



STAAR Surgical Reports Third Quarter 2016 Results

November 3, 2016

MONROVIA, Calif., Nov. 3, 2016 /PRNewswire/ -- 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 30, 2016.

Third Quarter 2016 Overview

- Record Quarter for ICL Units Sold Exceeds Q2 2016 Record
- Quarterly Net Sales of \$20.1 Million Up 7% from the Prior Year Quarter
- Worldwide ICL Sales and Units Up 15% from the Prior Year Quarter
- Worldwide IOL Sales Up 6% and Units Down 3% from the Prior Year Quarter
- Gross Margin Improved to 74.2% of Sales from 68.3% of Sales in the Prior Year Quarter
- On-Going FDA Remediation Effort Finished the Quarter On-Track and On-Budget
- Third Quarter Net Loss of \$0.04 per Share; Adjusted Net Loss of \$0.02 per Share
- Cash and Equivalents Increased by \$1.6 Million to \$14.3 Million
- Closed Strategic Cooperation Agreements with Leading Providers in S.E. Europe and India
- Completed Initial Human Implants of EVO+ Visian ICL™ Extended Depth of Field Lenses Designed to Address Presbyopia. Initial Results are Positive and the Clinical Study for these Lenses Continues.

"We delivered another successive record quarter for ICL units sold and signed two additional Strategic Cooperation Agreements during the quarter," said Caren Mason, President and CEO. "In addition, we have finalized the initial clinical design of our new extended depth of field EVO+ Visian ICL posterior chamber phakic lens and the initial clinical results are positive. The EVO and EVO+ ICL lenses are made of Collamer®, our proprietary highly biocompatible material that allows for long-term implantation. As patients age, they begin to lose near and then intermediate vision due to presbyopia, a long-term, natural progressive loss of accommodation experienced by all people," added Ms. Mason. "These lenses are designed to provide good vision for patients of all ages and prescriptions within our approved ranges while potentially extending by many years the period of time before reading glasses are required," said Vice President of Research and Development, Keith Holliday Ph.D. "Hyperopic [far-sighted] patients may benefit most from an extended depth of field as such patients suffer from the effects of presbyopia soonest. Subtle changes have been made to the optical surfaces of our EVO+ lens design to modify the hyperfocal distance of an eye implanted with the lens. This leads to an increase in the depth of field for the patient. As the lens is implanted between the cornea and the crystalline lens it works together with the crystalline lens without having to surgically alter the cornea," added Dr. Holliday.

Financial Overview

Net sales were \$20.1 million for the third quarter of 2016, up 7% compared to \$18.8 million reported in the prior year quarter. The sales increase was driven by ICL revenue and unit growth of 15% each, and IOL revenue growth of 6%. These increases were partially offset by planned lower sales of injector parts in the third quarter and a delay in orders from Canadian surgeons awaiting EVO Toric lens approval, which occurred on September 21, 2016. For the first nine months of 2016, ICL revenue and units increased 16% and 11%, respectively.

For the third quarter of 2016, gross profit margin was 74.2% compared to the prior year period of 68.3%. An increased mix of higher margin ICL units, lower ICL unit costs, higher average selling prices, and lower inventory reserves combined to improve gross margin by approximately 5.9 points.

Operating expenses for the quarter increased \$1.8 million to \$16.6 million compared to the prior year quarter primarily due to costs related to quality system improvements and investments made in the international selling and marketing organizations. General and administrative expense was \$5.0 million and the change from the prior year quarter was not material. Marketing and selling expense was \$7.1 million, \$0.9 million higher than the prior year quarter due to the re-branding efforts and international selling and promotional costs. Research and development expense was \$4.5 million, an increase of \$0.8 million due to investments in quality system improvements, clinical affairs, and project-related spending, partially offset by lower FDA remediation expenses. Remediation expense for the quarter was on budget.

The net loss for the third quarter of 2016 was \$1.8 million or \$0.04 per share compared with a net loss of \$1.8 million or \$0.04 per share for the prior year quarter.

The adjusted net loss for the third quarter of 2016 was \$0.9 million or \$0.02 per share, compared with an adjusted net loss of approximately breakeven and breakeven per share for the prior year quarter. The reconciliation between GAAP and non-GAAP financial information is provided in the financial tables included with this release.

Cash and cash equivalents at September 30, 2016 totaled \$14.3 million, compared to \$16.1 million at the end of the third quarter of 2015 and \$12.7 million at the end of the second quarter of 2016. Continued focus on optimizing the Company's cash position through revenue growth, expense mitigation, working capital management, and equipment leasing generated the increase in cash from the second quarter of 2016 to the third quarter of 2016. The Company has generated \$0.9 million in cash from operating activities during the first nine months of the year.

Conference Call

The Company will host a conference call and webcast on Thursday, November 3 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 97993546), 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 97993546) 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 (or Loss)" excludes the following items that are included in "Net Income (or 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.

Management believes that "Adjusted Net Income (or Loss)" and "Adjusted Net Income (or 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 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 (or Loss) 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". More than 600,000 Visian ICLs have been implanted to date. To learn more about the ICL go to: www.discovericl.com. STAAR has approximately 360 employees and markets lenses in over 60 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, marketing and clinical initiatives, investment imperatives, and any statements of assumptions underlying any of the foregoing. Important additional 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 January 1, 2016 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: our limited capital resources and limited access to financing; the negative effect of unstable global economic conditions on sales of products, especially products such as the ICL used in non-reimbursed elective procedures; 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 Visian Toric ICL and/or actions related to the FDA Warning Letter and Form FDA-483s), or to take enforcement action; research and development efforts may not be successful or may be delayed in delivering products for launch or may exceed anticipated costs; the purchasing patterns of our distributors carrying inventory in the market; the willingness of surgeons and patients to adopt a new or improved product and procedure; and patterns of Visian ICL use that have typically limited our penetration of the refractive procedure market. The Visian Toric ICL and the Visian ICL with CentraFLOW, now known as EVO Visian ICL, are not yet approved for sale in the United States.

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STAAR Surgical Company
Consolidated Balance Sheets
(In 000's)
Unaudited

ASSETS	September 30, 2016	January 1, 2016
Current assets:		
Cash and cash equivalents	\$ 14,284	\$ 13,402
Accounts receivable trade, net	14,372	15,675
Inventories, net	15,895	15,921
Prepayments, deposits, and other current assets	4,649	3,636
Deferred income taxes	518	439
Total current assets	49,718	49,073
Property, plant, and equipment, net	11,718	10,095
Intangible assets, net	607	666
Goodwill	1,786	1,786
Deferred income taxes	1,670	717
Other assets	835	617
Total assets	<u>\$ 66,334</u>	<u>\$ 62,954</u>

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Line of credit	\$ 4,941	\$ 4,159
Accounts payable	7,973	6,691
Deferred income taxes	370	370
Obligations under capital leases	398	362
Other current liabilities	7,568	6,305
Total current liabilities	21,250	17,887
Obligations under capital leases	1,676	204
Deferred income taxes	1,005	1,888
Asset retirement obligations	225	156
Deferred rent	68	87
Pension liability	4,380	3,886
Total liabilities	28,604	24,108

Stockholders' equity:

Common stock	406	399
Additional paid-in capital	196,411	187,007
Accumulated other comprehensive loss	(145)	(1,580)
Accumulated deficit	(158,942)	(146,980)
Total stockholders' equity	37,730	38,846
Total liabilities and stockholders' equity	<u>\$ 66,334</u>	<u>\$ 62,954</u>

STAAR Surgical Company
Consolidated Statements of Operations
(In 000's except for per share data)
Unaudited

	Three Months Ended						Nine Months Ended					
	% of Sales	September 30, 2016	% of Sales	October 2, 2015	Fav (Unfav) Amount	%	% of Sales	September 30, 2016	% of Sales	October 2, 2015	Fav (Unfav) Amount	%
Net sales	100.0%	\$ 20,052	100.0%	\$ 18,750	\$ 1,302	6.9%	100.0%	\$ 60,295	100.0%	\$ 56,264	\$ 4,031	7.2%
Cost of sales	25.8%	5,180	31.7%	5,951	771	13.0%	29.5%	17,804	32.4%	18,206	402	2.2%
Gross profit	74.2%	14,872	68.3%	12,799	2,073	16.2%	70.5%	42,491	67.6%	38,058	4,433	11.6%
Selling, general and administrative expenses:												
General and administrative	24.9%	4,985	25.9%	4,853	(132)	-2.7%	30.5%	18,378	26.2%	14,748	(3,630)	-24.6%
Marketing and selling	35.7%	7,149	33.5%	6,284	(865)	-13.8%	36.5%	22,006	31.6%	17,784	(4,222)	-23.7%
Research and development	22.2%	4,453	19.6%	3,684	(769)	-20.9%	26.6%	16,018	19.2%	10,800	(5,218)	-48.3%
Total selling, general, and administrative expenses	82.8%	16,587	79.0%	14,821	(1,766)	-11.9%	93.6%	56,402	77.0%	43,332	(13,070)	-30.2%
Operating loss	-8.6%	(1,715)	-10.7%	(2,022)	307	15.2%	-23.2%	(13,911)	-9.4%	(5,274)	(8,637)	-163.8%
Other income (expense):												
Interest income	0.0%	0	0.0%	1	(1)	-100.0%	0.0%	1	0.1%	50	(49)	-98.0%
Interest expense	-0.1%	(29)	-0.2%	(29)	-	0.0%	-0.1%	(86)	-0.2%	(97)	11	11.3%
Gain (loss) on foreign currency transactions	-0.1%	(29)	0.1%	20	(49)	—	0.0%	13	-1.2%	(692)	705	—
Royalty income	0.7%	134	1.2%	224	(90)	-40.2%	0.8%	507	0.7%	375	132	35.2%
Other income (expense), net	-0.3%	(68)	0.2%	43	(111)	—	-0.2%	(150)	0.1%	62	(212)	—
Total other income (expense), net	0.2%	8	1.3%	259	(251)	-96.9%	0.5%	285	-0.5%	(302)	587	—
Loss before provision (benefit) for income taxes	-8.4%	(1,707)	-9.4%	(1,763)	56	3.2%	-22.7%	(13,626)	-9.9%	(5,576)	(8,050)	-144.4%
Provision (benefit) for income taxes	0.4%	71	-0.1%	(11)	(82)	—	-2.8%	(1,664)	0.2%	114	(1,778)	—
Net loss	-8.8%	\$ (1,778)	-9.3%	\$ (1,752)	\$ (26)	-1.5%	-19.9%	\$ (11,962)	-10.1%	\$ (5,690)	\$ (6,272)	-110.2%
Net loss per share - basic and diluted												
		\$ (0.04)		\$ (0.04)				\$ (0.30)		\$ (0.14)		
Weighted average shares outstanding												
- basic and diluted		40,486		39,727				40,227		39,409		

STAAR Surgical Company
Consolidated Statements of Cash Flows
(in 000's)
Unaudited

	Three Months Ended		Nine Months Ended	
	September 30, 2016	October 2, 2015	September 30, 2016	October 2, 2015
Cash flows from operating activities:				
Net loss	\$ (1,778)	\$ (1,752)	\$ (11,962)	\$ (5,690)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:				
Depreciation of property and equipment	696	567	1,933	1,563
Amortization of intangibles	60	51	171	154
Deferred income taxes	(4)	(113)	(1,806)	(148)
Change in net pension liability	170	41	390	136
Stock-based compensation expense	385	924	8,143	2,747
Provision for sales returns and bad debts	10	88	99	331
Changes in working capital:				
Accounts receivable	1,772	(308)	1,707	(2,040)
Inventories, net	(12)	(172)	1,601	1,497
Prepayments, deposits and other current assets	(700)	131	(1,118)	737
Accounts payable	(688)	1,003	594	(991)
Other current liabilities	1,428	628	1,104	1,387
Net cash provided by (used in) operating activities	1,339	1,088	856	(317)
Cash flows from investing activities:				
Acquisition of property and equipment	(718)	(582)	(2,709)	(1,283)
Cash proceeds from sale of property, plant, and equipment	48	-	65	2
Net cash used in investing activities	(670)	(582)	(2,644)	(1,281)
Cash flows from financing activities:				
Repayment of capital lease lines of credit	(118)	(96)	(302)	(306)
Proceeds from sale-leaseback transactions	-	-	1,154	-
Repurchase of employee common stock for taxes withheld	-	-	(611)	-
Proceeds from the exercise of stock options	915	253	1,652	2,149
Proceed from the exercise of warrants	-	-	-	2,800
Net cash provided by financing activities	797	157	1,893	4,643
Effect of exchange rate changes on cash and cash equivalents	130	83	777	23
Increase in cash and cash equivalents	1,596	746	882	3,068
Cash and cash equivalents, at beginning of the period	12,688	15,335	13,402	13,013
Cash and cash equivalents, at end of the period	\$ 14,284	\$ 16,081	\$ 14,284	\$ 16,081

STAAR Surgical Company
Global Sales
(in 000's)
Unaudited

Sales by Region	Three Months Ended			% Change Fav (Unfav)	Nine Months Ended			% Change Fav (Unfav)		
	September 30, 2016	October 2, 2015			September 30, 2016	October 2, 2015				
North America	12.5%	\$ 2,502	16.3%	\$ 3,053	-18.1%	12.8%	\$ 7,726	15.9%	\$ 8,954	-13.7%
Europe, Middle East, Africa, Latin America	29.8%	5,985	28.8%	5,393	11.0%	31.1%	18,764	29.8%	16,779	11.8%
Asia Pacific	57.7%	11,565	55.0%	10,304	12.2%	56.1%	33,805	54.3%	30,531	10.7%
Total Sales	100.0%	\$ 20,052	100.0%	\$ 18,750	6.9%	100.0%	\$ 60,295	100.0%	\$ 56,264	7.2%
Product Sales										
ICLs	73.8%	\$ 14,801	68.8%	\$ 12,907	14.7%	72.0%	\$ 43,389	66.5%	\$ 37,396	16.0%
IOLs	23.2%	4,649	23.4%	4,390	5.9%	24.5%	14,783	26.6%	14,952	-1.1%
Other	3.0%	602	7.8%	1,453	-58.6%	3.5%	2,123	7.0%	3,916	-45.8%
Total Sales	100.0%	\$ 20,052	100.0%	\$ 18,750	6.9%	100.0%	\$ 60,295	100.0%	\$ 56,264	7.2%

STAAR Surgical Company
Reconciliation of Non-GAAP Financial Measure
(in 000's)
Unaudited

	Three Months Ended		Nine Months Ended	
	September 30, 2016	October 2, 2015	September 30, 2016	October 2, 2015
Net loss - (as reported)	\$ (1,778)	\$ (1,752)	\$ (11,962)	\$ (5,690)
Less:				
Foreign currency impact	29	(20)	(13)	692
Stock-based compensation expense	385	924	8,143	2,747
FDA panel/remediation expense	485	809	1,484	3,367
Net income (loss) - (adjusted)	\$ (879)	\$ (39)	\$ (2,348)	\$ 1,116
Net income (loss) per share, basic - (as reported)	\$ (0.04)	\$ (0.04)	\$ (0.30)	\$ (0.14)
Foreign currency impact	0.00	(0.00)	(0.00)	0.02
Stock-based compensation expense	0.01	0.02	0.20	0.07
FDA panel/remediation expense	0.01	0.02	0.04	0.09
Net income (loss) per share, basic - (adjusted)	\$ (0.02)	\$ (0.00)	\$ (0.06)	\$ 0.03
Net income (loss) per share, diluted - (as reported)	\$ (0.04)	\$ (0.04)	\$ (0.30)	\$ (0.14)
Foreign currency impact	0.00	(0.00)	(0.00)	0.02
Stock-based compensation expense	0.01	0.02	0.20	0.07
FDA panel/remediation expense	0.01	0.02	0.04	0.08
Net income (loss) per share, diluted - (adjusted)	\$ (0.02)	\$ (0.00)	\$ (0.06)	\$ 0.03
Weighted average shares outstanding - Basic	40,486	39,727	40,227	39,409
Weighted average shares outstanding - Diluted	40,486	39,727	40,227	40,628

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

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