

STAAR SURGICAL CO  
Form 10-Q  
November 08, 2006

Table of Contents

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**

**Form 10-Q**

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
**For the quarterly period ended: September 29, 2006**
- OR**
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
**For the transition period from            to**

**Commission File Number: 0-11634**

**STAAR SURGICAL COMPANY**

*(Exact name of registrant as specified in its charter)*

**Delaware**  
*(State of incorporation)*

**95-3797439**  
*(I.R.S. Employer Identification No.)*

**1911 Walker Avenue**  
**Monrovia, California 91016**  
*(Address of principal executive offices, including zip code)*

**(626) 303-7902**  
*(Registrant's telephone number, including area code)*

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. YES  NO

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer or large accelerated filer in Rule 12b-2 of the Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes  No

The registrant has 25,541,993 shares of common stock, par value \$0.01 per share, issued and outstanding as of November 6, 2006.

---

**STAAR SURGICAL COMPANY**

**INDEX**

	<b>Page Number</b>
<b><u>PART I FINANCIAL INFORMATION</u></b>	
<u>Item 1.</u>	1
<u>Financial Statements (Unaudited).</u>	
<u>Condensed Consolidated Balance Sheets September 29, 2006 and December 30, 2005.</u>	1
<u>Condensed Consolidated Statements of Operations Three and Nine Months Ended September 29, 2006 and September 30, 2005.</u>	2
<u>Condensed Consolidated Statements of Cash Flows Nine Months Ended September 29, 2006 and September 30, 2005.</u>	3
<u>Notes to the Condensed Consolidated Financial Statements.</u>	4
<u>Item 2.</u>	12
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations.</u>	
<u>Item 3.</u>	23
<u>Quantitative and Qualitative Disclosures About Market Risk.</u>	
<u>Item 4.</u>	23
<u>Controls and Procedures.</u>	
<b><u>PART II OTHER INFORMATION</u></b>	
<u>Item 1.</u>	23
<u>Legal Proceedings.</u>	
<u>Item 1A.</u>	24
<u>Risk Factors.</u>	
<u>Item 6.</u>	25
<u>Exhibits.</u>	
<u>Signatures</u>	26
<u>EXHIBIT 31.1</u>	
<u>EXHIBIT 31.2</u>	
<u>EXHIBIT 32.1</u>	

---

Table of Contents**PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****STAAR SURGICAL COMPANY AND SUBSIDIARIES****CONDENSED CONSOLIDATED BALANCE SHEETS**

	<b>September 29, 2006</b>	<b>December 30, 2005</b>
	<b>(Unaudited)</b>	
	<b>(In thousands, except par value)</b>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 8,193	\$ 12,708
Short-term investments restricted	150	
Accounts receivable, net	6,396	5,100
Inventories	13,837	14,699
Prepays, deposits and other current assets	2,569	1,763
Total current assets	31,145	34,270
Investment in joint venture	259	283
Property, plant and equipment, net	4,976	5,595
Patents and licenses, net	4,559	4,920
Goodwill	7,534	7,534
Other assets	264	153
Total assets	\$ 48,737	\$ 52,755
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Notes payable	\$ 1,767	\$ 1,676
Accounts payable	4,182	4,014
Other current liabilities	6,267	5,845
Total current liabilities	12,216	11,535
Other long-term liabilities	1,046	854
Total liabilities	13,262	12,389
Commitments and contingencies		
Stockholders equity:		

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

Preferred stock, \$.01 par value; 10,000 shares authorized, none issued or outstanding		
Common stock, \$.01 par value; 60,000 shares authorized, issued and outstanding 25,534 at September 29, 2006 and 24,819 at December 30, 2005	255	248
Additional paid-in capital	116,477	112,434
Accumulated other comprehensive income	635	146
Accumulated deficit	(81,022)	(71,653)
	36,345	41,175
Notes receivable from former directors	(870)	(809)
Total stockholders' equity	35,475	40,366
Total liabilities and stockholders' equity	\$ 48,737	\$ 52,755

See accompanying notes to the condensed consolidated financial statements.

Table of Contents

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 29,</b>	<b>September 30,</b>	<b>September 29,</b>	<b>September 30,</b>
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
	<b>(Unaudited)</b>			
	<b>(In thousands, except per share amounts)</b>			
Net sales	\$ 13,139	\$ 11,647	\$ 41,015	\$ 39,236
Cost of sales	6,738	6,450	21,175	20,978
Gross profit	6,401	5,197	19,840	18,258
General and administrative	2,598	2,321	8,135	6,898
Marketing and selling	5,158	4,290	15,798	13,884
Research and development	1,670	1,274	5,185	4,023
Notes reserves (reversals)	(331)	640	(331)	746
Operating loss	(2,694)	(3,328)	(8,947)	(7,293)
Other income (expense):				
Equity in operations of joint venture	102	122	(24)	158
Interest income	33	135	251	323
Interest expense	(44)	(35)	(131)	(136)
Other income	13	9	3	328
Total other income (expense), net	104	231	99	673
Loss before income taxes and minority interest	(2,590)	(3,097)	(8,848)	(6,620)
Provision for income taxes	199	210	521	1,152
Minority interest		(5)		(22)
Net loss	\$ (2,789)	\$ (3,302)	\$ (9,369)	\$ (7,750)
Loss per share basic and diluted	\$ (.11)	\$ (.13)	\$ (.37)	\$ (.33)
Weighted average shares outstanding basic and diluted	25,293	24,797	24,994	23,343

See accompanying notes to the condensed consolidated financial statements.

Table of Contents**STAAR SURGICAL COMPANY AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<b>Nine Months Ended</b>	
	<b>September 29, 2006</b>	<b>September 30, 2005</b>
	<b>(Unaudited)</b>	
	<b>(In thousands)</b>	
Cash flows from operating activities:		
Net loss	\$ (9,369)	\$ (7,750)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property, plant and equipment	1,391	1,507
Amortization of intangibles	361	360
Loss on disposal of fixed assets	144	23
Equity in operations of joint venture	24	(158)
Stock-based compensation	1,333	117
Common stock issued for services		78
Notes receivable reserve (reversal) charge	(331)	746
Other	(44)	(66)
Minority interest		(22)
Changes in working capital:		
Accounts receivable	(1,296)	586
Inventories	946	674
Prepays, deposits and other current assets	(806)	180
Accounts payable	168	(1,532)
Other current liabilities	243	99
Net cash used in operating activities	(7,236)	(5,158)
Cash flows from investing activities:		
Acquisition of property, plant and equipment	(747)	(745)
Proceeds from sale lease back of property, plant and equipment	271	
Purchase of short-term investments	(193)	(15,300)
Sale of short-term investments	43	20,425
Decrease (increase) in other assets	(111)	38
Proceeds from notes receivable and other	311	90
Net cash provided by (used) in investing activities	(426)	4,508
Cash flows from financing activities:		
Net payments (borrowings) under notes payable	44	(1,229)
Net proceeds from private placement		13,374
Proceeds from the exercise of stock options	2,614	58
Net cash provided by financing activities	2,658	12,203



Edgar Filing: STAAR SURGICAL CO - Form 10-Q

Effect of exchange rate changes on cash and cash equivalents	489	(686)
Increase (decrease) in cash and cash equivalents	(4,515)	10,867
Cash and cash equivalents, at beginning of the period	12,708	4,187
Cash and cash equivalents, at end of the period	\$ 8,193	\$ 15,054

See accompanying notes to the condensed consolidated financial statements.

**Table of Contents**

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 29, 2006**

**Note 1 Basis of Presentation and Significant Accounting Policies**

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. The financial statements for the three and nine months ended September 29, 2006 and September 30, 2005, in the opinion of management, include all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the financial condition and results of operations. These financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 30, 2005.

The results of operations for the three and nine months ended September 29, 2006 and September 30, 2005 are not necessarily indicative of the results to be expected for any other interim period or the entire year.

Each of the Company's reporting periods ends on the Friday nearest to the quarter ending date and generally consists of 13 weeks.

***Stock-Based Compensation***

Effective December 31, 2005, the Company adopted the fair value recognition provisions of Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), Share-Based Payment (SFAS 123R), using the modified prospective transition method and therefore has not restated results for prior periods. Under this transition method, stock-based compensation expense for the first nine months of fiscal 2006 includes compensation expense for all stock-based compensation awards granted prior to, but not yet vested as of December 30, 2005, based on the grant date fair value estimated in accordance with the original provision of SFAS No. 123, Accounting for Stock-Based Compensation (SFAS 123). Stock-based compensation expense for all stock-based compensation awards granted after December 30, 2005 is based on the grant-date fair value estimated in accordance with the provisions of SFAS 123R. The Company recognizes these compensation costs on a straight-line basis over the requisite service period of the award, which is generally the option vesting term of three to four years. Prior to the adoption of SFAS 123R, the Company recognized stock-based compensation expense in accordance with Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees (APB 25). In March 2005, the Securities and Exchange Commission (the SEC) issued Staff Accounting Bulletin No. 107 (SAB 107) regarding the SEC's interpretation of SFAS 123R and the valuation of share-based payments for public companies. The Company has applied the provisions of SAB 107 in its adoption of SFAS 123R. See Note 7 to the Consolidated Condensed Financial Statements for a further discussion of stock-based compensation.

***New Accounting Pronouncements***

In July 2006, the FASB issued FASB Interpretation Number 48, Accounting for Uncertainty in Income Taxes, an Interpretation of FASB Statement No. 109 (FIN 48). FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return, and provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. The Company is currently assessing the impact of the interpretation on its financial

statements and will adopt the provisions of this interpretation beginning in the first quarter of 2007.

In September 2006, the FASB issued SFAS No. 157 *Fair Value Measurements* ( SFAS 157 ). SFAS 157 provides a new single authoritative definition of fair value and provides enhanced guidance for measuring the fair value of assets and liabilities and requires additional disclosures related to the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value

**Table of Contents****STAAR SURGICAL COMPANY AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

measurements on earnings. SFAS 157 is effective for the Company as of December 29, 2007. The Company is currently assessing the impact, if any, of SFAS 157 on its consolidated financial statements.

In September 2006, the SEC issued Staff Accounting Bulletin (SAB) No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*, which sets forth the SEC staff's views on the proper method for quantifying and recording errors from prior years which have been carried forward in the current year's financial statements. The SAB requires registrants to quantify misstatements in current year financial statements by measuring the effect of the error on both the balance sheet and the income statement. If either current year statement contains a material error, the financial statements would be adjusted. Prior year financial statements would be restated if material to either the prior year balance sheet or income statement. SAB No. 108 is effective for fiscal years ending after November 15, 2006. The Company does not expect this SAB to have a material effect on its financial position and results of operations.

**Note 2 Short-Term Investments-Restricted**

Short-term investments consist of a 12-month Certificate of Deposit with a 4.5% interest rate used to collateralize capital leases funded under a lease line of credit with Mazuma Capital Corporation (See Note 6).

**Note 3 Inventories**

Inventories are stated at the lower of cost, determined on a first-in, first-out basis, or market and consisted of the following at September 29, 2006 and December 30, 2005 (in thousands):

	<b>September 29, 2006</b>	<b>December 30, 2005</b>
Raw materials and purchased parts	\$ 835	\$ 859
Work-in-process	2,028	2,259
Finished goods	10,974	11,581
	<b>\$ 13,837</b>	<b>\$ 14,699</b>

**Note 4 Stockholders Equity**

The consolidated financial statements include basic and diluted per share information. Basic per share information is calculated by dividing net loss by the weighted average number of shares outstanding. Diluted per share information is calculated by also considering the impact of potential common stock on both net income and the weighted number of shares outstanding. As the Company was in a loss position, potential common shares of 2,692,151 and 2,579,142 for the three and nine months ended September 29, 2006, respectively, and 3,369,248 and 3,334,222 for the three and nine months ended September 30, 2005, respectively, were excluded from the computation as the shares would have had an anti-dilutive effect.

***Comprehensive loss***

The components of comprehensive loss are as follows (in thousand \$):

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 29, 2006</b>	<b>September 30, 2005</b>	<b>September 29, 2006</b>	<b>September 30, 2005</b>
Net loss	\$ (2,789)	\$ (3,302)	\$ (9,369)	\$ (7,750)
Foreign currency translation adjustment	116	(6)	489	(686)
Total comprehensive loss	\$ (2,673)	\$ (3,308)	\$ (8,880)	\$ (8,436)

Table of Contents**STAAR SURGICAL COMPANY AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Note 5 Geographic and Product Data**

The Company reports segment information in accordance with SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information ( SFAS 131 ). Under SFAS 131 all publicly traded companies are required to report certain information about the operating segments, products, services and geographical areas in which they operate and their major customers.

The Company markets and sells its products in approximately 50 countries and has manufacturing sites in the United States and Switzerland. Other than the United States and Germany, the Company does not conduct business in any country in which its sales in that country exceed 5% of consolidated sales. Sales are attributed to countries based on location of customers. The composition of the Company's net sales to unaffiliated customers between those in the United States, Germany, and other locations for each year, is set forth below (in thousands):

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 29, 2006</b>	<b>September 30, 2005</b>	<b>September 29, 2006</b>	<b>September 30, 2005</b>
Sales to unaffiliated customers				
United States	\$ 5,579	\$ 4,393	\$ 16,717	\$ 14,460
Germany	4,969	5,072	15,491	17,071
Other	2,591	2,182	8,807	7,705
Total	\$ 13,139	\$ 11,647	\$ 41,015	\$ 39,236

100% of the Company's sales are generated from the ophthalmic surgical product segment and, therefore, the Company operates as one operating segment for financial reporting purposes. The Company's principal products are IOLs and ancillary products used in cataract and refractive surgery. The composition of the Company's net sales by surgical line is as follows (in thousands):

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 29, 2006</b>	<b>September 30, 2005</b>	<b>September 29, 2006</b>	<b>September 30, 2005</b>
Cataract	\$ 10,126	\$ 10,534	\$ 31,726	\$ 34,731
Refractive	2,852	997	8,791	4,020
Glaucoma	161	116	498	485
Total	\$ 13,139	\$ 11,647	\$ 41,015	\$ 39,236

The Company sells its products internationally, which subjects the Company to several potential risks, including fluctuating exchange rates (to the extent the Company's transactions are not in U.S. dollars), regulation of fund transfers by foreign governments, United States and foreign export and import duties and tariffs, and political instability.

**Note 6 Commitments and Contingencies**

***Litigation***

Settlement of *In re STAAR Surgical Co. Securities Litigation, No. CV 04-8007*. The Company and its Chief Executive Officer have been defendants in a class action lawsuit in the United States District Court for the Central District of California. A consolidated amended complaint filed by the plaintiffs on April 29, 2005 generally alleged that the defendants, STAAR Surgical Company and its Chief Executive Officer, violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder, by issuing false and misleading statements regarding the prospects for FDA approval of STAAR's Visian ICL, thereby artificially inflating the price of the Company's Common Stock. The plaintiffs sought to recover compensatory damages, including interest.

**Table of Contents**

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

On September 25, 2006, the Court held a hearing to consider granting final approval to the settlement of the lawsuit. At the conclusion of the hearing, the Court found that the settlement previously negotiated to resolve the lawsuit was fair, just, reasonable and adequate and approved the settlement in all respects. The Court finally certified for settlement purposes a class comprised of purchasers of STAAR's securities between October 6, 2003 and January 5, 2004. Under the terms of the settlement, in exchange for dismissal of the lawsuit and a general release of claims and without admission of liability, STAAR caused payment of \$3,700,000 to be made, all but \$100,000 of which was borne by STAAR's insurance carrier. STAAR's total expenditure in connection with the lawsuit will not exceed the \$500,000 retention amount under its insurance policy, which was fully accrued as of December 30, 2005.

From time to time the Company is subject to various claims and legal proceedings arising out of the normal course of our business. These claims and legal proceedings relate to contractual rights and obligations, employment matters, and claims of product liability. We do not believe that any of the claims known to us is likely to have a material adverse effect on our financial condition or results of operations.

***Lines of Credit***

On June 8, 2006 the Company signed a Credit and Security agreement with Wells Fargo Bank for a revolving credit facility. The credit facility provides for borrowings of 85% of eligible accounts receivable with a maximum of \$3.0 million, carries an interest rate of prime plus 1.5%, and is secured by substantially all of the assets of the Company's U.S. operations. The Company has \$1.9 million available for borrowing as of September 29, 2006. The term of the agreement is three years and it contains certain financial covenants relating to minimum calculated net worth, net loss, liquidity and restrictions on Company investments or loans to affiliates and investments in capital expenditures, which only apply if the Company borrows and/or maintains an outstanding advance. The Company has not borrowed against the facility as of September 29, 2006.

On May 30, 2006, the Company signed a lease agreement with Farnam Street Financial, Inc. The credit facility provides for purchases of up to \$855,000 of property, plant and equipment based on a lease amendment signed dated August 3, 2006. In accordance with the requirements of SFAS 13 Accounting for Leases, purchases under this facility are accounted for as operating leases and have a three year term. The Company also has the option to purchase any item of the leased property from Farnam at the end of the respective items lease terms at a mutually agreed fair value. The Company completed a sale-leaseback transaction on June 29, 2006 of certain assets originally purchased during 2006 and received a payment of approximately \$177,000. The Company retained use of all of the assets sold and then leased back.

The Company completed a second sale-leaseback transaction on September 7, 2006 of certain assets originally purchased during 2006 and received a payment of approximately \$94,000. The Company retained use of all of the assets sold and then leased back.

On October 9, 2006, the Company and Farnam Street Financial, Inc. completed a second amendment to the facility described above to increase the maximum borrowing amount from approximately \$855,000 to \$1,500,000. All other terms of the original agreement remain the same.

On May 25, 2006, the Company signed a lease agreement with Mazuma Capital Corporation. The credit facility provides for purchases of up to \$1,000,000 of property, plant and equipment. In accordance with the requirements of SFAS 13 Accounting for Leases, purchases under this facility are accounted for as capital leases and have a two-year



term. The Company is required to open a certificate of deposit as collateral in STAAR Surgical Company's name at the underwriting bank for 50% of the assets funded by Mazuma. As of September 29, 2006, the Company had a certificate of deposit for approximately \$150,000 recorded as a restricted short-term investment with a 12-month term at a fixed interest rate of 4.5%. The agreement allows the Company to purchase any item of the leased property at the end of its lease term for \$1.

**Table of Contents****STAAR SURGICAL COMPANY AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

On August 11, 2006, the Company unwound a portion of the sale-leaseback transaction previously completed with Mazuma on June 30, 2006 whereby the Company re-purchased the assets from Mazuma. The assets were then sold and leased back with Farnam Street Financial on September 7, 2006 as described above.

On August 16, 2006, Mazuma and the Company amended the lease agreement dated May 25, 2006 to reduce the credit facility limit to approximately \$301,000 which is the amount financed to date.

**Note 7 Stock-Based Compensation**

The Company has adopted Statement of Financial Accounting Standards No. 123 (revised) Share Based Payment, (SFAS 123R) effective December 31, 2005. The Company previously applied APB Opinion No. 25 Accounting for Stock Issued to Employees in accounting for stock option plans and in accordance with the Opinion, no compensation cost has been recognized for employee option grants for these plans in the prior period financial statements because there was no difference between the exercise and market price on the date of grant. The Company has elected to apply the Modified Prospective Application (MPA) in its implementation of SFAS 123R and its subsequent amendments and clarifications. Under this method, the Company has recognized stock based compensation expense only for awards newly made or modified on or after the effective date and for the portion of the outstanding awards for which requisite service will be performed on or after the effective date. Expenses for awards previously granted and earned have not been restated.

As of September 29, 2006, the Company has multiple share-based compensation plans, which are described below. The Company issues new shares upon option exercise once the optionee remits payment for the exercise price. The compensation cost that has been charged against income for the 2003 Omnibus Plan and the 1998 Stock Option Plan totaled \$474,000 and \$1,316,000 for the three and nine months ended September 29, 2006, respectively, which included \$443,000 and \$1,250,000, respectively, for the implementation of SFAS 123R, and \$31,000 and \$66,000, respectively, for restricted stock grants. In addition, for the three and nine months ended September 29, 2006, there was \$(76,000) and \$17,000, respectively, of compensation cost charged/(reversed) against income for consultant stock options. There was no income tax benefit recognized in the income statement for share-based compensation arrangements as the Company fully offsets net deferred tax assets with a valuation allowance. In addition, the Company capitalized \$42,000 and \$106,000 of SFAS 123R compensation to inventory for the three and nine months ended September 29, 2006 and recognizes those amounts as expense under in Cost of Sales as the inventory is sold. See the table below for comparative purposes of prior year amounts (in thousands, except per share data):

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 29, 2006</b>	<b>September 30, 2005</b>	<b>September 29, 2006</b>	<b>September 30, 2005</b>
Net loss as reported	\$ (2,789)	\$ (3,302)	\$ (9,369)	\$ (7,750)
Add: Stock-based compensation included in reported net loss	348		1,333	
Less: Stock-based compensation expense determined under the fair-value method for all awards	(348)	(138)	(1,333)	(798)

Edgar Filing: STAAR SURGICAL CO - Form 10-Q

Pro forma net loss	\$	(2,789)	\$	(3,440)	\$	(9,369)	\$	(8,548)
Net loss per share, basic and diluted, as reported	\$	(.11)	\$	(.13)	\$	(.37)	\$	(.33)
Pro forma net loss, basic and diluted, as reported		N/A	\$	(.14)		N/A	\$	(.37)

**Table of Contents**

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***Stock Option Plans***

In fiscal year 2003, the Board of Directors approved the 2003 Omnibus Equity Incentive Plan (the 2003 Plan ) authorizing awards of equity compensation, including options to purchase common stock and restricted shares of common stock. The 2003 Plan amends, restates and replaces the 1991 Stock Option Plan, the 1995 Consultant Stock Plan, the 1996 Non-Qualified Stock Plan and the 1998 Stock Option Plan (the Restated Plans ). Under provisions of the 2003 Plan, all of the unissued shares in the Restated Plans are reserved for issuance in the 2003 Plan. Each year the number of shares reserved for issuance under the 2003 Plan is increased by a number of shares equal to 2% of the total shares of common stock outstanding on the immediately preceding December 31, up to a maximum of 6,500,000 shares. The 2003 Plan provides for various forms of stock-based incentives. To date, of the available forms of awards under the 2003 Plan, the Company has granted only stock options and restricted stock. Options under the plan are granted at fair market value on the date of grant, become exercisable over a three- or four-year period, or as determined by the Board of Directors, and expire over periods not exceeding 10 years from the date of grant. Certain option and share awards provide for accelerated vesting if there is a change in control (as defined in the 2003 Plan). Restricted stock grants under the 2003 Plan generally vest over a period of three or four years. Pursuant to the plan, options for 1,740,000 shares were outstanding at September 29, 2006 with exercise prices ranging between \$3.70 and \$11.24 per share. There were 52,000 shares of restricted stock outstanding at September 29, 2006.

In fiscal year 2000, the Board of Directors approved the Stock Option Plan and Agreement for the Company's Chief Executive Officer authorizing the granting of options to purchase common stock or awards of common stock. The options under the plan were granted at fair market value on the date of grant, become exercisable over a three-year period, and expire 10 years from the date of grant. Pursuant to this plan, options for 500,000 were outstanding at September 29, 2006, with an exercise price of \$11.125.

In fiscal year 1998, the Board of Directors approved the 1998 Stock Option Plan, authorizing the granting of options to purchase common stock or awards of common stock. Under the provisions of the plan, 1.0 million shares were reserved for issuance; however, the maximum number of shares authorized may be increased provided such action is in compliance with Article IV of the plan. During fiscal year 2001, pursuant to Article IV of the plan, the stockholders of the Company authorized an additional 1.5 million shares. Generally, options under the plan are granted at fair market value at the date of the grant, become exercisable over a three-year period, or as determined by the Board of Directors, and expire over periods not exceeding 10 years from the date of grant. Pursuant to the plan, options for 1,028,000 were outstanding at September 29, 2006 with exercise prices ranging between \$2.15 and \$13.625 per share. No further awards may be made under this plan.

In fiscal year 1996, the Board of Directors approved the 1996 Non-Qualified Stock Plan, authorizing the granting of options to purchase common stock or awards of common stock. Under provisions of the Non-Qualified Stock Plan, 600,000 shares were reserved for issuance. Generally, options under the plan were granted at fair market value at the date of the grant, become exercisable over a three-year period, or as determined by the Board of Directors, and expire over periods not exceeding 10 years from the date of grant. The options were originally issued with an exercise price of \$12.50 per share. During fiscal year 1998 the exercise price of options held by employees was reduced to \$6.25 per share by action of the Board of Directors. As of September 29, 2006 there were no outstanding options. No further awards may be made under this plan.

In fiscal year 1995, the Company adopted the 1995 Consultant Stock Plan, authorizing the granting of options to purchase common stock or awards of common stock. Generally, options under the plan were granted at fair market

value at the date of the grant, become exercisable on the date of grant and expire 10 years from the date of grant. Pursuant to this plan, options for 95,000 shares were outstanding at September 29, 2006 with exercise prices ranging from \$1.70 to \$3.00 per share. No further awards may be made under this plan.

Under provisions of the Company's 1991 Stock Option Plan, 2.0 million shares were reserved for issuance. Generally, options under this plan were granted at fair market value at the date of the grant, become exercisable over

**Table of Contents****STAAR SURGICAL COMPANY AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

a three-year period, or as determined by the Board of Directors, and expire over periods not exceeding 10 years from the date of grant. Pursuant to this plan, options for 60,000 shares were outstanding at September 29, 2006 with exercise prices ranging from \$9.56 to \$10.18 per share. No further awards may be made under this plan.

During fiscal years 1999 and 2000, the Company issued non-qualified options to purchase shares of its Common Stock to employees and consultants. Pursuant to these agreements, options for 55,000 shares were outstanding at September 29, 2006 with exercise prices ranging between \$9.375 and \$10.63.

During the nine months ended September 29, 2006, officers, employees and others exercised 651,000 options from the 1995, 1996, 1998, non qualified and 2003 stock option plans at prices ranging from \$1.91 to \$7.00 resulting in net cash proceeds to the Company totaling \$2,614,000.

**Assumptions**

The fair value of each option award is estimated on the date of grant using a Black-Scholes option valuation model that uses the assumptions noted in the following table. Expected volatilities are based on historical volatility of the Company's stock. The Company uses historical data to estimate option exercise and employee termination behavior. The expected term of options granted is derived from the historical exercise activity over the past 15 years, and represents the period of time that options granted are expected to be outstanding. The Company used the shortcut method to calculate the expected term of its options granted during the first quarter of 2006 that had a four year vesting life. All other options granted with a three year vesting life during the three and nine months ended September 29, 2006 had an expected term of 5.2 years derived from historical exercise and termination activity. The Company has calculated a 10.5% estimated forfeiture rate used in the model for fiscal year 2006 option grants based on historical forfeiture experience. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

	Three Months Ended		Nine Months Ended	
	September 29, 2006	September 30, 2005	September 29, 2006	September 30, 2005
Expected dividends	0%	0%	0%	0%
Expected volatility	72.11%	70.35%	73.26%	70.35%
Risk-free rate	4.76%	4.23%	4.14%	4.23%
Expected term (in years)	5.2	4.3	5.2 & 7	4.3

A summary of option activity under the Plans as of September 29, 2006, and changes during the period then ended are presented below:

Options	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
---------	--------	------------------------------------	--	---------------------------------

	(000 s)				(000 s)	
Outstanding at December 30, 2005	3,870	\$	6.23			
Granted	306		7.35			
Exercised	(652)		3.81			
Forfeited or expired	(46)		4.28			
Outstanding at September 29, 2006	3,478	\$	6.47	5.7	\$	6,557
Exercisable at September 29, 2006	2,504	\$	7.15	4.6	\$	4,586

The weighted-average grant-date fair value of options granted during the nine-month period ended September 29, 2006 was \$4.97. The total fair value of options vested during the nine months ended September 29, 2006 was \$1,503,000. The total intrinsic value of options exercised during the nine months ended September 29, 2006 was \$2,408,000.

Table of Contents**STAAR SURGICAL COMPANY AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

A summary of the status of the Company's nonvested shares as of September 29, 2006 and changes during the period is presented below:

<b>Nonvested Shares</b>	<b>Shares (000 s)</b>		<b>Weighted-Average Grant Date Fair Value</b>
Nonvested at December 30, 2005	1,142	\$	2.99
Granted	306		4.61
Vested	(464)		2.27
Forfeited	(10)		5.94
Nonvested at September 29, 2006	974	\$	3.25

As of September 29, 2006, there was \$2.2 million of total unrecognized compensation cost related to nonvested share-based compensation arrangements granted under the Plans. That cost is expected to be recognized over a weighted-average period of 2.25 years.

**Note 8 Notes Receivable from Former Directors**

During the third quarter of 2006, the Company settled the last of its notes receivable from former directors and officers totaling \$1,961,000 (including accrued interest) for a cash payment of \$175,000 and proceeds from the sale of 120,000 shares of pledged Company stock of \$870,000, which was received on October 3, 2006. The deficiency on the notes was applied against reserves recorded against the notes in 2005 and 2004 and \$331,000 of excess reserves was reversed during the quarter.



**Table of Contents****ITEM 2. *MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS***

The matters addressed in this Item 2 that are not historical information constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Although the Company believes that the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risks and the Company can give no assurances that its expectations will prove to be correct. Actual results could differ from those described in this report because of numerous factors, many of which are beyond the control of the Company. These factors include, without limitation, those described in this report and in our Annual Report on Form 10-K under the heading Risk Factors. The Company undertakes no obligation to update these forward-looking statements that may be made to reflect events or circumstances after the date of this report or to reflect actual outcomes.

The following discussion should be read in conjunction with the Company's financial statements and the related notes provided under Item 1 Financial Statements above.

**Overview**

STAAR Surgical Company develops and manufactures visual implants and other innovative ophthalmic products to improve or correct the vision of patients with cataracts, refractive conditions and glaucoma and distributes these products throughout the world. Originally incorporated in California in 1982, STAAR Surgical Company reincorporated in Delaware in 1986. Unless the context indicates otherwise we, us, the Company, and STAAR refer to STAAR Surgical Company and its consolidated subsidiaries.

***Principal Products***

STAAR's products generally fall into two categories within the ophthalmic surgical product segment: products designed for cataract surgery and our Visian ICL<sup>™</sup> line of products designed to surgically correct refractive conditions such as myopia (nearsightedness), hyperopia (farsightedness) and astigmatism.

*Cataract Surgery.* Cataracts are a common age-related disorder in which vision deteriorates as the eye's natural lens becomes cloudy. Treatment of cataracts typically involves surgically extracting the natural lens and replacing it with a prosthetic lens.

STAAR developed, patented and licensed the foldable intraocular lens, or IOL, which permitted surgeons for the first time to replace a cataract patient's natural lens through minimally invasive surgery. In minimally invasive cataract surgery, a procedure called phacoemulsification is first used to soften the natural lens with sound waves and withdraw it through a small incision. The foldable IOL is then inserted through the same small incision using an injector system. STAAR introduced its first version of the folding IOL, made of silicone, in 1991. The production and sale of foldable IOLs and related products for the treatment of cataracts remains STAAR's core business.

STAAR's current cataract product offering includes silicone IOLs, IOLs made of Collamer<sup>®</sup>, our proprietary collage copolymer material, injector systems for minimally invasive implantation of lenses including an innovative preloaded injector system available outside the U.S., Toric IOLs designed for combined treatment of cataracts and astigmatism, the SonicWAVE<sup>™</sup> Phacoemulsification System, STAARVISC<sup>™</sup> II, a viscoelastic material used as a tissue protective lubricant and to maintain the shape of the eye during surgery, Cruise Control<sup>™</sup>, a disposable filter used to increase safety and control during phacoemulsification, and other auxiliary products for cataract surgery, some of which we

purchase from other manufacturers and resell.

*Refractive Surgery.* Manufacturing and selling lenses for refractive surgery is an increasingly important source of revenue for STAAR. The foldable lenses in our Visian ICL line of implantable Collamer lenses are used to treat myopia, hyperopia and astigmatism. Lenses of this type are generically called phakic IOLs or phakic implants because they work along with the patient's natural lens, or *phakos*, rather than replacing it. In international markets STAAR sells the Visian ICL for treatment of both myopia and hyperopia, and the Visian Toric ICL or TICL for combined treatment of myopia and astigmatism. Only the myopic Visian ICL is currently approved for use in the U.S for the correction of myopia in adults with myopia ranging from -3.0 to less than or equal to -15.0 diopters and the reduction of myopia in adults with myopia from greater than -15.0 to -20.0 diopters.

## **Table of Contents**

The ICL is folded and implanted into the eye behind the iris, using minimally invasive surgical techniques and resulting in a more satisfying aesthetic outcome than competing phakic implants that are placed in front of the iris. The surgical procedure to implant the ICL is typically performed with topical anesthesia on an outpatient basis. Visual recovery is usually within one to 24 hours.

We believe the ICL will complement current refractive technologies and allow refractive surgeons to expand their treatment range and customer base.

*Other Products.* Among STAAR's other products is the AquaFlow Collagen Glaucoma Drainage Device, an implantable device used for the surgical treatment of glaucoma.

STAAR Surgical Company, STAAR's Logo, Visian®, Collamer®, STAARvisc™, SonicWAVE™ and AquaFlow™ are trademarks of STAAR in the U.S. and other countries. Collamer® is the brand name for STAAR's proprietary collagen copolymer lens material.

## ***Strategy***

STAAR is currently focusing on the following four strategic goals:

successfully launching the ICL in the U.S. market and securing U.S. approval of the TICL;

generating further growth of the ICL and TICL in international markets;

reversing the decline in U.S. market share for our core cataract product lines by renewing and refining our product offering through enhanced R&D; and

maintaining our focus on regulatory compliance and continuous quality improvement.

*Successfully launching the ICL in the U.S. market and securing U.S. approval of the TICL.* Because the ICL's design has advantages over other refractive procedures for many patients and its proprietary nature permits STAAR to maintain its profit margin, STAAR's management believes that increased sales of the ICL are the key to the company's return to profitability. U.S. market penetration is considered essential because of the size of the U.S. refractive surgery market and the perceived leadership of the U.S. in adopting innovative medical technologies.

STAAR's strategy for the U.S. market is to make the ICL available to selected surgeons only after completion of a training program that includes proctoring of selected supervised surgeries. STAAR believes that this carefully guided method of product release is essential to help ensure the consistent quality of patient outcomes and the high levels of patient satisfaction needed to establish wide acceptance of the ICL as a choice for refractive surgery.

The Visian ICL was approved by the FDA for treatment of myopia on December 22, 2005. The U.S. rollout of the product began in the first quarter of 2006. As of September 29, 2006, 251 surgeons had completed training and STAAR recognized \$3,124,000 of U.S. sales revenue from ICLs in the first nine months of 2006. It is too early to determine whether STAAR's strategy will be successful or to estimate the ultimate size of the U.S. market for ICLs.

STAAR believes that the Visian TICL, a variant of the ICL that corrects both astigmatism and myopia in a single lens, also has a significant potential market in the U.S. When measured six months after surgery, approximately 75% of the patients receiving the TICL have shown better visual acuity than the best they previously achieved with glasses or contact lenses. Securing FDA approval of the TICL is therefore an integral part of STAAR's strategy to develop its U.S. refractive market. STAAR submitted a Pre-Market Approval (PMA) application for the TICL to the FDA on

April 28, 2006.

STAAR has relied on a largely independent sales force to sell its cataract products, and over the last several months has worked to re-orient this sales force to deal with the very different practice environment for refractive products. Because the refractive surgery market has been dominated by corneal laser-based techniques, STAAR faces special challenges in introducing an intraocular refractive implant. STAAR has developed a number of marketing tools and practice support programs to increase the use of the ICL and awareness of its advantages at laser-oriented surgery centers. During the third quarter, STAAR became aware of significant disparities in ICL sales among its U.S. regions, and concluded that its independent sales force was not uniformly implementing STAAR's ICL marketing plan. Accordingly, STAAR hired George Ludwig to serve as its Regional Sales Manager for the

**Table of Contents**

Great Lakes Region, which includes the major cities of Chicago, Minneapolis, Milwaukee, Detroit, Cleveland and Indianapolis.

Mr. Ludwig will work to build sales through the existing sales force in some of the region and add sales personnel in several key territories. He will also provide training and professional development nationwide through his consulting firm George Ludwig Unlimited, whose other clients include Johnson & Johnson, Abbott Laboratories, Sprint and Southwest Airlines. As the U.S. roll-out of the ICL continues, the Company expects to continually re-assess the effectiveness of its sales force and will likely continue to rely on a mixture of directly employed and independent sales representatives to sell its products in the U.S., including the ICL.

*Generating further growth of the ICL and TICL in international markets.* The ICL and TICL are currently approved for use in about 43 countries. Generally, in those markets STAAR has gradually increased its share of the refractive implant market and of the overall market for refractive surgery. In recent periods STAAR has received the majority of its revenue from international markets, and sales of ICLs have represented an increasing share of that revenue. STAAR received approval for the ICL in China on July 31, 2006 and we are awaiting approval of the TICL there as well. We also continue to seek new approvals for the ICL and TICL in other countries.

*Reversing the decline in U.S. market share for our core cataract product lines by intensifying selling efforts and renewing and refining our product offering through enhanced R&D.* During the last several years STAAR has experienced a decline in U.S. sales of IOLs. STAAR's management believes the decline principally resulted from the slow pace of cataract product improvement and enhancement during a period when we had to devote most of our research and development resources to introducing the ICL and to resolving the regulatory and compliance issues raised by the FDA, and the harm to our reputation from warning letters and other correspondence with the FDA during 2004 and 2005. This, in turn, resulted in our independent sales representatives' lack of effective selling time with our target surgeon market.

STAAR seeks to reverse the decline in its domestic cataract market share by intensifying the selling efforts of its independent representatives in the improved environment resulting from ICL approval. In addition, the resolution of FDA compliance issues has enabled STAAR to shift research and development resources to developing improved and enhanced cataract products intended to help reverse the decline.

While STAAR's U.S. cataract product sales which include accessory products such as surgery packs and phacoemulsification equipment during the third quarter of 2006 declined 3%, IOL sales were flat compared with the same period in 2005. Despite the decline in total U.S. cataract sales, this a marked improvement compared with the second and first quarters of 2006, which were down 8% and 13% when compared to their respective periods in 2005. To continue the trend of reversing sales declines in U.S. cataract product sales, STAAR must overcome several short and long-term challenges. The FDA's past findings of compliance deficiencies have harmed our reputation in the ophthalmic industry and affected our product sales and overcoming this will take time. We cannot ensure that this strategy will ultimately be successful.

*Maintaining our focus on regulatory compliance and continuous quality improvement.* As a manufacturer of medical devices, STAAR's manufacturing processes and facilities are regulated by the FDA. We also must satisfy the requirements of the International Standards Organization (ISO) to maintain approval to sell products in the European Community and other regions. Failure to demonstrate substantial compliance with FDA regulations can result in enforcement actions that terminate, suspend or severely restrict the ability to continue manufacturing and selling medical devices. Between December 29, 2003 and July 5, 2005, STAAR received Warning Letters, Form 483 Inspectional Observations and other correspondence from the FDA indicating deficiencies in STAAR's compliance with the FDA's Quality System Regulations and Medical Device Reporting regulations and warning of possible enforcement action. In response, STAAR implemented numerous improvements to its quality system. Among other

things, STAAR developed a Global Quality Systems Action Plan, which has been continuously updated since its adoption in April, 2004, and took steps to emphasize a focus on compliance throughout the organization.

The FDA's most recent inspections of STAAR's facilities were a post-market inspection of the Monrovia, California and Aliso Viejo, California facilities between August 2, 2006 and August 7, 2006, and a post-market inspection of the Nidau, Switzerland facilities between September 26 and September 28, 2006. These inspections resulted in no observations of noncompliance. Based in part on these inspections and the FDA inspections

**Table of Contents**

conducted in 2005, STAAR believes that it is substantially in compliance with the FDA's Quality System Regulations and Medical Device Reporting regulations. Nevertheless, the FDA's past findings of compliance deficiencies have harmed our reputation in the ophthalmic industry and affected our product sales. STAAR's ability to continue its U.S. business depends on the continuous improvement of its quality systems and its ability to demonstrate compliance with FDA regulations. Accordingly, for the foreseeable future STAAR's management expects its strategy to include devoting significant resources and attention to strict regulatory compliance and continuous improvement in quality.

In keeping with its compliance strategy, STAAR hired Rob Lally to serve as Vice President, Quality Assurance and Regulatory affairs. Prior to joining STAAR on October 23, 2006, Mr. Lally was most recently the Director of International Regulatory Affairs at Johnson & Johnson Vision Care in Florida. Mr. Lally previously served as Head of the Medical Devices Sector of the British Standards Institution, the National Standards Body of the United Kingdom responsible for independent certification of a variety of systems and products. Prior to this, he was a senior consultant at Quintiles, a global quality and regulatory consulting firm. Mr. Lally also served as General Manager, Quality and Certification at AMTAC Laboratories, a leading European Union notified body where he managed the medical device and drug sector.

***Other Recent Highlights***

*Competition with Multifocal IOLs.* The U.S. IOL market continues to be affected by the increased sales of multifocal and accommodative lenses resulting from a ruling of the Centers for Medicare and Medicaid Services (CMS). The ruling permits Medicare-covered cataract patients to receive more highly priced multifocal IOLs by paying only the additional cost of the lens and surgical procedure while still receiving reimbursement for the basic cost of cataract surgery and a monofocal IOL. This has increased the number of patients to whom surgeons offer the alternative of the higher-priced lenses, and in some cases surgeons who wish to offer these alternatives to patients must undergo training that involves using a significant number of our competitors' IOLs. While STAAR's U.S. cataract products sales increased in the first two quarters of 2006 over the preceding periods and have remained flat in the third quarter of 2006 compared to the same period in 2005, sales volume might have been greater were it not for increased sales of multifocal and accommodative lenses. The CMS ruling and the ability of surgeons to offer multifocal lenses with partial Medicare reimbursement is expected to continue to affect sales of STAAR's IOLs in future periods.

*Job Actions by Doctors in Germany.* STAAR receives significant revenue from its German subsidiary, Domilens GmbH, a distributor of ophthalmic products manufactured by STAAR and other manufacturers. As is the case in most countries, purchases of Domilens's cataract-related products in Germany depend on government reimbursement of cataract surgery. Germany has recently made a number of cost-cutting changes in its medical reimbursement policies, including a requirement that government-employed surgeons reduce the number of cataract surgeries performed to 20% below 2004 rates. In response to these changes in reimbursement policies, many medical doctors throughout Germany initiated job actions during the first and second quarters of 2006 such as strikes or slow-downs in which doctors provided only the most essential services to patients. While doctors and state-run and university clinics reached a settlement in June, strikes continue at city-run hospitals throughout Germany during the third quarter, but were ultimately resolved. These job actions, and the mandatory reduction in the number of cataract procedures, caused a significant reduction in ophthalmic surgeries and reduced sales of distributed products by Domilens, which during the third quarter declined 2% compared to the same quarter of 2005, but improved over the second quarter of 2006 by 7% indicating we may have seen the worst in this market.

*Foreign Currency Fluctuations.* Our products are sold in approximately 50 countries. Sales from international operations represented 58% of total sales for the quarter ended September 29, 2006. The results of operations and the financial position of certain of our international operations are reported in the relevant local currencies and then translated into U.S. dollars at the applicable exchange rates for inclusion in our consolidated financial statements, exposing us to currency translation risk.





**Table of Contents****Critical Accounting Policies**

Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our unaudited Consolidated Condensed Financial Statements, which we have prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. Management bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Senior management has discussed the development, selection and disclosure of these estimates with the Audit Committee of our Board of Directors. Actual results may differ from these estimates under different assumptions or conditions.

An accounting policy is deemed critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, if different estimates reasonably could have been used, or if changes in the estimate that are reasonably likely to occur could materially impact the financial statements. Management believes that other than the adoption of Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), Share-Based Payment (SFAS 123R), there have been no significant changes during the three and nine months ended September 29, 2006 to the items that we disclosed as our critical accounting policies and estimates in Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the fiscal year ended December 30, 2005.

We adopted Statement of Financial Accounting Standards No. 123 (revised) Share Based Payment, (SFAS 123R) effective December 31, 2005. STAAR previously applied APB Opinion No. 25 Accounting for Stock Issued to Employees in accounting for stock option plans and accordingly, no compensation cost has been recognized for these plans in the prior period financial statements. We have applied the Modified Prospective Application (MPA) in our implementation of the new accounting standards. Accordingly, we recognized stock-based compensation expense for these plans in the current and prospective periods only. Prior period amounts have not been restated. See the footnote disclosure information for a presentation showing prior year amounts with the stock option expense that would have been recognized had STAAR adopted during the prior periods. The compensation cost that has been charged against income for the 2003 Omnibus Plan and the 1998 Stock Option Plan totaled \$474,000 and \$1,316,000 for the three and nine months ended September 29, 2006, respectively, which included \$443,000 and \$1,250,000, respectively, for the implementation of SFAS 123R, and \$31,000 and \$66,000, respectively, for restricted stock grants. In addition for the three and nine months ended September 29, 2006, there was \$(76,000) and \$17,000, respectively, of compensation cost (reversed) charged against income for consultant stock options. There was no income tax benefit recognized in the income statement for share-based compensation arrangements as the Company fully offsets net deferred tax assets with a valuation allowance. In addition, the Company capitalized \$42,000 and \$106,000 of SFAS 123R compensation to inventory for the three and nine months ended September 29, 2006 and recognizes those amounts as expense in Cost of Sales as the inventory is sold.

We have not made any modifications to outstanding share options prior to the adoption of Statement 123R.

As of September 29, 2006, there was \$2.2 million of total unrecognized compensation cost related to nonvested share-based compensation arrangements granted under the Plans. That cost is expected to be recognized over a weighted-average period of 2.25 years.

**Table of Contents****Results of Operations**

The following table sets forth the percentage of total sales represented by certain items reflected in the Company's statements of operations for the periods indicated and the percentage increase or decrease in such items over the prior period.

	Percentage of Total Sales for Three Months September 29, September 30,		Percentage Change for Three Months 2006 vs. 2005	Percentage of Total Sales for Nine Months September 29, September 30,		Percentage Change for Nine Months 2006 vs. 2005
	2006	2005		2006	2005	
	Sales	100.0%	100.0%	12.8%	100.0%	100.0%
Cost of sales	51.3	55.4	4.5	51.6	53.5	0.9
Gross profit	48.7	44.6	23.2	48.4	46.5	8.7
General and administrative	19.8	19.9	11.9	19.8	17.6	17.9
Marketing and selling	39.2	36.8	20.2	38.5	35.4	13.8
Research and development	12.7	10.9	31.1	12.6	10.3	28.9
Note reserve (reversals)	(2.5)	5.5	(151.7)	(0.8)	1.9	(144.4)
Operating loss	(20.5)	(28.5)	(19.1)	(21.7)	(18.7)	22.7
Total other income, net	0.8	2.0	(55.0)	0.2	1.7	(85.3)
Loss before income taxes and minority interest	(19.7)	(26.5)	(16.4)	(21.5)	(17.0)	33.7
Provision for income taxes	1.5	1.8	(5.2)	1.3	2.9	(54.8)
Minority interest			(100.0)		(0.1)	(100.0)
Net loss	(21.2)%	(28.3)%	(15.5)%	(22.8)%	(19.8)%	20.9%

***Net Sales***

Net sales for the third quarter were \$13,139,000, an increase of 12.8% compared with \$11,647,000 reported for the same period of 2005. The year-over-year increase in sales during the third quarter of 2006 was the second consecutive quarter of year-over-year sales growth. Excluding the impact of changes in currency, third quarter 2006 net sales were \$12,894,000, up 10.7% compared with the third quarter of 2005.

Net sales for first nine months of 2006 were \$41,015,000, an increase of 4.5% compared with the same period of last year. Excluding the impact of changes in currency, sales in the first nine months of 2006 were \$41,295,000, up 5.3% compared with the same period of 2005.

U.S. net sales for the third quarter increased 27% to \$5,579,000 compared with the same period of 2005. For the first nine months of 2006, U.S. net sales were up 16% compared with the same period of 2005. The year-over-year increase in U.S. sales for both periods reflects both the recent approval of the Visian ICL for the treatment of myopia as well as the continued improvement in quarterly U.S. cataract sales when compared to the same periods in 2005. U.S. sales of the Visian ICL and all refractive support products were \$1,306,000 in the third quarter of 2006.

International net sales for the third quarter were \$7,560,000, an increase of 4.2% compared with the third quarter of 2005 and were impacted by a 4% decrease in cataract product sales. The decline in international cataract sales is primarily due to the remaining impact of the doctor strikes in Germany, one of STAAR's largest cataract sales markets. Sales in Germany were down 2% compared with third quarter of 2005. For the first nine months of 2006 international sales were \$24,298,000, down 1.9% compared with the same period of last year and were impacted by the aforementioned doctor strikes in Germany.

During the third quarter, global sales of ICLs and TICLs grew 179% to \$2,784,000 compared with the third quarter of 2005. Year-to-date international sales of ICLs and TICLs grew 32% to \$5,313,000, compared with the same period of last year.

## **Table of Contents**

Total refractive sales during the third quarter of 2006 grew 184% to \$2,853,000 compared with \$1,006,000 in the same period of 2005. During the first nine months of 2006, total refractive sales were \$8,791,000, up 117% compared with the same period of 2005 due to the launch of the ICL in the U.S. and increased international ICL sales in 2006.

### ***Gross Profit Margin***

Gross profit margin was 48.7% and 48.4% for the three and nine months ended September 29, 2006 compared with 44.6% and 46.5% for the three and nine months ended September 30, 2005. The increase in gross profit margin for both periods resulted from increased volume of higher margin ICLs in the U.S., partially offset by higher IOL and ICL unit costs due to lower manufacturing volumes.

### ***General and Administrative***

General and administrative expenses for the three months ended September 29, 2006 were up 11.9% or \$277,000 over the three months ended September 30, 2005 and 17.9% or \$1,237,000 for the same year-to-date period. Excluding the \$267,000 and \$738,000 impact of FAS 123R for the three and nine months ended September 29, 2006, general and administrative expenses were essentially equal for the three month period and increased 7.2% for the same respective periods. The increase to general and administrative costs exclusive of the impact of FAS 123R for the nine months ended September 29, 2006 was primarily due to increased insurance costs, directors' fees, and rent and utilities.

### ***Marketing and Selling***

Marketing and selling expenses for the three months ended September 29, 2006 increased 20.2% or \$868,000 compared with the three months ended September 30, 2005 and increased 13.8% or \$1,914,000 compared with the nine months ended September 30, 2005. Excluding the \$108,000 and \$307,000 impact of FAS 123R for the three and nine month periods ended September 29, 2006, marketing and selling expenses increased 17.7% and 11.6% for the same periods respectively. The increase in marketing and selling expenses during both periods primarily resulted from increased costs to support the roll-out of the Company's refractive products in new territories, including the U.S.

### ***Research and Development***

Research and development expenses, including regulatory and clinical expenses, for the third quarter of 2006, increased 31.1% or \$396,000 compared with the three months ended September 30, 2005 and increased \$1,162,000 or 28.9% compared with the nine months ended September 30, 2005. Excluding the impact of the implementation of FAS 123R, which was \$69,000 and \$205,000 for the three and nine month periods ended September 29, 2006, research and development expenses increased 25.7% and 23.8% for the same periods respectively. The increase in research and development expenses for both periods, excluding the impact of the adoption of FAS 123R, is due to costs associated with the Toric ICL pre-market approval supplement submitted during the second quarter of 2006 and new product development.

### ***Note Reserves (Reversals)***

During the third quarter, the Company settled the last of its notes receivable from former directors and officers totaling \$1,961,000 (including accrued interest) for a cash payment of \$175,000 and proceeds from the sale of 120,000 shares of pledged Company stock of \$870,000, which was ultimately received on October 3, 2006. The deficiency on the notes was applied against reserves recorded against the notes in 2005 and 2004 and \$331,000 of excess reserves was reversed during the quarter.

### ***Liquidity and Capital Resources***

The Company has funded its activities over the past several years principally from cash flow generated from operations, credit facilities provided by institutional domestic and foreign lenders, the private placement of Common Stock, the repayment of former directors' notes, and the exercise of stock options.

**Table of Contents**

As of September 29, 2006 and December 30, 2005, the Company had \$8.2 million and \$12.7 million, respectively, of cash and cash equivalents.

Net cash used in operating activities was \$7.2 million for the nine months ended September 29, 2006 versus \$5.2 million for the nine months ended September 30, 2005. This change was due to increased net losses primarily the result of increased selling, general, and administrative expenses.

Net cash used in investing activities was \$0.4 million for the nine months ended September 29, 2006 versus cash provided of \$4.5 million for the nine months ended September 30, 2005. The change is due primarily to the decrease of prior years purchase and sale of short term investments. The Company no longer holds the same investments. The Company entered into two lease lines of credit during the second quarter of 2006. The requirements of SFAS No. 13, Accounting for Leases, requires the financing of property, plant and equipment under one of the leases to be treated as an operating lease but requires the financing of property, plant and equipment under the other lease to be treated as a capital lease. The Company completed a sale-leaseback of property, plant and equipment under the capital lease line, which reduced purchases of property, plant and equipment in the Consolidated Statement of Cash Flows for the first nine months of 2006 by \$271,000.

Net cash provided by financing activities was \$2.7 million for the nine months ended September 29, 2006 versus \$12.2 million for the nine months ended September 30, 2005. The change was due primarily to the net proceeds of \$13.4 million received during the second quarter of 2005 from a private placement of 4,100,000 shares of the Company's common stock and the receipt of \$2.6 million of proceeds from stock option exercises during the nine months ended September 29, 2006.

Accounts receivable at September 29, 2006 increased \$1.3 million relative to December 30, 2005. The increase in accounts receivable relates primarily to increased international and domestic ICL sales during 2006 and the impact of foreign exchange. Days sales outstanding (DSO) were 44 days at September 29, 2006 compared to 38 days at December 30, 2005. The Company expects to maintain DSO within a range of 40 to 45 days during the course of the 2006 fiscal year.

Inventories at September 29, 2006 decreased \$0.9 million relative to December 30, 2005 due primarily to a decrease in preloaded IOL inventories in anticipation of the launch of a new aspheric design in the third quarter of 2006. Inventories of preloaded IOLs should increase as the prior inventory is replaced with the new model.

The (decrease) increase in cash and cash equivalents for the nine months ended September 29, 2006 and September 30, 2005 by the Company was approximately \$(4,515,000) and \$10,867,000, respectively per the U.S. Generally Accepted Accounting Principles ( GAAP )-based Consolidated Cash Flow statement. The increase for the nine months ended September 30, 2005 was due to the net proceeds of \$13.4 million received during the second quarter of 2005 from a private placement of 4,100,000 shares of the Company's common stock.

*Non-GAAP Measures*

The following financial measures included below are not prepared in accordance with GAAP: Cash Usage and Adjusted Net Loss. A reconciliation of these non-GAAP financial measures to the most directly comparable GAAP measures is presented as a table below. Non-GAAP financial measures should not be considered a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP.

*Cash Usage* The Cash Usage financial measure is not prepared in conformity with GAAP and excludes the purchase and sale of short-term investments from cash used in investing activities and net proceeds from private placement from cash provided by financing activities. Cash Usage is not a measurement of liquidity under GAAP and should not

be considered as an alternative to net income, operating income, cash used in investing activities, cash provided by financing activities, or the change in cash and cash equivalents on the Consolidated Balance Sheets and may not be comparable with Cash Usage as defined by other companies.

The Company's Cash Usage of \$4,365,000 during the first nine months of 2006 is 43% below the Company's Cash Usage of \$7,632,000 compared with the same period of 2005. The aforementioned Cash Usage amounts for the nine months ended 2006 and 2005 exclude the effect of purchases and sales of short term investments and proceeds from private placements.

**Table of Contents**

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 29, 2006</b>	<b>September 30, 2005</b>	<b>September 29, 2006</b>	<b>September 30, 2005</b>
Increase (decrease) in Cash and Cash				
Equivalents	\$ 148	\$ 12,297	\$ (4,515)	\$ 10,867
Add: purchase of short-term investments	14		193	15,300
Deduct: sale of short-term investments	(43)	(13,825)	(43)	(20,425)
Deduct: net proceeds from private placement		47		(13,374)
Cash Usage	\$ (177)	\$ (1,481)	\$ (4,365)	\$ (7,632)

*Adjusted Net Loss* The Adjusted Net Loss financial measure is not prepared in conformity with GAAP and excludes compensation expense calculated under FAS 123R and reserves and the reversal of reserves on notes receivable from former directors. Adjusted Net Loss is not a measurement of operations under GAAP and should not be considered as an alternative to net income or operating income and may not be comparable with Adjusted Net Loss as defined by other companies.

The Company's Adjusted Net Loss of \$8,450,000 for the nine months ended September 29, 2006 was 21% higher when compared with the same period of 2005. The Adjusted Net Loss calculation excludes the effect of compensation expense related to the implementation of FAS 123R and the reserve and reversal of reserves on notes receivable from former directors.

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 29, 2006</b>	<b>September 30, 2005</b>	<b>September 29, 2006</b>	<b>September 30, 2005</b>
Net Loss	\$ (2,789)	\$ (3,302)	\$ (9,369)	\$ (7,750)
Add: compensation expense under FAS 123R	443		1,250	
Add (deduct): Note reserves (reversals)	(331)	640	(331)	746
Adjusted Net Loss	\$ (2,677)	\$ (2,662)	\$ (8,450)	\$ (7,004)

Management believes Cash Usage and Adjusted Net Loss financial information provides meaningful supplemental information regarding our performance and liquidity by excluding the items described above in order to show the Cash Usage and Adjusted Net Loss from normal operations. STAAR believes that this financial information is useful to our management and investors in assessing STAAR's historical performance and liquidity and when planning, forecasting and analyzing future periods.

*Credit Facilities*

The Company and its subsidiaries have credit facilities with different banks to support operations in the U.S., and Switzerland and Germany, respectively.



On June 8, 2006 the Company signed a Credit and Security agreement with Wells Fargo Bank for a revolving credit facility. The credit facility provides for borrowings of 85% of eligible accounts receivable with a maximum of \$3.0 million, carries an interest rate of prime plus 1.5%, and is secured by substantially all of the assets of the Company's U.S. operations. The Company has \$1.9 million available for borrowing as of September 29, 2006. The term of the agreement is three years and it contains certain financial covenants relating to minimum calculated net worth, net loss, liquidity and restrictions on Company investments or loans to affiliates and investments in capital expenditures, which only apply if the Company borrows and/or maintains an outstanding advance. The Company has not borrowed against the facility as of September 29, 2006.

**Table of Contents**

On May 30, 2006, the Company signed a lease agreement with Farnam Street Financial, Inc. The credit facility provides for purchases of up to \$855,000 of property, plant and equipment based on a lease amendment signed dated August 3, 2006. In accordance with the requirements of SFAS 13 Accounting for Leases, purchases under this facility are accounted for as operating leases and have a three-year term. The Company also has the option to purchase any item of the leased property from Farnam at the end of the respective items lease terms at a mutually agreed fair value. The Company completed a sale-leaseback transaction on June 29, 2006 of certain assets originally purchased during 2006 and received a payment of approximately \$177,000. The Company retained use of all of the assets sold and then leased back.

The Company completed a second sale-leaseback transaction on September 7, 2006 of certain assets originally purchased during 2006 and received a payment of approximately \$94,000. The Company retained use of all of the assets sold and then leased back. The Company has approximately \$156,000 available under this facility as of September 29, 2006.

On October 9, 2006, the Company and Farnam Street Financial, Inc. completed a second amendment to the facility described above to increase the maximum borrowing amount from approximately \$855,000 to \$1,500,000. All other terms of the original agreement remain the same.

On May 25, 2006, the Company signed a lease agreement with Mazuma Capital Corporation. The credit facility provides for purchases of up to \$1,000,000 of property, plant and equipment. In accordance with the requirements of SFAS 13 Accounting for Leases, purchases under this facility are accounted for as capital leases and have a two-year term. The Company is required to open a certificate of deposit as collateral in STAAR Surgical Company's name at the underwriting bank for 50% of the assets funded by Mazuma. As of September 29, 2006, the Company had a certificate of deposit for approximately \$150,000 recorded as a restricted short-term investment with a 12-month term at a fixed interest rate of 4.5%. The agreement allows the Company to purchase any item of the leased property at the end of its lease term for \$1.

On August 11, 2006, the Company unwound a portion of the sale-leaseback transaction previously completed with Mazuma on June 30, 2006 whereby the Company re-purchased the assets from Mazuma. The assets were then sold and leased back with Farnam Street Financial on September 7, 2006 as described above.

On August 16, 2006, Mazuma and the Company amended the original lease agreement to reduce the credit facility limit to approximately \$301,000 which is the amount financed to date.

The Company's Swiss credit agreement, as amended on August 2, 2004, provides for borrowings of up to 3 million Swiss Francs CHF (approximately \$2.4 million based on the rate of exchange on September 29, 2006), and permits either fixed-term or current advances. The Swiss credit facility does not have a termination date. The interest rate on current advances is 6.0% per annum at both September 29, 2006 and December 30, 2005, plus a commission rate of 0.25% payable quarterly. There were no current advances outstanding at September 29, 2006. The base interest rate for fixed-term advances follows Euromarket conditions for loans of a corresponding term and currency plus an individual margin (4.8% at September 29, 2006 and 4.25% at December 30, 2005, respectively). Borrowings outstanding under the fixed-term advances at September 29, 2006 and December 30, 2005, respectively, were CHF 2.2 million (approximately \$1.8 million based on the rate of exchange at September 29, 2006) and CHF 2.2 million (approximately \$1.7 million based on the rate of exchange on December 30, 2005). The credit facility is secured by a general assignment of claims and includes positive and negative covenants which, among other things, require the maintenance of a minimum level of equity of at least \$12.0 million and prevents the Swiss subsidiary from entering into other secured obligations or guaranteeing the obligations of others. The agreement also prohibits the sale or transfer of patents or licenses without the prior consent of the lender and the terms of inter-company receivables may not exceed 90 days.

The Company's German subsidiary, Domilens, entered into a new credit agreement at August 30, 2005. The renewed credit agreement provides for borrowings of up to 100,000 EUR (\$127,000 at the rate of exchange on September 29, 2006), at a rate of 8.5% per annum and does not have a termination date. The credit facility is not secured. There were no borrowings outstanding as of September 29, 2006 and December 30, 2005.

The Company was in compliance with the covenants of these credit facilities as of September 29, 2006.

**Table of Contents**

As of September 29, 2006, the Company had a current ratio of 2.5:1, net working capital of \$18.9 million and net equity of \$35.4 million compared to December 30, 2005 when the Company's current ratio was 3.0:1, its net working capital was \$22.7 million, and its net equity was \$40.4 million.

While the Company's international business generates positive cash flow and represents approximately 59% of consolidated net sales, the Company has reported losses on a consolidated basis for several years due to a number of factors, including eroding sales of cataract products in the U.S. and FDA compliance issues that consumed additional resources while delaying the introduction of new products in the U.S. market. During these years the Company has secured additional capital to sustain operations through private sales of equity securities. The Company believes that as a result of these financings, along with expected cash from operations, it currently has sufficient cash to meet its funding requirements over the next year.

The Company believes that in the near term its best prospect for returning its U.S. and consolidated operations to profitability is the successful launch of the ICL in the U.S. In the longer term the Company seeks to develop and introduce products in the U.S. cataract market to stop further erosion of its market share and resume growth in that sector. Nevertheless, success of these strategies is not assured and, even if successful, the company is not likely to achieve positive cash flow on a consolidated basis during fiscal 2006.

The Company plans to finance its operations, including the launch of the ICL, through cash provided by operations, existing cash on hand, proceeds from the exercise of stock options, debt repayment by former officers of the Company, and borrowings under credit facilities. As of September 29, 2006, the Company had \$2.8 million available for borrowing under U.S. and International bank credit facilities and lease lines of credit. In this regard, the Company has obtained three credit facilities, with separate lenders, all of which were completed during the second quarter of 2006. The first is a line of credit which provides for borrowings of up to \$3.0 million and has \$1.9 million of borrowing available as of September 29, 2006 (see Note 6). The two other facilities are lease lines of credit which provide for borrowings of up to \$1.2 million with \$156,000 of availability as of September 29, 2006 which will be used to fund the majority of the Company's planned investments in property, plant and equipment. One of the lease lines of credit was amended on October 9, 2006 which increased availability by \$645,000 to allow for total borrowing of \$1.8 million. These credit facilities will be used to finance U.S. operations. To support international operations, the Company's Swiss subsidiary has \$0.6 million in borrowing capacity available for Swiss operations under its line of credit and the German subsidiary has a 100,000 EUR (\$127,000 at the rate of exchange on September 29, 2006) line of credit available to support German operations. However, given its history of losses and negative cash flows, it is possible that the Company will find it necessary to supplement these sources of capital with additional financing to sustain operations until the Company returns to profitability.

The credit facilities are subject to various financial covenants and if our losses continue, we risk defaulting on the terms of our credit facilities. Our limited borrowing capacity could cause a shortfall in working capital or prevent us from making expenditures to expand or enhance our business. A default on any of our loan agreements could cause our long term obligations to be accelerated, make further borrowing difficult and jeopardize our ability to continue operations.

If the Company is unable to rely solely on existing debt financing and is unable to obtain additional debt financing, the Company may find it necessary to raise additional capital in the future through the sale of equity or debt securities.

The Company has filed a shelf registration statement with the Securities and Exchange Commission, which provides for the public offering and sale of up to \$15 million in debt or equity securities pursuant to the Securities Act of 1933, as amended. The registration statement became effective on August 8, 2006. The Company is not obligated to sell any amount of securities under the registration statement, and as of the date of this report it has not entered into any commitment to do so. Notwithstanding the availability of shelf registration, the Company's ability to raise financing

through sales of securities depends on general market conditions and the demand for STAAR's common stock or debt securities. The conditions prevailing at the time the Company seeks to raise capital may prevent it from selling securities under the shelf registration on favorable terms, or at all. If our common stock has a low market price at a time when we sell equity securities, our existing shareholders could experience substantial dilution. An inability to secure additional financing could limit our ability to expand our business. If we fail to achieve profitability and cannot secure adequate funding, our ability to continue operations would be in jeopardy.

## **Table of Contents**

The Company's liquidity requirements arise from the funding of its working capital needs, primarily inventory, work-in-process and accounts receivable. The Company's primary sources for working capital and capital expenditures are cash flow from operations, which will largely depend on the success of the ICL, proceeds from option exercises, debt repayments by former directors, borrowings under the Company's bank credit facilities and proceeds from the private placement of common stock. Any withdrawal of support from its banks could have serious consequences on the Company's liquidity. The Company's liquidity also depends, in part, on customers paying within credit terms, and any extended delays in payments or changes in credit terms given to major customers may have an impact on the Company's cash flow. In addition, any abnormal product returns or pricing adjustments may also affect the Company's short-term funding. Changes in the market price of our common stock affect the value of our outstanding options, and lower market prices could reduce our expected revenue from option exercises.

The business of the Company is subject to numerous risks and uncertainties that are beyond its control, including, but not limited to, those set forth above and in the other reports filed by the Company with the Securities and Exchange Commission. Such risks and uncertainties could have a material adverse effect on the Company's business, financial condition, operating results and cash flows.

### **ITEM 3. *QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK***

There have been no material changes in the Company's qualitative and quantitative market risk since the disclosure in the Company's Annual Report on Form 10-K for the year ended December 30, 2005.

### **ITEM 4. *CONTROLS AND PROCEDURES***

Attached as exhibits to this Quarterly Report on Form 10-Q are certifications of STAAR's Chief Executive Officer ( CEO ) and Chief Financial Officer ( CFO ), which are required in accordance with Rule 13a-14 of the Securities Exchange Act of 1934, as amended (the Exchange Act ). This Controls and Procedures section includes information concerning the controls and controls evaluation referred to in the certifications.

#### **Evaluation of Disclosure Controls and Procedures**

The Company's management, with the participation of the CEO and CFO, conducted an evaluation of the effectiveness of the Company's disclosure controls and procedures, as defined in Exchange Act Rule 13a-15(e), as of the end of the period covered by this Form 10-Q. Based on that evaluation, the CEO and the CFO concluded that, as of the end of the period covered by this Form 10-Q, the Company's disclosure controls and procedures are effective in accumulating and communicating to them in a timely manner material information relating to the Company (including its consolidated subsidiaries) required to be included in its periodic reports filed with the Securities Exchange Commission.

#### **Changes in Internal Control Over Financial Reporting**

There was no change in internal control over financial reporting, known to the Chief Executive Officer and Chief Financial Officer, during the fiscal quarter ended September 29, 2006 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

## **PART II OTHER INFORMATION**

### **ITEM 1. *LEGAL PROCEEDINGS***

Settlement of *In re STAAR Surgical Co. Securities Litigation, No. CV 04-8007*. The Company and its Chief Executive Officer have been defendants in a class action lawsuit in the United States District Court for the Central District of California. A consolidated amended complaint filed by the plaintiffs on April 29, 2005 generally alleged that the defendants, STAAR Surgical Company and its Chief Executive Officer, violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder, by issuing false and misleading statements regarding the prospects for FDA approval of STAAR's Visian ICL, thereby artificially

**Table of Contents**

inflating the price of the Company's Common Stock. The plaintiffs sought to recover compensatory damages, including interest.

On September 25, 2006, the Court held a hearing to consider granting final approval to the settlement of the lawsuit. At the conclusion of the hearing, the Court found that the settlement previously negotiated to resolve the lawsuit was fair, just, reasonable and adequate and approved the settlement in all respects. The Court finally certified for settlement purposes a class comprised of purchasers of STAAR's securities between October 6, 2003 and January 5, 2004. Under the terms of the settlement, in exchange for dismissal of the lawsuit and a general release of claims and without admission of liability, STAAR caused payment of \$3,700,000 to be made, all but \$100,000 of which was borne by STAAR's insurance carrier. STAAR's total expenditure in connection with the lawsuit will not exceed the \$500,000 retention amount under its insurance policy, which was fully accrued as of December 30, 2005.

From time to time the Company is subject to various claims and legal proceedings arising out of the normal course of our business. These claims and legal proceedings relate to contractual rights and obligations, employment matters, and claims of product liability. We do not believe that any of the claims known to us is likely to have a material adverse effect on our financial condition or results of operations.

**ITEM 1A. RISK FACTORS**

An investment in securities of STAAR Surgical Company involves a high degree of risk. You should carefully consider the information in our Annual Report on Form 10-K for the fiscal year ended December 30, 2005 ( Form 10-K ) under the heading Risk Factors, which describes a number of important factors that can affect our business, operating results, financial condition and the value of an investment in our securities.

The following information updates the risk factors described in our Form 10-K. Except as set forth below, there have been no material changes to the risk factors disclosed in our Form 10-K.

***Strikes, slow-downs or other job actions by doctors can reduce sales of cataract-related products.***

In many countries where STAAR sells its products, ophthalmologists and other doctors are employees of the government, government-sponsored enterprises or large health maintenance organizations. In recent years employed doctors who object to salary limitations, working rules, reimbursement policies or other conditions have sought redress through strikes, slow-downs and other job actions. These actions often result in the deferral of non-essential procedures, such as cataract surgeries, which can affect sales of our products. For example, in the first nine months of 2006, strikes and slow-downs by doctors in Germany were partly responsible for a drop in sales by our wholly owned subsidiary Domilens GmbH, which distributes ophthalmic products in Germany. Depending on the importance of the affected region to STAAR's business, the length of the action and its pervasiveness, job actions by doctors can materially reduce our sales revenue and earnings.

Because state-sponsored healthcare systems, health maintenance organizations and insurance reimbursement usually do not cover refractive surgery, job actions by doctors are unlikely to affect ICL sales.

***We have a history of losses and anticipate future losses.***

We have reported losses in each of the last four fiscal years and have an accumulated deficit of \$81.0 million as of September 29, 2006. There can be no assurance that we will report net income in any future period.

***We have only limited working capital.***



We believe that our current sources of working capital are sufficient to satisfy our anticipated working capital requirements for fiscal 2006. However, the sufficiency of our working capital largely depends on a successful launch of the ICL and reversing the declining trends in our cataract business. If acceptance of the ICL is slower than anticipated and we are unable to reverse the declines in our cataract business, our working capital may be insufficient for future years and we may have to consider alternative sources of funding. We can provide no assurance as to the availability of such funding or the terms upon which it might be available.

**Table of Contents**

***We have limited access to credit and could default of the terms of our loan agreements.***

As of September 29, 2006, the Company had \$2.8 million available for borrowing under U.S. and International bank credit facilities and lease lines of credit. The credit facilities are subject to various financial covenants and if our losses continue, we risk defaulting on the terms of our credit facilities. Our limited borrowing capacity could cause a shortfall in working capital or prevent us from making expenditures to expand or enhance our business. A default on any of our loan agreements could cause our long term obligations to be accelerated, make further borrowing difficult and jeopardize our ability to continue operations.

***We have only limited access to financing.***

Because of our history of losses, our ability to obtain adequate financing on satisfactory terms or at all is limited. On May 17, 2006, our stockholders approved an increase on our authorized shares of common stock from 30 million shares to 60 million shares, which could enable STAAR to obtain financing in the public equity markets. In addition, the Company has an effective shelf registration statement filed with the Securities and Exchange Commission, which provides for the public offering and sale of up to \$15 million in debt or equity securities pursuant to the Securities Act of 1933, as amended. However, our ability to raise financing through sales of equity securities depends on general market conditions and the demand for STAAR's common stock. We may be unable to raise adequate capital through sales of equity securities or debt securities, and if our stock has a low market price at the time of such sales our existing shareholders could experience substantial dilution. An inability to secure additional financing could limit our ability to expand our business. If we fail to achieve profitability and cannot secure adequate funding, our ability to continue operations would be in jeopardy.

**ITEM 6. EXHIBITS**

**Exhibits**

- 3.1 Certificate of Incorporation, as amended to date.(1)
- 3.2 By-laws, as amended to date.(1)
- 31.1 Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.(\*)
- 31.2 Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.(\*)
- 32.1 Certification Pursuant to 18 U.S.C. Section 1350, Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.(\*)

(1) Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on May 23, 2006.

(\*) Filed herewith.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

STAAR SURGICAL COMPANY

By: /s/ DEBORAH ANDREWS  
Deborah Andrews  
**Chief Financial Officer**  
**(on behalf of the Registrant and as its**  
**chief accounting officer)**

Date: November 8, 2006