



STAAR Surgical Reports Second Quarter 2016 Results

August 3, 2016

MONROVIA, Calif., Aug. 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 second quarter ended July 1, 2016.

Second Quarter 2016 Overview

- Record Quarterly Net Sales of \$21.0 Million Up 12% from the Prior Year Quarter
- Worldwide ICL Sales Up 26% and Units Up 18% from the Prior Year Quarter
- Worldwide IOL Sales Down 3% and Units Down 15% from the Prior Year Quarter
- Gross Margin Improved to 69.7% of Sales from 66.3% of Sales in the Prior Year Quarter
- On-Going FDA Remediation Effort Finished the Quarter On-Track and On-Budget
- Second Quarter Net Loss of \$0.05 per Share; Adjusted Net Loss of \$0.02 per Share
- Cash Optimization Strategy and Operating Success Increased Cash and Equivalents by \$3.7 Million to \$12.7 Million.

"We delivered record quarterly net sales of \$21 million and achieved record quarterly ICL sales and units as well. Continuing strength and momentum is evident in most of the Asia Pacific region leading with China and in Europe leading with Germany," said Caren Mason, President and CEO. "We advanced a number of strategic priorities for 2016 in the quarter including the finalization of four additional Strategic Cooperation Agreements in the Asia Pacific region. During the quarter, we also finalized the clinical study agreements for our first-in-man implants of the Presbyopic ICL and we are on schedule to provide lenses for surgeries scheduled during the third quarter. In addition, we continued the evaluation process concerning our Cataract Care strategy and have decided to discontinue the manufacturing of silicone IOL lenses for distribution in North America. Consequently, our proprietary Collamer® material IOL lenses will be the only lens version offered in North America at this time. We are currently developing a competitive commercial strategy to encourage users of silicone IOL lenses to use our nanoFLEX® Collamer lenses," added Ms. Mason.

Financial Overview

Net sales were \$21.0 million for the second quarter of 2016, up 12% compared to \$18.7 million reported in the prior year quarter. On a constant currency basis, second quarter net sales increased 10% compared to the prior year quarter. The sales increase was driven by ICL revenue and unit growth of 26% and 18%, respectively, with strong double-digit unit growth in all of the Asia Pacific ("APAC") markets and in Germany. These increases were partially offset by lower IOL revenues and lower sales of injector parts. For the first half of 2016, ICL revenue and unit growth was 17% and 9%, respectively.

For the second quarter of 2016, gross profit margin was 69.7% compared to the prior year period of 66.3%. An increased mix of higher margin ICL units, higher average selling prices, and lower ICL unit costs improved gross margin by approximately 7.0 points which was partially offset by approximately 3.6 points in higher IOL unit costs and reserves for the discontinuation of the Company's silicone IOL product line.

Operating expenses for the quarter increased \$2.7 million to \$16.8 million primarily due to costs related to quality system improvements and investments made in the international selling and marketing organizations. General and administrative expense was \$4.9 million and the change from the prior year quarter was not material. Marketing and selling expense was \$7.2 million, \$1.3 million higher than the prior year quarter due to higher international selling and marketing expenses, including the cost of direct selling in Germany. Research and development expense was \$4.7 million, an increase of \$1.1 million due to investments in quality system improvements, regulatory and clinical affairs, and project-related spending, partially offset by lower remediation expenses. Remediation expense for the quarter was on budget.

The net loss for the second quarter of 2016 was \$2.1 million or \$0.05 per share compared with a net loss of \$1.6 million or \$0.04 per share for the prior year quarter. Charges of \$0.4 million or \$0.01 per share associated with the discontinuation of the silicone IOL product line are included in the second quarter results.

The adjusted net loss for the second quarter of 2016 was \$0.9 million or \$0.02 per share, compared with adjusted net income of \$0.2 million or 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 July 1, 2016 totaled \$12.7 million, compared to \$15.3 million at the end of the second quarter of 2015 and \$9.0 million at the end of the first quarter 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 first quarter of 2016 to the second quarter of 2016. The Company has used \$0.5 million in cash from operating activities during the first six months of the year.

Conference Call

The Company will host a conference call and webcast on Wednesday, August 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 48714531), 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 48714531) 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.

The Company conducts a significant part of its activities outside the U.S. It receives sales revenue and pays expenses principally in U.S. dollars, Swiss francs, Japanese yen and euros. The exchange rates between dollars and non-U.S. currencies can fluctuate greatly and can have a significant effect on the Company's results when reported in U.S. dollars. When preparing its financial statements in conformity with GAAP, the Company translates foreign currency sales and expenses denominated in Japanese yen to dollars at the weighted average of exchange rates in effect during the period. As a result, the Company's reported performance may be significantly affected by currency fluctuations. In order to compare the Company's performance from period to period without the effect of currency, the Company will apply the same average exchange rate applicable in the prior period, or the "constant currency" rate to sales or expenses in the current period as well. Because changes in currency are outside of the control of the Company and its managers, management finds this non-GAAP measure useful in determining the long-term progress of its initiatives and determining whether its managers are achieving their performance goals. The Company believes that the non-GAAP constant-currency sales results measures provided in this press release are similarly useful to investors to give insight on long term trends in the Company's performance without the external effect of changes in relative currency values. The table below shows sales results calculated in accordance with GAAP, the effect of currency, and the resulting non-GAAP measure expressed in constant currency.

"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)" is 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". Over 600,000 Visian ICLs have been implanted to date. To learn more about the ICL go to: www.visianinfo.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 working capital requirements; 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 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	July 1, 2016	January 1, 2016
Current assets:		
Cash and cash equivalents	\$ 12,688	\$ 13,402
Accounts receivable trade, net	16,112	15,675
Inventories, net	15,692	15,921
Prepayments, deposits, and other current assets	3,938	3,636
Deferred income taxes	510	439
Total current assets	<u>48,940</u>	<u>49,073</u>
Property, plant, and equipment, net	11,424	10,095
Intangible assets, net	659	666
Goodwill	1,786	1,786
Deferred income taxes	1,664	717
Other assets	828	617
Total assets	<u>\$ 65,301</u>	<u>\$ 62,954</u>

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Line of credit	\$ 4,866	\$ 4,159
Accounts payable	8,725	6,691
Deferred income taxes	370	370
Obligations under capital leases	346	362
Other current liabilities	6,078	6,305
Total current liabilities	<u>20,385</u>	<u>17,887</u>
Obligations under capital leases	1,384	204
Deferred income taxes	1,006	1,888
Asset retirement obligations	222	156
Deferred rent	77	87
Pension liability	4,240	3,886
Total liabilities	<u>27,314</u>	<u>24,108</u>

Stockholders' equity:		
Common stock	404	399
Additional paid-in capital	195,073	187,007
Accumulated other comprehensive loss	(326)	(1,580)
Accumulated deficit	<u>(157,164)</u>	<u>(146,980)</u>
Total stockholders' equity	<u>37,987</u>	<u>38,846</u>
Total liabilities and stockholders' equity	<u>\$ 65,301</u>	<u>\$ 62,954</u>

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

	Three Months Ended						Six Months Ended					
	% of Sales	July 1, 2016	% of Sales	July 3, 2015	Fav (Unfav)		% of Sales	July 1, 2016	% of Sales	July 3, 2015	Fav (Unfav)	
					Amount	%					Amount	%
Net sales	100.0%	\$ 20,974	100.0%	\$ 18,657	\$ 2,317	12.4%	100.0%	\$ 40,243	100.0%	\$ 37,514	\$ 2,729	7.3%
Cost of sales	30.3%	6,348	33.7%	6,296	(52)	-0.8%	31.4%	12,624	32.7%	12,254	(370)	-3.0%
Gross profit	69.7%	14,626	66.3%	12,361	2,265	18.3%	68.6%	27,619	67.3%	25,260	2,359	9.3%
Selling, general and administrative expenses:												
General and administrative	23.5%	4,928	25.4%	4,736	(192)	-4.1%	33.3%	13,393	26.4%	9,896	(3,497)	-35.3%
Marketing and selling	34.2%	7,181	31.3%	5,832	(1,349)	-23.1%	36.9%	14,856	30.7%	11,500	(3,356)	-29.2%
Research and development	22.2%	4,659	19.0%	3,536	(1,123)	-31.8%	28.7%	11,565	19.0%	7,116	(4,449)	-62.5%
Total selling, general, and administrative expenses	79.9%	16,768	75.7%	14,104	(2,664)	-18.9%	98.9%	39,814	76.0%	28,512	(11,302)	-39.6%
Operating loss	-10.2%	(2,142)	-9.4%	(1,743)	(399)	-22.9%	-30.3%	(12,195)	-8.7%	(3,252)	(8,943)	—
Other income (expense):												
Interest income	0.0%	0	0.3%	49	(49)	100.0%	0.0%	0	0.1%	49	(49)	-100.0%
Interest expense	-0.1%	(29)	-0.2%	(33)	4	12.1%	-0.1%	(57)	-0.2%	(68)	11	-16.2%
Gain (loss) on foreign currency transactions	-2.0%	(416)	1.0%	180	(596)	—	0.1%	42	-1.9%	(711)	753	—
Royalty income	1.7%	351	0.6%	106	245	—	0.9%	373	0.4%	151	222	—
Other income (expense), net	-0.2%	(38)	0.0%	(5)	(33)	—	-0.2%	(82)	0.1%	19	(101)	—
Total other income (expense), net	-0.6%	(132)	1.7%	297	(429)	—	0.7%	276	-1.5%	(560)	836	—
Loss before provision (benefit) for income taxes	-10.8%	(2,274)	-7.7%	(1,446)	(828)	-57.3%	-29.6%	(11,919)	-10.2%	(3,812)	(8,107)	—
Provision (benefit) for income taxes	-0.6%	(131)	0.8%	153	284	—	-4.3%	(1,735)	0.3%	126	(1,861)	—
Net loss	-10.2%	<u>\$ (2,143)</u>	-8.5%	<u>\$ (1,599)</u>	<u>\$ (544)</u>	-34.0%	-25.3%	<u>\$ (10,184)</u>	-10.5%	<u>\$ (3,938)</u>	<u>\$ (6,246)</u>	—
Net loss per share - basic and diluted		<u>\$ (0.05)</u>		<u>\$ (0.04)</u>				<u>\$ (0.25)</u>		<u>\$ (0.10)</u>		
Weighted average shares outstanding - basic and diluted		<u>40,210</u>		<u>39,066</u>				<u>40,097</u>		<u>38,769</u>		

STAAR Surgical Company
Consolidated Statements of Cash Flows

(in 000's)

Unaudited

	Three Months Ended		Six Months Ended	
	July 1, 2016	July 3, 2015	July 1, 2016	July 3, 2015
Cash flows from operating activities:				
Net loss	\$ (2,143)	\$ (1,599)	\$(10,184)	\$ (3,938)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:				
Depreciation of property and equipment	646	499	1,237	996
Amortization of long-lived intangibles	57	51	111	103
Deferred income taxes	(163)	83	(1,802)	(35)
Change in net pension liability	102	45	220	95
Stock-based compensation expense	300	829	7,758	1,823
Accretion of asset retirement obligation	-	(1)	-	-
Provision for sales returns and bad debts	111	144	89	243
Changes in working capital:				
Accounts receivable	252	(1,676)	(65)	(1,732)
Inventories, net	1,049	1,052	1,613	1,669
Prepayments, deposits and other current assets	494	1,179	(418)	606
Accounts payable	1,715	(253)	1,280	(1,994)
Other current liabilities	74	450	(324)	759
Net cash provided by (used in) operating activities	<u>2,494</u>	<u>803</u>	<u>(485)</u>	<u>(1,405)</u>
Cash flows from investing activities:				
Acquisition of property and equipment	(985)	(373)	(1,991)	(701)
Sale of property and equipment	17	-	17	2
Net cash used in investing activities	<u>(968)</u>	<u>(373)</u>	<u>(1,974)</u>	<u>(699)</u>
Cash flows from financing activities:				
Repayment of capital lease obligations	(92)	(95)	(184)	(210)
Proceeds from sale-leaseback transactions	1,154	-	1,154	-
Taxes paid related to net share settlement of equity awards	-	-	(611)	-
Proceeds from exercise of stock options	730	1,475	737	1,896
Proceed from exercise of warrants	-	2,800	-	2,800
Net cash provided by financing activities	<u>1,792</u>	<u>4,180</u>	<u>1,096</u>	<u>4,486</u>
Effect of exchange rate changes on cash and cash equivalents	<u>402</u>	<u>(85)</u>	<u>649</u>	<u>(60)</u>
Increase (decrease) in cash and cash equivalents	3,720	4,525	(714)	2,322
Cash and cash equivalents, at beginning of the period	<u>8,968</u>	<u>10,809</u>	<u>13,402</u>	<u>13,013</u>
Cash and cash equivalents, at end of the period	<u>\$12,688</u>	<u>\$15,334</u>	<u>\$ 12,688</u>	<u>\$15,335</u>

STAAR Surgical Company

Global Sales

(in 000's)

Unaudited

					Three Months Ended			Six Months Ended						
					July 1, 2016	July 3, 2015	% Change Fav (Unfav)							
					July 1, 2016	July 3, 2015	% Change Fav (Unfav)							
Sales by Region					July 1, 2016	July 3, 2015	% Change Fav (Unfav)							
North America					12.0%	\$ 2,523	15.4%	\$ 2,864	-12%	13.0%	\$ 5,224	15.7%	\$ 5,901	-11%
Europe, Middle East, Africa, Latin America					32.2%	6,751	30.9%	5,772	17%	31.8%	12,779	30.3%	11,380	12%
Asia Pacific					55.8%	11,700	53.7%	10,021	17%	55.3%	22,240	53.9%	20,233	10%
Total Sales					100.0%	\$ 20,974	100.0%	\$ 18,657	12%	100.0%	\$ 40,243	100.0%	\$ 37,514	7%
Product Sales														
Core products														
ICLs					73.5%	\$ 15,408	65.6%	\$ 12,236	26%	71.0%	\$ 28,588	65.3%	\$ 24,490	17%
IOLs					24.2%	5,068	27.9%	5,204	-3%	25.2%	10,134	28.2%	10,562	-4%
Total core products					97.7%	20,476	93.5%	17,440	17%	96.2%	38,722	93.5%	35,052	10%
Non-core products														
Other					2.4%	498	6.5%	1,217	-59%	3.8%	1,521	6.6%	2,462	-38%
Total Sales					100.1%	\$ 20,974	100.0%	\$ 18,657	12%	100.0%	\$ 40,243	100.1%	\$ 37,514	7%

STAAR Surgical Company

Reconciliation of Non-GAAP Financial Measure

(in 000's)

Unaudited

	Three Months Ended		Six Months Ended	
	July 1, 2016	July 3, 2015	July 1, 2016	July 3, 2015
Net loss - (as reported)	\$(2,143)	\$(1,599)	\$(10,184)	\$(3,938)
Less:				
Foreign currency impact	416	(180)	42	711
Stock-based compensation expense	300	829	7,758	1,823
FDA panel/remediation expense	491	1,117	1,000	2,558
Net income (loss) - (adjusted)	<u>\$ (936)</u>	<u>\$ 167</u>	<u>\$ (1,384)</u>	<u>\$ 1,154</u>
Net income (loss) per share, basic - (as reported)	\$ (0.05)	\$ (0.04)	\$ (0.25)	\$ (0.10)
Foreign currency impact	0.01	(0.00)	0.00	0.02
Stock-based compensation expense	0.01	0.02	0.19	0.05
FDA panel/remediation expense	0.01	0.03	0.02	0.07
Net income (loss) per share, basic - (adjusted)	<u>\$ (0.02)</u>	<u>\$ 0.00</u>	<u>\$ (0.03)</u>	<u>\$ 0.03</u>
Net income (loss) per share, diluted - (as reported)	\$ (0.05)	\$ (0.04)	\$ (0.25)	\$ (0.10)
Foreign currency impact	0.01	(0.00)	0.00	0.02
Stock-based compensation expense	0.01	0.02	0.19	0.05
FDA panel/remediation expense	0.01	0.03	0.02	0.06
Net income (loss) per share, diluted - (adjusted)	<u>\$ (0.02)</u>	<u>\$ 0.00</u>	<u>\$ (0.03)</u>	<u>\$ 0.03</u>
Weighted average shares outstanding - Basic	40,210	39,066	40,097	38,769
Weighted average shares outstanding - Diluted	40,210	40,386	40,097	40,048

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

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

Three Months Ended								
	GAAP Sales			July 1, 2015	As Reported		Constant Currency	
	July 1, 2016	Effect of Currency	Constant Currency		\$ Change	% Change	\$ Change	% Change
ICL	\$ 15,408	\$ (82)	\$ 15,326	\$12,236	\$ 3,172	26%	\$ 3,090	25%
IOL	5,068	(344)	4,724	\$ 5,204	(136)	-3%	(480)	-9%
Other	498	(27)	471	\$ 1,217	(719)	-59%	(746)	-61%
Total Sales	\$ 20,974	\$ (453)	\$ 20,521	\$18,657	\$ 2,317	12%	\$ 1,864	10%

Six Months Ended								
	GAAP Sales			July 1, 2015	As Reported		Constant Currency	
	July 1, 2016	Effect of Currency	Constant Currency		\$ Change	% Change	\$ Change	% Change
ICL	\$ 28,588	\$ (100)	\$ 28,488	\$24,490	\$ 4,098	17%	\$ 3,998	16%
IOL	10,134	(450)	9,684	10,562	(428)	-4%	(878)	-8%
Other	1,521	(51)	1,470	2,462	(941)	-38%	(992)	-40%
Total Sales	\$ 40,243	\$ (601)	\$ 39,642	\$37,514	\$ 2,729	7%	\$ 2,128	6%

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/staar-surgical-reports-second-quarter-2016-results-300308715.html>

SOURCE STAAR Surgical Company