STAAR SURGICAL CO Form 10-Q May 12, 2015

## UNITED STATES

## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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Form 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE <sup>X</sup>ACT OF 1934

For the quarterly period ended: April 3, 2015

Or

# "TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number: 0-11634

## STAAR SURGICAL COMPANY

(Exact name of registrant as specified in its charter)

Delaware

95-3797439

(State or other jurisdiction of (I.R.S. Employer

incorporation or organization) Identification No.)

#### 1911 Walker Avenue

#### Monrovia, California 91016

(Address of principal executive offices)

#### (626) 303-7902

(Registrant's telephone number, including area code))

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

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 x No o

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):

o Large accelerated filerx Accelerated filer o Non-accelerated filer	o 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 o No x

The registrant has 38,845,236 shares of common stock, par value \$0.01 per share, issued and outstanding as of May 1, 2015.

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## **PART 1 – FINANCIAL INFORMATION**

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## **ITEM 1. FINANCIAL STATEMENTS**

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# **STAAR SURGICAL COMPANY**

## CONDENSED CONSOLIDATED BALANCE SHEETS

# (In thousands, except par value amounts)

(Unaudited)

	April 3,	January 2,
	2015	2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$10,809	\$13,013
Accounts receivable trade, net of allowance for doubtful accounts of \$1,688 and \$1,589 respectively	11,035	11,054
Inventories, net	15,273	15,717
Prepaids, deposits and other current assets	5,271	4,517
Deferred income taxes	600	596
Total current assets	42,988	44,897
Property, plant and equipment, net	9,923	10,066
Long-lived Intangible assets, net	824	870
Goodwill	1,786	1,786
Deferred income taxes	698	695
Other assets	590	597
Total assets	\$56,809	\$58,911
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Line of credit	\$4,178	\$4,150
Accounts payable	4,943	6,620
Deferred income taxes	301	301
Obligations under capital leases	342	399
Other current liabilities	5,284	4,976
Total current liabilities	15,048	16,446

Obligations under capital leases Deferred income taxes Asset retirement obligations Pension liability Total liabilities	411 1,756 117 3,128 20,460	468 1,704 115 3,079 21,812
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Common stock, \$0.01 par value; 60,000 shares authorized; 38,790 and 38,429 shares issued and outstanding at April 3, 2015 and January 2, 2015, respectively	386	384
Additional paid-in capital	179,767	178,232
Accumulated other comprehensive loss	(1,017)	(1,070)
Accumulated deficit	(142,787)	(140,447)
Total stockholders' equity	36,349	37,099
Total liabilities and stockholders' equity	\$56,809	\$58,911
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See accompanying notes to the condensed consolidated financial statements.

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#### CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

## (In thousands, except per share amounts)

(Unaudited)

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	Three Me Ended April 3,		
	2015	2014	
Net sales Cost of sales	\$18,858 5,959	\$20,178 6,294	
Gross profit	12,899	13,884	
General and administrative Marketing and selling Research and development Medical device tax Other general and administrative expenses	5,114 5,668 3,579 48	5,396 6,138 3,484 40 168	
Operating loss	(1,510)	(1,342)	
Other income (expense): Interest income Interest expense Gain (loss) on foreign currency transactions Other income, net Total other income (expense), net	. ,	9 (33)) 66 160 202	
Loss before provision (benefit) for income taxes Provision (benefit) for income taxes Net loss	(2,368) (28) \$(2,340)		
Net loss per share - basic Net loss per share - diluted	\$(0.06) \$(0.06)	\$(0.04) \$(0.04)	
Weighted average shares outstanding - basic Weighted average shares outstanding - diluted	38,481 38,481		

See accompanying notes to the condensed consolidated financial statements.

## CONDENSED CONSOLIDATED STATEMENTS

#### **OF COMPREHENSIVE LOSS**

(In thousands)

(Unaudited)

	Three Months Ended		
	April	April	
	3, 2015	4, 2014	
Net loss	\$(2,340)	\$(1,359	))
Other comprehensive loss:			
Defined Benefit Pension Plans:			
Net change in plan assets	(8)	(11	)
Reclassification into earnings	15	6	
Foreign currency translation	79	11	
Tax effect	(24)	(4	)
Other comprehensive income, net of tax	62	2	
Comprehensive loss	\$(2,278)	\$(1,357	7)

See accompanying notes to the condensed consolidated financial statements.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

# (In thousands)

## (Unaudited)

	Three Mo Ended April 3,	
Cash flows from operating activities:	2015	2014
Net loss Adjustments to reconcile net loss to net cash used in operating activities:	\$(2,340)	\$(1,359)
Depreciation of property and equipment Amortization of long-lived intangibles	497 52	453 106
Deferred income taxes	(118)	24
Change in net pension liability Stock-based compensation expense	50 994	45 1,500
Accretion of asset retirement obligation Provision for sales return and bad debt expense	1 99	1 (55)
Changes in working capital: Accounts receivable trade, net Inventories	(56) 617	(295) (1,137)
Prepaids, deposits and other current assets Accounts payable	(573) (1,741)	(1,270)
Other current liabilities Net cash used in operating activities	309	3 (2,594)
Cash flows from investing activities:	( ) /	( ) )
Acquisition of property and equipment Sale of property and equipment	(328 ) 2	(1,414)
Net cash used in investing activities	-	(1,414)
Cash flows from financing activities:	(11 <b>7</b> )	
Repayment of capital lease obligations Proceeds from exercise of stock options Net cash provided by financing activities	(115) 421 306	(46) 2,188 2,142
Effect of exchange rate changes on cash and cash equivalents	25	(18)
Decrease in cash and cash equivalents	(2,204)	(1,884)

Cash and cash equivalents, at beginning of the period	13,013	22,954
Cash and cash equivalents, at end of the period	\$10,809	\$21,070

See accompanying notes to the condensed consolidated financial statements.

#### Note 1 - Basis of Presentation and Significant Accounting Policies

The consolidated financial statements of the Company present the financial position, results of operations, and cash flows of STAAR Surgical Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities Exchange Commission. In accordance with those rules and regulations certain information and footnote disclosures normally included in comprehensive financial statements have been condensed or omitted pursuant to such rules and regulations. The consolidated balance sheet as of January 2, 2015 was derived from the audited financial statements at that date, but does not include all the information and footnotes required by GAAP. These financial statements should be read in conjunction with the audited financial statements and notes thereto include in the Company's Annual Report on Form 10-K for the year ended January 2, 2015.

The condensed consolidated financial statements for the three months ended April 3, 2015 and April 4, 2014, 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 3, 2015 and April 4, 2014 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 Not Yet Effective

There have been no recent accounting pronouncements or changes in accounting pronouncements during the three months ended April 3, 2015, as compared to the recent accounting pronouncements described in our Annual Report on Form 10-K for the fiscal year ended January 2, 2015, that are of significance or potential significance to us.

Prior Year Reclassifications

Certain reclassifications have been made to the prior periods' unaudited condensed financial statements and related note disclosures to conform to current period's presentation.

#### Note 2 - Inventories

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

	April 3,	January 2,
	2015	2015
Raw materials and purchased parts	\$2,078	\$2,146
Work-in-process	1,881	1,781
Finished goods	14,115	14,504
	18,074	18,431
Less: inventory reserves	2,801	2,714
	\$15,273	\$15,717

#### Note 3 - Prepaids, Deposits, and Other Current Assets

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

	April 3, 2015	January 2, 2015
Prepaids and deposits	\$2,835	\$ 1,991
Income tax receivable	967	1,084
Value added tax (VAT) receivable	622	721
Deferred charge for foreign profits	483	338
Other current assets	364	383
	\$5,271	\$4,517

#### Note 4 - Property, Plant and Equipment, Net

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

	April 3,	January 2,
	2015	2015
Machinery and equipment	\$15,969	\$15,674
Furniture and fixtures	6,540	6,535
Leasehold improvements	8,413	8,400
	30,922	30,609
Less: accumulated depreciation	20,999	20,543
	\$9,923	\$10,066

## Note 5 - Long-lived Intangible Assets, Net

Long-lived intangible assets, net consisted of the following (in thousands):

	April 3, 2 Gross	2015		January Gross	2, 2015	
	Accumulated		Accumulated			
	Carrying	g Amortizati	Net ion	Carrying	g Amortizati	Net
	Amount			Amount		
Long-lived intangible assets:						
Patents and licenses	\$9,209	(8,868	) \$341	\$9,205	\$ (8,859	) \$346
Customer relationships	1,310	(950	) 360	1,302	(911	) 391
Developed technology	833	(710	) 123	827	(694	) 133
Total	\$11,352	\$ (10,528	) \$824	\$11,334	\$ (10,464	) \$870

#### **Note 6 - Other Current Liabilities**

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

	April 3,	January 2,
	2015	2015
Accrued salaries and wages	\$2,050	\$ 1,647
Accrued insurance	677	550
Accrued bonuses	553	75
Customer credit balances	230	186
Accrued income taxes	204	867
Accrued audit fees	194	352
Accrued commissions	179	309
Other <sup>(1)</sup>	1,197	990
	\$5,284	\$ 4,976

<sup>(1)</sup>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	Three Months
	Ended	Ended
	April 3, 2015	April 4, 2014
Service cost Interest cost	\$ 107 19	\$ 116 35
Expected return on plan assets Net amortization of transitional obligation (a) Actuarial loss, recognized in current period (a)	(21 3 12 \$ 120	) (27 ) - 6 \$ 130

(a) Amounts reclassified from accumulated other comprehensive income.

During the three months ended April 3, 2015 and April 4, 2014, the Company made cash contributions totaling approximately \$400,200 and \$558,000, respectively, to its Swiss pension plan and does not expect to make additional cash contributions during the remainder of 2015. 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 3, April 4, 2015 2014

Numerator:		
Net loss	\$(2,340)	\$(1,359)
Denominator:		
Weighted average common shares and denominator for basic calculation:		
Weighted average common shares outstanding	38,638	38,116
Less: Unvested restricted stock	157	322
Denominator for basic calculation	38,481	37,794
Weighted average effects of potentially dilutive common stock:		
Stock options	-	-
Warrants	-	-
Restricted stock	-	-
Denominator for diluted calculation	38,481	37,794
Net loss per share - basic	\$(0.06)	\$(0.04)
Net loss per share - diluted	\$(0.06)	\$(0.04)

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	April	
	3,	4,	
	2015	2014	
Options	1,187	1,905	
Restricted stock and units	237	365	
Warrants	316	528	
Total	1,740	2,798	

#### Note 9 - Geographic and Product Data

The Company markets and sells its products in over 60 countries and has manufacturing sites in the United States and Switzerland. Other than the United States, Japan, Korea, China, Spain, and France, 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 3,	April 4,		
	2015	2014		
Japan	\$4,286	\$5,008		
United States	2,867	2,874		
China	2,371	2,225		
Korea	2,343	2,621		
Spain	1,478	1,618		
France	1,150	946		
Other	4,363	4,886		
Total	\$18,858	\$20,178		

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 3, 2015	April 4, 2014		
ICLs IOLs	\$12,255 5,358	\$12,241 6,613		
Core products	17,613	18,854		
Other Surgical Products Total	1,245 \$18,858	1,324 \$20,178		

The Company sells its products internationally, which subjects the Company to several potential 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.

A single customer, our distributor in South Korea, has accounted for 12% and 13% of net sales for the three months ended April 3, 2015 and April 4, 2014, 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 3,	April 4,	
	2015	2014	
Employee stock options	\$725	\$859	
Restricted stock	271	299	
Restricted stock units	129	398	
Nonemployee stock options	(7)	22	
Total	\$1,116	\$1,578	

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 3,	April 4,	
	2015	2014	
General and administrative	\$593	\$928	
Marketing and selling	251	302	
Research and development	150	270	
Total stock compensation expense	\$994	\$1,500	
Amounts capitalized as part of inventory	122	78	
Total	\$1,116	\$1,578	

#### Stock Option Plans

The Amended and Restated 2003 Omnibus Equity Incentive Plan ("the Plan") provides for various forms of stock-based incentives. To date, of the available forms of awards under the Plan, the Company has granted only stock options, restricted stock, unrestricted share grants, restricted stock units, and performance contingent stock units. Options under the plan are granted at fair market value on the date of grant, become exercisable over a three year period, or as determined by the Board of Directors, and expire over periods not exceeding 10 years from the date of grant. Certain option and share awards provide for accelerated vesting if there is a change in control (as defined in the Plan). Pursuant to the Plan, options for 3,619,790 shares were outstanding at April 3, 2015 with exercise prices ranging between \$0.95 and \$17.62 per share. Restricted stock grants under the Plan generally vest over a period between one to four years. There were 156,763 shares of restricted stock and 135,500 restricted stock units (RSUs) outstanding at April 3, 2015. As of April 3, 2015, there were 1,662,958 shares authorized and available for grants under the Plan.

#### Assumptions

The fair value of each option award is estimated on the date of grant using a Black-Scholes option valuation model applying the 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 6.92% 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	April		
	3,	4,		
	2015	2014		
Expected dividend yield	0 %	0 %		
Expected volatility	57.46%	55.25%		
Risk-free interest rate	1.70 %	1.28 %		
Expected term (in years)	5.64	4.12		

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

#### Options

Shares

	(000's)	
Outstanding at January 2, 2015	3,175	
Granted	568	
Exercised	(104	)
Forfeited or expired	(19	)
Outstanding at April 3, 2015	3,620	
Exercisable at April 3, 2015	2,384	

Warrants outstanding and exercisable for the period ended April 3, 2015 and January 2, 2015 were 700,000.

A summary of restricted stock and restricted stock units activity under the Plan for the period ended April 3, 2015 is presented below:

	Restricted	Restricted
	Shares	Units
	(000's)	( <b>000's</b> )
Outstanding at January 2, 2015	247	156
Granted	-	12
Vested	(90	) (10 )
Forfeited	-	(22)
Outstanding at April 3, 2015	157	136

#### Note 11 - Income Taxes

The provision for income taxes is determined using an estimated annual effective tax rate, which is generally less than the U.S. federal statutory rate, primarily due to the Company's net operating losses in the U.S. and certain lower- or zero- rate foreign jurisdictions where the Company operates. The effective tax rate may be subject to fluctuations during the year as new information is obtained, which may affect the assumptions used to estimate the annual effective tax rate, including factors such as the mix of pre-tax earnings in the various tax jurisdictions applicable to the Company, valuation allowances against deferred tax assets, the recognition or derecognition of tax benefits related to uncertain tax positions, if any, and changes in or the interpretation of tax laws in jurisdictions where the Company conducts business.

The Company recorded an income tax benefit of \$28,000 and an income tax provision of \$219,000 for the three months ended April 3, 2015 and April 4, 2014, respectively. The income tax benefit for the three months ended April 3, 2015 includes the pre-tax losses generated in certain foreign jurisdictions the Company consolidates for Swiss income tax purposes. There are no unrecognized tax benefits as of any period presented.

#### Note 12 - Commitments and Contingencies

Lines of Credit

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 \$4.2 million based on the rate of exchange on April 3, 2015), at an interest rate equal to the Tokyo short-term prime interest rate (approximately 1.475% as of April 3, 2015). The line of credit expires June 30, 2015 and is renewable quarterly. The Company had 500,000,000 Yen outstanding on the line of credit as of April 3, 2015 and January 2, 2015 (approximately \$4.2 million based on the foreign currency exchange rates on April 3, 2015 and January 2, 2015). As of April 3, 2015 there were no available borrowings under the line.

In August 2010, the Company's wholly-owned Swiss subsidiary, STAAR Surgical AG, entered into a credit agreement with Credit Suisse (the "Bank"). The credit agreement provides for borrowings of up to 1,000,000 Swiss Francs (approximately \$1.0 million at the rate of exchange on April 3, 2015), to be used for working capital purposes. Borrowings, if any, on the credit line are due in one year from the borrowing date. The credit agreement is renewed every three years with a current expiration date of September 1, 2016. There were no borrowings outstanding as of April 3, 2015 and January 2, 2015, and the full amount of the line was available for borrowing (see Note 13).

#### Covenant Compliance

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

#### Litigation and Claims

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

On July 8, 2014, a putative securities class action lawsuit was filed by Edward Todd against STAAR and three officers in the federal court located in Los Angeles, California. The plaintiff claims that STAAR made misleading statements to and omitted material information from our investors between February 27, 2013 and June 30, 2014 about alleged regulatory violations at STAAR's Monrovia manufacturing facility. On July 21, 2014, the Company was served with the Complaint. On October 20, 2014, plaintiff amended its complaint, dismissed two Company officers, added one other officer, and reduced the alleged Class Period to November 1, 2013 to June 30, 2014. Although the ultimate outcome of this action cannot be determined with certainty, the Company believes that the allegations in the Complaint are without merit. The Company intends to vigorously defend against this lawsuit. The Company intends to file a motion to dismiss the complaint, when appropriate, in the ongoing proceeding.

#### **Employment Agreements**

The Company's Chief Executive Officer and certain officers have as provisions of their agreements certain rights, including continuance of cash compensation and benefits, upon a "change in control," which may include an acquisition of substantially all of its assets, or termination "without cause or for good reason" as defined in the employment agreements (see Note 13).

On April 7, 2015 the Company granted approximately 214,000 options and 88,000 restricted stock units to certain executives, directors and other employees.

On May 1, 2015, STAAR Surgical AG entered into a guarantee agreement with Bankinter Spain ("Bankinter"). The agreement provides Bankinter with a guarantee of up to EUR 400,000 (approximately \$446,000 at the rate of exchange on May 1, 2015) for trade receivables from the Company's Spanish customers. The total guarantee amount can be offset against the credit agreement in place with Credit Suisse and therefore reduces the credit line available to STAAR Surgical AG for working capital requirements to up to 581,000 Swiss Francs (approximately up to \$619,000 at the rate of exchange on May 1, 2015). Unless terminated sooner by Bankinter, the guarantee agreement expires on May 1, 2017. To date, no amounts are outstanding on the credit line with Credit Suisse or the guarantee with Bankinter.

In May 2015, the Company recorded separation costs approximating \$469,000 for certain executives and other employees.

# 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. Any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words "believes," "anticipates," "plans," "expects," "seeks," "estimates," and similar expressions are intended to identify forward-looking statements. While the Company may elect to update forward-looking statements in the future, it specifically disclaims any obligation to do so, even if the Company's estimates change, and readers should not rely on those forward-looking statements as representing the Company's views as of any date subsequent to the date of the filing of this Quarterly Report. Although we believe that the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risks and STAAR can give no assurances that its expectations will prove to be correct. Actual results could differ materially from those described in this report because of numerous factors, many of which are beyond the control of STAAR. A number of important factors could cause the results of the company to differ materially from those indicated by such forward-looking statements, including those detailed under the heading "Risk Factors" in Part II, Item 1A of this report on Form 10-Q.

The following discussion should be read in conjunction with STAAR's interim condensed consolidated financial statements and the related notes provided under "*Item 1- Financial Statements*" above.

#### Overview

STAAR Surgical Company ("we," "us," the "Company," and "STAAR") designs, develops, manufactures and sells implantable lenses and delivery systems for the eye. We are the world's leading manufacturer of intraocular lenses used in "refractive" surgery, and we also make lenses for use in surgery to treat cataracts. All of the lenses we make are foldable, which allows the surgeon to insert them into the eye through a small incision during minimally invasive surgery. Refractive surgery is performed to treat the type of visual disorders that have traditionally been corrected using eyeglasses or contact lenses. We refer to our lenses used in refractive surgery as "implantable Collamer® lenses" or "ICLs" and market them under the Visian® brand name. The field of refractive surgery includes both lens-based procedures, using products like the Visian ICL®, and laser-based procedures like LASIK. Successful refractive surgery is a common outpatient procedure where the eye's natural lens that has become cloudy with age is removed and replaced with an artificial lens called an intraocular lens (IOL) to restore the patient's vision.

STAAR®, Visian®, Collamer®, STAARVISC®, Elastimide®, nanoFLEX®, nanoPOINT, CentraFLOW® AquaPORT®, Epiphany® and AquaFlow are trademarks or registered trademarks of STAAR in the U.S. and other countries.

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

#### **Products**

A detailed description of STAAR's business appears in our Annual Report on Form 10-K for the fiscal year ended January 2, 2015, along with a glossary explaining many of the specialized terms used in describing our products and our business. We recommend that readers unfamiliar with STAAR refer to that description.

*ICLs - Implantable Collamer Lenses for Refractive Surgery.* Sales of refractive lenses make up over sixty (60%) percent of our total sales. Made from our proprietary biocompatible Collamer material, highlights of STAAR's family of Visian ICL products are as follows:

The Visian ICL treats refractive disorders such as myopia (near-sightedness) and hyperopia (far-sightedness). STAAR began selling the Visian ICL outside the U.S. in 1996 and inside the U.S. in 2006.

The Visian Toric ICL, or TICL, treats myopic and hyperopic patients with astigmatism. Astigmatism is a condition that causes blurred vision when an irregular shape of the cornea or defects in the natural lens prevents light from ·coming to a single focusing properly on the retina. STAAR has been selling the Visian TICL outside the U.S. since 2002. STAAR remains in dialogue with the FDA regarding its PMA Supplement submission seeking approval to sell the TICL in the U.S. This matter is further discussed below under, "Status of Regulatory Submission."

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

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

Aspheric IOLs, available in single-piece and three-piece designs made from (i) Collamer, STAAR's proprietary biocompatible collagen copolymer lens material, and (ii) from silicone. Aspheric IOLs are designed to improve the •patient's quality of vision when compared to earlier spherical IOL designs. The three-piece aspheric silicone IOL is sold preloaded in certain markets outside of the U.S. The three piece Collamer IOL is only marketed and sold in the U.S.

The nanoFLEX IOL, a single-piece Collamer aspheric IOL that can be implanted through a micro-incision with a single-use disposable nanoPOINT injector system, is available in the U.S. and territories that accept the CE Mark.

The Preloaded IOL line consists of a three-piece silicone and a three-piece and single-piece acrylic IOL preloaded into a single-use disposable injector which is currently available outside the U.S. The acrylic Preloaded IOL line utilizes an acrylic lens sourced from another manufacturer. The KS-SP is the single-piece preloaded acrylic IOL and the KS-X is the three-piece preloaded acrylic IOL. The KS IOL line is available in Japan and parts of Europe.

STAAR Toric IOL is a single-piece silicone toric IOL, used in cataract surgery to treat preexisting astigmatism and is currently only marketed in the U.S.

Because most cataract patients are elderly, government agencies or government sponsored entities generally pay all or part of the cost of IOLs in our major markets, including the U.S. As a result, cataract procedure volumes will likely remain relatively stable even under adverse conditions in the general economy. However, changes in reimbursement policy under these agencies and entities can reduce our selling prices or reduce the volume of cataract procedures.

*Other Surgical Products.* We also sell certain instruments, devices, and injector system. Although we have been deemphasizing these products since 2009 because of their lower overall gross profit margins, we expect that sales of these products will continue to increase due to an increase in demand of injector systems.

**Operations** 

STAAR is a global company. Activities outside the U.S. accounted for approximately 85% of our total sales in fiscal year 2014, primarily due to the pacing of product approvals and commercialization that tend to occur first outside the U.S. STAAR sells its products in more than 60 countries, with direct distribution in the United States, Canada, Japan and Spain, and independent distribution in the remainder of the world.

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

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

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

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

The global nature of STAAR's business operations subjects it to risks due to many factors some of which are beyond our control. As noted above, investors and prospective investors should consider carefully, in addition to other information contained in this report, the risks and uncertainties described in "Part I-Item 1A-Risk Factors" of the Company's Form 10-K for the fiscal year ended January 2, 2015. Such risks and uncertainties could materially adversely affect our business, financial condition or operating results.

## **Other Highlights**

In the first quarter of 2015, ICL sales were essentially flat as compared with the first quarter of 2014. ICL sales in the Europe, Middle East and Africa (EMEA) region decreased 2% compared to the prior year period, but increased 9% in units. The decrease in sales was attributable to the weakening of the Euro and its impact on average selling prices. ICL sales in the Asia Pacific (APAC) region decreased 3% compared to the prior year period, which was comprised of a 6% decrease in units mostly offset by a 3% increase in average selling prices. In the first quarter of 2015, 78% of all ICLs shipped to China incorporated the CentraFLOW technology. ICL sales in North America increased 18% in units and dollars compared to the prior year period, primarily due to the shipment of an order to large customer that last year was shipped in the second quarter. Backlog of ICLs decreased to \$340,000 from a \$3.3 million peak during the first quarter of 2015. ICL manufacturing production increased during the first quarter and we anticipate returning to customary order fulfillment levels for the toric ICL during the second quarter of 2015. IOL sales in the first quarter of 2015 decreased 19% percent primarily due to a high comparable from the first quarter of 2014 caused by increased purchases by Japanese customers for tax planning purposes. Our third party supplier of components for the KS-IOL product line experienced manufacturing challenges that limited supply. We expect to resolve the KS-IOL production challenges by the end of the second quarter of 2015. We sold more acrylic preloaded IOL systems than silicone preloaded IOL systems during the first quarter and expect that trend to continue. We continue to devote significant effort towards rebuilding our quality system and our remediation efforts. If we cannot resolve our manufacturing challenges, our financial results may be adversely impacted.

#### Status of Regulatory Submission

As previously disclosed, STAAR received an FDA Warning Letter, dated May 21, 2014, regarding compliance with current Good Manufacturing Practices at the Monrovia facility. Upon receipt of this letter, STAAR initiated development and subsequent implementation of corrective action plans related to this letter. Beginning on November 14, 2014 and continuing through February 4, 2015, the U.S. Food and Drug Administration (FDA) inspected the Company's Monrovia facility as a follow-up to the 2014 Warning Letter and also as a post-approval inspection regarding the approved PMA supplement that added the Monrovia facility as an alternate manufacturing facility for the ICL. On February 4, 2015, at the conclusion of the inspections, the FDA issued a Form 483 with ten inspectional observations (2015 FDA-483). The observations focus primarily on the need for adherence to and improved procedures, processes and documentation relating to design change, design transfer into specifications and production, verification and validation associated with device design and production, improvement in Good Documentation Practices, and broader environmental monitoring.

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

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

Regarding our PMA Supplement submission to the FDA seeking approval of the TICL, on March 14, 2014 a FDA Ophthalmic Devices Panel of the Medical Devices Advisory Committee voted favorably in response to the three questions posed to it by the FDA's Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices (regarding the TICL's safety and effectiveness as well as whether the TICL's benefits outweigh its risks). Once again, STAAR cannot predict when, or if, the FDA will grant approval of the TICL for use in the United States. We do not expect a decision from the FDA regarding the TICL's PMA Supplement until the FDA determines that we have resolved or made sufficient progress in addressing the issues raised in the 2014 Warning Letter and 2015 FDA-483.

On October 9, 2012, STAAR submitted a clinical study protocol regarding the ICL with CentraFLOW technology. On December 12, 2013, we met with the FDA in Washington D.C. to discuss the protocol and we are in the process of preparing a revised proposed protocol.

#### **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 3, 2015 to the items that we disclosed as our critical accounting policies and estimates in Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the fiscal year ended January 2, 2015.

#### **Results of Operations**

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

Percentage of Net Sales for Percentage

**Three Months** 

Change for

Three

	April 3,		April 4,		Months 2015	
	2015		2014		vs. 2014	
Net sales	100.0	%	100.0	%	(6.5	)%
Cost of sales	31.6		31.2		5.3	
Gross profit	68.4		68.8		(7.1	)
General and administrative	27.1		26.7		(5.2	)
Marketing and selling	30.1		30.4		(7.7	)
Research and development	19.0		17.3		2.7	
Medical device tax	0.3		0.2		20.0	
Other general and administrative expenses	-		0.9		*	
	76.5		75.5		(5.4	)
Operating loss	(8.0	)	(6.7	)	12.4	
Other income (expense), net	(4.5	)	1.1		*	
Loss before provision (benefit) for income taxes	(12.6	)	(5.6	)	*	
Provision (benefit) for income taxes	(0.1	)	1.1	-	*	
Net loss	(12.5	)%	(6.7	)%	72.2	

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

#### Net Sales

			Percentage Change			
	Three Me	nths Ended				
	T III ee Ivio	for Three				
	April 3, April 4,		Months 2015			
	2015	2014	vs. 2014			
Net sales	\$ 18,858	\$ 20,178	(6.5	)%		
ICL IOL Other	12,255 5,358 1,245	12,241 6,613 1,324	0.1 (19.0 (6.0	)		
ound	1,273	1,524	(0.0	,		

Net sales for the three months ended April 3, 2015 were \$18.9 million, a decrease of 6.5% compared with \$20.2 million reported during the same period of 2014. Changes in currency had a \$0.7 million unfavorable impact on net sales for the first quarter of 2015 as compared to the first quarter of 2014.

Total ICL sales for the three months ended April 3, 2015 were \$12.3 million, an increase of 0.1% compared with \$12.2 million reported during the same period of 2014. EMEA ICL sales were \$4.5 million during the first quarter, a decrease of 2% compared to the prior year period, but an increase of 9% in units. The decrease in sales was attributable to the weakening of the Euro and its impact on average selling prices. APAC ICL sales were \$6.0 million during the first quarter, a decrease of 3% compared to the prior year period, which was comprised of a 6% decrease in units, partially offset by a 3% increase in average selling prices. North America ICL sales were \$1.7 million during the first quarter, an increase of 18% in units and dollars compared to the prior year period.

Total IOL sales for the three months ended April 3, 2015 were \$5.4 million, a decrease of 19% compared with \$6.6 million reported during the same period of 2014. The decline was due to an increased supply of the KS-IOL preloaded acrylic product in the first quarter of 2014 and higher than usual distributor stocking of that product following an extended period of backorders.

Other product sales for the three months ended April 3, 2015 were \$1.2 million, a decrease of 6% compared with the \$1.3 million reported during the same period of 2014. Increased sales of injector parts were more than offset by decreased sales of other products which the Company continues to deemphasize.

#### Gross Profit

			Percentage Change			
	Three Mon	the Ended				
	Three Mon	tills Ellueu	for Three			
	April 3,	April 4,	Months 2015			
	2015	2014	vs. 2014			
Gross Profit Gross Profit Margin	\$12,899 68.4 %	\$13,884 68.8	(7.1)%			

Gross profit for the first quarter was \$12.9 million, or 68.4% of revenue, compared with \$13.9 million, or 68.8% of revenue, in the prior year period. Compared to the first quarter of 2014, gross margin benefited from improved average unit costs and a smaller proportion of lower-margin product sales, offset by the impact of a weaker Euro on average selling prices and moderately higher inventory reserves and freight and distribution costs.

#### General and Administrative

					Percentag	e	
	Three Months Ended				Change		
					for Three		
	April 3,		April 4,		Months 2015		
	2015		2014		vs. 2014		
General and Administrative Percentage of Sales	\$ 5,114 27.1	%	\$ 5,396 26.7	%	(5.2	)%	

General and administrative expenses for the quarter were \$5.1 million, a decrease of 5.2% when compared with \$5.4 million reported last year. The decrease is due to decreased compensation and consulting costs, partially offset by accrued separation costs.

## Marketing and Selling

	Three Months Ended				Percentage		
					Change		
					for Three		
	April 3,		April 4,		Months 2015		
	2015		2014		vs. 2014		
Marketing and Selling	\$ 5,668		\$ 6,138		(7.7	)%	
Percentage of Sales	30.1	%	30.4	%			

Marketing and selling expenses for the quarter were \$5.7 million, a decrease of 8% when compared with \$6.1 million reported last year. The decrease is due to decreased marketing costs internationally, stock-based compensation, and the favorable impact of exchange, partially offset by increased ICL and online marketing cost and commissions in the U.S.

#### **Research and Development**

#### Percentage

#### Change Three Months Ended

#### for Three

# Months

	April 3,	April 4,			2015		
	2015		2014		vs. 2014		
Research and Development	\$ 3,579		\$ 3,484		2.7	%	
Percentage of Sales	19.0	%	17.3	%			

Research and development expenses for the quarter were \$3.6 million, an increase of 3% when compared with \$3.5 million reported last year. FDA remediation expenses were \$1.4 million during the first quarter of 2015, approximately the same amount as the FDA panel expenses reported in the first quarter of 2014. We expect to incur an additional \$2.6 million of FDA remediation expenses for the remainder of 2015.

#### Other Income (Expense), Net

#### Percentage

	Three Months Ended			Change for	
	I hree M	ont	Three		
	April 3,		April 4,	Months 2015	
	2015		2014	vs. 2014	
Other Income (Expense), Net	\$ (858	)	\$ 202	_ *	

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

Other expense for the quarter was \$0.9 million compared to other income of \$0.2 million in the first quarter of 2014. The increase in other expense is due to foreign currency transaction losses recorded in the first quarter of 2015, compared to foreign currency transaction gains recorded during the first quarter of 2014. Foreign currency gains and losses result from transactions primarily denominated in currencies other than the U.S. dollar.

#### Income taxes

			Percentage
		Change for	
	Three Mon	ths Ended	Three
	April 3,	April 4,	Months 2015
	2015	2014	vs. 2014
Provision (benefit) for income taxes	\$ (28 ) 16	\$ 219	_ *

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

The provision for income taxes is determined using an estimated annual effective tax rate. Income tax benefit for the quarter was \$28,000, compared to an income tax provision of \$219,000 reported last year. The income tax benefit for the three months ended April 3, 2015 includes the pre-tax losses we generated in certain foreign jurisdictions we consolidate for Swiss income tax purposes. There are no unrecognized tax benefits as of any period presented.

Based on current year projections, we expect the estimated annual effective tax rate to be 21%.

### 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 \$4 million cost in 2015 associated with our FDA remediation efforts of which \$1.4 million was incurred in Q1 2015. Although we anticipate these costs will continue into 2016, we cannot currently estimate the amount but will update as more information becomes available. If the need for financing arises which we cannot rule out, STAAR cannot assure that it will be available on acceptable terms, or if at all. STAAR's Japanese and Swiss subsidiaries have bank lines of credit in place for working capital purpose, 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 demands, STAAR intends to invest its cash in expanding and improving its business. It does not anticipate paying dividends from its earnings for the foreseeable future.

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

As of April 3, 2015 and January 2, 2015, respectively, STAAR had \$10.8 million and \$13.0 million of cash and cash equivalents, respectively.

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Net cash used in operating activities was \$2.2 million for the three months ended April 3, 2015 and \$2.6 million for the three months ended April 4, 2014 and consisted of net loss of \$2.3 million, plus \$1.6 million in non-cash items, offset by a \$1.5 million increase in net working capital for the three months ended April 3, 2015.

Net cash used in investing activities was \$0.3 million for the three months ended April 3, 2015, compared to \$1.4 million in net cash used in investing activities for the three months ended April 4, 2014. Net cash used in investing activities was due to the acquisition of property, plant and equipment.

Net cash provided by financing activities was \$0.3 million for the three months ended April 3, 2015, compared with \$2.1 million in net cash provided by financing activities for the three months ended April 4, 2014. The decrease in cash provided by financing activities was primarily due to a decrease in proceeds from exercise of stock options.

### Credit Facilities, Contractual Obligations and Commitments

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 \$4.2 million based on the rate of exchange on April 3, 2015), at an interest rate equal to the Tokyo short-term prime interest rate (approximately 1.475% as of April 3, 2015). The line of credit expires June 30, 2015 and is renewable quarterly. The Company had 500,000,000 Yen outstanding on the line of credit as of April 3, 2015 and January 2, 2015 (approximately \$4.2 million based on the foreign currency exchange rates on April 3, 2015 and January 2, 2015). As of April 3, 2015 there were no available borrowings under the line.

In August 2010, the Company's wholly-owned Swiss subsidiary, STAAR Surgical AG, entered into a credit agreement with Credit Suisse (the "Bank"). The credit agreement provides for borrowings of up to 1,000,000 Swiss Francs (approximately \$1.0 million at the rate of exchange on April 3, 2015), to be used for working capital purposes. Borrowings, if any, on the credit line are due in one year from the borrowing date. The credit agreement is renewed every three years with a current expiration date of September 1, 2016. There were no borrowings outstanding as of April 3, 2015 and January 2, 2015, and the full amount of the line was available for borrowing

On May 1, 2015, STAAR Surgical AG entered into a guarantee agreement with Bankinter Spain ("Bankinter"). The agreement provides Bankinter with a guarantee of up to EUR 400,000 (approximately \$446,000 at the rate of exchange on May 1, 2015) for trade receivables from the Company's Spanish customers. The total guarantee amount can be offset against the credit agreement in place with Credit Suisse and therefore reduces the credit line available to

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STAAR Surgical AG for working capital requirements to up to 581,000 Swiss Francs (approximately up to \$619,000 at the rate of exchange on May 1, 2015). Unless terminated sooner by Bankinter, the guarantee agreement expires on May 1, 2017. To date, no amounts are outstanding on the credit line with Credit Suisse or the guarantee with Bankinter.

### Covenant Compliance

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

#### **Employment Agreements**

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

#### Capital Lease Obligations

STAAR leases certain property, plant, and equipment under non-cancelable capital lease agreements. These leases vary in amount, duration, and rates.

Estimated future minimum payments under capital lease obligations were as follows (in thousands):

Fiscal Year	April 3, 2015
2015	\$315
2016	349
2017	144
Total minimum lease payments	\$808
Less: interest	55
Total lease obligation	\$753
Current	\$342
Long-term	\$411

#### **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 2, 2015.

#### **ITEM 4.** CONTROLS AND PROCEDURES

#### **Disclosure Controls and Procedures**

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

Our management, including the CEO and the CFO, do not expect that our disclosure controls and procedures or our internal control over financial reporting will necessarily prevent all fraud or material errors. An internal control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations on all internal control systems, our internal control system can provide only reasonable assurance of achieving its objectives and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more

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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 3, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### **PART II - OTHER INFORMATION**

### ITEM 1. LEGAL PROCEEDINGS

#### Litigation and Claims

From time to time the Company may be subject to various claims and legal proceedings arising out of the normal course of our business. These claims and legal proceedings may relate to contractual rights and obligations, employment matters, and claims of product liability. The most significant of these actions, proceedings and investigations are described below. STAAR maintains insurance coverage for product liability and certain securities. 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.

#### Securities and Exchange Commission Informal Inquiry

In a letter dated July 3, 2014, the United States Securities and Exchange Commission ("SEC") advised STAAR that it would be conducting an informal inquiry into compliance with U.S. securities laws. The letter requested documents concerning any FDA inspections, investigations, observations, noted violations, or warnings since January 1, 2014. In a letter dated April 1, 2015, the SEC advised STAAR that it concluded its informal inquiry and did not intend to recommend any enforcement action. We believe that this concludes the matter.

On July 8, 2014, a putative securities class action lawsuit was filed by Edward Todd against STAAR and three officers in the federal court located in Los Angeles, California. The plaintiff claims that STAAR made misleading statements to and omitted material information from our investors between February 27, 2013 and June 30, 2014 about alleged regulatory violations at STAAR's Monrovia manufacturing facility. On July 21, 2014, the Company was served with the Complaint. On October 20, 2014, plaintiff amended its complaint, dismissed two Company officers, added one other officer, and reduced the alleged Class Period to November 1, 2013 to June 30, 2014. Although the ultimate outcome of this action cannot be determined with certainty, the Company believes that the allegations in the Complaint are without merit. The Company intends to vigorously defend against this lawsuit. The Company intends to file a motion to dismiss the complaint, when appropriate, in the ongoing proceeding.

# ITEM 1A. RISK FACTORS

Our short and long-term success is subject to many factors that are beyond our control. Investors and prospective investors should consider carefully, in addition to other information contained in this report, the risks and uncertainties described in "Part I-Item 1A-Risk Factors" of the Company's Form 10-K for the fiscal year ended January 2, 2015. Such risks and uncertainties could materially adversely affect our business, financial condition or operating results.

# 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)

3.2By-laws, as amended to date.(1)

- 4.4 Form of Certificate for Common Stock, par value \$0.01 per share.(2)
- 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 3, 2015, formatted in XBRL, are filed herewith and include: (i) the Condensed Consolidated Balance

101 Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Consolidated Statements of Comprehensive Income, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) the Notes to Condensed Consolidated Financial Statements tagged as blocks of text. \*

(1) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Commission on June 11, 2014.

(2) Incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the Company's Registration Statement on Form  $(2)_{8-A/A}$ , as filed with the Commission on April 18, 2003.

\* Filed herewith.

### 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 12, 2015 By: <u>/s/ STEPHEN P. BROWN</u> Stephen P. Brown

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