costs will continue, we cannot currently estimate the amount but will update as more information becomes available. If the need for financing arises, which we cannot rule out, STAAR cannot assure that it will be available on acceptable terms, or 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 April 1, 2016 and January 1, 2016, respectively, STAAR had \$9.0 million and \$13.4 million, of cash and cash equivalents, respectively.

Net cash used in operating activities was \$3.0 million for the three months ended April 1, 2016 and \$2.2 million for the three months ended April 3, 2015. The net cash used in operating activities consisted of net loss of \$8.0 million, plus \$6.6 million in non-cash items, offset by a \$1.5 million decrease in net working capital for the three months ended April 1, 2016.

Net cash used in investing activities was \$1.0 million for the three months ended April 1, 2016, compared to \$0.3 million in net cash used in investing activities for the three months ended April 3, 2015. Net cash used in investing activities was due to the acquisition of property, plant and equipment.

Net cash used in financing activities was \$0.7 million for the three months ended April 1, 2016, compared with \$0.3 million in net cash provided by financing activities for the three months ended April 3, 2015. The decrease in cash provided by financing activities was primarily due to the repurchase of employee stock for tax withholdings related to the immediate vesting of all unvested equity awards triggered by the “Change of Control” provision in the Company’s equity incentive plan, as well as, a decrease in proceeds from exercise of stock options.

Credit Facilities and Commitments

Lines of Credit and Guarantee

See Note 12 of the Consolidated Financial Statements.

Covenant Compliance

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

Employment Agreements

On October 3, 2014, the Company’s former Chief Executive Officer announced his retirement effective March 1, 2015. Effective with his retirement, he became a consultant to the Company through March 31, 2016. In March 2015, the Company accrued approximately \$300,000 in benefits due to the former CEO, such benefits were paid over a one year period beginning on March 1, 2015 and ending on March 31, 2016. As of April 1, 2016, there were no remaining amounts payable under the agreement.

The Company’s Chief Executive Officer entered into an employment agreement with the Company, effective March 1, 2015. She and certain officers have 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*

There have been no material changes to 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 April 1, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Litigation and Claims

From time to time the Company may be subject to various claims and legal proceedings arising out of the normal course of our business. These claims and legal proceedings may relate to contractual rights and obligations, employment matters, and claims of product liability. The most significant of these actions, proceedings and investigations are described below. STAAR maintains insurance coverage for product liability and certain securities. Legal proceedings can extend for several years, and the matters described below concerning the Company are at very early stages of the legal and administrative process. As a result, these matters have not yet progressed sufficiently through discovery and/or development of important factual information and legal issues to enable the Company to determine whether the proceedings are material to the Company or to estimate a range of possible loss, if any. Unless otherwise disclosed, the Company is unable to estimate the possible loss or range of loss for the legal proceedings described below. While it is not possible to accurately predict or determine outcomes of these items, an adverse determination in one or more of these items currently pending could have a material adverse effect on the Company's consolidated results of operations, financial position or cash flows.

Todd v. STAAR

On July 8, 2014, a putative securities class action lawsuit was filed by Edward Todd against STAAR and three officers in the federal court located in Los Angeles, California. The plaintiff claims that STAAR made misleading statements to and omitted material information from our investors between February 27, 2013 and June 30, 2014 about alleged regulatory violations at STAAR's Monrovia manufacturing facility. On 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 fees. On September 21, 2015, the Company filed a motion to dismiss the amended complaint. On April 12, 2016, the court denied the motion to dismiss. Although the ultimate outcome of this action cannot be determined with certainty, the Company believes that the allegations in the Complaint are without merit. The Company intends to vigorously defend itself against this lawsuit. The Company has not recorded any loss or accrual in the accompanying condensed consolidated financial statements for this matter as the likelihood and amount of loss, if any, has not been determined and is not currently estimable.

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, in addition to other information contained in this report, the risks and uncertainties described in "Part I-Item 1A-Risk Factors" of the Company's Form 10-K for the fiscal year ended January 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.(4)
- †4.5 Amended and Restated 2003 Omnibus Equity Incentive Plan, effective February 25, 2016.(3)
- 10.35 Amendment Agreement between STAAR Surgical Company and Nidek Co., Ltd., dated March 31, 2016.*
- 31.1 Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *
- 31.2 Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *
- 32.1 Certification Pursuant to 18 U.S.C. Section 1350, Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *

Financial statements from the quarterly report on Form 10-Q of STAAR Surgical Company for the quarter ended April 1, 2016, formatted in Extensible Business Reporting Language (XBRL), are filed herewith and include: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Comprehensive Loss, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) the Notes to Condensed Consolidated Financial Statements tagged as blocks of text. *

- (1) Incorporated by reference to 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 December 17, 2015.
- (3) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Commission on March 1, 2016.
- (4) Incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the Company's Registration Statement on Form 8-A/A, as filed on April 18, 2003.

* Filed 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: May 11, 2016 By: /s/ STEPHEN P. BROWN

Stephen P. Brown

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