

STAAR SURGICAL CO
Form 10-Q
May 01, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended: March 29, 2019

Or

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

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.) |
| 25651 Atlantic Ocean Drive | |
| Lake Forest, California | 92630 |
| (Address of Principal Executive Offices) | (Zip Code) |

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(626) 303-7902

(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---------------------|-------------------|---|
| Common | STAA | NASDAQ |

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

Indicate by check mark whether the registrant has submitted electronically 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 No

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

| | |
|-------------------------|---------------------------|
| Large accelerated filer | Accelerated filer |
| Non-accelerated filer | Smaller reporting company |
| 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

The registrant has 44,472,846 shares of common stock, par value \$0.01 per share, issued and outstanding as of April 26, 2019.

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)

| | March 29, 2019 | December 28, 2018 |
|---|-------------------|----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 102,111 | \$ 103,877 |
| Accounts receivable trade, net of allowance of doubtful accounts of | | |
| \$437 and \$550, respectively | 26,601 | 25,946 |
| Inventories, net | 16,439 | 16,704 |
| Prepayments, deposits and other current assets | 7,534 | 5,045 |
| Total current assets | 152,685 | 151,572 |
| Property, plant and equipment, net | 11,300 | 11,451 |
| Finance lease right-of-use assets, net | 2,445 | — |
| Operating lease right-of-use assets, net | 6,629 | — |
| Intangible assets, net | 263 | 243 |
| Goodwill | 1,786 | 1,786 |
| Deferred income taxes | 1,275 | 1,278 |
| Other assets | 836 | 1,009 |
| Total assets | \$ 177,219 | \$ 167,339 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Line of credit | \$ 3,272 | \$ 3,780 |
| Accounts payable | 7,018 | 6,524 |
| Obligations under finance leases | 1,158 | 1,098 |
| Obligations under operating leases | 2,495 | — |
| Allowance for sales returns | 2,971 | 2,895 |
| Other current liabilities | 11,317 | 13,431 |
| Total current liabilities | 28,231 | 27,728 |
| Obligations under finance leases | 656 | 459 |
| Obligations under operating leases | 4,270 | — |
| Deferred income taxes | 1,100 | 1,022 |
| Asset retirement obligations | 206 | 206 |
| Deferred rent | — | 188 |
| Pension liability | 5,418 | 5,310 |
| Total liabilities | 39,881 | 34,913 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |

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Common stock, \$0.01 par value; 60,000 shares authorized: 44,447 and

44,195 shares issued and outstanding at March 29, 2019 and

| | | |
|--|------------|------------|
| December 28, 2018, respectively | 444 | 442 |
| Additional paid-in capital | 292,722 | 289,584 |
| Accumulated other comprehensive loss | (1,343) | (1,320) |
| Accumulated deficit | (154,485) | (156,280) |
| Total stockholders' equity | 137,338 | 132,426 |
| Total liabilities and stockholders' equity | \$ 177,219 | \$ 167,339 |

See accompanying notes to the condensed consolidated financial statements.

STAAR SURGICAL COMPANY

CONDENSED CONSOLIDATED STATEMENTS OF INCOME

(In thousands, except per share amounts)

(Unaudited)

| | Three Months Ended | |
|--|-----------------------|----------|
| | March March 29,30, | |
| | 2019 | 2018 |
| Net sales | \$32,583 | \$27,093 |
| Cost of sales | 8,403 | 7,662 |
| Gross profit | 24,180 | 19,431 |
| Selling, general and administrative expenses: | | |
| General and administrative | 6,837 | 5,771 |
| Marketing and selling | 10,143 | 7,454 |
| Research and development | 5,635 | 5,407 |
| Total selling, general and administrative expenses | 22,615 | 18,632 |
| Operating income | 1,565 | 799 |
| Other income (expense), net: | | |
| Interest income (expense), net | 271 | (12) |
| Loss on foreign currency transactions | (248) | (77) |
| Royalty income | 171 | 157 |
| Other income, net | 97 | 17 |
| Total other income, net | 291 | 85 |
| Income before income taxes | 1,856 | 884 |
| Provision for income taxes | 489 | 301 |
| Net income | \$1,367 | \$583 |
| Net income per share: | | |
| Basic | \$0.03 | \$0.01 |
| Diluted | \$0.03 | \$0.01 |
| Weighted average shares outstanding: | | |
| Basic | 44,235 | 41,410 |
| Diluted | 46,913 | 43,087 |

See accompanying notes to the condensed consolidated financial statements.

STAAR SURGICAL COMPANY

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(In thousands)

(Unaudited)

| | Three Months Ended | |
|---|-----------------------|---------|
| | March | |
| | March 2019, | |
| | 2019 | 2018 |
| Net income | \$1,367 | \$583 |
| Other comprehensive income (loss): | | |
| Defined benefit plans: | | |
| Net change in plan assets | (26) | (9) |
| Reclassification into other income, net | 26 | 25 |
| Foreign currency translation gain (loss) | (43) | 728 |
| Tax effect | 20 | (223) |
| Other comprehensive income (loss), net of tax | (23) | 521 |
| Comprehensive income | \$1,344 | \$1,104 |

See accompanying notes to the condensed consolidated financial statements.

STAAR SURGICAL COMPANY

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands)

(Unaudited)

| | Three Months Ended | | | Accumulated | | |
|--|--------------------|--------------|-----------------|---------------|---------------|------------|
| | | | | Other | | |
| | | | | Compre- | | |
| | Common Stock | Common Stock | Additional | hensive | Accumulated | Total |
| | Shares | Par Value | Paid-In Capital | Income (Loss) | Deficit | |
| Balance, at December 28, 2018 | 44,195 | \$ 442 | \$ 289,584 | \$ (1,320) | \$ (156,280) | \$ 132,426 |
| Net income | — | — | — | — | 1,367 | 1,367 |
| Adoption of ASC 842 | — | — | — | — | 113 | 113 |
| Adoption of ASU 2018-07 | — | — | (315) | — | 315 | — |
| Other comprehensive loss | — | — | — | (23) | — | (23) |
| Common stock issued upon exercise of options | 74 | — | 623 | — | — | 623 |
| Stock-based compensation | — | — | 2,830 | — | — | 2,830 |
| Vested restricted stock | 178 | 2 | — | — | — | 2 |
| Balance, at March 29, 2019 | 44,447 | \$ 444 | \$ 292,722 | \$ (1,343) | \$ (154,485) | \$ 137,338 |
| Balance, at December 29, 2017 | 41,383 | \$ 414 | \$ 204,920 | \$ (1,150) | \$ (161,248) | \$ 42,936 |
| Net income | — | — | — | — | 583 | 583 |
| Other comprehensive income | — | — | — | 521 | — | 521 |
| Common stock issued upon exercise of options | 57 | 1 | 452 | — | — | 453 |
| Stock-based compensation | — | — | 1,423 | — | — | 1,423 |
| Vested restricted stock | 152 | 1 | — | — | — | 1 |
| Balance, at March 30, 2018 | 41,592 | \$ 416 | \$ 206,795 | \$ (629) | \$ (160,665) | \$ 45,917 |

See accompanying notes to the condensed consolidated financial statements.

STAAR SURGICAL COMPANY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

| | Three Months Ended March 29, 2019 | March 30, 2018 |
|---|---|-----------------------|
| Cash flows from operating activities: | | |
| Net income | \$ 1,367 | \$ 583 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Depreciation of property, plant, and equipment | 1,222 | 549 |
| Amortization of intangibles | 8 | 9 |
| Deferred income taxes | 79 | 92 |
| Change in net pension liability | 119 | 87 |
| Loss on disposal of property and equipment | — | 6 |
| Stock-based compensation expense | 2,641 | 1,301 |
| Provision for sales returns and bad debts | (34) | 514 |
| Inventory provision | 455 | 506 |
| Changes in working capital: | | |
| Accounts receivable | (554) | (2,755) |
| Inventories | (7) | (396) |
| Prepayments, deposits, and other current assets | (2,317) | (730) |
| Accounts payable | (185) | 2,038 |
| Other current liabilities | (2,063) | 726 |

| | | |
|---|------------|-----------|
| Net cash provided by operating activities | 731 | 2,530 |
| Cash flows from investing activities: | | |
| Acquisition of property and equipment | (2,203) | (965) |
| Acquisition of patents and licenses | (30) | — |
| Net cash used in investing activities | (2,233) | (965) |
| Cash flows from financing activities: | | |
| Repayment of finance lease obligations | (365) | (380) |
| Repayment on line of credit | (499) | — |
| Proceeds from the exercise of stock options | 622 | 453 |
| Proceeds from vested restricted stock | 2 | 1 |
| Net cash provided by (used in) financing activities | (240) | 74 |
| Effect of exchange rate changes on cash, cash equivalents and restricted cash | (24) | 612 |
| Increase (decrease) in cash, cash equivalents and restricted cash | (1,766) | 2,251 |
| Cash, cash equivalents and restricted cash, at beginning of year | 103,999 | 18,641 |
| Cash, cash equivalents and restricted cash, at end of year | \$ 102,233 | \$ 20,892 |

See accompanying notes to the condensed consolidated financial statements.

STAAR SURGICAL COMPANY

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

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 28, 2018 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 28, 2018.

The Condensed Consolidated Financial Statements for the three months ended March 29, 2019 and March 30, 2018, in the opinion of management, include all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the Company’s financial condition and results of operations. The results of operations for the three months ended March 29, 2019 and March 30, 2018, 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):

| | March 29, 2019 | December 28, 2018 | March 30, 2018 |
|--|-------------------|----------------------|-------------------|
| Cash and cash equivalents | \$ 102,111 | \$ 103,877 | \$ 20,771 |
| Restricted cash ⁽¹⁾ | 122 | 122 | 121 |
| Total cash, cash equivalents and restricted cash | \$ 102,233 | \$ 103,999 | \$ 20,892 |

⁽¹⁾Included in other assets on the Condensed Consolidated Balance Sheets.

The Company has restricted cash 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.

Lease Accounting

On December 29, 2018 (beginning of fiscal year 2019), the Company adopted Financial Accounting Standards Board (“FASB”) Accounting Standards Update (“ASU”) 2016-02, “Leases (Topic 842)” and its subsequent amendments affecting the Company: (i) ASU 2018-10, “Codification Improvements to Topic 842, Leases,” and (ii) ASU 2018-11, “Leases (Topic 842): Targeted improvements,” using the modified retrospective method. Upon adoption of ASU 2016-02, the Company recognized a cumulative adjustment of \$113,000 which decreased the accumulated deficit and recognized right-of-use (“ROU”) assets and lease liabilities for operating leases, whereby the Company’s accounting finance leases remained substantially unchanged.

The Company recognizes ROU assets and lease liabilities for leases with terms greater than twelve months in the Condensed Consolidated Balance Sheets. Leases are classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement.

STAAR SURGICAL COMPANY

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

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

Lease Accounting (Continued)

A contract contains a lease if the contract conveys the right to control an identified asset for a period of time in exchange for consideration. An asset is either explicitly identified or implicitly identified and must be physically distinct. In addition, the Company must have both the right to obtain substantially all of the economic benefits from use of the identified asset and has the right to direct the use of the identified asset.

Certain leases may have non-lease components such as common area maintenance expense for building leases and maintenance expenses for automobile leases. In general, the Company separates common area maintenance expense component from the value of the ROU asset and lease liability when evaluating rental properties under ASU 2016-02, whereas, the Company includes the maintenance and service components in the value of the ROU asset and lease liability while evaluating automobile leases under ASU 2016-02.

When determining whether a lease is a finance lease or an operating lease, ASU 2016-02 does not specifically define criteria to determine “major part of remaining economic life of the underlying asset” and “substantially all of the fair value of the underlying asset.” For lease classification determination, the Company continues to use (i) greater to or equal to 75% to determine whether the lease term is a major part of the remaining economic life of the underlying asset and (ii) greater to or equal to 90% to determine whether the present value of the sum of lease payments is substantially of the fair value of the underlying asset.

The Company uses either the rate implicit in the lease or its incremental borrowing rate as the discount rate in lease accounting.

When adopting ASU 2016-02, the Company did not reassess any expired or existing contracts, reassess the lease classification for any expired or existing leases and reassess initial direct costs for exiting leases. The Company also elected not to capitalize leases that have terms of twelve months or less.

The Company reviews ROU assets, for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. The Company measures recoverability of these assets by comparing the carrying value of such assets to the estimated undiscounted future cash flows the assets are expected to generate. When the estimated undiscounted future cash flows are less than their carrying amount, an impairment loss is recognized equal to the difference between the assets' fair value and their carrying value.

Recently Adopted Accounting Pronouncements and Recent Accounting Pronouncements Not Yet Adopted

On December 29, 2018 (beginning of fiscal year 2019), the Company adopted 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. The adoption of ASU 2018-02 did not have material impact on the Condensed Consolidated Financial Statements.

On December 29, 2018 (beginning of fiscal year 2019), the Company adopted 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. Upon the adoption of ASU 2018-07, the Company recognized a cumulative adjustment of \$315,000 which decreased the accumulated deficit.

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.

STAAR SURGICAL COMPANY

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

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

Recently Adopted Accounting Pronouncements and Recent Accounting Pronouncements Not Yet Adopted
(Continued)

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.

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):

| | March 29, 2019 | December 28, 2018 |
|-----------------------------------|-------------------|----------------------|
| Raw materials and purchased parts | \$ 3,081 | \$ 2,678 |
| Work in process | 2,144 | 2,195 |
| Finished goods | 12,592 | 13,214 |
| Total inventories, gross | 17,817 | 18,087 |
| Less inventory reserves | 1,378 | 1,383 |
| Total inventories, net | \$ 16,439 | \$ 16,704 |

Note 3 — Prepayments, Deposits, and Other Current Assets

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

| | March 29, 2019 | December 28, 2018 |
|----------------------------------|-------------------|----------------------|
| Prepayments and deposits | \$ 2,716 | \$ 1,707 |
| Prepaid insurance | 1,268 | 1,271 |
| Consumption tax receivable | 1,007 | 912 |
| Value added tax (VAT) receivable | 1,089 | 565 |
| Income tax receivable | 319 | 285 |
| BVG Prepayment | 543 | 16 |

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| | | |
|--|----------|----------|
| Other ⁽¹⁾ | 592 | 289 |
| Total prepayments, deposits and other current assets | \$ 7,534 | \$ 5,045 |

⁽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):

| | March 29, 2019 | December 28, 2018 |
|--|-------------------|----------------------|
| Machinery and equipment | \$ 19,127 | \$ 19,000 |
| Furniture and fixtures | 9,328 | 9,860 |
| Leasehold improvements | 10,030 | 10,045 |
| Total property, plant and equipment, gross | 38,485 | 38,905 |
| Less accumulated depreciation | 27,185 | 27,454 |
| Total property, plant and equipment, net | \$ 11,300 | \$ 11,451 |

STAAR SURGICAL COMPANY

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

Note 5 –Intangible Assets

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

| | March 29, 2019 | | | December 28, 2018 | | |
|--|----------------------|--------------|--------|----------------------|--------------|--------|
| | Gross | | | Gross | | |
| | Carrying Accumulated | | | Carrying Accumulated | | |
| Long-lived amortized intangible assets | Amount | Amortization | Net | Amount | Amortization | Net |
| Patents and licenses | \$9,284 | \$ (9,021) | \$ 263 | \$9,257 | \$ (9,014) | \$ 243 |

Note 6 – Other Current Liabilities

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

| | December 28, | |
|---------------------------------|----------------|-----------|
| | March 29, 2019 | 2018 |
| Accrued salaries and wages | \$ 5,397 | \$ 3,172 |
| Accrued insurance | 666 | 1,061 |
| Accrued consumption tax | 1,155 | 995 |
| Accrued bonuses | 944 | 5,113 |
| Income taxes payable | 1,183 | 1,105 |
| Other ⁽¹⁾ | 1,972 | 1,985 |
| Total other current liabilities | \$ 11,317 | \$ 13,431 |

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

Note 7 – 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 March 29, 2019) plus a 0.50% spread, and may be renewed quarterly (the current line expires on May 21, 2019). The credit facility is not collateralized. The Company had 362,500,000 Yen and 417,500,000 Yen outstanding on the line of credit as of March 29, 2019 and December 28, 2018, respectively

(approximately \$3,272,000 and 3,780,000 based on the foreign exchange rates on March 29, 2019 and December 28, 2018, 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. There was 137,500,000 Yen and 82,500,000 Yen available for borrowing as of March 29, 2019 and December 28, 2018, respectively (approximately \$1,241,000 and \$747,000 based on the foreign exchange rate on March 29, 2019 and December 28, 2018, respectively). At maturity on May 21, 2019, 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 March 29, 2019 and December 28, 2018), 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 March 29, 2019 and December 28, 2018.

The Company is in compliance with covenants of its credit facilities and lines of credit as of March 29, 2019.

During the three months ended March 29, 2019, the Company converted the lease line of credit schedule 011 with Farnam Street Financial, Inc. into a finance lease liability of approximately \$500,000.

STAAR SURGICAL COMPANY

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

Note 8 – Leases

Finance Leases

The Company entered into finance leases primarily related to purchases of equipment used for manufacturing or computer-related equipment. These finance leases are two to five years in length and have fixed payment amounts for the term of the contract and have options to purchase the assets at the end of the lease term. Supplemental balance sheet information related to finance leases was as follows (dollars in thousands):

| | March 29, 2019 |
|--|-------------------|
| Machinery and equipment | \$ 2,121 |
| Furniture and fixtures | 1,123 |
| Leasehold improvements | 27 |
| Finance lease right-of-use assets, gross | 3,271 |
| Less accumulated depreciation | 826 |
| Finance lease right-of-use assets, net | \$ 2,445 |
| Total finance lease liability | \$ 1,814 |
| Weighted-average remaining lease term (in years) | 1.5 |
| Weighted-average discount rate | 6.63 % |

Supplemental cash flow information related to finance leases was as follows (dollars in thousands):

| | Three Months Ended March 29, 2019 |
|---|---|
| Amortization of finance lease right-of-use asset | \$ 161 |
| Interest on finance lease liabilities | 19 |
| Cash paid for amounts included in the measurement of finance lease liabilities: | |
| Operating cash flows | 19 |
| Financing cash flows | 365 |
| Right-of-use assets obtained in exchange for new finance lease liabilities | 642 |

Operating Leases

The Company entered into operating leases primarily related to real property (office, manufacturing and warehouse facilities), automobiles and copiers. These operating leases are two to five years in length with options to extend. The

Company did not include any lease extensions in the initial valuation unless the Company was reasonably certain to extend the lease. Depending on the lease, there are those with fixed payment amounts for the entire length of the contract or payments which increase periodically as noted in the contract or increased at an inflation rate indicator. For operating leases that increase using an inflation rate indicator, the Company used the inflation rate at the time the lease was entered into for the length of the lease term. Supplemental balance sheet information related to operating leases was as follows (dollars in thousands):

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STAAR SURGICAL COMPANY

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

Note 8 – Leases (Continued)

Operating Leases (Continued)

| | March 29, 2019 |
|--|-------------------|
| Machinery and equipment | \$ 734 |
| Furniture and fixtures | 462 |
| Real property | 9,370 |
| Operating lease right-of-use assets, gross | 10,566 |
| Less accumulated depreciation | 3,937 |
| Operating lease right-of-use assets, net | \$ 6,629 |
| Total operating lease liability | \$ 6,765 |
| Weighted-average remaining lease term (in years) | 2.5 |
| Weighted-average discount rate | 1.83 % |

Supplemental cash flow information related to operating leases was as follows (dollars in thousands):

| | Three Months Ended March 29, 2019 |
|---|---|
| Operating lease cost | \$ 611 |
| Cash paid for amounts included in the measurement of operating lease liabilities: | |
| Operating cash flows | 601 |
| Right-of-use assets obtained in exchange for new operating lease liabilities | 1,464 |

Future Minimum Lease Commitments

Estimated future minimum lease payments under operating and finance leases having initial or remaining non-cancelable lease terms more than one year as of March 29, 2019 and December 28, 2018 are as follows (in thousands):

As of March 29, 2019

12 Months Ended

| | |
|---------------------|-------------------|
| Operating Leases | Finance Leases |
|---------------------|-------------------|

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| | | |
|--|----------|----------|
| March 2020 | \$ 2,663 | \$ 1,221 |
| March 2021 | 2,237 | 572 |
| March 2022 | 1,042 | 110 |
| March 2023 | 779 | — |
| March 2024 | 349 | — |
| Thereafter | 7 | — |
| Total minimum lease payments, including interest | \$ 7,077 | \$ 1,903 |
| Less amounts representing interest | 312 | 89 |
| Total minimum lease payments | \$ 6,765 | \$ 1,814 |

As of December 28, 2018

| 12 Months Ended | Operating Leases | Finance Leases |
|--|---------------------|-------------------|
| December 2019 | \$ 2,606 | \$ 1,153 |
| December 2020 | 2,202 | 332 |
| December 2021 | 980 | 143 |
| December 2022 | 507 | 4 |
| December 2023 | 202 | — |
| Thereafter | 12 | — |
| Total minimum lease payments, including interest | 6,509 | 1,632 |
| Less amounts representing interest | — | 75 |
| Total minimum lease payments | \$ 6,509 | \$ 1,557 |

STAAR SURGICAL COMPANY

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

Note 9 — Income Taxes

The Company recorded an income tax provision as follows (in thousands):

| | Three Months Ended | March March 30, 2019 | 2018 |
|----------------------------|--------------------------|----------------------------|------|
| Provision for income taxes | \$489 | \$301 | |

The income tax provision is primarily due to pre-tax income generated in certain foreign jurisdictions. 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. There are no unrecognized tax benefits related to uncertain tax positions taken by the Company.

All earnings from the Company's subsidiaries are not considered to be permanently reinvested. Accordingly, the Company provides withholding and U.S. taxes on all unremitted foreign earnings.

The 2017 Tax Act subjects a U.S. shareholder to tax on Global Intangible Low Tax Income ("GILTI") earned by certain foreign subsidiaries. In general, GILTI is the excess of a U.S. shareholder's total net foreign income over a deemed return on tangible assets. The provision further allows a deduction of 50 percent of GILTI, however this deduction is limited to the Company's pre-GILTI U.S. income. The Company has elected to account for GILTI as a current period expense when incurred.

For the three months ended March 29, 2019, the Company included GILTI of \$2,064,000 in U.S. gross income, which was fully offset with net operating loss carryforwards. The Company was not able to utilize the deduction of 50 percent of GILTI, as this deduction is limited to the Company's pre-GILTI U.S. tax income.

As of March 29, 2019, the Company established a full valuation allowance in the U.S. for all periods presented due to the significant uncertainty of realizing future tax benefits from its net operating loss carryforwards and other deferred tax assets, with the exception of the refundable alternative minimum tax credit of \$273,000. Management will continue to monitor and evaluate all available positive and negative evidence, including scheduled reversals of deferred tax liabilities, projected future taxable income, impact of GILTI in the U.S., tax-planning strategies, and results of recent operations. In projecting future taxable income, the Company begins with historical results and incorporates assumptions including overall current and projected business and industry conditions, the amount of future federal, state, and foreign pretax operating income, the reversal of temporary differences and the feasible and prudent tax-planning strategies. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates the Company uses to manage the underlying businesses. In evaluating the objective evidence, the Company considers three years of cumulative operating results. Valuation allowances, or reductions to deferred tax assets, are recognized if, based on the weight of all the available evidence, it is more likely than not that some portion or all the deferred tax asset may not be realized. As the Company

experiences continued growth and profits the need for a valuation allowance will be evaluated each reporting period by Management to determine whether it is more likely than not that the Company's deferred tax assets will be realizable in a later period. Any such changes in the assessment of a full or partial valuation allowance could have a material impact on earnings.

STAAR SURGICAL COMPANY

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

Note 10 – 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 March March 30, | |
|--|--|--------|
| | 2019 | 2018 |
| Service cost ⁽¹⁾ | \$ 232 | \$ 138 |
| Interest cost | 20 | 14 |
| Expected return on plan assets | (33) | (26) |
| Net amortization of transitional obligation ⁽²⁾ | — | 3 |
| Prior service credit ⁽²⁾ | (6) | (6) |
| Actuarial loss recognized in current period ⁽²⁾ | 32 | 28 |
| Net periodic pension cost | \$ 245 | \$ 151 |

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

⁽²⁾ Amounts reclassified from accumulated other comprehensive income (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 March March 30, | |
|-----------------------|--|-------|
| | 2019 | 2018 |
| Employer contribution | \$ 126 | \$ 66 |

Note 11 — Stockholders' Equity

Stock-Based Compensation

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

| | Three Months Ended March March 29, 2019 | | 2018 |
|--|---|--|---------|
| Employee stock option | \$1,430 | | \$619 |
| Restricted stock | 82 | | 51 |
| Restricted stock units | 1,104 | | 598 |
| Nonemployee stock options | 25 | | 33 |
| Total stock-based compensation expense | \$2,641 | | \$1,301 |

The Company recorded stock-based compensation costs in the following categories (in thousands):

| | Three Months Ended March March 29, 2019 | | 2018 |
|---|---|--|---------|
| Cost of sales | \$14 | | \$3 |
| General and administrative | 778 | | 519 |
| Marketing and selling | 1,171 | | 460 |
| Research and development | 678 | | 319 |
| Total stock-based compensation expense, net | 2,641 | | 1,301 |
| Amounts capitalized as part of inventory | 189 | | 122 |
| Total stock-based compensation expense, gross | \$2,830 | | \$1,423 |

STAAR SURGICAL COMPANY

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

Note 11 — Stockholders' Equity (Continued)

Incentive Plan

The Amended and Restated Omnibus Equity Incentive Plan (“the Plan”) provides for various forms of stock-based incentives. To date, of the available forms of awards under the Plan, the Company has granted only stock options, restricted stock, unrestricted share grants, and restricted stock units (“RSUs”). Options under the Plan are granted at fair market value on the date of grant, become exercisable generally over a three-year period, or as determined by the Board of Directors, and expire over periods not exceeding 10 years from the date of grant. Certain option and share awards provide for accelerated vesting if there is a change in control and pre-established financial metrics are met (as defined in the Plan). Grants of restricted stock outstanding under the Plan generally vest over periods of one to three years. Grants of RSUs outstanding under the Plan generally vest based on service, performance, or a combination of both. As of March 29, 2019, there were 1,694,616 shares available for grant 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 8% 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 March March 29, 2019 | | | |
| | 2019 | 2018 | | |
| Expected dividend yield | 0 % | 0 % | | |
| Expected volatility | 53 % | 53 % | | |
| Risk-free interest rate | 2.43 % | 2.61 % | | |
| Expected term (in years) | 5.67 | 5.72 | | |

Stock Options

A summary of stock option activity under the Plan for the three months ended March 29, 2019 is presented below:

| | | |
|-------|---------|---------|
| Stock | Minimum | Maximum |
|-------|---------|---------|

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| | Options | Exercise | Exercise |
|----------------------------------|---------|----------|----------|
| | (in | Price | Price |
| | 000's) | | |
| Outstanding at December 28, 2018 | 3,920 | | |
| Granted | 749 | | |
| Exercised | (74) | | |
| Forfeited or expired | (1) | | |
| Outstanding at March 29, 2019 | 4,594 | \$ 1.92 | \$ 43.84 |
| Exercisable at March 29, 2019 | 2,839 | | |

STAAR SURGICAL COMPANY

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

Note 11 — Stockholders' Equity (Continued)

Restricted Stock and Restricted Stock Units

A summary of restricted stock and RSU activity under the Plan for the three months ended March 29, 2019 is presented below:

| | Restricted | |
|-------------------------------|------------------|------------|
| | Restricted Stock | |
| | Stock | Units |
| | (in 000's) | (in 000's) |
| Unvested at December 28, 2018 | 11 | 322 |
| Granted | — | 19 |
| Vested | — | (178) |
| Forfeited or expired | — | (1) |
| Unvested at March 29, 2019 | 11 | 162 |

Note 12 - Commitments and Contingencies

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

STAAR SURGICAL COMPANY

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

Note 13 — Basic and Diluted Net Income Per Share

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

| | Three Months Ended March March 29,30, | |
|---|--|--------|
| | 2019 | 2018 |
| Numerator: | | |
| Net income | \$1,367 | \$583 |
| Denominator: | | |
| Weighted average common shares: | | |
| Common shares outstanding | 44,246 | 41,431 |
| Less: Unvested restricted stock | (11) | (21) |
| Denominator for basic calculation | 44,235 | 41,410 |
| Weighted average effects of potentially diluted common stock: | | |
| Stock options | 2,418 | 1,396 |
| Unvested restricted stock | 252 | 264 |
| Restricted stock units | 8 | 17 |
| Denominator for diluted calculation | 46,913 | 43,087 |
| Net income per share: | | |
| Basic | \$0.03 | \$0.01 |
| Diluted | \$0.03 | \$0.01 |

The following table sets forth (in thousands) the weighted average number of options 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 March March 30, | |
|---------------|--|------|
| | 2019 | 2018 |
| Stock options | 672 | 385 |

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| | | |
|---|-----|-----|
| Restricted stock and restricted stock units | — | 4 |
| Total | 672 | 389 |

Note 14 — 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 | |
|-----------------------|-----------------------|----------|
| | March March 29,30, | |
| | 2019 | 2018 |
| Non-consignment sales | \$28,266 | \$22,181 |
| Consignment sales | 4,317 | 4,912 |
| Total net sales | \$32,583 | \$27,093 |

STAAR SURGICAL COMPANY

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

Note 14 — 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, Japan and Korea, 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 | |
|----------------------|-----------------------|----------|
| | March March 29,30, | |
| | 2019 | 2018 |
| China | \$11,771 | \$7,910 |
| Japan | 5,519 | 5,083 |
| Korea | 3,291 | 2,195 |
| Other ⁽¹⁾ | 12,002 | 11,905 |
| Total net sales | \$32,583 | \$27,093 |

⁽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 | |
|-----------------|-----------------------|----------|
| | March March 29,30, | |
| | 2019 | 2018 |
| Domestic | \$1,952 | \$1,756 |
| Foreign | 30,631 | 25,337 |
| Total net sales | \$32,583 | \$27,093 |

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 | |
|---------------------------|-----------------------|----------|
| | March | |
| | March 29,30, | |
| | 2019 | 2018 |
| ICLs | \$27,786 | \$21,158 |
| Other product sales | | |
| IOLs | 4,017 | 4,058 |
| Other surgical products | 780 | 1,877 |
| Total other product sales | 4,797 | 5,935 |
| Total net sales | \$32,583 | \$27,093 |

One customer, our distributor in China, accounted for 36% and 29% of net sales for the three months ended March 29, 2019 and March 30, 2018, respectively. As of March 29, 2019 and December 28, 2018, respectively, one customer, our distributor in China, accounted for 37% and 36% of consolidated trade receivables.

Note 15 — Reclassifications

Certain compensation related expenses were reclassified from General and Administrative to Marketing and Selling and Research and Development line items on the Condensed Consolidated Statement of Income for the three months ended March 30, 2018.

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 of future operating or financial performance. In particular, these include statements about any of the following: any projections of or guidance as to earnings, revenue, sales, profit margins, expense rate, cash, effective tax rate remediation expense or capital expense or any other financial items; the plans, strategies, and objectives of management for future operations or prospects for achieving such plans; statements regarding new, existing, or improved products, including but not limited to, expectations for success of new, existing, and improved products in the U.S. or international markets or government approval of a 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; expected costs of quality system remediation efforts; statements of belief, including as to achieving 2019 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 in our Annual Report on Form 10-K in “Item 1A. Risk Factors” filed on February 21, 2019. 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 audited 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 believe that the ICL continues to gain vision correction market share. Total ICL net sales for the first quarter of 2019 grew 31% over prior year quarter. Total ICL units grew 39% globally in the first quarter, including 86% growth in Japan, 62% in Korea, 56% in China, 27% in Germany and 23% in India as compared to the prior year quarter. The leading refractive ophthalmic societies in Germany and Japan have now expanded the recommended lower diopter range for use of the EVO Visian ICL to negative 3 diopters from negative 6 diopters. We believe current versions of the ICL can, in the near-to-medium term, achieve a 20% to 30% market share for myopia or distance vision correction, which would equate to between 800,000 and 1.2 million lenses per year. We anticipate the “Other” product sales rate of decline will be sequentially less in the second and third quarters, in line with previously disclosed expectations. On an annual basis we continue to anticipate an approximately \$3.6 million decline compared to prior year for the Other products segment. We purchased equipment for manufacture of our EVO Visian ICL with an EDOF optic (intended to treat presbyopia) at our Lake Forest facility and construction of clean rooms is underway at that facility. For our myopia lenses, the planned doubling of manufacturing capacity at our Monrovia, California facility is expected to begin in the second half of 2019.

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 29, 2018 (beginning of fiscal year 2019), the Company adopted Accounting Standards Update 2016-02, "Leases (Topic 842)" and its subsequent amendments, the impact of this new accounting standard are discussed in Notes 1 and 8 of the Condensed Consolidated Financial Statements. Other than the adoption of Topic 842, management believes that there have been no significant changes during the three months ended March 29, 2019 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 28, 2018.

Results of Operations

The following table shows the percentage of our total sales represented by certain items reflected in our Condensed Consolidated Statements of Income for the periods indicated.

| | Percentage of Net | | | |
|---|----------------------|--|--------|--|
| | Sales for Three | | | |
| | Months | | | |
| | March | | | |
| | March 29, 2019, | | | |
| | 2019 | | 2018 | |
| Net sales | 100.0% | | 100.0% | |
| Cost of sales | 25.8 % | | 28.3 % | |
| Gross profit | 74.2 % | | 71.7 % | |
| General and administrative | 21.0 % | | 21.3 % | |
| Marketing and selling | 31.1 % | | 27.5 % | |
| Research and development | 17.3 % | | 20.0 % | |
| Total selling, general and administrative | 69.4 % | | 68.8 % | |
| Operating income | 4.8 % | | 2.9 % | |

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| | | | | |
|----------------------------|-----|---|-----|---|
| Total other income, net | 0.9 | % | 0.4 | % |
| Income before income taxes | 5.7 | % | 3.3 | % |
| Provision for income taxes | 1.5 | % | 1.1 | % |
| Net income | 4.2 | % | 2.2 | % |

Net Sales

| | Three Months Ended March March 29,30, 2019 | | Percentage Change 2019 vs. 2018 | |
|---------------------------|--|----------|--|----|
| ICLs | \$27,786 | \$21,158 | 31.3 | % |
| Other product sales | | | | |
| IOLs | 4,017 | 4,058 | (1.0 |)% |
| Other surgical products | 780 | 1,877 | (58.4 |)% |
| Total other product sales | 4,797 | 5,935 | (19.2 |)% |
| Net sales | \$32,583 | \$27,093 | 20.3 | % |

Net sales for the three months ended March 29, 2019 were \$32.6 million, an increase of 20% from \$27.1 million reported during the same period of 2018. The increase in net sales was due to increases in ICL sales of \$6.6 million, slightly offset by a decrease in other product sales of \$1.1 million. Currency, primarily the Euro, negatively impacted net sales by approximately \$0.7 million for the three months ended March 29, 2019.

Total ICL sales for the three months ended March 29, 2019 were \$27.8 million, a 31% increase from \$21.2 million reported for the same period of 2018, with unit growth up 39%. The sales increase was driven by the APAC region, which grew 51% with unit growth of 55%, primarily due to sales growth in Japan up 94%, Korea up 50% and China up 49%. The Europe region, grew 5% with unit growth of 15%, primarily due to increased sales in Germany up 10% and Distributor Operations up 9% offset by decreased sales in Spain of 4%. The Middle East and Latin America region decreased 19%, with units down 14% due to decreased sales in both the Middle East and Latin America. The North America region grew 15%, with units down 1%, primarily due to sales growth of 24% in the U.S., as a result of sales of Toric ICL in 2019 (none in 2018), slightly offset by a decrease in Canada. ICL sales represented 85.3% of our total sales for the three months ended March 29, 2019.

Other product sales, including IOLs were \$4.8 million for the three months ended March 29, 2019, a decrease of 19% from \$5.9 million reported for the same period of 2018. The decrease is due to the decrease in preloaded injector part sales to a third-party manufacturer for product they sell to their customers. Other product sales represented 14.7% of our total sales for the three months ended March 29, 2019.

Gross Profit

| | Three Months Ended | | Percentage Change | |
|--------------|--------------------|----------|-------------------|---|
| | March 29, 30, | | 2019 vs. 2018 | |
| | 2019 | 2018 | | |
| Gross profit | \$24,180 | \$19,431 | 24.4 | % |
| Gross margin | 74.2 % | 71.7 % | | |

Gross profit for the three months ended March 29, 2019 was \$24.2 million, a 24.4% increase compared to the \$19.4 million reported for the same period of 2018. Gross profit margin increased to 74.2% of revenue for the three months ended March 29, 2019 compared to 71.7% of revenue for the three months ended March 30, 2018, due to increased sales of ICLs and decreased sales of injector parts resulting in favorable product mix and lower unit costs as a result of significantly increased production volumes, to support the 39% growth in ICL unit sales, partially offset by the effect of lower average selling prices.

General and Administrative Expense

| | Three Months Ended | | Percentage Change | |
|--|--------------------|--|-------------------|--|
| | | | | |

| | March March 29, 30, | | 2019 vs. 2018 | |
|------------------------------------|------------------------|---------|------------------|---|
| | 2019 | 2018 | 2019 vs. 2018 | |
| General and administrative expense | \$6,837 | \$5,771 | 18.5 | % |
| Percentage of sales | 21.0 % | 21.3 % | | |

General and administrative expenses for the three months ended March 29, 2019 were \$6.8 million, an increase of 18.5% when compared with \$5.8 million reported for same period of 2018. The increase in general and administrative expenses was due to an increase in headcount and salary-related expenses including stock-based compensation, and increased facility costs.

Marketing and Selling Expense

| | Three Months Ended March March 29, 30, | | Percentage Change 2019 vs. 2018 | |
|-------------------------------|---|---------|--|---|
| | 2019 | 2018 | 2019 vs. 2018 | |
| Marketing and selling expense | \$10,143 | \$7,454 | 36.1 | % |
| Percentage of sales | 31.1 % | 27.5 % | | |

Marketing and selling expenses for the three months ended March 29, 2019 were \$10.1 million, an increase of 36.1% when compared with \$7.5 million reported for same period of 2018. The increase in marketing and selling expenses was due

to an increase in headcount and salary-related expenses including stock-based compensation, increased travel expenses, and investments in digital, consumer, and strategic marketing and commercial infrastructure.

Research and Development Expense

| | Three Months Ended | | Percentage Change | |
|----------------------------------|--------------------|---------|-------------------|---|
| | March 29, 30, | | 2019 vs. 2018 | |
| | 2019 | 2018 | | |
| Research and development expense | \$5,635 | \$5,407 | 4.2 | % |
| Percentage of sales | 17.3 % | 20.0 % | | |

Research and development expenses for the three months ended March 29, 2019 were \$5.6 million, an increase of 4.2% compared to \$5.4 million for the for same period of 2018. The increase was mainly due to an increase in headcount and salary-related expenses including stock-based compensation.

Other Income, Net

| | Three Months Ended | | Percentage Change | |
|---------------------|--------------------|-------|-------------------|--|
| | March 29, 30, | | 2019 vs. 2018 | |
| | 2019 | 2018 | | |
| Other income, net | \$291 | \$ 85 | —* | |
| Percentage of sales | 0.9 % | 0.4 % | | |

*Denotes change is greater than +100%.

Other income, net for the three months ended March 29, 2019 was \$0.3 million, an increase from \$0.1 million reported for the same period of 2018. The increase in other income, net was due to the increase in interest income earned on cash and cash equivalents, offset by an increase in foreign exchange losses (primarily the euro).

Income Taxes

| Three Months Ended | Percentage Change |
|--------------------|-------------------|
|--------------------|-------------------|

| | | | | |
|----------------------|-----------|--------|----------|---|
| | March | | | |
| | March 29, | | | |
| | | | 2019 vs. | |
| | 2019 | 2018 | 2018 | |
| Income tax provision | \$ 489 | \$ 301 | 62.5 | % |

The provision for income taxes is determined using an estimated annual effective tax rate. We recorded income taxes of \$0.5 million and \$0.3 million for the three months ended March 29, 2019 and March 30, 2018, respectively. 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.

For the three months ended March 29, 2019, we included Global Intangible Low Tax Income (“GILTI”) of \$2.1 million in U.S. gross income, which was fully offset with net operating loss carryforwards. We were not able to utilize the deduction of 50 percent of GILTI, as this deduction is limited to the Company’s pre-GILTI U.S. tax income.

Due to our history of losses in the U.S., we have maintained a full valuation allowance to offset the value of our U.S. net deferred tax assets on our balance sheet as of March 29, 2019, with the exception of the remaining refundable alternative minimum tax credit of \$0.3 million. However, global profit is now includable in U.S. income under GILTI and as a result we have reported income in the U.S. in fiscal year 2018. As our global profitability improves, including our ability to meet or exceed forecasts, we will continue to reassess at each reporting period the need for a full or partial valuation allowance on our U.S. net deferred tax assets. We determine the need for a valuation allowance based upon all available positive and negative evidence, including reversals of deferred tax liabilities, projected future taxable income, impact of GILTI in the U.S., tax planning strategies, and results of recent operations. If it is more likely than not that the deferred tax asset is realizable, we would record an income tax benefit for all or a portion of the valuation allowance in the period in which such determination is made. Any such changes in the assessment of a full or partial valuation allowance could have a material impact on earnings. The valuation allowance was approximately \$45.1 million as of March 29, 2019.

Liquidity and Capital Resources

We believe our current cash balances coupled with cash flows from operating activities is expected to be adequate to cover our operational and business needs through at least the next 12 months. Our financial condition at March 29, 2019 and December 28, 2018 included the following (in millions):

| | March 29, 2019 | December 28, 2018 | 2019 vs. 2018 |
|---------------------------|-------------------|----------------------|---------------------|
| Cash and cash equivalents | \$ 102.1 | \$ 103.9 | \$(1.8) |
| Current assets | \$ 152.7 | \$ 151.6 | \$1.1 |
| Current liabilities | 28.2 | 27.7 | 0.5 |
| Working capital | \$ 124.5 | \$ 123.9 | \$0.6 |

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. Additionally, at March 29, 2019, we have a line of credit with a Japanese lender, in the amount of \$4.5 million, with \$1.2 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.

Net cash provided by operating activities was \$0.7 million and \$2.5 million for the three months ended March 29, 2019 and March 28, 2018, respectively. Net cash provided by operating activities for the three months ended March 29, 2019, consisted of \$4.5 million in non-cash items and \$1.4 million in net income, offset by \$5.1 million in working-capital changes. The decrease in net cash provided by operating activities during the three months ended March 29, 2019 was due to the decrease in net working capital of \$4.0 million, offset by an increase of \$1.4 million in non-cash items and an increase in net income of \$0.8 million.

Net cash used in investing activities was \$2.2 million and \$1.0 million for the three months ended March 29, 2019 and March 28, 2018, respectively, and relate primarily to the acquisition of property, plant, and equipment. The increase in investment in property, plant and equipment during 2019, relative to 2018, is primarily due to continued increased investments in manufacturing and quality system improvement projects.

Net cash used in financing activities was \$0.2 million for the three months ended March 29, 2019 and net cash provided by financing activities of \$0.1 million March 28, 2018. Net cash used in financing activities consisted of \$0.5 million repayment on the Japan line of credit and \$0.4 million repayment of finance lease obligations, offset by \$0.6 million of proceeds from the exercise of stock options.

Credit Facilities and Commitments

Lines of Credit and Leases

See Notes 7 and 8 of the accompanying Condensed Consolidated Financial Statements.

Covenant Compliance

The Company is in compliance with the covenants of its credit facilities as of March 29, 2019.

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 agreement's 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 three months ended March 29, 2019, 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 28, 2018.

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 March 29, 2019 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 28, 2018. 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

STAAR Surgical Company's Swiss subsidiary STAAR Surgical Ltd (the "Company") entered into a lease agreement (the "Lease") with GZK Real Estate Ltd ("Lessor"), to lease the real property located at Portstr. 35, 2555 Brügg, Switzerland including a commercial building of approximately 1,500 square meters (the "Premises"). The Lease is dated January 29, 2019, went into effect on March 1, 2019 and has an initial term through February 29, 2024. The foregoing summary is qualified in its entirety by reference to the Lease, which is filed as Exhibit 10.36 to this Quarterly Report on Form 10-Q and incorporated herein by this reference.

ITEM 6. EXHIBITS

3.1 Amended and 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)

10.36 Lease Agreement dated January 29, 2019 between GZK Real Estate Ltd. and STAAR Surgical Ltd.*

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 March 29, 2019, formatted in Extensible Business Reporting Language (XBRL), are filed herewith and include: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Income, (iii) the Condensed Consolidated Statements of Comprehensive Income, (iv) the Condensed Consolidated Statements of Stockholders' Equity, (v) the Condensed Consolidated Statements of Cash Flows, and (vi) 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.

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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: May 1, 2019 By: /s/ DEBORAH J. ANDREWS

Deborah J. Andrews

Chief Financial Officer

(on behalf of the Registrant and as its principal financial officer)