STAAR SURGICAL CO
Form 10-Q
October 31, 2018

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: September 28, 2018
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 þ No o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes þ No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

o Large accelerated filer þ Accelerated filer o Non-accelerated filer o Smaller reporting company

o Emerging growth company

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

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 44,131,509 shares of common stock, par value $0.01 per share, issued and outstanding as of October 26, 2018.

STAAR SURGICAL COMPANY

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PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

STAAR SURGICAL COMPANY

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except par value amounts)

(Unaudited)

	September 28, 2018	December 29, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 102,195	$ 18,520
Accounts receivable trade, net of allowance for doubtful accounts of $616 and $350, respectively	23,732	20,035
Inventories, net	16,180	13,674
Prepayments, deposits, and other current assets	5,190	4,207
Total current assets	147,297	56,436
Property, plant and equipment, net	11,462	9,776
Intangible assets, net	244	271
Goodwill	1,786	1,786
Deferred income taxes	1,201	1,242
Other assets	998	967
Total assets	$ 162,988	$ 70,478
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Line of credit	$ 4,162	$ 4,438
Accounts payable	8,282	6,033
Obligations under capital leases	1,359	1,278
Allowance for sales returns	2,802	2,546
Other current liabilities	10,935	7,339
Total current liabilities	27,540	21,634
Obligations under capital leases	662	531
Deferred income taxes	679	350
Asset retirement obligations	201	202
Deferred rent	203	172
Pension liability	4,839	4,653

Total liabilities	34,124	27,542
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Common stock, $0.01 par value; 60,000 shares authorized: 44,104 and 41,383 shares issued and outstanding at September 28, 2018 and December 29, 2017, respectively	441	414
Additional paid-in capital	287,000	204,920
Accumulated other comprehensive loss	(1,201)	(1,150)
Accumulated deficit	(157,376)	(161,248)
Total stockholders' equity	128,864	42,936
Total liabilities and stockholders' equity	$ 162,988	$ 70,478

See accompanying notes to the condensed consolidated financial statements.

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STAAR SURGICAL COMPANY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 28, 2018	September 29 2017	September 28, 2018	September 29, 2017
Net sales	$ 31,770	$ 23,473	$ 92,768	$ 65,759
Cost of sales	7,910	6,624	24,250	18,859
Gross profit	23,860	16,849	68,518	46,900
Selling, general and administrative expenses:				
General and administrative	6,087	4,716	18,054	14,380
Marketing and selling	10,620	6,495	28,733	20,473
Research and development	5,570	4,594	16,323	14,418
Total selling, general and administrative expenses	22,277	15,805	63,110	49,271
Operating income (loss)	1,583	1,044	5,408	(2,371)
Other income (expense):				
Interest expense, net	(29)	(27)	(65)	(88)
Gain (loss) on foreign currency transactions	52	444	(545)	738
Royalty income	159	141	465	400
Other income (expense), net	40	(19)	61	17
Other income (expense), net	222	539	(84)	1,067
Income (loss) before income taxes	1,805	1,583	5,324	(1,304)
Income tax provision	346	410	1,452	697
Net income (loss)	$ 1,459	$ 1,173	$ 3,872	$ (2,001)
Net income (loss) per share:				
Basic	$ 0.03	$ 0.03	$ 0.09	$ (0.05)
Diluted	$ 0.03	$ 0.03	$ 0.09	$ (0.05)
Weighted average shares outstanding:				
Basic	43,054	41,110	42,065	40,939
Diluted	46,025	42,104	44,618	40,939

See accompanying notes to the condensed consolidated financial statements.

STAAR SURGICAL COMPANY

CONDENSED CONSOLIDATED STATEMENTS

OF COMPREHENSIVE INCOME (LOSS)

(In thousands)

(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
Net income (loss)	$ 1,459	$ 1,173	$ 3,872	$ (2,001)
Other comprehensive income (loss)				
Defined benefit plans:				
Net change in plan assets	(21)	(17)	(51)	(54)
Reclassification into other income (expense), net	25	18	76	55
Foreign currency translation gains (losses)	(321)	(46)	(114)	360
Tax effect	105	13	38	(99)
Other comprehensive income (loss), net of tax	(212)	(32)	(51)	262
Comprehensive income (loss)	$ 1,247	$ 1,141	$ 3,821	$ (1,739)

See accompanying notes to the condensed consolidated financial statements.

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STAAR SURGICAL COMPANY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended	
	September 28, 2018	September 29, 2017
Cash flows from operating activities:		
Net income (loss)	$ 3,872	$ (2,001)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation of property, plant, and equipment	1,792	2,344
Amortization of intangibles	26	166
Deferred income taxes	363	164
Change in net pension liability	233	95
Loss on disposal of property and equipment	8	22
Stock-based compensation expense	4,926	2,185
Provision for sales returns and bad debts	892	186
Inventory provision	1,181	1,267
Changes in working capital:		
Accounts receivable	(3,989)	41
Inventories	(3,625)	725
Prepayments, deposits, and other current assets	(1,021)	(764)
Accounts payable	2,121	(2,751)
Other current liabilities	3,643	62
Net cash provided by operating activities	10,422	1,741
Cash flows from investing activities:		
Acquisition of property and equipment	(1,721)	(969)
Net cash used in investing activities	(1,721)	(969)
Cash flows from financing activities:		
Proceeds from public offering of stock	72,150	—
Repayment of capital lease obligations	(1,396)	(984)
Repayment on line of credit	(251)	—
Repurchase of employee common stock for taxes withheld	—	(234)
Proceeds from vested restricted stock and exercise of stock options	4,582	2,276
Net cash provided by financing activities	75,085	1,058
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(111)	305
Increase in cash, cash equivalents and restricted cash	83,675	2,135

Cash, cash equivalents and restricted cash, at beginning of the period	18,641	14,118
Cash, cash equivalents and restricted cash, at end of the period	$ 102,316	$ 16,253
Supplemental disclosure of non-cash operating activities		
Insurance receivable	—	$ 7,000
Settlement liability	—	$ 7,000

See accompanying notes to the condensed consolidated financial statements.

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STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

Note 1 — Basis of Presentation and Significant Accounting Policies

The Condensed Consolidated Financial Statements of the Company present the financial position, results of operations, and cash flows of STAAR Surgical Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities Exchange Commission. In accordance with those rules and regulations certain information and footnote disclosures normally included in Comprehensive Financial Statements have been condensed or omitted pursuant to such rules and regulations. The Consolidated Balance Sheet as of December 29, 2017 was derived from the audited financial statements at that date, but does not include all the information and footnotes required by GAAP. These financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 29, 2017.

The Condensed Consolidated Financial Statements for the three and nine months ended September 28, 2018 and September 29, 2017, in the opinion of management, include all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the Company's financial condition and results of operations. The results of operations for the three and nine months ended September 28, 2018 and September 29, 2017, are not necessarily indicative of the results to be expected for any other interim period or for the entire year.

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

Cash, Cash Equivalents and Restricted Cash

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the condensed Consolidated Balance Sheets that sum to the total of the same such amounts shown in the Condensed Consolidated Statements of Cash Flows (in 000's):

	September 28, 2018	December 29, 2017	September 29, 2017
Cash and cash equivalents	$ 102,195	$ 18,520	$ 16,133
Restricted cash included in other long-term assets	121	121	120
Total cash, cash equivalents and restricted cash as shown in the Consolidated Statements of Cash Flows	$ 102,316	$ 18,641	$ 16,253

The Company has restricted cash of approximately $121,000 set aside as collateral for a standby letter of credit required by the California Department of Public Health for unforeseen future regulatory costs related to the decommissioning of certain manufacturing equipment.

Revenue

On December 30, 2017 (beginning of FY 2018), the Company adopted Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU") 2014-09, "Revenue from Contracts with Customers (Topic 606)" and its subsequent amendments: (i) ASU No. 2015-14, "Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date"; (ii) ASU No. 2016-10, "Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing;" (iii) ASU No. 2016-11, "Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815): Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting"; (iv) ASU No. 2016-12, "Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients"; and (v) ASU No. 2016-20, "Revenue from Contracts with Customers (Topic 606): Technical Corrections and Improvements to Topic 606", using the modified retrospective method, and determined that there was no cumulative effect adjustment on the Consolidated Financial Statements. The Company determined that the adoption of the new standard did not materially impact the revenue recognition on its Consolidated Financial Statements.

STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (CONTINUED)

Note 1 — Basis of Presentation and Significant Accounting Policies (Continued)

Revenue (Continued)

The Company recognizes revenue when its contractual performance obligations with customers are satisfied. The Company’s performance obligations are generally limited to single sales orders with product shipping to the customer within a month of receipt of the sales order. Substantially all of the Company’s revenues are recognized at a point-in-time when control of its products transfers to the customer, which is typically upon shipment (as discussed below). The Company presents sales tax and similar taxes it collects from its customers on a net basis (excluded from revenues).

The Company sells certain injector parts to an unrelated customer and supplier (collectively referred to as “supplier”) whereby these injector part sales are either made as a final sale to the supplier or, are sold to be combined with an acrylic IOL by the supplier into finished goods inventory (a preloaded acrylic IOL). These finished goods are then sold back to the Company at an agreed upon, contractual price. The Company makes a profit margin on either type of sale with the supplier and each type of sale is made under separate purchase and sales orders between the two parties resulting in cash settlement for the orders sold or repurchased. For parts that are sold as a final sale, the Company recognizes a sale and those sales are classified as other product sales in total net sales. For the injector parts that are sold to be combined with an acrylic IOL into finished goods, the Company records the transaction at its carrying value deferring any profit margin as contra-inventory, until the finished goods inventory is sold to an end-customer (not the supplier) at which point the Company recognizes revenues.

For all sales, the Company is considered the principal in the transaction as the Company is the party providing specified goods it has control over prior to when control is transferred to the customer. Cost of sales includes cost of production, freight and distribution, and inventory provisions, net of any purchase discounts. Shipping and handling activities that occur after the customer obtains control of the goods are recognized as fulfillment costs.

The Company generally permits returns of product if the product is returned within the time allowed by its return policies and records an allowance for estimated returns at the time revenue is recognized. The Company’s allowance for estimated returns considers historical trends and experience, the impact of new product launches, the entry of a competitor, availability of timely and pertinent information and the various terms and arrangements offered, including sales with extended credit terms. For estimated returns, sales are reported net of estimated returns and cost of sales are reported net of estimated returns that can be resold. On the Condensed Consolidated Balance Sheets, the balances associated for estimated sales returns are as follows:

	September 28, 2018	December 29, 2017
Estimated returns - inventory[1]	$ 678	$ 534
Allowance for sales returns	2,802	2,546

(1) Recognized in inventories, net on the Condensed Consolidated Balance Sheets

The Company performs ongoing credit evaluations of its customers and adjusts credit limits based on customer payment history and credit worthiness, as determined by the Company's review of its customers' current credit information. The Company continuously monitors collections and payments from customers and maintains a provision for estimated credit losses and uncollectible accounts based upon its historical experience and any specific customer collection issues that have been identified. Amounts determined to be uncollectible are written off against the allowance for doubtful accounts.

The Company disaggregates its revenue into the following categories: non-consignment sales, consignment sales and royalty income.

Non-consignment Sales

The Company recognizes revenue from non-consignment product sales at a point-in-time when control has been transferred, which is typically at shipping point, except for certain customers and for the STAAR Japan subsidiary, which is typically recognized when the customer receives the product. The Company does not have significant deferred revenues as of September 28, 2018 or September 29, 2017, as delivery to the customer is generally made within the same or the next day of shipment.

STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (CONTINUED)

Note 1 — Basis of Presentation and Significant Accounting Policies (Continued)

Revenue (Continued)

The Company also enters into certain strategic cooperation agreements with customers in which, as consideration for certain commitments made by the customer, including minimum purchase commitments, the Company agrees, among other things, to pay for marketing, educational training and general support of the Company’s products. The provisions in these arrangements allow for these payments to be made directly to the customer or payments can be made directly to a third party for distinct marketing, educational training and general support services provided to or on behalf of the customer by the third party. For payments the Company makes to another party, or reimburses the customer for distinct marketing and support services, the Company recognizes these payments as sales and marketing expense as incurred. These strategic cooperation agreements are generally for periods of 12 months or more with quarterly minimum purchase commitments. The Company recognizes sales and marketing expenses in the period in which it expects the customer will achieve its minimum purchase commitment, generally quarterly, and any unpaid amounts are recorded in Other Current Liabilities in “Other” on the Condensed Consolidated Statements of Operations, see Note 6. Reimbursements made directly to the customer for general marketing incentives are treated as a reduction in revenues. The Company’s performance obligations generally occur in the same quarter as the shipment of product.

Since the payments for distinct or non-distinct services occur within the quarter corresponding with the purchases made by the customer and the shipments made by the Company to that customer, there is no remaining performance obligation by the Company to the customer. Accordingly, there are no deferred revenues associated with these types of arrangements as of September 28, 2018 or September 29, 2017.

<u>Consignment Sales</u>

The Company’s products are marketed to ophthalmic surgeons, hospitals, ambulatory surgery centers or vision centers, and distributors. IOLs and ICLs may be offered to surgeons and hospitals on a consignment basis. The Company maintains title and risk of loss on consigned inventory and recognizes revenue for consignment inventory at a point-in-time when the Company is notified that the lenses have been implanted, thus completing the performance obligation.

Royalty Income

From time to time, the Company licenses its patents to third parties in connection with the manufacture of product. One type of licensing contract requires that the licensee pay the Company a quarterly royalty based on a percentage of the licensee's quarterly sales. The Company recognizes the revenue at a point-in-time, typically quarterly based on various factors including information from the licensee, historical performance and contract minimums; royalty income was as follows (in thousands):

	Three Months Ended		Nine Months Ended	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
Royalty income (1)	$ 159	$ 141	$ 465	$ 400

(1) Shown as a separate line item in other income, net on the Condensed Consolidated Statements of Operations.

Another type of licensing contract requires that the licensee pay the Company a lump sum royalty once certain milestones are achieved, such as upon the first commercial sale of a product incorporating a licensed patent or technology (performance obligation occurs over a period of time); no such income was recognized for the three and nine months ended September 28, 2018 or September 29, 2017, respectively.

See Note 9 for additional information on disaggregation of revenues, geographic sales information and product sales.

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STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (CONTINUED)

Note 1 — Basis of Presentation and Significant Accounting Policies (Continued)

Revenue (Continued)

The following table summarizes the impact of adopting Topic 606 on the Company's Condensed Consolidated Balance Sheets for September 28, 2018 (in 000's) (see also Note 14):

	As Reported	Adjustments	Balances without the adoption of 606
Accounts receivable trade, net	$ 23,732	$ (2,802)	$ 20,930
Total current assets	147,297	(2,802)	144,495
Total assets	162,988	(2,802)	160,186
Allowance for sales returns	2,802	(2,802)	—
Total current liabilities	27,540	(2,802)	24,738
Total liabilities	34,124	(2,802)	31,322
Total liabilities and stockholders' equity	162,988	(2,802)	160,186

Recently Adopted Accounting Pronouncements

On December 30, 2017 (beginning of FY 2018), the Company adopted ASU 2017-09 "Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting," which amends the scope of modification accounting for share-based payment arrangements, provides guidance on the types of changes to the terms or conditions of share-based payment awards to which an entity would be required to apply modification accounting under ASC 718. The adoption of ASU 2017-09 did not have a material impact on the Condensed Consolidated Financial Statements.

On December 30, 2017 (beginning of FY 2018), the Company adopted ASU 2017-07, "Compensation-Retirement Benefits (Topic 715): Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost." The standard requires that an employer report the service cost component in the same line items as other compensation costs arising from services rendered by the pertinent employees during the period. The other components of net benefit cost are required to be presented in the income statement separately from the service cost component and outside of operating profit. The adoption of ASU 2017-09 did not have a material impact on the Condensed Consolidated Financial Statements, see Note 7 for additional information.

On December 30, 2017 (beginning of FY 2018), the Company adopted ASU 2016-16, “Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory”, which removes the prohibition in ASC 740 against the immediate recognition of the current and deferred income tax effects of intra-entity transfers of assets other than inventory, using the modified retrospective method, and determined that there was no cumulative effect adjustment on the Consolidated Financial Statements. The adoption of ASU 2016-16 did not have a material impact on the Condensed Consolidated Financial Statements.

On December 30, 2017 (beginning of FY 2018), the Company adopted ASU 2016-15, “Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments” (“ASU 2016-15”), which clarifies how companies present and classify certain cash receipts and cash payments in the statement of cash flows. The adoption of ASU 2016-15 did not have a material impact on the Condensed Consolidated Financial Statements.

Recent Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, “Leases (Topic 842)”, which requires lessees to recognize assets and liabilities for leases with lease terms greater than twelve months in the statement of financial position. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2016-02 also requires improved disclosures to help users of financial statements better understand the amount, timing and uncertainty of cash flows arising from leases. The update is effective for fiscal years beginning after December 15, 2018, including interim reporting periods within that reporting period. Early adoption is permitted.

STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (CONTINUED)

Note 1 — Basis of Presentation and Significant Accounting Policies (Continued)

Recent Accounting Pronouncements Not Yet Adopted (Continued)

In July 2018, the FASB issued ASU 2018-10, "Codification Improvements to Topic 842, Leases," which narrows aspects of the guidance issued in ASU 2016-02 including those regarding residual value guarantees, rate implicit in the lease, lessee reassessment of lease classification, lessor reassessment of lease term and purchase option, variable lease payments that depend on an index or a rate, investment tax credits, lease term and purchase option, transition guidance for amounts previously recognized in business combinations, certain transition adjustments, transition guidance for leases previously classified as capital leases under Topic 840, transition guidance for modifications to leases previously classified as direct financing or sales-type leases under Topic 840, transition guidance for sale and leaseback transactions, impairment of net investment in the lease, unguaranteed residual asset, effect of initial direct costs on rate implicit in the lease, and failed sale and leaseback transactions.

Also, in July 2018, the FASB issued ASU 2018-11, "Leases (Topic 842): Targeted improvements," which provide an additional and optional transition method to adopt the new leases standard. Under this new transition method, an entity initially applies the new leases standard at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Consequently, an entity's reporting for the comparative periods presented in the financial statements in which it adopts the new leases standard will continue to be in accordance with current GAAP (Topic 840, Leases).

The Company is nearing the completion of its assessment and is performing a final review of its evaluation of the new standard. The Company elected to use the practical expedients of not assessing expired contracts, using current lease classification and not assessing any initial direct costs. The Company has also elected not to capitalize leases that have terms less than 12 months. The Company will initially apply the new standard on December 29, 2018 (beginning of Fiscal Year 2019) and recognize a cumulative-effect adjustment to the opening balance of retained earnings. The Company does not believe the adoption of the new standard will result in a material adjustment to beginning retained earnings. The Company is still evaluating the effects on its financial statement disclosures.

In February 2018, the FASB issued ASU 2018-02, "Income Statement – Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income," provides an option to reclassify stranded tax effects within Accumulated Other Comprehensive Income to retained earnings in each period in which the effect of the change in the U.S. federal corporate income tax rate in the Tax Cuts and Jobs Act is recorded. This is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted. The Company will adopt this standard as of December 29, 2018 (beginning of Fiscal Year 2019) and is currently evaluating the impact on ASU 2018-02 will have on its Condensed Consolidated Financial Statements.

In June 2018, the FASB issued ASU 2018-07, "Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting," aligns the accounting for share-based payments to nonemployees similar to employees. This is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted. The Company will adopt this standard as of December 29, 2018 (beginning of Fiscal Year 2019) and is currently evaluating the impact on ASU 2018-07 will have on its Condensed Consolidated Financial Statements.

In August 2018, the FASB issued ASU 2018-13, "Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement," which modifies certain disclosures requirements for reporting fair value measurements. This is effective for fiscal years ending after December 15, 2019. Early adoption is permitted. The Company will adopt this standard as of January 4, 2020 (beginning of Fiscal Year 2020) and is currently evaluating the disclosure requirements and its effect on the Condensed Consolidated Financial Statements.

In August 2018, the FASB issued ASU 2018-14, "Compensation – Retirement Benefits – Defined Benefit Plans – General (Subtopic 715-20); Disclosure Framework – Changes in the Disclosure Requirement for Defined Benefit Plans," which modifies disclosure requirements for employers that sponsor defined benefit pension or other post retirement plans. This is effective for fiscal years ending after December 15, 2020. Early adoption is permitted. The Company will adopt this standard as of January 2, 2021 (beginning of Fiscal Year 2021) and is currently evaluating the disclosure requirements and its effect on the Condensed Consolidated Financial Statements.

STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (CONTINUED)

Note 2 — Inventories

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

	September 28, 2018	December 29, 2017
Raw materials and purchased parts	$ 2,586	$ 2,506
Work in process	2,755	1,996
Finished goods	12,247	11,533
	17,588	16,035
Less inventory reserves	1,408	2,361
Total	$ 16,180	$ 13,674

Note 3 — Prepayments, Deposits, and Other Current Assets

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

	September 28, 2018	December 29, 2017
Prepayments and deposits	$ 2,039	$ 1,435
Prepaid insurance	529	943
Consumption tax receivable	764	541
Value added tax (VAT) receivable	1,198	910
Other current assets(1)	660	378
Total	$ 5,190	$ 4,207

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

Note 4 — Property, Plant and Equipment

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

	September 28, 2018	December 29, 2017
Machinery and equipment	$ 18,607	$ 16,562
Furniture and fixtures	9,853	9,201
Leasehold improvements	9,883	9,631
	38,343	35,394
Less accumulated depreciation	26,881	25,618
Total	$ 11,462	$ 9,776

Note 5 –Intangible Assets

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

	September 28, 2018			December 29, 2017		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Long-lived amortized intangible assets:						
Patents and licenses	$9,240	$ (8,996)	$244	$9,244	$ (8,973)	$271
Customer relationships	1,381	(1,381)	—	1,392	(1,392)	—
Developed technology	878	(878)	—	885	(885)	—
Total	$11,499	$ (11,255)	$244	$11,521	$ (11,250)	$271

STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (CONTINUED)

Note 6 – Other Current Liabilities

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

	September 28, 2018	December 29, 2017
Accrued salaries and wages	$ 3,792	$ 2,407
Accrued insurance	33	565
Accrued consumption tax	820	446
Accrued income taxes	1,121	210
Accrued bonuses	3,408	2,026
Other[(1))]	1,761	1,685
Total	$ 10,935	$ 7,339

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

Note 7 – Defined Benefit Pension Plans

The Company has defined benefit plans covering employees of its Switzerland and Japan operations. The following table summarizes the components of net periodic pension cost recorded for the Company's defined benefit pension plans (in thousands):

	Three Months Ended		Nine Months Ended	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
Service cost[(1)]	$ 137	$ 128	$ 414	$ 386
Interest cost[(2)]	15	14	44	42
Expected return on plan assets[(2)]	(28)	(24)	(82)	(71)

Net amortization of transitional obligation[2],[3]	3	3	8	9
Prior service credit[2],[3]	(6)	(2)	(17)	(6)
Actuarial loss recognized in current period[2],[3]	28	17	85	52
Net periodic pension cost	$ 149	$ 136	$ 452	$ 412

(1) Recognized in selling general and administrative expenses on the Condensed Consolidated Statements of Operations.

(2) For 2018, recognized in other income (expense), net, and for 2017, recognized in selling, general and administrative on the Condensed Consolidated Statements of Operations.

(3) Amounts reclassified from accumulated other comprehensive loss.

The Company currently is not required to and does not make contributions to its Japan pension plan. The Company's contributions to its Swiss pension plan are as follows (in thousands):

	Three Months Ended		Nine Months Ended	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
Employer contribution	$ 80	$ 66	$ 225	$ 197

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STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (CONTINUED)

Note 8 — Basic and Diluted Net Income (Loss) Per Share

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

	Three Months Ended		Nine Months Ended	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
Numerator:				
Net income (loss)	$ 1,459	$ 1,173	$ 3,872	$ (2,001)
Denominator:				
Weighted average common shares:				
Common shares outstanding	43,065	41,131	42,076	40,960
Less: Unrestricted stock	(11)	(21)	(11)	(21)
Denominator for basic calculation	43,054	41,110	42,065	40,939
Weighted average effects of potentially dilutive common stock:				
Stock options	2,686	837	2,245	—
Unvested restricted stock	4	—	12	—
Restricted stock units	281	157	296	—
Warrants	—	—	—	—
Denominator for diluted calculation	46,025	42,104	44,618	40,939
Net income (loss) per share:				
Basic	$ 0.03	$ 0.03	$ 0.09	$ (0.05)
Diluted	$ 0.03	$ 0.03	$ 0.09	$ (0.05)

Because the Company had a net loss for the nine months ended September 29, 2017, the number of diluted shares is equal to the number of basic shares. Outstanding options and warrants to purchase common stock, restricted stock and restricted stock units would have had an anti-dilutive effect on diluted per share amounts.

The following table sets forth (in thousands) the weighted average number of options and warrants to purchase shares of common stock, restricted stock, and restricted stock units with either exercise prices or unrecognized compensation cost per share greater than the average market price per share of the Company’s common stock, which were not included in the calculation of diluted per share amounts because the effects would be anti-dilutive.

	Three Months Ended		Nine Months Ended	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
Options	389	1,545	278	2,497
Restricted stock and restricted stock units	—	—	1	159
Total	389	1,545	279	2,656

Note 9 — Disaggregation of Revenues, Geographic Sales and Product Sales

In the following tables, revenues are disaggregated by category, sales by geographic market and sales by product data. The following breaks down revenues into the following categories (in thousands):

	Three Months Ended		**Nine Months Ended**	
	September 28, 2018	**September 29, 2017**	**September 28, 2018**	**September 29, 2017**
Non-consignment sales	$27,503	$ 19,590	$79,345	$ 53,432
Consignment sales	4,267	3,883	13,423	12,327
Total net sales	31,770	23,473	92,768	65,759
Royalty income [(1)]	159	141	465	400
Total revenues	$31,929	$ 23,614	$93,233	$ 66,159

(1) Shown as a separate line item in other income, net on the Condensed Consolidated Statements of Operations.

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STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (CONTINUED)

Note 9 — Disaggregation of Revenues, Geographic Sales and Product Sales (Continued)

The Company markets and sells its products in over 75 countries and conducts its manufacturing in the United States. Other than China and Japan, the Company does not conduct business in any country in which its sales exceed 10% of worldwide consolidated net sales. Sales are attributed to countries based on location of customers. The composition of the Company’s net sales to unaffiliated customers is set forth below (in thousands):

	Three Months Ended		Nine Months Ended	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
China	$ 13,349	$ 7,397	$ 35,224	$ 18,069
Japan	6,006	4,633	17,781	12,849
Other [(1)]	12,415	11,443	39,763	34,841
Total revenues	$ 31,770	$ 23,473	$ 92,768	$ 65,759

(1) No other location individually exceeds 10% of the total sales.

In addition, domestic and foreign sales are as follows (in thousands):

	Three Months Ended		Nine Months Ended	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
Domestic	$ 1,676	$ 1,896	$ 5,327	$ 5,946
Foreign	30,094	21,577	87,441	59,813
Total revenues	$ 31,770	$ 23,473	$ 92,768	$ 65,759

100% of the Company’s sales are generated from the ophthalmic surgical product segment and the chief operating decision maker makes operating decisions and allocates resources based upon the consolidated operating results, 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	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
ICLs	$ 26,418	$ 18,110	$ 74,868	$ 49,698
Other product sales				
IOLs	3,824	3,892	12,068	12,875
Other surgical products	1,528	1,471	5,832	3,186
Total other product sales	5,352	5,363	17,900	16,061
Total net sales	$ 31,770	$ 23,473	$ 92,768	$ 65,759

One customer, our distributor in China, accounted for 42% and 38% of net sales for the three and nine months ended September 28, 2018, respectively, and the same customer accounted for 32% and 27% of net sales for the three and nine months ended September 29, 2017, respectively. As of September 28, 2018 and December 29, 2017, respectively, one customer, our distributor in China, accounted for 36% and 24% of consolidated trade receivables.

STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (CONTINUED)

Note 10 — Stock-Based Compensation

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

	Three Months Ended		Nine Months Ended	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
Employee stock options	$ 1,197	$ 443	$ 2,713	$ 1,204
Restricted stock	82	50	192	136
Restricted stock units	501	314	1,593	845
Nonemployee stock options	247	—	428	—
Total	$ 2,027	$ 807	$ 4,926	$ 2,185

The Company recorded stock-based compensation costs in the following categories on the accompanying Condensed Consolidated Statements of Operations (in thousands):

	Three Months Ended		Nine Months Ended	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
Cost of sales	$ 4	$ 2	$ 11	$ 6
General and administrative	701	377	1,875	1,035
Marketing and selling	471	214	1,297	558
Research and development	851	214	1,743	586
Total stock-based compensation expense	2,027	807	4,926	2,185
Amounts capitalized as part of inventory	182	107	449	269
Total stock-based compensation	$ 2,209	$ 914	$ 5,375	$ 2,454

Stock Option Plan

Our Amended and Restated Omnibus Equity Incentive Plan (“the Plan”) provides for various forms of stock-based incentives. To date, of the available forms of awards under the Plan, the Company has granted stock options, restricted stock, unrestricted share grants, restricted stock units (“RSUs”), and performance contingent stock units. Options under the plan are granted at fair market value on the date of grant, become exercisable over a three-year period, or as determined by our Board of Directors, and expire over periods not exceeding 10 years from the date of grant. Certain option and share awards provide for accelerated vesting under certain circumstances in the event of a change in control (as defined in the Plan). Restricted stock grants under the Plan generally vest over a period between one to three years. As of September 28, 2018, there were 2,488,237 shares 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 an 11% estimated forfeiture rate based on historical forfeiture experience. The risk-free rate is based on the U.S. Treasury yield curve corresponding to the expected term at the time of the grant.

	Three Months Ended				Nine Months Ended			
	September 28, 2018		September 29, 2017		September 28, 2018		September 29, 2017	
Expected dividend yield	0	%	0	%	0	%	0	%
Expected volatility	53	%	57	%	53	%	57	%
Risk-free interest rate	2.84	%	1.83	%	2.71	%	1.95	%
Expected term (in years)	5.72		5.67		5.72		5.67	

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STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (CONTINUED)

Note 10 — Stock-Based Compensation (Continued)

A summary of option activity under the Plan for the quarter ended September 28, 2018 is presented below:

	Option Shares (000's)
Outstanding at December 29, 2017	3,725
Granted	805
Exercised	(524)
Forfeited or expired	(27)
Outstanding at September 28, 2018	3,979
Exercisable at September 28, 2018	2,584

As of September 28, 2018, exercise prices of outstanding stock options ranged between $0.95 and $39.90 per share.

A summary of restricted stock and RSU activity under the Plan for the quarter ended September 28, 2018 is presented below:

	Restricted Shares (000's)	Restricted Units (000's)
Outstanding at December 29, 2017	21	488
Granted	11	49
Vested	(21)	(185)
Forfeited or expired	—	(8)
Outstanding at September 28, 2018	11	344

Note 11 — Income Taxes

The Company's quarterly provision for income taxes is determined by estimating an annual effective tax rate. This estimate may fluctuate throughout the year as new information becomes available affecting its underlying assumptions.

The Company recorded an income tax provision of $346,000 and $1,452,000 for the three and nine months ended September 28, 2018, respectively, and $410,000 and $697,000 for the three and nine months ended September 29, 2017, respectively, primarily due to pre-tax income generated in certain foreign jurisdictions. There are no unrecognized tax benefits related to uncertain tax positions taken by the Company.

For the fiscal year-ended December 29, 2017 and prior years, the Company provided foreign withholding and U.S. income taxes on all unremitted foreign earnings, as the earnings from the Company's foreign subsidiaries were not considered to be permanently reinvested. Effective for the current year, the Company no longer provides U.S. income taxes on foreign earnings (see discussion below). Although foreign earnings are no longer subject to U.S. taxation, the Company continues to provide withholding taxes related to such unremitted earnings.

U.S. Federal Income Tax Reform

On December 22, 2017, the United States enacted major tax reform legislation. Most of the changes from the new law are effective for years beginning after December 31, 2017 with the noted exemption of the deemed repatriation of offshore earnings. Public Law No. 115-97, commonly referred to as the 2017 Tax Cuts and Jobs Act ("2017 Tax Act") put into effect a number of changes impacting operations outside the United States including, but not limited to, the imposition of a one-time tax "deemed repatriation" on accumulated offshore earnings not previously subject to U.S. tax, and shifts the U.S taxation of multinational corporations from a worldwide system of taxation to a territorial system. As such, the 2017 Tax Act provides an exemption against U.S. federal taxation on foreign earnings generated after December 31, 2017 and repatriated back to the U.S.

STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (CONTINUED)

Note 12 - Commitments and Contingencies

Lines of Credit

Since 1998, the Company’s wholly owned Japanese subsidiary, STAAR Japan, has had an agreement with Mizuho Bank which provides for borrowings of up to 500,000,000 Yen, at an interest rate equal to the uncollateralized overnight call rate (approximately 0.06% as of September 28, 2018) plus a 0.50% spread, and may be renewed quarterly (the current line expires on November 21, 2018). The credit facility is not collateralized. The Company had 472,500,000 Yen and 500,000,000 Yen outstanding on the line of credit as of September 28, 2018 and December 29, 2017, respectively (approximately $4,162,000 and $4,438,000 based on the foreign exchange rates on September 28, 2018 and December 29, 2017, respectively), which approximates fair value due to the short-term maturity and market interest rates of the line of credit. In case of default, the interest rate will be increased to 14% per annum. As of September 28, 2018 there was 27,500,000 Yen (approximately $242,000) available for borrowing and as of December 29, 2017 there were no available borrowings under the line. At maturity on November 21, 2018, the Company expects to renew this line of credit for an additional three months, with similar terms.

In September 2013, the Company’s wholly owned Swiss subsidiary, STAAR Surgical AG, entered into a framework agreement for loans (“framework agreement”) with Credit Suisse (the “Bank”). The framework agreement provides for borrowings of up to 1,000,000 CHF (Swiss Francs) (approximately $1,000,000 at the rate of exchange on September 28, 2018 and December 29, 2017), to be used for working capital purposes. Accrued interest and 0.25% commissions on average outstanding borrowings is payable quarterly and the interest rate will be determined by the Bank based on the then prevailing market conditions at the time of borrowing. The framework agreement is automatically renewed on an annual basis based on the same terms assuming there is no default. The framework agreement may be terminated by either party at any time in accordance with its general terms and conditions. The framework agreement is not collateralized and contains certain conditions such as providing the Bank with audited financial statements annually and notice of significant events or conditions, as defined in the framework agreement. The Bank may also declare all amounts outstanding to be immediately due and payable upon a change of control or a “material qualification” in STAAR Surgical independent auditors’ report, as defined. There were no borrowings outstanding as of September 28, 2018 and December 29, 2017.

Covenant Compliance

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

Lease Line of Credit (Capital Leases)

On March 8, 2018, the Company entered into lease schedule 011 with Farnam Street Financial, Inc. (“Farnam”). The line of credit provides for borrowings of up to $500,000 at a lease rate factor of 3.94% per $1 for hardware equipment and 4.75% per $1 for non-hardware equipment. Interim rent is paid until the full amount of the line is used at which time the lease commences. As of September 28, 2018, approximately $392,000 of the line was available for borrowing.

On March 8, 2018, the Company entered into lease schedule 010R with Farnam. Under 010R, equipment with a cost of $1,560,000 was financed over a period of 24 months at a lease rate factor of 3.94% per $1 for hardware equipment and 4.75% per $1 for non-hardware equipment. At the end of the lease the Company can opt to continue to rent the equipment, return the equipment, or exercise a fair market value purchase option. As of September 28, 2018, approximately $1,044,000 was outstanding on this capital lease.

On January 31, 2017, the Company entered into lease schedule 009R with Farnam. Under 009R, equipment with a cost of $1,957,000 was financed over a period of 24 months at a lease rate factor of 3.94% per $1 for hardware equipment and 4.75% per $1 for non-hardware equipment. At the end of the lease the Company can opt to continue to rent the equipment, return the equipment, or exercise a fair market value purchase option. As of September 28, 2018 and December 29, 2017, approximately $330,000 and $1,067,000, respectively, was outstanding on this capital lease.

STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (CONTINUED)

Note 12 - Commitments and Contingencies (Continued)

Litigation and Claims

From time to time, the Company is involved in various legal proceedings and other matters arising in the normal course of business. These legal proceedings and other matters may relate to, among other things, contractual rights and obligations, employment matters, or claims of product liability. STAAR maintains insurance coverage for various matters, including product liability and certain securities claims. While the Company does not believe that any of the claims known is likely to have a material adverse effect on the Company’s financial condition or results of operations, new claims or unexpected results of existing claims could lead to significant financial harm.

Employment Agreements

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

Note 13 – Stockholders’ Equity

On August 10, 2018, the Company closed an offering of its common stock. As part of this transaction, the Company issued 1,999,850 shares of its common stock at a price of $36.309 per share. Net proceeds, after deducting expenses, received from this offering were $72,150,000. The Company intends to use the net proceeds of this offering to fund operations, which may include advancing and broadening commercialization of its ICL family of products, funding pipeline research and development activities and clinical trials, funding incremental investments in automation and precision manufacturing, and capital expenditures, such as information systems, and for general corporate purposes, including working capital. The Company has not yet determined the amounts on any of the areas listed above or the timing of these expenditures. The Company invests the net proceeds in short-term interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

Note 14 — Reclassifications

In accordance with ASU 2014-09, in order to disclose contract assets and contract liabilities, the Company reclassified the estimated amount of inventory expected to be returned from the allowance for sales returns to inventories, net on the Condensed Consolidated Balance Sheets. In addition, the Company reclassified the allowance for sales returns from accounts receivable, net to a separate line item in current liabilities on the Condensed Consolidated Balance Sheets, see Note 1.

Certain compensation related expenses were reclassified from General and Administrative to Marketing and Selling and Research and Development line items on the Condensed Consolidated Statements of Operations for the three and nine months ended September 29, 2017 to conform with 2018 presentation.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The matters addressed in this Item 2 that are not historical information constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Readers can recognize forward-looking statements by the use of words like "anticipate," "estimate," "expect," "intend," "plan," "believe," "will," "should," "forecast" and similar expressions in connection with any discussio operating or financial performance. In particular, these include statements about any of the following: any projections of or guidance as to earnings, revenue, sales, profit margins, expense rate, cash, effective tax rate, capital expense or any other financial items; the plans, strategies, and objectives of management for future operations or prospects for achieving such plans; statements regarding new, existing, or improved products, including but not limited to, expectations for success of new, existing, and improved products in the U.S. or international markets or government approval of new or improved products (including the EVO family of lenses in the U.S.); commercialization of new or improved products; future economic conditions or size of market opportunities; and expected costs of quality systems or operations; statements of belief, including as to achieving 2018 business plans; expected regulatory activities and approvals, product launches, and any statements of assumptions underlying any of the foregoing.

Although we believe that the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risks and we can give no assurance that our expectations will prove to be correct. Actual results could differ from those described in this report because of numerous factors, many of which are beyond our control. These factors include, without limitation, those described in our Annual Report on Form 10-K in "Item 1A. Risk Factors" filed on February 28, 2018. We undertake no obligation to update these forward-looking statements after the date of this report to reflect future events or circumstances or to reflect actual outcomes.

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

Overview

STAAR Surgical Company designs, develops, manufactures, and sells implantable lenses for the eye and companion delivery systems used to deliver the lenses into the eye. We are the world's leading manufacturer of intraocular lenses for patients seeking refractive vision correction, and we also make lenses for use in surgery to treat cataracts. All the lenses we make are foldable, which allows the surgeon to insert them into the eye through a small incision during minimally invasive surgery. Refractive surgery is performed to treat the type of visual disorders that have traditionally been corrected using eyeglasses or contact lenses. We refer to our lenses used in refractive surgery as "implantable Collamer® lenses" or "ICLs." The field of refractive surgery includes both lens-based procedures, using products like our ICL family of products, and laser-based procedures like LASIK. Successful refractive surgery can correct common vision disorders such as myopia, hyperopia, and astigmatism. Cataract surgery is a common outpatient procedure where the eye's natural lens that has become cloudy with age is removed and replaced with an artificial lens called an intraocular lens (IOL) to restore the patient's vision. STAAR employs a commercialization strategy that strives for sustainable profitable growth. Our goal is to position our refractive lenses throughout the world as primary and premium solutions for patients seeking visual freedom from wearing glasses or contact lenses while achieving excellent visual acuity through refractive vision correction. We position our IOL lenses used in surgery that treats cataracts based on quality and value.

Recent Developments

We achieved a 35% increase in net total sales and a 46% increase in ICL sales in the third quarter of 2018 as compared to the third quarter of 2017. ICL unit growth of 56% for the third quarter of 2018 arose in part from EVO Visian ICL unit growth of 100% in China, 95% growth in Japan, 27% growth in India and 20% growth in Germany. Sales of "Other" products, representing approximately 17% of overall sales in the third quarter of 2018, were essentially flat from the third quarter of 2017 at $5.4 million in sales.

We believe our sales momentum can continue for the remainder of the year. Therefore, we believe our full year fiscal 2018 sales growth percentage target should exceed 30% over 2017 based on current market conditions.

Furthermore, we continue to believe gross margins will increase as compared to 2017. We expect operating expenses in the fourth quarter of 2018 will exceed that of the fourth quarter of 2017 as we continue to invest in the business.

We continue to expect profitability improvement as compared to 2017 and expect to achieve positive GAAP net income for the full year of 2018. We continue to expect to increase cash from operations for the full year.

On September 13, 2018, we announced that the FDA granted approval of our PMA Supplement for the Visian Toric ICL for the correction of myopia with astigmatism. Our staged rollout of that product is in process. Our European multi-site EVO with EDOF presbyopia clinical trial remains ongoing. While the clinical trial continues, we cannot predict when, or if, we will succeed in meeting our end-points.

Critical Accounting Policies

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

An accounting policy is deemed critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, if different estimates reasonably could have been used, or if changes in the estimate that are reasonably likely to occur could materially impact the financial statements. On December 30, 2017 (beginning of fiscal year 2018), the Company adopted Accounting Standards Update 2014-09, "Revenue from Contract with Customers (Topic 606)"and its subsequent amendments. The Company determined that the adoption of this new standard did not materially impact revenue recognition, see Note 1 of the Condensed Consolidated Financial Statements. Other than the adoption of Topic 606, management believes that there have been no significant changes during the nine months ended September 28, 2018 to the items that we disclosed as our critical accounting policies and estimates in Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the fiscal year ended December 29, 2017.

Results of Operations

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

	Percentage of Net Sales for Three Months		Percentage of Net Sales for Nine Months	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
Net sales	100.0 %	100.0 %	100.0 %	100.0 %
Cost of sales	24.9	28.2	26.1	28.7
Gross profit	75.1	71.8	73.9	71.3
General and administrative	19.2	20.1	19.5	21.9
Marketing and selling	33.4	27.7	31.0	31.1
Research and development	17.5	19.6	17.6	21.9
Total selling, general and administrative expenses	70.1	67.4	68.1	74.9
Operating income (loss)	5.0	4.4	5.8	(3.6)
Other income (expense), net	0.7	2.3	(0.1)	1.7
Income (loss) before provision for income taxes	5.7	6.7	5.7	(1.9)
Provision for income taxes	1.1	1.7	1.6	1.1
Net income (loss)	4.6 %	5.0 %	4.1 %	(3.0)%

Net Sales

	Three Months Ended		Percentage Change	Nine Months Ended		Percentage Change
	September 28, 2018	September 29, 2017	**2018 vs. 2017**	September 28, 2018	September 29, 2017	**2018 vs. 2017**
ICL	$ 26,418	$ 18,110	45.9 %	$ 74,868	$ 49,698	50.6 %
Other product sales:						
IOL	3,824	3,892	(1.7)	12,068	12,875	(6.3)
Other	1,528	1,471	3.9	5,832	3,186	83.1
Total other product sales	5,352	5,363	(0.2)	17,900	16,061	11.5
Net sales	31,770	23,473	35.3 %	92,768	65,759	41.1 %

Net sales for the three months ended September 28, 2018 were $31.8 million, an increase of 35% from $23.5 million reported during the same period of 2017. Net sales for the nine months ended September 28, 2018 were $92.8 million, an increase of 41% from $65.8 million reported during the same period of 2017.

Total ICL sales for the three months ended September 28, 2018 were $26.4 million, an increase of 46% from $18.1 million reporting during the same period of 2017, with unit growth of 56%. The sales increase was driven by the APAC region, which grew 68% with unit growth of 79%, primarily due to sales growth in Japan up 90%, China up 83%, Korea up 16% and India up 20%. The Europe region grew 18% with unit growth of 17% primarily due to increased sales in Germany, Spain and Distributor Operations. In addition, the Middle East and Latin America region grew 6% with unit growth of 4%. Within North America, Canada sales increased 11%. ICL sales represented 83.2% and 77.2% of total sales for the three months ended September 28, 2018 and September 29, 2017, respectively.

Total ICL sales for the nine months ended September 28, 2018 were $74.9 million, an increase of 51% from $49.7 million reported during the same period of 2017, with unit growth of 55%. The sales increase was driven by the APAC region, which grew 76% with unit growth of 81%, primarily due to sales growth in China up 98%, Japan up 90%, and Korea up 28%. The Europe region grew 24% with unit growth of 13% primarily due to increased sales in Germany, Distributor Operations and Spain. ASPs in Europe were favorably impacted by the strength of the Euro compared to the U.S. dollar. In addition, the Middle East and Latin America region grew 20% with unit growth of 11%. Within North America, Canada sales increased 23%. ICL sales represented 80.7% and 75.6% of total sales for the nine months ended September 28, 2018 and September 29, 2017, respectively.

Other product sales, including IOLs, for the three months ended September 28, 2018 and September 29, 2017, were $5.4 million. Other product sales, including IOLs, for the nine months ended September 28, 2018 were $17.9 million, compared to $16.1 million reported during the same period of 2017. The increase in other product sales for the nine months is due to an increase in injector part sales, partially offset by a decrease in IOL sales.

Gross Profit

	Three Months Ended		Percentage Change	Nine Months Ended		Percentage Change
	September 28, 2018	September 29, 2017	**2018 vs. 2017**	September 28, 2018	September 29, 2017	**2018 vs. 2017**
Gross Profit	$ 23,860	$ 16,849	41.6 %	$ 68,518	$ 46,900	46.1 %
Gross Profit Margin	75.1 %	71.8 %		73.9 %	71.3 %	

Gross profit for the three months ended September 28, 2018 was $23.9 million or 75.1% of sales, an increase of 42% from $16.8 million, or 71.8% of sales, reported during the same period of 2017. Gross profit for the nine months ended September 28, 2018 was $68.5 million or 73.9% of sales, an increase of 46% from $46.9 million, or 71.3% of sales, reported during the same period of 2017. The improvement in gross margin for both periods resulted primarily from lower unit costs as a result of significantly increased production volumes resulting in better overhead absorption, favorable product and country mix, and due to lower freight and inventory provisions, partially offset by the effect of lower average selling prices.

General and Administrative

	Three Months Ended		Percentage Change **2018 vs. 2017**	Nine Months Ended		Percentage Change **2018 vs. 2017**
	September 28, 2018	September 29, 2017		September 28, 2018	September 29, 2017	
General and Administrative	$ 6,087	$ 4,716	29.1 %	$ 18,054	$ 14,380	25.5 %
Percentage of Sales	19.2 %	20.1 %		19.5 %	21.9 %	

General and administrative expenses for the three months ended September 28, 2018 was $6.1 million, an increase of 29% from $4.7 million reported for the same period of 2017. General and administrative expenses for the nine months ended September 28, 2018 was $18.1 million, an increase of 26% from $14.4 million reported for the same period of 2017. The increase in general and administrative expenses for both periods was due to an increase in salary-related expenses including stock-based compensation, facility costs, legal fees, travel, and investments in enhanced cybersecurity systems.

Marketing and Selling

	Three Months Ended		Percentage Change **2018 vs. 2017**	Nine Months Ended		Percentage Change **2018 vs. 2017**
	September 28, 2018	September 29, 2017		September 28, 2018	September 29, 2017	
Marketing and Selling	$ 10,620	$ 6,495	63.5 %	$ 28,733	$ 20,473	40.3 %
Percentage of Sales	33.4 %	27.7 %		31.0 %	31.1 %	

Marketing and selling expenses for the three months ended September 28, 2018 was $10.6 million, an increase of 64% from $6.5 million reported for the same period of 2017. Marketing and selling expenses for the nine months ended September 29, 2018 was $28.7 million, an increase of 40% from $20.5 million reported for the same period of 2017. The increase for both periods was due to investments in digital, consumer, and strategic marketing and commercial infrastructure and due to a calendar shift in ESCRS from the prior year’s fourth quarter to the third quarter of 2018.

Research and Development

	Three Months Ended		Percentage Change	Nine Months Ended		Percentage Change
	September 28, 2018	September 29, 2017	**2018 vs. 2017**	September 28, 2018	September 29, 2017	**2018 vs. 2017**
Research and Development	$ 5,570	$ 4,594	21.2 %	$ 16,323	$ 14,418	13.2 %
Percentage of Sales	17.5 %	19.6 %		17.6 %	21.9 %	

Research and development expenses for the three months ended September 28, 2018 was $5.6 million, an increase of 21% from $4.6 million reported for the same period of 2017. Research and development expenses for the nine months ended September 29, 2018 was $16.3 million, an increase of 13% from $14.4 million reported for the same period of 2017. The increase for both periods was primarily due to an increase in clinical expenses associated with our clinical trial for the next generation ICL with an EDOF optic, an increase in medical affairs expenses and for the three-month period, increased regulatory costs.

Research and development expense consists primarily of compensation and related costs for personnel responsible for the research and development of new and existing products and the regulatory and clinical activities required to acquire and maintain product approvals globally. These costs are expensed as incurred.

Other Income, Net

	Three Months Ended		Percentage Change **2018** **vs. 2017**	Nine Months Ended		Percentage Change **2018** **vs. 2017**
	September 28, 2018	September 29, 2017		September 28, 2018	September 29, 2017	
Other Income (Expense), Net	$ 222	$ 539	(58.8)%	$ (84)	$ 1,067	— *
Percentage of Sales	0.7 %	2.3 %		(0.1)%	1.7 %	

* Denotes change is greater than ±100%.

Other income, net for the three months ended September 28, 2018 was $0.2 million, a decrease from $0.5 million reported for the same period of 2017. The decrease was a result of lower foreign exchange gains (primarily the euro). Other expense, net for the nine months ended September 28, 2018 was $0.1 million compared to other income, net of $1.1 million reported for the same period of 2017. This change was a result of foreign exchange losses during the nine months ended September 28, 2018 compared to foreign exchange gains during the same period of 2017, due primarily to fluctuations in the euro rates.

Income Taxes

	Three Months Ended		Percentage Change **2018** **vs. 2017**	Nine Months Ended		Percentage Change **2018** **vs. 2017**
	September 28, 2018	September 29, 2017		September 28, 2018	September 29, 2017	
Income tax provision	$ 346	$ 410	(15.6)%	$ 1,452	$ 697	— *
Percentage of Sales	1.1 %	1.7 %		1.6 %	1.1 %	

* Denotes change is greater than ±100%.

The provision for income taxes is determined using an estimated annual effective tax rate. We recorded income taxes of $0.3 million and $1.5 million for the three and nine months ended September 28, 2018, respectively and $0.4 million and $0.7 million for the three and nine months ended September 29, 2017. The income tax provision was due primarily to pre-tax income generated in certain foreign jurisdictions. We have no unrecognized tax benefits pertaining to any uncertain tax positions as of any period presented.

Liquidity and Capital Resources

On August 10, 2018, we closed an offering of our common stock. As part of this transaction, we issued 1,999,850 shares of common stock at a price of $36.309 per share. Net proceeds, after deducting expenses, received from this offering were $72,150,000. We intend to use the net proceeds of this offering to fund operations, which may include advancing and broadening commercialization of its ICL family of products, funding pipeline research and development activities and clinical trials, funding incremental investments in automation and precision manufacturing, and capital expenditures, such as information systems, and for general corporate purposes, including working capital. We have not yet determined the amounts on any of the areas listed above or the timing of these expenditures. We invest the net proceeds in short-term interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

As of September 28, 2018, we had cash, cash equivalents and restricted cash of $102.3 million. Additionally, we have a line of credit with a Japanese lender, in the amount of $4.4 million, with $0.2 million of availability and a line of credit with a Swiss lender, in the amount of $1.0 million, which is fully available for borrowing. Cash provided by operations and financing activities is expected to be adequate to cover our operational and business needs through at least the next 12 months.

Net cash provided by operating activities was $10.4 million for the nine months ended September 28, 2018 and $1.7 million for the nine months ended September 29, 2017. The net cash provided by operating activities for the nine months ended September 28, 2018, resulted from net income of $3.9 million and $9.4 million in non-cash items offset by a $2.9 million decrease in net working capital. The increase in net cash provided by operating activities during the nine months ended September 28, 2018 was due to recognition of net income of $3.9 million for the nine months ended September 28, 2018 compared to a net loss of $2.0 million for the nine months ended September 29, 2017 and an increase of $3.0 million in non-cash items.

Net cash used in investing activities was $1.7 million and $1.0 million for the nine months ended September 28, 2018 and September 29, 2017, respectively, due to the acquisition of property, plant and equipment.

Net cash provided by financing activities was $75.1 million and $1.1 million for the nine months ended September 28, 2018 and September 29, 2017, respectively. Net cash provided by financing activities during the first nine months of 2018 resulted primarily from the proceeds from the equity offering, as discussed above. In addition, the increase is due to vested restricted stock and exercises of stock options, partially offset by the repayment of capital lease obligations and repayment on the line of credit.

Credit Facilities and Commitments

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

See Note 12 of the accompanying Condensed Consolidated Financial Statements.

Covenant Compliance

The Company is in compliance with the covenants of its credit facilities as of September 28, 2018.

Employment Agreements

The Company's Chief Executive Officer entered into an employment agreement with the Company, effective March 1, 2015. She and certain officers have as provisions of their agreements certain rights, including continuance of cash compensation and benefits, upon a "change in control," which may include an acquisition of substantially all of its assets, or termination "without cause or for good reason" as defined in the employment agreements.

Off-Balance Sheet Arrangements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

During the nine months ended September 28, 2018, there have been no material changes in the Company's qualitative and quantitative market risk since the disclosure in the Company's Annual Report on Form 10-K for the year ended December 29, 2017.

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 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 Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

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

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 28, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, the Company is involved in various legal proceedings and other matters arising in the normal course of business. These legal proceedings and other matters may relate to, among other things, contractual rights and obligations, employment matters, or claims of product liability. STAAR maintains insurance coverage for various matters, including product liability and certain securities claims. While we do not believe that any of the claims known is likely to have a material adverse effect on our financial condition or results of operations, new claims or unexpected results of existing claims could lead to significant financial harm.

ITEM 1A. RISK FACTORS

Our short and long-term success is subject to many factors that are beyond our control. Investors and prospective investors should consider carefully information contained in this report and the risks and uncertainties described in "Part I—Item 1A—Risk Factors" of the Company's Form 10-K for the fiscal year ended December 29, 2017. 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	Amended Restated Certificate of Incorporation.(1)
3.2	Amended and Restated Bylaws.(2)
4.1	Form of Certificate for Common Stock, par value $0.01 per share.(3)
†4.2	Amended and Restated Omnibus Equity Incentive Plan.(4)
31.1	Certifications Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certifications Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification Pursuant to 18 U.S.C. Section 1350, Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. **
101	Financial statements from the quarterly report on Form 10-Q of STAAR Surgical Company for the quarter ended September 28, 2018, formatted in Extensible Business Reporting Language (XBRL), are filed herewith and include: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Comprehensive Loss, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) the Notes to Condensed Consolidated Financial Statements tagged as blocks of text.*

(1) Incorporated by reference to Appendix 2 of the Company's Proxy Statement on Form DEF 14A as filed with the Commission on April 13, 2018.

(2) Incorporated by reference to Appendix 3 of the Company's Proxy Statement on Form DEF 14A as filed with the Commission on April 13, 2018.

(3) 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.

(4) Incorporated by reference to Appendix 1 of the Company's Proxy Statement on Form DEF 14A as filed with the Commission on April 13, 2018.

* Filed herewith.

** Furnished herewith.

† Management contract or compensatory plan.

SIGNATURES

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

	STAAR SURGICAL COMPANY
Dated: October 31, 2018	By: /s/ DEBORAH J. ANDREWS **Deborah J. Andrews** **Chief Financial Officer** **(on behalf of the Registrant and as its principal financial officer)**