

# STAAR Surgical Reports First Quarter 2015 Results

April 29, 201

MONROVIA, Calif., April 29, 2015 /PRNewswire/ -- STAAR Surgical Company (NASDAQ: STAA), a leading developer, manufacturer and marketer of implantable lenses and delivery systems for the eye, today reported financial results for the first quarter ended April 3, 2015.

#### First Quarter Overview

- Net Sales of \$18.9 Million Decreased 7% from the Year Ago Period and 3% on a Constant Currency Basis
- ICL Units in North America Increased 18% and EMEA Units Increased 9%
- CentraFLOW® Accounted for 78% of ICL Shipments in China
- Gross Margin Increased to 68% in Q1 vs. 57% in Q4 2014
- Backlog Decreased to \$340,000 from a \$3.3 Million Peak During the First Quarter
- FDA Remediation Expense of \$1.4 Million for the Quarter
- First Quarter Net Loss of \$0.06 per Share; Adjusted Net Income of \$0.03 per Share

"Our first quarter results clearly indicate the work we have accomplished in rebuilding our manufacturing efficiency and meeting volume demands," said Caren Mason, President and CEO. "We exceeded our ICL manufacturing production record during the month of March and reduced our backlog significantly. The unit growth in our EMEA markets is trending nicely with currency challenge continuing to dampen the dollar impact. We are also pleased that the CentraFLOW has had such a positive reception in China as the momentum continues to build internationally. The global opportunity for STAAR's proprietary lenses and work we have initiated to strengthen our foundational business practices is front and center. We will remain significantly focused on all global regulatory requirements and FDA remediation efforts while undertaking the systemic changes required including the building of an enhanced Quality System."

#### Financial Overview

Net sales were \$18.9 million for the first quarter of 2015, a decrease of 7% compared to \$20.2 million reported in the prior year. Adjusting for the negative effect of changes in foreign currency, first quarter net sales declined 3% compared to the prior period.

International sales represented 85% of total net sales for the first quarter. In China, STAAR continued shipping the CentraFLOW® product, following final approval for the ICL and TICL with CentraFLOW® in November 2014. In the first quarter 78% of all ICL shipments to China were the CentraFLOW technology.

For the first quarter of 2015, the gross profit margin declined 40 basis points compared to the prior year period to 68.4%, which was also a sequential improvement over the 56.7% gross margin reported in the fourth quarter of 2014. Compared to the first quarter of 2014, the gross margin benefited from improved average unit costs and a smaller proportion of lower-margin product sales, offset by the impact of a weaker Euro on average selling prices and moderately higher inventory reserves and freight and distribution costs as a proportion of sales.

Operating expenses for the quarter declined 5% to \$14.4 million from \$15.2 million in the prior year, primarily due to lower general and administrative expense and lower marketing and selling expense than the prior year period. General and administrative expense was \$5.1 million and approximately \$280,000 lower than the prior year due to decreased compensation and tax consulting costs, partially offset by accrued separation costs.

Marketing and selling expense was \$5.7 million and approximately \$470,000 lower than the prior year due to decreased marketing costs internationally, stock-based compensation and favorable currency exchange, partially offset by higher ICL and online marketing support and U.S. commissions. Research and development expense, which includes remediation and other FDA expenses, was relatively flat at \$3.6 million compared to \$3.5 million in the prior year period. R&D expense includes \$1.4 million of remediation expenses for the first quarter of 2015 and approximately the same amount in FDA panel expenses for the first quarter of 2014. The Company's full year 2015 budget contemplates future remediation expenses of approximately \$4 million that are expected to be fully funded from internally generated cash flows.

The net loss for the first quarter of 2015 was \$2.3 million or \$0.06 per diluted share, compared with a net loss of \$1.4 million or \$0.04 per diluted share, for the prior year period.

Adjusted net income for the first quarter of 2015 was \$1.1 million or \$0.03 per diluted share, compared with adjusted net income of \$1.6 million or \$0.04 per diluted share, for the prior year period. The reconciliation between GAAP and non-GAAP financial information is provided in the financial tables included with this release.

Cash and cash equivalents at April 3, 2015 totaled \$10.8 million. The Company used \$2.2 million in cash during the first quarter of 2015.

## Conference Call

The Company will host a conference call and webcast on Wednesday, April 29 at 4:30 p.m. Eastern / 1:30 p.m. Pacific to discuss its financial results. To access the conference call (Conference ID 26021251), please dial 855-765-5684 for domestic participants and 262-912-6252 for international participants. No passcode is necessary. The live webcast can be accessed from the investor relations section of the STAAR website at <a href="https://www.staar.com">www.staar.com</a>.

A taped replay of the conference call will also 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 <a href="https://www.staar.com">www.staar.com</a>.

## 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" excludes the following items that are included in "Net Income" as calculated in accordance with U.S. generally accepted accounting principles ("GAAP"): manufacturing consolidation expenses, gain or loss on foreign currency transactions, stock-based compensation expenses, and FDA panel and remediation expenses.

Management believes that "Adjusted Net Income" 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 manufacturing consolidation expenses and FDA panel and remediation expenses because these are non-recurring expenses and their inclusion may mask underlying trends in our business performance. Expenses associated with the consolidation of the Company's manufacturing operations to the U.S. were largely completed by the end of the second quarter of 2014.

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 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.

The Company has provided below a detailed reconciliation table, which is useful to investors in providing the context to understand STAAR Surgical's Adjusted Net Income and how it differs from Net Income calculated in accordance with GAAP

# About STAAR Surgical

STAAR, which has been dedicated solely to ophthalmic surgery for over 25 years, designs, develops, manufactures and markets implantable lenses for the eye and delivery systems therefor. All of these lenses are foldable, which permits the surgeon to insert them through a small incision. STAAR's lens used in refractive surgery as an alternative to LASIK is called an Implantable Collamer® Lens or "ICL." A lens used to replace the natural lens after cataract surgery is called an intraocular lens or "ICL." More than 500,000 Visian ICLs have been implanted to date. To learn more about the ICL go to: <a href="https://www.visianinfo.com">www.visianinfo.com</a>. STAAR has approximately 300 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 <a href="https://www.staar.com">www.staar.com</a>.

## Safe Harbo

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; the plans, strategies, and objectives of management for future operations or prospects for achieving such plans; statements regarding new or improved products, including but not limited to, expectations for success of new, existing, or improved products in the U.S. or international markets or US and/or foreign government approval of new or improved products (including the Toric ICL in the U.S.) or commercialization of new products; the nuture, timing and likelihood of resolving issues cited in the FDA's Warning Letter or the Form FDA-483s; future economic conditions or size of market opportunities; expected costs of quality system and FDA remediation efforts; expected costs and savings from business

consolidation plans and the timetable for those plans; statements of belief; expected regulatory activities and approvals, product launches, 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 2, 2015, 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."

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; the challenge of managing our foreign subsidiaries; backlog or supply delays; the risk of unfavorable changes in currency exhange rate; 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 TICL and/or actions related to the FDA Warning Letter and Form FDA-483s), or to take enforcement action; unexpected costs or delays that could reduce or eliminate the expected benefits of our consolidation plans; the risk that research and development efforts will not be successful or may be delayed in delivering for launch; 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; patterns of Visian ICL use that have typically limited our penetration of the refractive procedure market, negative media coverage in different regions regarding refractive procedures, and a general decline in the demand for refractive surgery particularly in the U.S. and the Asia Pacific region, which STAAR believes has resulted from both concerns about the safety and effectiveness of laser procedures and current economic conditions. 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 Condensed Consolidated Balance Sheets (in 000's) Unaudited

ASSETS	,	April 3, 2015	January 2, 2015		
Current assets:					
Cash and cash equivalents	\$	10,809	\$	13,013	
Accounts receivable trade, net	•	11.035		11,054	
Inventories, net		15,273		15,717	
Prepaids, deposits, and other current assets		5,271		4,517	
Deferred income taxes		600		596	
Total current assets		42,988		44,897	
Property, plant, and equipment, net		9,923	-	10,066	
Intangible assets, net		824		870	
Goodwill		1.786		1.786	
Deferred income taxes		698		695	
Other assets		590		597	
Total assets	\$	56,809	\$	58,911	
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current liabilities:					
Line of credit	\$	4,178	\$	4,150	
Accounts payable		4,943		6,620	
Deferred income taxes		301		301	
Obligations under capital leases		342		399	
Other current liabilities		5,284		4,976	
Total current liabilities		15,048		16,446	
Obligations under capital leases		411		468	
Deferred income taxes		1,756		1,704	
Asset retirement obligations		117		115	
Pension liability		3,128		3,079	
Total liabilities		20,460		21,812	
Stockholders' equity:					
Common stock		386		384	
Additional paid-in capital		386 179.767		384 178.232	
Accumulated other comprehensive income		(1,017)		(1,070)	
Accumulated other comprehensive income Accumulated deficit		(1,017)		(1,070)	
Total stockholders' equity		36,349		37,099	
• •	\$	56,809	\$	58,911	
Total liabilities and stockholders' equity	Ψ	50,003	Ψ	JU, J I I	

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

	Three Months Ended									
	% of	Α	pril 3,	% of	-	April 4,	, Change			
	Sales		2015	Sales		2014	Amount	%	_	
Net sales	100.0%	\$	18,858	100.0%	\$	20,178	\$ (1,320)	-6.5	%	
Cost of sales	31.6%		5,959	31.2%		6,294	335	-5.3	%	
Gross profit	68.4%		12,899	68.8%		13,884	(985	-7.1	%	
Selling, general and administrative expenses:										
General and administrative	27.1%		5,114	26.7%		5,396	(282)	-5.2	%	
Marketing and selling	30.1%		5,668	30.4%		6,138	(470)	-7.7	%	
Research and development	19.0%		3,579	17.3%		3,484	95	2.7	%	
Medical device tax	0.3%		48	0.2%		40	8	20.0	%	
Selling, general, and administrative expenses	76.5%		14,409	74.6%		15,058	(649)	-4.3	%	
Other general and administrative expenses	0.0%			0.8%		168	(168	-100.0	%	
Total selling, general and administrative expenses	76.5%		14,409	75.4%		15,226	(817	-5.4	%	
Operating loss	-8.1%		(1,510)	-6.6%		(1,342)	(168	12.5	%	
Other income (expense):										
Interest income	0.0%		0	0.0%		9	(9)	-100.0	%	
Interest expense	-0.2%		(36)	-0.2%		(33)	(3)	9.1	%	
Gain (loss) on foreign currency transactions	-4.7%		(892)	0.3%		66	(958)		%	
Other income, net	0.4%			0.8%			(90	-56.3	%	
Total other income (expense), net	-4.5%		(858)	0.9%		202	(1,060)	-524.8	%	

Loss before provision (benefit) for income taxes	-12.6%	(2,368)	-5.7%	(1,140)	(1,228)	107.7%
Provision (benefit) for income taxes	-0.1%	(28)	1.1%	219	(247)	-112.8%
Net loss	-12.5% <u>\$</u>	(2,340)	-6.8% <u>\$</u>	(1,359)	\$ (981)	72.2%
Net loss per share-basic Net loss per share-diluted	\$ \$	(0.06) (0.06)	\$ \$	(0.04)		
Weighted average shares outstanding - basic Weighted average shares outstanding - diluted	_	38,481 38,481	_	37,794 37,794		

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

	Three Months Ended			
		April 3, 2015		April 4, 2014
Cash flows from operating activities:				
Net loss	\$	(2,340)	\$	(1,359)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation of property and equipment		497		453
Amortization of intangibles		52		106
Deferred income taxes		(118)		24
Change in net pension liability		50		45
Stock-based compensation expense		1,116		1,500
Accretion of asset retirement obligation		1		1
Provision for sales returns and bad debt expense		174		(55)
Changes in working capital:				
Accounts receivable trade, net		(131)		(295)
Inventories		495		(1,137)
Prepaids, deposits and other current assets		(573)		(1,270)
Accounts payable		(1,741)		(610)
Other current liabilities		309		3
Net cash used in operating activities		(2,209)		(2,594)
Cash flows from investing activities:				
Acquisition of property and equipment		(328)		(1,414)
Sale of property and equipment		2		-
Net cash used in investing activities		(326)		(1,414)
Cash flows from financing activities:				
Repayment of capital lease lines of credit		(115)		(46)
Proceeds from exercise of stock options		421		2,188
Net cash provided by financing activities		306		2,142
Effect of exchange rate changes on cash and cash equivalents		25		(18)
Decrease in cash and cash equivalents		(2,204)		(1,884)
Cash and cash equivalents, at beginning of the period		13,013		22,954
Cash and cash equivalents, at end of the period	\$	10,809	\$	21,070

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

	Three Months Ended										
Geographic Sales			April 3, 2015		April 4, 2014	% Change					
United States	15.2%	\$	2,867	14.2%	\$	2,874	-0.2%				
Japan	22.7%		4,286	24.8%		5,008	-14.4%				
Korea	12.4%		2,343	13.0%		2,621	-10.6%				
China	12.6%		2,371	11.0%		2,225	6.6%				
Spain	7.8%		1,478	8.0%		1,618	-8.7%				
France	6.1%		1,150	4.7%		946	21.6%				
Other	23.1%		4,363	24.2%		4,886	-10.7%				
Total International Sales	84.8%		15,991	85.8%		17,304	-7.6%				
Total Sales	100.0%	\$	18,858	100.0%	\$	20,178	-6.5%				
Product Sales											
Core products											
ICLs	65.0%	\$	12,255		\$	12,241	0.1%				
IOLs	28.4%	_	5,358	32.8%		6,613	-19.0%				
Total core products	93.4%		17,613	93.4%		18,854	-6.6%				
Non-core products											
Other	6.6%		1,245	6.6%		1,324	-6.0%				
Total Sales	100.0%	\$	18,858	100.0%	\$	20,178	-6.5%				

STAAR Surgical Company Reconciliation of Non-GAAP Financial Measure Adjusted Net Income Unaudited

	1	Three Mon	ths En	ded
		oril 3, 1015		pril 4, 2014
Net loss (as reported)	\$	(2,340)	\$	(1,359)
Less: Manufacturing consolidation expenses	¢		¢	160

Foreign currency impact Stock-based compensation expense FDA panel/remediation expense	\$ \$ \$	892 1,116 1,441	\$ \$ \$	(66) 1,500 1,394
Net income (adjusted)	\$	1,109	\$	1,637
Net loss per share, basic (as reported)	\$	(0.06)	\$	(0.04)
Manufacturing consolidation expenses	\$	-	\$	0.00
Foreign currency impact	\$	0.02	\$	(0.00)
Stock-based compensation expense	\$	0.03	\$	0.04
FDA panel/remediation expense	\$	0.04	\$	0.04
Net income per share, basic (adjusted)	\$	0.03	\$	0.04
Net loss per share, diluted (as reported)	\$	(0.06)	\$	(0.03)
Manufacturing consolidation expenses	\$	-	\$	0.00
Foreign currency impact	\$	0.02	\$	(0.00)
Stock-based compensation expense	\$	0.03	\$	0.04
FDA panel/remediation expense	\$	0.04	\$	0.03
Net income per share, diluted (adjusted)	\$	0.03	\$	0.04
Weighted average shares outstanding - Basic		38,481		37,794
Weighted average shares outstanding - Diluted		39,583		40,244

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

STAAR Surgical Company Reconcilitation of Non-GAAP Financial Measure Constant Currency Sales Unaudited

	GAAP Sales April 3, Effect of Constant						April 4,	 As Re	ported		Constant	Currency
		2015	Cui	rency	С	urrency	 2014	\$ Change	% Change		Change	% Change
ICL	\$	12,255	\$	66	\$	12,321	\$ 12,241	\$ 14	0%	, 0	\$ 80	1%
IOL		5,358		489		5,847	6,613	(1,255)	-19%	ó	(766)	-12%
Other		1,245		143		1,388	1,324	 (79)	-6%	<u>6</u>	64	5%
<b>Total Sales</b>	\$	18,858	\$	698	\$	19,556	\$ 20,178	\$ (1,320)	-7%	<b>5</b> \$	(622)	-3%

To view the original version on PR Newswire, visit: <a href="http://www.prnewswire.com/news-releases/staar-surgical-reports-first-quarter-2015-results-300074564.html">http://www.prnewswire.com/news-releases/staar-surgical-reports-first-quarter-2015-results-300074564.html</a>
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