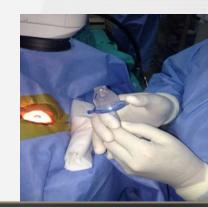


# STAAR®

SURGICAL

NASDAQ: STAA

Q3 2014 Results – Investor Presentation



### Forward-Looking Statements

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 projections of earnings, revenue, sales, profit margins, cash, effective tax rate or any other financial items; the plans, strategies, and objectives of management for future operations or prospects for achieving such plans; metrics for 2014; statements regarding new or improved products, including but not limited to, expectations for success of new or improved products in the U.S. or international markets or government approval of new or improved products (including the Toric ICL in the U.S.); the nature, timing and likelihood of resolving issues cited in the FDA's Warning Letter; future economic conditions or size of market opportunities; expected costs of quality system remediation; statements of belief, including as to achieving 2014 growth plans or metrics; 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 3, 2014, under the caption "Risk Factors," and also in the company's Quarterly Report on Form 10-Q for the quarter ended July 4, 2014, under the caption "Risk Factors," both of which are 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 as we fully integrate our manufacturing facility consolidation; the risk of unfavorable changes in currency exchange rate; the discretion of regulatory agencies to approve or reject 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); 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.

In addition, to supplement the GAAP numbers, this presentation includes supplemental non-GAAP financial information, which STAAR believes investors will find helpful in understanding its operating performance. "Adjusted Net Income" excludes the following items that are included in "Net Income (Loss)" as calculated in accordance with U.S. generally accepted accounting principles ("GAAP"): manufacturing consolidation expenses, gain or loss on foreign currency transactions, Spain distribution transition cost, the fair value adjustment of outstanding warrants issued in 2007, stock-based compensation expenses and FDA Panel/Remediation expenses. A table reconciling the GAAP information to the non-GAAP information is included in our financial release which can be found in our Form 8-K filed on October 30, 2014 and also available on our website.

### Agenda

2014 Annual Objectives	Barry G. Caldwell Chief Executive Officer
Q3 & YTD Key Financial Results	Steve Brown Chief Financial Officer
Operational Updates	Barry G. Caldwell Chief Executive Officer
Q&A Session	Your Questions



# Key Operating Metrics for 2014 Annual Objectives

- Annual Key Operating Metrics established at the beginning of 2014 are Annual Objectives to Which We Report Our Progress Quarterly
  - Revenue Growth of 8% to 10%
  - ICL Revenue Growth of 20%
  - Gross Margin Expansion of 300 bps
  - GAAP Profitable Full Year
  - Successfully Complete Manufacturing Consolidation by Mid-Year

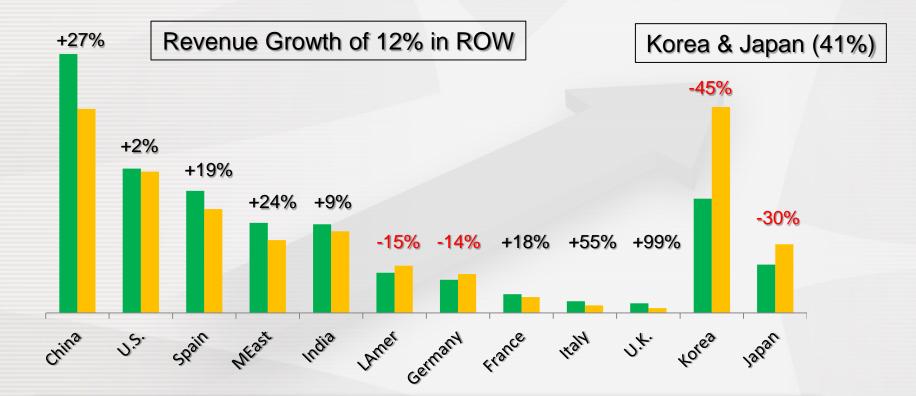


## 2014 Annual Objectives Report Q3 Revenue Growth

- Q3 Revenue Growth of 6.3% to \$18.2M
  - \$18.6M in Constant Currency (CC)/+9%
- Visian ICL Revenue Declined 1%
  - 58.5% of total sales vs. 62.7%
- IOL Revenue Increased 8.3%
  - 31.7% of total sales vs. 31.1%
- "Other Product" Revenue Increased 68%
  - 9.8% of total sales vs. 6.2%
- YTD Revenue Growth of 10% to \$58.4M/12% Growth in CC



# 2014 Annual Objectives Report Q3 ICL Growth



**Total ICL Revenue Increased in 8 of 12 Focus Markets** 



### 2014 Annual Objectives Report Korean Refractive Market

- Negative media coverage of LASIK complications began on a "Regional Network" and Expanded to "National Network"-MBC
  - Focus was <u>only</u> on patients with Complications from LASIK
  - Theme was "Patients giving up on their Dreams because of LASIK"
- Major refractive practices report 50%+ decline in patients and procedures the second half of Q3
- ICL "out the door" sales from our distributor declined 40% during Q3
  - ICL purchases from our distributor declined by 45% in the quarter
- In October starting to see some encouraging signs









### 2014 Annual Objectives Report New Korean DTC Marketing Program Initiation

- The "Big Model Strategy" Campaign (Lee Bo-young)
- Engaged a famous Korean actress who has Visian ICLs
  - She was about -8.0 in both eyes, has ICLs for 8 years
- Multiple marketing avenues for the Campaign
  - First ever TV Commercials for the Visian ICL in Korea
  - Movie Theater Commercials
  - Bus Wraps
  - Online Marketing Activities to Answer Patient Inquiries



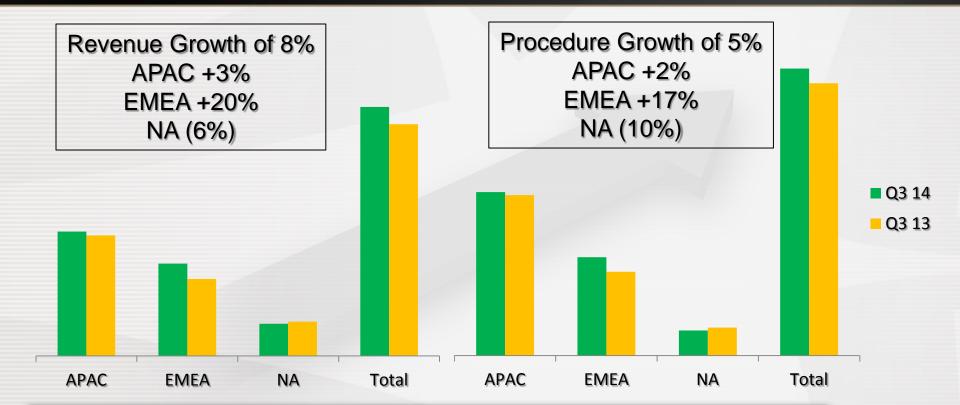


Big Model Strategy





### 2014 Annual Objectives Report YTD ICL Growth



Visian ICL Revenue and Units Increase in 9 of 12 Focus Markets

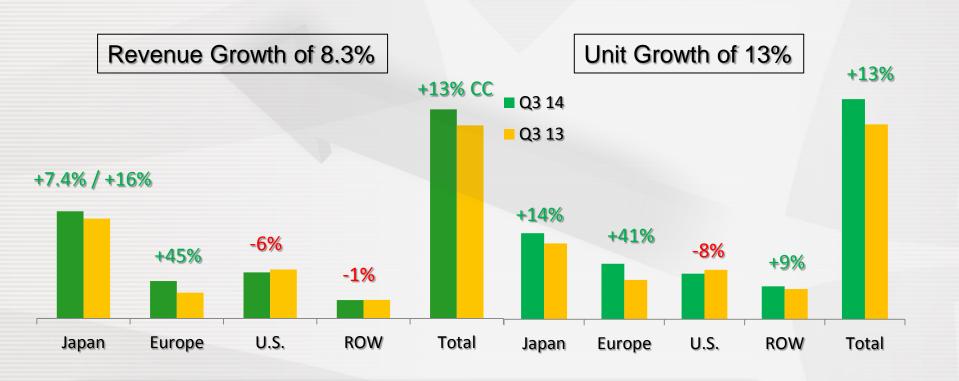


# 2014 Annual Objectives Report Q3 IOL Revenue Growth

- Q3 Sales Were \$5.8M, Increase of 8.3%/+13% in CC
  - 7.4% Increase in Japan/+16% in CC, +45% in Europe
- IOL Units Increased 13% during the Quarter
  - 14% Unit Increase in Japan, 41% in Europe
- KS-IOL Units Increase 58% in Quarter
  - Acrylic Preloaded now 41% of all IOL units
  - Silicone is 47% of IOL units
- Lack of Backorders now Allow us to Expand to New Markets
  - KS-IOL Supply for 2015 looks to be Stronger



### 2014 Annual Objectives Report Q3 IOL Revenue and Unit Growth



Revenue in CC +\$669k an Increase of 13%



## 2014 Annual Objectives Report Gross Margin Expansion

- Headwinds Continue in Three Areas:
  - Geographic Mix of IOL Sales
  - Start up Costs for ICL in U.S. Higher
  - Increased Sales of Lower Margin IOL Injectors
- Steve will cover in more detail



## 2014 Annual Objectives Report GAAP Profitability

- Not Profitable in Q3 with Increased Spending
  - Investment Spending in R&D for V5 and V6a ICLs
  - Investment Spending in Sales and Marketing for Launch of TICL
  - Expense of ESCRS meeting, \$1.2M, in Q3 versus \$750k cost in Q4 PY
  - Higher Expenses for Remediation Efforts around the Warning Letter
- Other Income Line Negative Swing of \$900k
- Target to make a profit in Q4
  - Will not be profitable for the Full Year



## 2014 Annual Objectives Report Manufacturing Consolidation

- All Approved Products being Manufactured in Monrovia
- Still working through inventory of some product which was manufactured in Switzerland
- Maintaining manufacturing capability in Switzerland which adds some additional facility and overhead costs
- Continue to make progress on cost of product in Monrovia though not yet at the yield level and cost level expected



### Q3 Adds to Solid Start of 2014 Puts and Takes YTD

- Revenue Growth currently at Upper Range of Expectations
  - IOL and "Other Product" Growth Higher than Expected
  - ICL Growth not as High as Expected
  - Impact of Yen a Negative Factor during H2
- ICL Positive Price Variances with New Product Introductions
- Continued Gross Margin Headwinds from Higher than Expected IOL and Injector sales
- Continuing to Invest in key parts of business to drive expanded future growth



# Q3 Key Financial Results Topics to Discuss

- GAAP and non-GAAP P&L
- Gross Margin Expansion Challenges
- Operating Expenses
- Below Operating Income line
  - Tax Provisions
  - Other Income



# Q3 Key Financial Results 2014 GAAP (\$000's except per share)

	Q3 2014	Q3 2013	Change
Revenue	\$18,188	\$17,106	+\$1,082/+6%
Gross Profit	\$11,869	\$12,059	\$(190)/(1.6%)
Gross Profit Margin	65.3%	70.5%	(520bps)
Operating Expenses	\$13,422	\$11,886	+\$1,536/+13%
Other Income (Loss)	\$( 605)	\$ 327	\$( 932)
Income (Loss) Before Taxes	\$(2,158)	\$ 500	\$(2,658)
Income Taxes	\$ 548	\$( 25)	\$( 573)
Net Income (Loss)	\$ (2,706)	\$ 525	\$(3,231)
Net Inc. (Lost) per Diluted Share	\$(0.07)	\$0.01	\$(0.08)



# Q3 Key Financial Results 2014 Non-GAAP Measures (\$000's except per share)

Measure	Q3 2014	Q3 2013	
GAAP Net Income (Loss)	\$(2,706)	\$525	
Mfg. Consolidation Expenses		\$490	
Spain Distribution Transition Cost			
Foreign Currency Impact	\$628	\$(226)	
Adjustment of Warrant Value			
Stock-based Compensation Expense	\$1,553	\$905	
FDA Panel/Remediation Expenses	\$612		
Adjusted Net Income (Loss)	\$ 87	\$1,694	
Adjusted Net Income (Loss) Per Share	\$0.00	\$0.04	7

### YTD Key Financial Results

2014 GAAP (\$000's except per share)

	YTD Q3 2014	YTD Q3 2013	Change
Revenue	\$58,414	\$53,271	+\$5,143/+10%
Gross Profit	\$39,419	\$37,332	+\$2,087/+6%
Gross Profit Margin	67.5%	70.1%	(260bps)
Operating Expenses	\$43,705	\$35,381	+\$8,324/+23.5%
Other Income (Loss)	\$( 434)	\$ <b>211</b>	\$( 645)
Income (Loss) Before Taxes	\$(4,720)	\$ 2,162	\$(6,882)
Income Taxes	\$ 1,134	\$ 888	\$( 246)
Net Income (Loss)	\$ (5,854)	\$ 1,274	\$(7,128)
Net Inc. (Loss) per Diluted Share	\$(0.15)	\$0.03	\$(0.18)

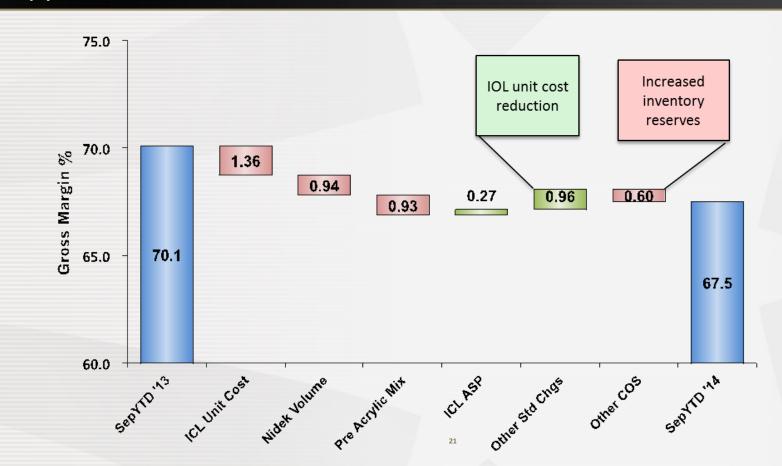


### YTD Key Financial Results 2014 Non-GAAP Measures (\$000's except per share)

Measure	YTD Q3 2014	YTD Q3 2013
GAAP Net Income (Loss)	\$(5,854)	\$1,274
Mfg. Consolidation Expenses	\$334	\$2,004
Spain Distribution Transition Cost		\$442
Foreign Currency Impact	\$696	\$ 38
Adjustment of Warrant Value		\$(27)
Stock-based Compensation Expense	\$4,736	\$2,924
FDA Panel/Remediation Expenses	\$2,104	
Adjusted Net Income (Loss)	\$2,016	\$6,655
Adjusted Net Income (Loss) Per Share	\$0.05	\$0.17



### Gross Margin Expansion Opportunities and Headwinds YTD





## Operating Expenses Q3 Expenses

- R&D Increased by \$1.5M
  - Key Project Costs on V5 and V6a ICL new products
  - Remediation actions relating to the Warning Letter
- Sales and Marketing Increased by \$1.5M
  - \$1.2M Expense of ESCRS in Q3 vs. Q4 of PY at \$750k
  - Some of Increase Related to Anticipated Launch of TICL in U.S.
- G&A Declined by \$900k
  - Reversal of Bonus Plan Pool as Profit Target missed
- Benefit of no manufacturing consolidation charges, \$500k in Q3 2013



### Below Operating Income Line Other Income and Tax Provisions During the Quarter

- Other Income Line
  - Recorded as \$(605k) vs. \$327k, Impact of \$(932k) in quarter
  - Primarily driven by foreign currency transactions \$(854k)
- Tax Provisions
  - Provision of \$548k vs. \$(25k), Impact of \$(573k) in quarter
  - Primarily driven by profit driven outside the U.S.



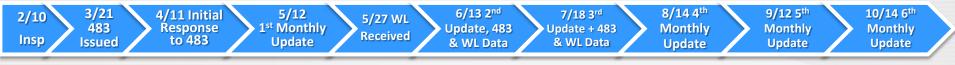
### Operational Updates Opportunities and Challenges H2

- Warning Letter Remediation Actions
- Regulatory Approval Process Updates
  - CentraFLOW ICL in China
  - TICL in U.S.
  - V6a ICL in Europe
- Clinical Updates on ICL with CentraFLOW



# GMP Warning Letter Updates Working Diligently to Resolve

- A Total of Eight Responses to the Agency with Data
  - Initial Response Plus Six Proactive Monthly Progress Reports
  - Proactive Reporting has included Remediation Action Items
- October 15 response on current MICL process in U.S.



- Four Key Categories Under Review
  - Design Control Documents
  - Validation of Software for On-Line Calculator
  - Data Collection and Trending on ICL Vault Complaints
  - Shelf Life Data on the ICL Product



### Regulatory Process CentraFLOW ICL in China

- Successful May 15<sup>th</sup> Expert Panel Meeting in China
- September 24<sup>th</sup> Technical Recommendation of Approval from CMDE
  - Both ICL and TICL
- Learned of Marketing Approval from CFDA on October 29<sup>th</sup>
- Final Step is the Approval Certification
  - Necessary to ship product
  - This is normally within a 10 working day period
- Additional Surgeon Training in China during November
- China is the Largest Refractive market in the world
  - Today ICL only about 2% of refractive surgeries





### Regulatory Process Toric ICL in U.S.

- September 3<sup>rd</sup> received questions from the FDA on the TICL Calculator System
  - Response was required by October 3<sup>rd</sup>
- The Calculator Software was updated, verified and validated during September
- Submitted our Response to the Agency on September 25<sup>th</sup>
- Waiting to Hear Next Steps from the Agency



### Regulatory Process V6a ICL in Europe

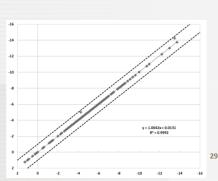


- V6a designed to bring new optic to the ICL which would provide near vision capability for one who is approaching presbyopia
- Could delay the need for reading glasses for several years
- Optical bench results have been very good using a concept known as EDOF (Extended Depth of Focus)
- Dr. Robert Ang will conduct a Confirmatory Study in the coming months with implants of the new design
- Believe we could gain CE Mark Approval during 2015
  - Potential market over 3 billion eyes

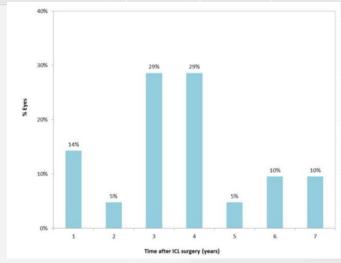


### Operational Updates <a href="ESCRS & AAO Clinical Data on CentraFLOW ICL">ESCRS & AAO Clinical Data on CentraFLOW ICL</a>

- Very interesting clinical data presented
- Dr. Alfonso data from Spain
  - Zero Cataracts in over 1,000 ICLs with CentraFLOW
  - Two years out
- Dr. Mertens data from Belgium
  - Zero cataracts in nearly 1,000 ICLs with CentraFLOW
  - Three years out



	V4	V <sub>4</sub> B	V4c
N	1106	1276	1048
Cases of Cataract	16	5	0
% of cases	0.5%	0.2%	0
Years of follow-up	Up to 12 y	Up to 4 y	Up to 2 y



Visian ICL with CentraFLOW not yet approved in the U.S.

### **Upcoming Investor Meetings**

- November 11-12 at Stephens Healthcare Conference in New York City
- November 20-21 at Canaccord Genuity Conference in New York City
- December 2-3 at Piper Jaffray Healthcare Conference in New York City
- We Expect to Report our Q4/FY Results on February 25, 2015



## Upcoming STAAR Catalysts Q4 and 2015 Growth Roadmap

- Continued Adoption of ICL with CentraFLOW technology
  - Should begin shipping product to China during Q4
  - Interesting Clinical results seen in First Three Years
- We are committed to enhancement of our Quality System and investing significant resources to improve
- Continue to Dialogue with the Agency on TICL in the U.S.
- On-going progress of V6a ICL including the Confirmatory Study
- Increased Supply of Preloaded Acrylic IOLs should enhance growth rate
- Working with distributor on DTC Campaign to address Korean media focus on LASIK complications with new ICL Messaging



#### Thank You

### YOUR QUESTIONS PLEASE





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