



STAAR Surgical ICL Sales Up 46%; Company Raises Outlook for Full Year 2018

October 31, 2018

MONROVIA, Calif. --(BUSINESS WIRE)--Oct. 31, 2018-- STAAR Surgical Company (NASDAQ: STAA), a leading developer, manufacturer and marketer of implantable lenses and companion delivery systems for the eye, today reported financial results for the third quarter ended September 28, 2018.

Third Quarter 2018 Overview

- Net Sales of \$31.8 Million Up 35% from the Prior Year Quarter
- ICL Sales Up 46% and Units Up 56% from the Prior Year Quarter
- Gross Margin at 75.1% of Sales from 71.8% of Sales in the Prior Year Quarter
- Earnings per Share of \$0.03 versus Earnings per Share of \$0.03 in the Prior Year Quarter
- Non-GAAP Earnings per Share of \$0.07 versus Earnings per Share of \$0.04 in the Prior Year Quarter
- Cash, Cash Equivalents and Restricted Cash of \$102.3 Million at Quarter End
- The STAAR Visian® Toric ICL for Myopia received FDA Approval on September 13, 2018.

"STAAR's operating momentum continued during the third quarter resulting in an increase in sales of 35% over the prior year driven by the growth of our EVO Visian ICL™ family of lenses," said Caren Mason, President and CEO. "ICL unit growth highlights for the quarter included China up 100%, Japan up 95%, India up 27% and Germany up 20%. We continue to see strengthening in our key international markets as we prepare for Europe's and Korea's high implant season beginning this quarter and extending into Q1 2019 with strong trends continuing in our Asian markets as well. In addition, we believe our full year fiscal 2018 sales growth should exceed 30% over 2017, based on current market conditions, and we fully expect to maintain GAAP profitability for the year."

"We are also pleased to report that implants have begun and the staged rollout of our Toric ICL lens in the U.S. with certified surgeons is in progress and ahead of schedule. Based upon the enthusiastic reception from prominent surgeons to the Toric ICL, we anticipate that this product introduction represents a positive re-entry point for STAAR in the U.S., the world's second largest market for refractive vision correction procedures. Finally, outside the U.S. our multi-site EVO with Aspheric (EDOF) Optic clinical trial for presbyopia is ongoing. Our Principal Investigator from the initial first-in-person clinical trial of the EVO with Aspheric (EDOF) Optic lens for presbyopia presented his study data during our invitation only Experts Summit for surgeons held immediately ahead of the European Society of Cataract and Refractive Surgeons (ESCRS) meeting in Vienna last month. We are very pleased with the enthusiastic reception his presentation received," concluded Ms. Mason.

Financial Overview – Q3 2018

Net sales were \$31.8 million for the third quarter of 2018, up 35% compared to \$23.5 million reported in the prior year quarter. The sales increase was driven by ICL revenue growth of 46% and ICL unit growth of 56% reflecting the increasing contribution from lower diopter lenses and contracted pricing terms based on customer volume achievements.

Gross profit margin for the third quarter of 2018, was 75.1% compared to the prior year period of 71.8%. The 330 basis point improvement in gross margin resulted from lower unit costs, favorable product and country mix, and lower freight and inventory provisions, partially offset by the effect of lower average selling prices.

Operating expenses for the third quarter of 2018 were \$22.3 million compared to the prior year quarter of \$15.8 million and flat sequentially. General and administrative expenses were \$6.1 million compared to the prior year quarter of \$4.7 million. The increase in general and administrative expenses was due to an increase in compensation costs including stock-based compensation, facilities costs, travel, and investments in enhanced cybersecurity systems. Marketing and selling expenses were \$10.6 million compared to the prior year quarter of \$6.5 million and flat sequentially. The increase in marketing and selling expenses was due to a calendar shift in ESCRS from the prior year's fourth quarter and increased investments in digital, consumer, and strategic marketing and commercial infrastructure. Research and development expenses were \$5.6 million compared to the prior year quarter of \$4.6 million. The increase in research and development expenses was due to an increase in clinical trial expenses, medical affairs, and regulatory expenses.

Net income for the third quarter of 2018 was approximately \$1.5 million or \$0.03 per share compared with net income of \$1.2 million or \$0.03 per share for the prior year quarter. Adjusted Net Income for the third quarter of 2018 was \$3.4 million or \$0.07 per share, compared to Adjusted Net Income in the prior year quarter of \$1.5 million or \$0.04 per share. The reconciliation between GAAP and non-GAAP financial information is provided in the financial tables included with this release.

Cash, cash equivalents and restricted cash at September 28, 2018 totaled \$102.3 million, compared to \$18.6 million at the end of the fourth quarter of 2017, and \$21.4 million at the end of the second quarter of 2018. The sequential increase in cash, cash equivalents and restricted cash includes \$8.1 million in cash generated from operations and approximately \$72.2 million in net cash from financing activities reflecting primarily the proceeds from the sale of common stock, which closed August 10, 2018.

Conference Call

The Company will host a conference call and webcast today, Wednesday, October 31, 2018 at 4:30 p.m. Eastern / 1:30 p.m. Pacific to discuss its financial results and operational progress. To access the conference call (Conference ID 7281609), please dial 855-765-5684 for domestic participants and 262-912-6252 for international participants. The live webcast can be accessed from the investor relations section of the STAAR website at www.staar.com.

A taped replay of the conference call (Conference ID 7281609) will be available beginning approximately one hour after the call's conclusion for seven days. This replay can be accessed by dialing 855-859-2056 for domestic callers and 404-537-3406 for international callers. An archived webcast will also be available at www.staar.com.

Use of Non-GAAP Financial Measures

This press release includes supplemental non-GAAP financial information, which STAAR believes investors will find helpful in understanding its operating performance. "Adjusted Net Income (Loss)" and "Adjusted Net Income (Loss) Per Share" exclude the following items that are included in "Net Income (Loss)" as calculated in accordance with U.S. generally accepted accounting principles ("GAAP"): gain or loss on foreign currency transactions, stock-based compensation expenses, and quality remediation expenses in 2017. Management believes that "Adjusted Net Income (Loss)," "Adjusted Net Income (Loss) Per Share" are useful to investors in gauging the outcome of the key drivers of the business performance: the ability to increase sales revenue and our ability to increase profit margin by improving the mix of high value products while reducing the costs over which management has control. Management has excluded quality remediation expenses in 2017 because their inclusion may mask underlying trends in our business performance.

Management has also excluded gains and losses on foreign currency transactions because of the significant fluctuations that can result from period to period as a result of market driven factors. Stock-based compensation expenses consist of expenses for stock options and restricted stock under the Financial Accounting Standards Board's Accounting Standards Codification (ASC) 718. In calculating Adjusted Net Income (Loss) and Adjusted Net Income (Loss) Per Share, STAAR excludes these expenses because they are non-cash expenses and because of the complexity and considerable judgment involved in calculating their values. In addition, these expenses tend to be driven by fluctuations in the price of our stock and not by the same factors that generally affect our other business expenses.

About STAAR Surgical

STAAR, which has been dedicated solely to ophthalmic surgery for over 30 years, designs, develops, manufactures and markets implantable lenses for the eye with companion delivery systems. These lenses are intended to provide visual freedom for patients, lessening or eliminating the reliance on glasses or contact lenses. All of these lenses are foldable, which permits the surgeon to insert them through a small incision. STAAR's lens used in refractive surgery is called an Implantable Collamer® Lens or "ICL", which includes the EVO Visian ICL™ product line. More than 900,000 Visian ICLs have been implanted to date. To learn more about the ICL go to: www.discovetrl.com. STAAR has approximately 400 full-time equivalent employees and markets lenses in over 75 countries. Headquartered in Monrovia, CA, the company operates manufacturing facilities in Aliso Viejo, CA and Monrovia, CA. For more information, please visit the Company's website at www.staar.com.

Safe Harbor

All statements in this press release that are not statements of historical fact are forward-looking statements, including statements about any of the following: any financial projections, including those relating to the plans, strategies, and objectives of management for future operations or prospects for achieving such plans, expectations for sales, revenue, earnings, marketing and clinical initiatives, regulatory approvals, quality, operations and other expense, or expense timing, success and timing of new or improved products, clinical trials, research and development activities, investment imperatives, and any statements of assumptions underlying any of the foregoing. Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements are set forth in the Company's Annual Report on Form 10-K for the year ended December 29, 2017 under the caption "Risk Factors," which is on file with the Securities and Exchange Commission and available in the "Investor Information" section of the company's website under the heading "SEC Filings." We disclaim any intention or obligation to update or revise any financial projections or forward-looking statement due to new information or events.

These statements are based on expectations and assumptions as of the date of this press release and are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those described in the forward-looking statements. The risks and uncertainties include the following: global economic conditions; changes in currency exchange rates; the discretion of regulatory agencies to approve or reject existing, new or improved products, or to require additional actions before approval (including but not limited to FDA requirements regarding the EVO Visian ICL family of lenses and international regulatory requirements to obtain a presbyopia correction claim for the EVO Visian ICL with EDOF), or to take enforcement action; research and development efforts; potential international trade disputes; the purchasing patterns of our distributors carrying inventory in the market; and the willingness of surgeons and patients to adopt a new or improved product and procedure. The Visian ICL with CentraFLOW, now known as EVO Visian ICL, is not approved for sale in the United States.

Consolidated Balance Sheets
(in 000's)
Unaudited

September 28, December 29,

ASSETS	2018	2017
Current assets:		
Cash and cash equivalents	\$ 102,195	\$ 18,520
Accounts receivable trade, net	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

Stockholders' equity:		
Common stock	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

Consolidated Statements of Operations

(In 000's except for per share data)

Unaudited

	Three Months Ended				Nine-Months Ended							
	% of	September 28,	% of	September 29, Fav (Unfav)	% of	September 28,	% of	September 29, Fav (Unfav)				
	Sales	2018	Sales	2017	Amount	%	Sales	2018	Sales	2017	Amount	%
Net sales	100.0 %	\$ 31,770	100.0 %	\$ 23,473	\$ 8,297	35.3 %	100.0 %	\$ 92,768	100.0 %	\$ 65,759	\$ 27,009	41.1 %
Cost of sales	24.9 %	7,910	28.2 %	6,624	(1,286)	-19.4 %	26.1 %	24,250	28.7 %	18,859	(5,391)	-28.6 %
Gross profit	75.1 %	23,860	71.8 %	16,849	7,011	41.6 %	73.9 %	68,518	71.3 %	46,900	21,618	46.1 %
Selling, general and administrative expenses:												
General and administrative	19.2 %	6,087	20.1 %	4,716	(1,371)	-29.1 %	19.5 %	18,054	21.9 %	14,380	(3,674)	-25.5 %
Marketing and selling	33.4 %	10,620	27.7 %	6,495	(4,125)	-63.5 %	31.0 %	28,733	31.1 %	20,473	(8,260)	-40.3 %
Research and development	17.5 %	5,570	19.6 %	4,594	(976)	-21.2 %	17.6 %	16,323	21.9 %	14,418	(1,905)	-13.2 %
Total selling, general, and administrative expenses	70.1 %	22,277	67.4 %	15,805	(6,472)	-40.9 %	68.1 %	63,110	74.9 %	49,271	(13,839)	-28.1 %
Operating income (loss)	5.0 %	1,583	4.4 %	1,044	539	51.6 %	5.8 %	5,408	-3.6 %	(2,371)	7,779	328.1 %
Other income (expense):												
Interest expense, net	-0.1 %	(29)	-0.1 %	(27)	(2)	-7.4 %	-0.1 %	(65)	-0.1 %	(88)	23	26.1 %
Gain (loss) on foreign currency transactions	0.2 %	52	1.9 %	444	(392)	-88.3 %	-0.6 %	(545)	1.2 %	738	(1,283)	-173.8 %
Royalty income	0.5 %	159	0.6 %	141	18	12.8 %	0.5 %	465	0.6 %	400	65	16.3 %
Other income (expense), net	0.1 %	40	-0.1 %	(19)	59	310.5 %	0.1 %	61	0.0 %	17	44	258.8 %
Total other income (expense), net	0.7 %	222	2.3 %	539	(317)	-58.8 %	-0.1 %	(84)	1.7 %	1,067	(1,151)	-107.9 %
Income (loss) before provision for income taxes	5.7 %	1,805	6.7 %	1,583	222	14.0 %	5.7 %	5,324	-1.9 %	(1,304)	6,628	508.3 %
Provision for income taxes	1.1 %	346	1.7 %	410	64	15.6 %	1.6 %	1,452	1.1 %	697	(755)	-108.3 %
Net income (loss)	4.6 %	\$ 1,459	5.0 %	\$ 1,173	\$ 286	24.4 %	4.1 %	\$ 3,872	-3.0 %	\$ (2,001)	\$ 5,873	293.5 %
Net income (loss) per share - basic		\$ 0.03		\$ 0.03				\$ 0.09		\$ (0.05)		
Net income (loss) per share - diluted		\$ 0.03		\$ 0.03				\$ 0.09		\$ (0.05)		
Weighted average shares outstanding - basic		43,054		41,110				42,065		40,939		
Weighted average shares outstanding - diluted		46,025		42,104				44,618		40,939		

Consolidated Statements of Cash Flows

(in 000's)

Unaudited

Three Months Ended		Nine-Months Ended	
September 28,	September 29,	September 28,	September 29,
2018	2017	2018	2017

Cash flows from operating activities:				
Net income (loss)	\$ 1,459	\$ 1,173	\$ 3,872	\$ (2,001)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:				
Depreciation of property and equipment	624	796	1,792	2,344
Amortization of long-lived intangibles	9	56	26	166
Deferred income taxes	5	155	363	164
Change in net pension liability	74	65	233	95
Stock-based compensation expense	2,027	807	4,926	2,185
Loss on disposal of property and equipment	2	22	8	22
Provision for sales returns and bad debts	248	120	892	186
Inventory provision	428	478	1,181	1,267
Changes in working capital:				
Accounts receivable	2,401	62	(3,989)	41
Inventories	(2,089)	(183)	(3,625)	725
Prepayments, deposits and other current assets	(132)	(486)	(1,021)	(764)
Accounts payable	1,165	(984)	2,121	(2,751)
Other current liabilities	1,895	1,023	3,643	62
Net cash provided by (used in) operating activities	8,116	3,104	10,422	1,741
Cash flows from investing activities:				
Acquisition of property and equipment	(452)	(345)	(1,721)	(969)
Net cash used in investing activities	(452)	(345)	(1,721)	(969)
Cash flows from financing activities:				
Repayment on line of credit	(251)	-	(251)	-
Repayment of capital lease obligations	(515)	(323)	(1,396)	(984)
Proceeds from sale-leaseback transactions	-	-	-	-
Net proceeds from public offering of common stock	72,150	-	72,150	-
Repurchase of employee common stock for taxes withheld	-	-	-	(234)
Proceeds from vested restricted stock and exercise of stock options	2,175	313	4,582	2,276
Net cash provided by (used in) financing activities	73,559	(10)	75,085	1,058
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(274)	(54)	(111)	305
Increase in cash, cash equivalents and restricted cash	80,949	2,695	83,675	2,135
Cash, cash equivalents and restricted cash, at beginning of the period	21,367	13,558	18,641	14,118
Cash, cash equivalents and restricted cash, at end of the period	\$ 102,316	\$ 16,253	\$ 102,316	\$ 16,253

Global Sales
(in 000's)
Unaudited

	Three Months Ended			Nine-Months Ended		
	September 28, 2018	September 29, 2017	% Change Fav (Unfav)	September 28, 2018	September 29, 2017	% Change Fav (Unfav)
Sales by Region						
North America	6.3 % \$ 2,003	9.3 % \$ 2,192	-8.6 %	6.9 % \$ 6,357	10.3 % \$ 6,786	-6.3 %
Europe	17.3 % 5,482	21.6 % 5,073	8.1 %	20.8 % 19,290	25.1 % 16,499	16.9 %
Middle East, Africa, Latin America	4.5 % 1,428	5.8 % 1,364	4.7 %	4.5 % 4,193	5.4 % 3,530	18.8 %
Asia Pacific	71.9 % 22,857	63.3 % 14,844	54.0 %	67.8 % 62,928	59.2 % 38,944	61.6 %
Total Sales	100.0 % \$ 31,770	100.0 % \$ 23,473	35.3 %	100.0 % \$ 92,768	100.0 % \$ 65,759	41.1 %
Core Product Sales						
ICLs	83.2 % \$ 26,418	77.2 % \$ 18,110	45.9 %	80.7 % \$ 74,868	75.6 % \$ 49,698	50.6 %
Other Product Sales						
IOLs	12.0 % 3,824	16.5 % 3,892	-1.7 %	13.0 % 12,068	19.6 % 12,875	-6.3 %
Injector Parts and Other	4.8 % 1,528	6.3 % 1,471	3.9 %	6.3 % 5,832	4.8 % 3,186	83.1 %
Total Other Sales	16.8 % 5,352	22.8 % 5,363	-0.2 %	19.3 % 17,900	24.4 % 16,061	11.5 %
Total Sales	100.0 % \$ 31,770	100.0 % \$ 23,473	35.3 %	100.0 % \$ 92,768	100.0 % \$ 65,759	41.1 %

Reconciliation of Non-GAAP Financial Measure
(in 000's)

Unaudited	Three Months Ended		Nine-Months Ended	
	September 28, 2018	September 29, 2017	September 28, 2018	September 29, 2017
Net income (loss) - (as reported)	\$ 1,459	\$ 1,173	\$ 3,872	\$ (2,001)
Less:				
Foreign currency impact	(52)	(444)	545	(738)
Stock-based compensation expense	2,027	807	4,926	2,185
Quality remediation expense	-	-	-	210
Net income (loss) - (adjusted)	\$ 3,434	\$ 1,536	\$ 9,343	\$ (344)
Net income (loss) per share, basic - (as reported)	\$ 0.03	\$ 0.03	\$ 0.09	\$ (0.05)
Foreign currency impact	-	(0.01)	0.01	(0.02)
Stock-based compensation expense	0.05	0.02	0.12	0.05
Quality remediation expense	-	-	-	0.01
Net income (loss) per share, basic - (adjusted)	\$ 0.08	\$ 0.04	\$ 0.22	\$ (0.01)
Net income (loss) per share, diluted - (as reported)	\$ 0.03	\$ 0.03	\$ 0.09	\$ (0.05)
Foreign currency impact	-	(0.01)	0.01	(0.02)
Stock-based compensation expense	0.04	0.02	0.11	0.05
Quality remediation expense	-	-	-	0.01
Net income (loss) per share, diluted - (adjusted)	\$ 0.07	\$ 0.04	\$ 0.21	\$ (0.01)

Weighted average shares outstanding - Basic	43,054	41,110	42,065	40,939
Weighted average shares outstanding - Diluted	46,025	42,104	44,618	40,939

Note: Net income (loss) per share (adjusted), basic and diluted, may not add due to rounding

View source version on businesswire.com: <https://www.businesswire.com/news/home/20181031005787/en/>

Source: STAAR Surgical Company

STAAR Surgical Company
Investors & Media
EVC Group
Brian Moore, 310-579-6199
Doug Sherk, 415-652-9100