STAAR SURGICAL CO
Form 10-Q
November 04, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

þ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended: October 2, 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 incorporation or organization)	*(I.R.S. Employer 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 þ 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 þ 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 þ Accelerated filer ¨ Non-accelerated filer (Do not check if a smaller reporting company) ¨ 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 þ

The registrant has 39,888,716 shares of common stock, par value $0.01 per share, issued and outstanding as of October 23, 2015.

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)

	October 2, 2015	January 2, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$16,081	$13,013
Accounts receivable trade, net of allowance for doubtful accounts of $1,921 and $1,589, respectively	12,776	11,054
Inventories, net	14,622	15,717
Prepayments, deposits and other current assets	4,008	4,517
Deferred income taxes	598	596
Total current assets	48,085	44,897
Property, plant and equipment, net	9,944	10,066
Intangible assets, net	719	870
Goodwill	1,786	1,786
Deferred income taxes	759	695
Other assets	617	597
Total assets	$61,910	$58,911
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Line of credit	$4,168	$4,150
Accounts payable	5,790	6,620
Deferred income taxes	301	301
Obligations under capital leases	336	399
Other current liabilities	6,280	4,901

Total current liabilities	16,875	16,371
Obligations under capital leases	224	468
Deferred income taxes	1,866	1,704
Asset retirement obligations	116	115
Pension liability	3,202	3,079
Other long-term liabilities	88	75
Total liabilities	22,371	21,812
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Common stock, $0.01 par value; 60,000 shares authorized; 39,883 and 38,429 shares issued and outstanding at October 2, 2015 and January 2, 2015, respectively	399	384
Additional paid-in capital	186,294	178,232
Accumulated other comprehensive loss	(1,017)	(1,070)
Accumulated deficit	(146,137)	(140,447)
Total stockholders' equity	39,539	37,099
Total liabilities and stockholders' equity	$61,910	$58,911

See accompanying notes to the condensed consolidated financial statements.

STAAR SURGICAL COMPANY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended		Nine Months Ended	
	October 2, 2015	October 3, 2014	October 2, 2015	October 3, 2014
Net sales	$ 18,750	$ 18,188	$ 56,264	$ 58,414
Cost of sales	5,951	6,319	18,206	18,995
Gross profit	12,799	11,869	38,058	39,419
General and administrative	4,853	3,259	14,748	14,064
Marketing and selling	6,284	7,026	17,784	20,189
Research and development	3,684	3,137	10,800	9,118
Other general and administrative expenses	—	—	—	334
Operating loss	(2,022)	(1,553)	(5,274)	(4,286)
Other income (expense):				
Interest income	1	7	50	26
Interest expense	(29)	(35)	(97)	(102)
Gain (loss) on foreign currency transactions	20	(628)	(692)	(696)
Other income, net	267	51	437	338
Other income (expense), net	259	(605)	(302)	(434)
Loss before provision for income taxes	(1,763)	(2,158)	(5,576)	(4,720)
Provision (benefit) for income taxes	(11)	548	114	1,134
Net loss	$ (1,752)	$ (2,706)	$ (5,690)	$ (5,854)
Net loss per share – basic and diluted	$ (0.04)	$ (0.07)	$ (0.14)	$ (0.15)
Weighted average shares outstanding – basic and diluted	39,727	38,369	39,409	38,044

See accompanying notes to the condensed consolidated financial statements.

STAAR SURGICAL COMPANY

CONDENSED CONSOLIDATED STATEMENTS

OF COMPREHENSIVE LOSS

(In thousands)

(Unaudited)

	Three Months Ended		Nine Months Ended	
	October 2, 2015	October 3, 2014	October 2, 2015	October 3, 2014
Net loss	$ (1,752)	$ (2,706)	$ (5,690)	$ (5,854)
Other comprehensive income (loss):				
Defined benefit pension plans:				
Net change in plan assets	(9)	(9)	(27)	(32)
Reclassification into earnings	14	6	44	18
Impact of change in discount rate	—	—	—	(558)
Curtailment gain	—	150	—	687
Foreign currency translation gain (loss)	288	(704)	54	(402)
Tax effect	(99)	231	(18)	124
Other comprehensive income (loss), net of tax	194	(326)	53	(163)
Comprehensive loss	$ (1,558)	$ (3,032)	$ (5,637)	$ (6,017)

See accompanying notes to the condensed consolidated financial statements.

STAAR SURGICAL COMPANY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended	
	October 2, 2015	October 3, 2014
Cash flows from operating activities:		
Net loss	$ (5,690)	$ (5,854)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property, plant and equipment	1,563	1,520
Amortization of intangibles	154	317
Deferred income taxes	(148)	161
Change in net pension liability	136	118
Stock-based compensation expense	2,747	4,736
Accretion of asset retirement obligation	—	3
Provision for sales returns and bad debts	331	75
Changes in working capital:		
Accounts receivable, net	(2,040)	(1,139)
Inventories, net	1,497	(3,191)
Prepayments, deposits and other current assets	737	207
Accounts payable	(991)	(17)
Other current liabilities	1,387	(1,364)
Net cash used in operating activities	(317)	(4,428)
Cash flows from investing activities:		
Acquisition of property, plant and equipment	(1,283)	(2,517)
Cash proceeds from sale of property, plant and equipment	2	68
Net cash used in investing activities	(1,281)	(2,449)
Cash flows from financing activities:		
Repayment of capital lease obligations	(306)	(372)
Proceeds from exercise of stock options	2,149	2,793
Proceeds from exercise of warrants	2,800	—
Net cash provided by financing activities	4,643	2,421
Effect of exchange rate changes on cash and cash equivalents	23	(139)
Increase (decrease) in cash and cash equivalents	3,068	(4,595)
Cash and cash equivalents, at beginning of the period	13,013	22,954
Cash and cash equivalents, at end of the period	$ 16,081	$ 18,359

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 included in the Company's Annual Report on Form 10-K for the year ended January 2, 2015.

The accompanying interim condensed consolidated financial statements, in the opinion of management, include all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the Company's financial condition and results of operations. The condensed consolidated results of operations are not necessarily indicative of the results to be expected for any other interim period or for the entire year.

Each of the Company's reporting periods ends on the Friday nearest to the quarter ending date and generally consists of 13 weeks. Unless the context indicates otherwise "we," "us," the "Company," and "STAAR" refer to STAAR Surgical Company and its consolidated subsidiaries.

Recent Accounting Pronouncements

There have been no recent accounting pronouncements or changes in accounting pronouncements during the three months ended October 2, 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 and Quarterly Report on Form 10-Q for the fiscal quarter ended July 3, 2015, that are significant to us.

Prior Year Reclassifications

During the quarter ended October 2, 2015 the Company reclassified $96,000 from medical device tax to general and administrative expenses in the condensed consolidated statement of operations and $75,000 from other current liabilities to other long-term liabilities in the condensed consolidated balance sheet as of January 2, 2015 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 value and consisted of the following (in thousands):

	October 2, 2015	January 2, 2015
Raw materials and purchased parts	$ 2,539	$ 2,146
Work-in-process	1,879	1,781
Finished goods	13,666	14,504
	18,084	18,431
Less: inventory reserves	3,462	2,714
	$ 14,622	$ 15,717

Note 3 — Prepayments, Deposits, and Other Current Assets

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

	October 2, 2015	January 2, 2015
Prepayments and deposits	$ 2,325	$ 1,991
Income tax receivable	34	1,084
Value added tax (VAT) receivable	747	721
Deferred charges for foreign profits	612	338
Other current assets	290	383
	$ 4,008	$ 4,517

Note 4 — Property, Plant and Equipment

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

	October 2, 2015	January 2, 2015
Machinery and equipment	$ 16,714	$ 15,674
Furniture and fixtures	6,840	6,535
Leasehold improvements	8,451	8,400
	32,005	30,609
Less: accumulated depreciation	22,061	20,543
	$ 9,944	$ 10,066

Note 5 –Intangible Assets

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

	October 2, 2015			January 2, 2015		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Intangible assets:						
Patents and licenses	$9,208	(8,884)	$324	$9,205	$ (8,859)	$346
Customer relationships	1,307	(1,013)	294	1,302	(911)	391
Developed technology	831	(730)	101	827	(694)	133
Total	$11,346	$ (10,627)	$719	$11,334	$ (10,464)	$870

Note 6 – Other Current Liabilities

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

	October 2, 2015	January 2, 2015
Accrued salaries and wages	$ 2,208	$ 1,647
Accrued insurance	113	550

Accrued bonuses	1,610	75
Customer credit balances	212	186
Accrued income taxes	148	867
Accrued audit fees	402	352
Accrued commissions	137	309
Other[(1)]	1,450	915
	$ 6,280	$ 4,901

[(1)]No individual item in “Other” above exceeds 5% of the total other current liabilities

Note 7 – Defined Benefit Pension Plans

The Company has defined benefit plans covering employees of its Switzerland and Japan operations.

The following table summarizes the components of net periodic pension cost recorded for the Company's defined benefit pension plans (in thousands):

	Three Months Ended		Nine Months Ended	
	October 2, 2015	October 3, 2014	October 2, 2015	October 3, 2014
Service cost	$ 107	$ 116	$ 321	$ 349
Interest cost	19	30	57	102
Expected return on plan assets	(22)	(22)	(64)	(76)
Net amortization of transitional obligation (a)	3	—	8	—
Actuarial loss recognized in current period (a)	12	6	37	18
Total	$ 119	$ 130	$ 359	$ 393

(a) Amounts reclassified from accumulated other comprehensive income.

During the nine months ended October 2, 2015 and October 3, 2014, the Company made cash contributions totaling approximately $400,000 and $558,000, respectively, to its Swiss pension plan and does not expect to make any additional cash contributions during the remainder of 2015, as the Company has met the annual contribution requirement. The Company is not required to and does not make contributions to its Japan pension plan.

Note 8 — Basic and Diluted Loss Per Share

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

	Three Months Ended		Nine Months Ended	
	October 2, 2015	October 3, 2014	October 2, 2015	October 3, 2014
Numerator:				
Net loss	$ (1,752)	$ (2,706)	$ (5,690)	$ (5,854)
Denominator:				
Weighted average common shares and denominator for basic and diluted calculation:				

Weighted average common shares outstanding	39,851	38,618	39,533	38,311
Less: Unvested restricted stock	(124)	(249)	(124)	(267)
Denominator for basic and diluted calculation	39,727	38,369	39,409	38,044
Net loss per share – basic and diluted	$ (0.04)	$ (0.07)	$ (0.14)	$ (0.15)

The following table sets forth 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 (in thousands).

	Three Months Ended		Nine Months Ended	
	October 2 , 2015	October 3, 2014	October 2, 2015	October 3, 2014
Options	2,615	2,198	2,446	2,067
Restricted stock and units	124	312	193	244
Warrants	—	460	345	509
Total	2,739	2,970	2,984	2,820

Note 9 — Geographic and Product Data

The Company markets and sells its products in over 60 countries and has manufacturing sites in the United States. Other than Japan, China, United States, Korea, Spain and Germany, the Company does not conduct business in any country in which its sales exceed 5% of consolidated sales. Sales are attributed to countries based on location of customers. The composition of the Company’s net sales to unaffiliated customers is set forth below (in thousands):

	Three Months Ended		Nine Months Ended	
	October 2, 2015	October 3, 2014	October 2, 2015	October 3, 2014
Japan	$ 4,249	$ 4,792	$ 12,514	$ 14,349
China	3,095	2,915	8,794	7,675
United States	2,873	2,875	8,464	8,676
Korea	1,690	1,098	5,303	5,671
Spain	1,137	1,178	4,101	4,270
Germany	962	713	2,151	2,625
Other	4,744	4,617	14,937	15,148
Total	$ 18,750	$ 18,188	$ 56,264	$ 58,414

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

	Three Months Ended		Nine Months Ended	
	October 2, 2015	October 3, 2014	October 2, 2015	October 3, 2014
ICLs	$ 12,907	$ 10,640	$ 37,396	$ 35,052
IOLs	4,390	5,763	14,952	18,804
Core products	17,297	16,403	52,348	53,856
Other surgical products	1,453	1,785	3,916	4,558
Total	$ 18,750	$ 18,188	$ 56,264	$ 58,414

One customer, a distributor, accounted for 16% and 14% of net sales for the three and nine months ended October 2, 2015. One customer, a distributor, accounted for 14% and 11% of net sales for the three months and nine months ended October 3, 2014, respectively. As of October 2, 2015, one customer accounted for 16% of consolidated trade receivables. As of January 2, 2015, there were two customers with trade receivable balances of 10% and 11% of consolidated trade receivables, respectively.

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

Note 10 — Stock-Based Compensation

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

	Three Months Ended		Nine Months Ended	
	October 2, 2015	October 3, 2014	October 2, 2015	October 3, 2014
Employee stock options	$ 625	$ 666	$ 1,818	$ 2,138
Restricted stock	88	141	396	666
Restricted stock units	210	705	484	1,857
Nonemployee stock options	—-	41	49	75
Total	$ 923	$ 1,553	$ 2,747	$ 4,736

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

	Three Months Ended		Nine Months Ended	
	October 2, 2015	October 3, 2014	October 2, 2015	October 3, 2014
Cost of sales	$ 9	$ 32	$ 33	$ 77
General and administrative	543	837	1,667	2,848
Marketing and selling	184	326	539	906
Research and development	187	358	508	905
Total	923	1,553	2,747	4,736
Amounts capitalized as part of inventory	130	131	258	279
Total stock compensation expense	$ 1,053	$ 1,684	$ 3,005	$ 5,015

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 3,579,441 shares were outstanding at October 2, 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 123,803 shares of restricted stock and 317,858 restricted stock units (RSUs) outstanding at October 2, 2015. As of October 2, 2015, there were 1,142,202 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 weighted-average assumptions noted in the following table. Expected volatilities are based on historical volatility of the Company’s stock. The expected term of options granted is derived from the historical exercises and post-vesting cancellations and represents the period of time that options granted are expected to be outstanding. The Company has calculated a 7% estimated forfeiture rate based on historical forfeiture experience. The risk-free rate is based on the U.S. Treasury yield curve corresponding to the expected term at the time of the grant.

	Three Months Ended		Nine Months Ended	
	October 2, 2015	October 3, 2014	October 2, 2015	October 3, 2014
Expected dividend yield	0 %	0 %	0 %	0 %
Expected volatility	58 %	56 %	57 %	55 %
Risk-free interest rate	1.60 %	1.36 %	1.61 %	1.29 %
Expected term (in years)	5.62	4.12	5.61	4.12

A summary of option activity under the Plan for the nine-month period ended October 2, 2015 is presented below:

	Options Shares (000's)
Outstanding at January 2, 2015	3,175
Granted	1,074
Exercised	(472)
Forfeited or expired	(198)
Outstanding at October 2, 2015	3,579
Exercisable at October 2, 2015	2,088

On June 1, 2009, the Company issued warrants to Broadwood Partners, L.P. ("Broadwood"), pursuant to a Warrant Agreement granting the right to purchase 700,000 shares of the Company's common stock at a strike price of $4.00 per share. On May 27, 2015, Broadwood gave notice to exercise the 700,000 warrants and paid the $2.8 million exercise price in cash. On July 27, 2015, the Company issued 700,000 shares of Common Stock to Broadwood pursuant to an exercise of the Warrant Agreement dated June 1, 2009, and no warrants of the Company are currently outstanding.

A summary of restricted stock and restricted stock unit's activity under the Plan for the nine-month period ended October 2, 2015 is presented below:

	Restricted Shares (000's)	Restricted Units (000's)
Outstanding at January 2, 2015	247	156
Granted	34	205
Exercised	(142)	(16
Forfeited	(15)	(27
Outstanding at October 2, 2015	124	318

Note 11 — Income Taxes

The provision for income taxes is determined using an estimated annual effective tax rate. 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 de-recognition 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 $11,000 for the quarter ended October 2, 2015 and an income tax provision of $548,000 for the quarter ended October 3, 2014, respectively. The income tax provision for the nine months ended October 2, 2015 and October 3, 2014 was $114,000 and $1.1 million, respectively. The decrease in the provision was primarily due to benefits from the mix of pre-tax earnings in lower- and zero- rate foreign jurisdictions. There are no unrecognized tax benefits as of any period presented.

Note 12 - Commitments and Contingencies

Lines of Credit and Guarantee

The Company's wholly owned Japanese subsidiary, STAAR Japan, entered into an agreement on December 28, 2012, as amended, 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 October 2, 2015), at an interest rate equal to the Tokyo short-term prime

interest rate (approximately 1.475% as of October 2, 2015). 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 October 2, 2015 and January 2, 2015 (approximately $4.2 million based on the foreign currency exchange rates on October 2, 2015 and January 2, 2015, respectively). As of October 2, 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 ("Credit Suisse"). The credit agreement provides for borrowings of up to 1,000,000 Swiss Francs (approximately $1.0 million at the rate of exchange on October 2, 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 renewable every three years with a current expiration date of September 1, 2016. There were no borrowings outstanding as of October 2, 2015 and January 2, 2015, and the full amount of the line, reduced by any guarantees made to Bankinter Spain ("Bankinter") (described below), was available for borrowing.

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 400,000 (approximately $436,000 at the rate of exchange on October 2, 2015) 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 564,000 Swiss francs (approximately up to $578,000 at the rate of exchange on October 2, 2015). 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, among other things, contractual rights and obligations, employment matters, and claims of product liability. The most significant of these actions, proceedings and investigations are described below. STAAR maintains insurance coverage for product liability and certain securities claims. Legal proceedings can extend for several years, and the matters described below concerning the Company are at 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 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 through 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. On September 21, 2015, the Company filed a motion to dismiss the amended complaint. The Company has not recorded any loss or accrual in the accompanying condensed consolidated financial statements at October 2 2015 and January 2, 2015 for this matter as the likelihood and amount of loss, if any, has not been determined and is not currently estimable.

In 2015, the Company received a claim from a certain supplier who is also a customer. The supplier is claiming damages related to allegedly defective injectors. The Company is currently investigating the matter and is in discussions with the supplier. The ultimate outcome of this matter cannot be determined with certainty and the Company intends to vigorously protect its interests and work with all parties involved to resolve this matter. The Company has not recorded any loss or accrual in the accompanying condensed consolidated financial statements at October 2, 2015for 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.

Decommissioning Fund

The Company is required by the California Department of Public Health ("CDPH") to set aside funds for future estimated decommissioning expenses related to certain equipment used in the manufacturing process. The Company has set aside approximately $120,000, as determined and mandated by the CDPH, for such costs included in other assets as of October 2, 2015 and January 2, 2015, respectively.

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, including statements about any of the following: any projections of earnings, revenue, sales, profit margins, cash, effective tax rate, use of net operating losses, or any other financial items; the plans, strategies and objectives of management for future operations or prospects for achieving such plans, and any statements of assumptions underlying any of the foregoing. 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 I, Item 1A of the Company's Form 10-K for the fiscal year ended January 2, 2015.

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 can correct common vision disorders such as myopia, hyperopia and astigmatism. Cataract surgery is a common outpatient procedure where the eye's natural lens that has become cloudy with age is removed and replaced with an artificial lens called an intraocular lens (IOL) to restore the patient's vision.

STAAR®, 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 made up sixty-nine (69%) percent of our total sales in the third quarter of 2015. 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 focus 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 globally and Visian TICL outside the U.S.; 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 outside the U.S., 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.

- STAAR's goal is to position the Visian ICL and TICL products throughout the world as primary choices for refractive surgery.

IOLs - Intraocular Lenses for Cataract Surgery. Our sales of IOLs made up 23% our total sales in the third quarter of 2015. 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.

- Preloaded IOLs, available in a three-piece silicone material and a three-piece and single-piece acrylic material, which is currently available outside the U.S. The preloaded acrylic IOL line uses 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 systems. Although we have been deemphasizing these products because of their lower overall gross profit margins, we expect that sales of injector systems will continue.

Operations

STAAR is a global company. Activities outside the U.S. accounted for approximately 85% of our total sales during the first nine months of 2015, 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, Spain, and Germany, 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.

Recent Developments

We continue to devote significant effort towards improving our quality system and our remediation efforts. We believe we are on track for achieving our internal remediation metrics, and on budget. We increased prices on our products globally, on average by 5% to 7%, with most price increases taking effect on or about October 1, 2015. We expect to introduce in Europe the expanded optic version of the Visian ICL and TICL with CentraFLOW technology in the first quarter of 2016.

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 the 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 our 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 us. Any such further action could have a material and negative impact on our 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.

Critical Accounting Policies

This Management's Discussion and Analysis of Financial Condition and Results of Operations discusses and analyzes data in our unaudited Condensed Consolidated Financial Statements, which we have prepared in accordance with U.S. generally accepted accounting principles. Preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. Management bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Senior management has discussed the development, selection and disclosure of these estimates with the Audit Committee of our Board of Directors. Actual conditions may differ from our assumptions and actual results may differ from our estimates.

An accounting policy is deemed critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, if different estimates reasonably could have been used, or if changes in the estimate that are reasonably likely to occur could materially impact the financial statements. Management believes that there have been no significant changes during the nine months ended October 2, 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.

	Percentage of Net Sales for Three Months		Percentage of Net Sales for Nine Months	
	October 2, 2015	October 3, 2014	October 2, 2015	October 3, 2014
Net sales	100.0 %	100.0 %	100.0 %	100.0 %
Cost of sales	31.7	34.7	32.4	32.5
Gross profit	68.3	65.3	67.6	67.5
General and administrative	25.9	18.0	26.2	24.0
Marketing and selling	33.5	38.6	31.6	34.6
Research and development	19.6	17.2	19.2	15.6

Other general and administrative expenses	0.0		0.0		0.0		0.6	
	79.0		73.8		77.0		74.8	
Operating loss	(10.7	)	(8.5	)	(9.4	)	(7.3	)
Other income (expense), net	1.4		(3.4	)	(0.5	)	(0.8	)
Loss before provision for income taxes	(9.4	)	(11.9	)	(9.9	)	(8.1	)
Provision for income taxes	(0.1	)	3.0		0.2		1.9	
Net loss	(9.3	)%	(14.9	)%	(10.1	)%	(10.0	)%

Net Sales

	Three Months Ended		Fav/ (Unfav) % Change		Nine Months Ended		Fav/ (Unfav) % Change	
	October 2, 2015	October 3, 2014	2015 vs. 2014		October 2, 2015	October 3, 2014	2015 vs. 2014	
Net sales	$ 18,750	$ 18,188	3	%	$ 56,264	$ 58,414	(4	)%
ICL	12,907	10,640	21		37,396	35,052	7	
IOL	4,390	5,763	(24	)	14,952	18,804	(20	)
Other	1,453	1,785	(19	)	3,916	4,558	(14	)

Net sales for the three months ended October 2, 2015 were $18.8 million, an increase of 3% compared to the $18.2 million reported during the three months ended October 3, 2014. Net sales for the nine months ended October 2, 2015 were $56.3 million, a decrease of 4% compared to the $58.4 million reported during the nine months ended October 3, 2014. The effect of changes in currency exchange rates had a negative impact on net sales of $1.8 million and $5.2 million, respectively, for the three and nine months ended October 2, 2015 when compared to their respective prior year periods.

Total ICL sales for the three months ended October 2, 2015 and October 3, 2014 were $12.9 million and $10.6 million, respectively or an increase of 21%. The sales increase was driven by higher ICL unit sales in each region, with EMEA, APAC and North America growing 37%, 13% and 10%, respectively. EMEA ICL sales were $4.8 million during the third quarter of 2015, a 25% increase over the prior year. Sales in Germany tripled over the prior year period due to the conversion of the market from the former distributor to direct selling which began July 1, 2015. APAC ICL sales were $6.4 million during the third quarter of 2015, an increase of 21% as compared to the prior year period. Korea sales continue to recover and China ICL sales increased 20% due to the adoption of the CentraFLOW® technology introduced in December 2014 and price increases in certain markets beginning in July 2015.

Total ICL sales for the nine months ended October 2, 2015 and October 3, 2014 were $37.4 million and $35.1 million, respectively an increase of 7%. The sales increase was driven by higher ICL unit sales in each region, with EMEA and North America growing 23% and 8%, respectively. These impacts were partially offset by foreign currency changes due to the strengthening U.S. dollar against the euro and yen.

Total IOL sales for the three months ended October 2, 2015 were $4.4 million, a decrease of 24% compared with $5.8 million for the three months ended October 3, 2014. Total IOL sales for the nine months ended October 2, 2015 were $15.0 million, a decrease of 20% compared with $18.8 million for the nine months ended October 3, 2014. The decrease in IOL sales for both periods is due to: 1) changes in currency exchange rates that had a negative impact on IOL sales of $0.5 million and $2.0 million, respectively, for the three and nine months ended October 2, 2015 as a result of a weakening yen effecting Japan sales, the weakening euro effecting France sales; 2) a planned phase-out of sales in China; 3) a planned hold on sales in Germany due to the distributor-to-direct conversion; and 4) a continued decline in the U.S. In Japan, where we have over half of our IOL business, unit sales increased 5% for the quarter.

Other product sales for the three and nine months ended October 2, 2015 were $1.5 million and $3.9 million, respectively, a decrease of 19% and 14%, respectively, compared with $1.8 million and $4.6 million for the three and nine months ended October 3, 2014, respectively. The decrease in both periods was primarily driven by currency impacts on injector part sales and lower sales of other products which the Company has been deemphasizing.

Gross Profit

	Three Months Ended		Fav/ (Unfav) % Change 2015 vs. 2014	Nine Months Ended		Fav/ (Unfav) % Change 2015 vs. 2014
	October 2, 2015	October 3, 2014		October 2, 2015	October 3, 2014	
Gross Profit	$ 12,799	$ 11,869	8 %	$ 38,058	$ 39,419	(4)%
Gross Profit Margin	68.3 %	65.3 %		67.6 %	67.5 %	

Gross profit for the third quarter of 2015 was $12.8 million, or 68.3% of net sales, compared with $11.9 million, or 65.3% of net sales, in the prior year period. During the first nine months of 2015, gross profit was $38.1 million, or 67.6% of net sales, compared with $39.4 million, or 67.5% of net sales, in the prior year period. The increase in gross profit for the third quarter of 2015 was primarily due to an increased mix of higher margin ICL units, higher average selling prices exclusive of currency impacts, and lower unit and other costs partially offset by the impact of the weaker euro on average selling prices. For the nine month period, the negative effect of the weaker euro on gross profit was offset by lower unit costs.

General and Administrative

	Three Months Ended		Fav/ (Unfav) % Change 2015 vs. 2014	Nine Months Ended		Fav/ (Unfav) % Change 2015 vs. 2014
	October 2, 2015	October 3, 2014		October 2, 2015	October 3, 2014	
General and Administrative	$ 4,853	$ 3,259	(49)%	$ 14,748	$ 14,064	(5)%
Percentage of Net Sales	25.9 %	18.0 %		26.2 %	24.0 %	

General and administrative expenses increased by 49% to $4.9 million in the third quarter of 2015 from the $3.3 million reported in the third quarter of 2014. General and administrative expenses for the nine months ended October 2, 2015 were $14.8 million, an increase of 5% when compared with $14.1 million reported last year. The increase in both periods primarily was the result of the reversal of a bonus accrual of $1.6 million in the prior year period.

Marketing and Selling

	Three Months Ended		Fav/ (Unfav) % Change	Nine Months Ended		Fav/ (Unfav) % Change
	October 2, 2015	October 3, 2014	2015 vs. 2014	October 2, 2015	October 3, 2014	2015 vs. 2014
Marketing and Selling	$ 6,284	$ 7,026	11 %	$ 17,784	$ 20,189	12 %
Percentage of Net Sales	33.5 %	38.6 %		31.6 %	34.6 %	

Marketing and selling expenses decreased 11% to $6.3 million in the third quarter of 2015, compared with $7.0 million in the third quarter of 2014. Marketing and selling expenses for the nine months ended October 2, 2015 were $17.8 million, a decrease of 12% when compared with $20.2 million reported last year. The decrease is due to optimization of North American selling and promotional costs, a decrease in selling and promotional costs in Japan, partially offset by increased selling costs in Germany as a result of the conversion to a direct sales force in that market and moving to direct distribution in Spain during the first half of 2015.

Research and Development

	Three Months Ended		Fav/ (Unfav) % Change	Nine Months Ended		Fav/ (Unfav) % Change
	October 2, 2015	October 3, 2014	2015 vs. 2014	October 2, 2015	October 3, 2014	2015 vs. 2014
Research and Development	$ 3,684	$ 3,137	(17)%	$ 10,800	$ 9,118	(18)%
Percentage of Net Sales	19.6 %	17.2 %		19.2 %	15.6 %	

Research and development expense increased in the third quarter of 2015, by 17% to $3.7 million, compared with $3.1 million in the third quarter of 2014. Research and development expense for the nine months ended October 2, 2015 was $10.8 million, an increase of 18%, when compared with $9.1 million reported last year. The increase is primarily the result of increased validation, remediation and other FDA expenses.

Other General and Administrative Expenses

	Three Months Ended		Fav/ (Unfav) % Change	Nine Months Ended		Fav/ (Unfav) % Change
	October 2, 2015	October 3, 2014	2015 vs. 2014	October 2, 2015	October 3, 2014	2015 vs. 2014

Other General and Administrative Expenses	$ —	$ —	— %	$ —	$ 334	100 %		
Percentage of Net Sales	—%	— %		—%	0.6 %			

Other general and administrative expenses for the nine months ended October 3, 2014 related to the Company's manufacturing consolidation project which was completed in June 2014.

Other Income (Expense), Net

	Three Months Ended		Fav/ (Unfav) % Change	Nine Months Ended		Fav/ (Unfav) % Change
	October 2, 2015	October 3, 2014	2015 vs. 2014	October 2, 2015	October 3, 2014	2015 vs. 2014
Other Income (Expense), Net	$ 259	$ (605)	— *	$ (302)	$ (434)	30 %

* Denotes change is greater than ±100%

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

Income Taxes

	Three Months Ended		Fav/ (Unfav) % Change	Nine Months Ended		Fav/ (Unfav) % Change
	October 2, 2015	October 3, 2014	2015 vs. 2014	October 2, 2015	October 3, 2014	2015 vs. 2014
Provision (benefit) for Income Taxes	$ (11)	$ 548	—*	$ 114	$ 1,134	90 %

* Denotes change is greater than ±100%

The provision for income taxes is determined using an estimated annual effective tax rate. The income tax benefit for the three months ended October 2, 2015 was $11,000. The income tax provision for the nine months ended October 2, 2015 was $0.1 million, compared to a provision of $0.5 million and $1.1 million reported for the three and nine months ended October 3, 2014. The income tax provision primarily benefited from the mix of pretax earnings in lower- and zero- rate foreign jurisdictions and includes pre-tax losses generated in certain foreign jurisdictions which are consolidated for Swiss income tax purposes. There are no unrecognized tax benefits as of any period presented.

Based on current year projections, we currently expect the estimated annual effective tax rate to be 67%.

The provision for income taxes is determined using an estimated annual effective tax rate. 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 de-recognition 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.

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 or warrants, 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 quality system remediation efforts of which $3.4 million was incurred during the first nine months of 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 purposes, but STAAR does not maintain such a credit line in the U.S. STAAR Japan's line of credit is currently fully drawn (renewable annually) and the total amount available under the Swiss credit line is reduced by the guarantee issued by Bankinter Spain described below.

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 October 2, 2015 and January 2, 2015, respectively, STAAR had $16.1 million and $13.0 million, of cash and cash equivalents.

Net cash used in operating activities for the nine months ended October 2, 2015 and October 3, 2014, respectively, was $0.3 million and $4.4 million. Net cash used by operating activities for the nine months ended October 2, 2015 consisted of net loss of $5.7 million and a decrease in net working capital of $0.6 million and $4.8 million in non-cash items.

Net cash used in investing activities for the nine months ended October 2, 2015 and October 3, 2014, respectively, was $1.3 million and $2.4 million, primarily due to acquisition of property, plant and equipment.

Net cash provided by financing activities was $4.6 million and $2.4 million for the nine months ended October 2, 2015 and October 3, 2014, respectively. Net cash provided by financing activities for the nine months ended October 2, 2015 consisted of $2.8 million in proceeds from the exercise of warrants, $2.1 million in proceeds from the exercise of stock options, partially offset by $0.3 million in capital lease repayments.

Credit Facilities, Contractual Obligations and Commitments

Lines of Credit and Guarantee

The Company's wholly-owned Japanese subsidiary, STAAR Japan, entered into an agreement on December 28, 2012, as amended, 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 October 2, 2015), at an interest rate equal to the Tokyo short-term prime interest rate (approximately 1.475% as of October 2, 2015). 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 October 2, 2015 and January 2, 2015 (approximately $4.2 million based on the foreign currency exchange rates on October 2, 2015 and January 2, 2015, respectively). As of October 2, 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 ("Credit Suisse"). The credit agreement provides for borrowings of up to 1,000,000 Swiss Francs (approximately $1.0 million at the rate of exchange on October 2, 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 renewable every three years with a current expiration date of September 1, 2016. There were no borrowings outstanding as of October 2, 2015 and January 2, 2015, and the full amount of the line, reduced by any guarantees made to Bankinter Spain ("Bankinter") (described below), was available for borrowing.

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 400,000 (approximately $436,000 at the rate of exchange on October 2, 2015) 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 564,000 Swiss francs (approximately up to $578,000 at the rate of exchange on October 2, 2015). 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.

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.

Supply Agreement

On April 11, 2014, the Company entered into an Amendment Agreement with Nidek Co., Ltd., which extended the term to December 31, 2016 during which STAAR would supply injectors to Nidek and Nidek would supply acrylic lenses to STAAR.

Decommissioning Fund

The Company is required by the California Department of Public Health ("CDPH") to set aside funds for future estimated decommissioning expenses related to certain equipment used in its manufacturing process. The Company has set aside approximately $120,000, as determined and mandated by CDPH, for such costs included in other assets as of October 2, 2015 and October 3, 2014, respectively.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as that term is defined in the rules of the SEC, that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors.

ITEM 3. ***QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK***

There have been no material changes in the Company's qualitative and quantitative market risk since the disclosure in the Company's Annual Report on Form 10-K for the year ended January 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 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 October 2, 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, among other things, contractual rights and obligations, employment matters, and claims of product liability. The most significant of these actions, proceedings and investigations are described below. STAAR maintains insurance coverage for product liability and certain securities claims. Legal proceedings can extend for several years, and the matters described below concerning the Company are at 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, and reduced the alleged Class Period to November 1, 2013 through 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. On September 21, 2015, the Company filed a motion to dismiss the amended complaint. The Company has not recorded any loss or accrual in the accompanying condensed consolidated financial statements at October 2, 2015 and January 2, 2015 for this matter as the likelihood and amount of loss, if any, has not been determined and is not currently estimable.

Nidek Co., Ltd.

In 2015, Nidek Co., Ltd, has written to us claiming damages related to allegedly defective injectors. We are currently investigating the matter and are in discussions with them. The ultimate outcome of this matter cannot be determined with certainty and we intend to vigorously protect our interests and work with all parties involved to resolve this matter. The Company has not recorded any loss or accrual in the accompanying consolidated financial statements at October 2, 2015 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 information contained in this report and the risks and uncertainties described in "Part I—Item 1A—Risk Factors" of the Company's Form 10-K for the fiscal year ended January 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

Not Applicable.

ITEM 6. EXHIBITS

3.1	Certificate of Incorporation, as amended to date.(1)
3.2	Amended and Restated By-laws.(1)
4.4	Form of Certificate for Common Stock, par value $0.01 per share.(2)
†4.5	Amended and Restated 2003 Omnibus Equity Incentive Plan and form of Option Grant and Stock Option Agreement.(3)
†10.37	Letter of the Company dated June 15, 2015 to Jon Hayashida, Vice President of Global Clinical and Medical Affairs.*
†10.38	Letter of the Company dated July 27, 2015 to Keith Holliday, Vice President of Research and Development.*
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.*
101	Financial statements from the quarterly report on Form 10-Q of STAAR Surgical Company for the quarter ended October 2, 2015, formatted in 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 Exhibit 4.1 to Amendment No. 1 to the Company's Registration Statement on Form 8-A/A, as filed with the Commission on April 18, 2003.

(3) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the period ended July 4, 2014, as filed on July 31, 2014.

* Filed herewith.

† Management contract or compensatory plan or arrangement.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

STAAR SURGICAL COMPANY

Date: November 3, 2015 By:/s/ STEPHEN P. BROWN
Stephen P. Brown

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

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