STAAR SURGICAL CO
Form 10-Q
November 07, 2007

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended: September 28, 2007

OR

o 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	95-3797439
(State of incorporation)	(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 R 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 and large accelerated filer” in Rule 12b-2 of the Exchange Act.

Large accelerated filer £ Accelerated filer R 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 R

The registrant has 29,381,009 shares of common stock, par value $0.01 per share, issued and outstanding as of November 7, 2007.

STAAR SURGICAL COMPANY

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PART I. FINANCIAL INFORMATION
ITEM 1. ***FINANCIAL STATEMENTS***

STAAR SURGICAL COMPANY
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except par value)
(Unaudited)

ASSETS	September 28, 2007	December 29, 2006
Current assets:		
Cash and cash equivalents	$ 14,196	$ 7,758
Short-term investments - restricted	150	150
Accounts receivable, net	5,961	6,524
Inventories	13,789	12,939
Prepaids, deposits and other current assets	2,614	1,923
Total current assets	36,710	29,294
Investment in joint venture	--	397
Property, plant and equipment, net	5,598	5,846
Patents and licenses, net	4,079	4,439
Goodwill	7,534	7,534
Other assets	256	260
Total assets	$ 54,177	$ 47,770
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Notes payable	$ --	$ 1,802
Accounts payable	4,572	5,055
Obligations under capital lease-current	859	500
Other current liabilities	8,215	7,574
Total current liabilities	13,646	14,931
Obligations under capital lease - long-term	1,305	1,079
Warrant obligation	102	--
Total liabilities	15,053	16,010
Commitments and contingencies (Note 8)		
Stockholders' equity:		
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 29,374 at September 28, 2007 and 25,618 at December 29, 2006	294	256
Additional paid-in capital	135,691	117,312
Accumulated other comprehensive income	1,544	889
Accumulated deficit	(98,405)	(86,697)
Total stockholders' equity	39,124	31,760
Total liabilities and stockholders' equity	$ 54,177	$ 47,770

See accompanying notes to the condensed consolidated financial statements.

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STAAR SURGICAL COMPANY
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 28, 2007	September 29, 2006	September 28, 2007	September 29, 2006
Net sales	$ 13,629	$ 13,313	$ 43,478	$ 41,511
Cost of sales	6,859	6,980	22,176	21,859
Gross profit	6,770	6,333	21,302	19,652
General and administrative	2,868	2,598	9,581	8,135
Marketing and selling	5,775	5,090	17,223	15,610
Research and development	1,743	1,670	4,987	5,185
Note reserve reversal	--	(331)	--	(331)
Operating loss	(3,616)	(2,694)	(10,489)	(8,947)
Other income (expense):				
Equity in operations of joint venture	(365)	102	(280)	(24)
Interest income	134	33	322	251
Interest expense	(128)	(44)	(445)	(131)
Other income (expense)	(50)	13	(477)	3
Total other income (expense), net	(409)	104	(880)	99
Loss before provision (benefit) for income taxes	(4,025)	(2,590)	(11,369)	(8,848)
Provision (benefit) for income taxes	(195)	199	339	521
Net loss	$ (3,830)	$ (2,789)	$ (11,708)	$ (9,369)
Loss per share - basic and diluted	$ (.13)	$ (.11)	$ (.42)	$ (.37)
Weighted average shares outstanding - basic and diluted	29,374	25,293	27,993	24,994

See accompanying notes to the condensed consolidated financial statements.

STAAR SURGICAL COMPANY
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Nine Months Ended	
	September 28, 2007	September 29, 2006
Cash flows from operating activities:		
Net loss	$ (11,708)	$ (9,369)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property, plant and equipment	1,463	1,389
Amortization of intangible assets	361	361
Amortization of note payable discount	17	--
Loss on extinguishment of note payable	233	--
Fair value adjustment of warrant obligation	(148)	--
Loss on disposal of property, plant and equipment	150	150
Equity in operations of joint venture	280	24
Stock-based compensation	1,074	1,389
Note reserve reversal	--	(331)
Other	107	(41)
Changes in working capital:		
Accounts receivable	630	(1,152)
Inventories	(242)	1,221
Prepaids, deposits and other current assets	(675)	(660)
Accounts payable	(636)	88
Other current liabilities	583	39
Net cash used in operating activities	(8,512)	(6,892)
Cash flows from investing activities:		
Acquisition of property, plant and equipment	(368)	(670)
Proceeds from sale lease back of property, plant and equipment	--	271
Proceeds from sale of property, plant and equipment	12	--
Purchase of short-term investments	--	(193)
Sale of short-term investments	--	43
Dividend received from joint venture	117	--
Proceeds from notes receivable and other	--	308
Increase (decrease) in other assets	6	(111)
Net cash used in investing activities	(233)	(352)
Cash flows from financing activities:		
Borrowings under line of credit	1,812	1,767
Repayment of line of credit	(3,610)	(1,676)
Repayment of capital lease obligations	(444)	(135)
Proceeds from note payable	4,000	--
Repayment of note payable	(4,000)	--
Net proceeds from private placement	16,613	--
Proceeds from the exercise of stock options	584	2,614
Net cash provided by financing activities	14,955	2,570

Effect of exchange rate changes on cash and cash equivalents		229		159
Increase (decrease) in cash and cash equivalents		6,438		(4,515)
Cash and cash equivalents, at beginning of the period		7,758		12,708
Cash and cash equivalents, at end of the period	$	14,196	$	8,193

See accompanying notes to the condensed consolidated financial statements.

STAAR SURGICAL COMPANY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 28, 2007
(Unaudited)

Note 1 — Basis of Presentation and Significant Accounting Policies

The following a) condensed balance sheet as of December 29, 2006, which has been derived from audited financial statements, and b) the accompanying unaudited interim 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 condensed consolidated financial statements for the three and nine months ended September 28, 2007 and September 29, 2006, 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 29, 2006.

The results of operations for the three and nine months ended September 28, 2007 and September 29, 2006 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 last day of the calendar quarter and generally consists of 13 weeks.

Consolidated Statement of Cash Flows

The Company has historically characterized proceeds received from the collection of notes from former officers and directors as an investing activity in the Consolidated Statement of Cash Flows in accordance with guidance provided by paragraph 16 of Financial Accounting Standards Board ("FASB") SFAS No. 95 *Statement of Cash Flows* ("SFAS 95"). The Company also considered guidance provided by paragraph 19 of SFAS 95 which would result in the characterization of such proceeds as a financing activity, but concluded that its treatment as an investing activity was appropriate based on fact that the notes were full recourse. Had the Company adopted the alternative presentation as a financing activity, Cash Provided by Financing Activities for the nine months ended September 29, 2006 would have been larger by $308,000 and Cash Used in Investing Activities would have been smaller by an equal amount.

New Accounting Pronouncements

In February 2007, The FASB issued SFAS No. 159 *The Fair Value Option for Financial Assets and Financial Liabilities* ("SFAS 159"). SFAS 159 permits entities to choose to measure at fair value many financial instruments and certain other items that are not currently required to be measured at fair value. SFAS 159 is intended to improve financial reporting by allowing companies to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently and to do so without having to apply complex hedge accounting provisions. SFAS 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between entities that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 does not affect any existing accounting literature that requires certain assets and liabilities to be carried at fair value or and does not affect disclosure requirements in other accounting standards. SFAS 159 will be effective for the Company its next next fiscal year starting on December 30, 2007, and it is currently evaluating whether it will adopt the fair value measurement option allowed by the standard.

Prior Year Reclassifications

Certain reclassifications have been made to the prior financial statement information to conform with current period presentation.

Restatement of Prior Periods

The Company has restated the Consolidated Statement of Cash Flows for the nine months ended September 29, 2006 to comply with the requirements of paragraph 25 of SFAS 95 related to foreign currency cash flows. While the Company believes the changes to the prior period amounts are not material, it also determined it was appropriate to restate the amounts to conform to the current year presentation. The changes had no effect on net loss or loss per share, or the increase (decrease) in cash equivalents for the period. The Company has prepared a summary of the changes to the Statement of Cash Flows for the nine months ended September 29, 2006 below:

	As Reported	Adjustment	As Filed
Cash used in operating activities	$ (7,236)	$ 344	$ (6,892)
Cash used in investing activities	(426)	74	(352)
Cash used in financing activities	2,658	(88)	2,570
Effect of exchange rate changes	489	(330)	159
Decrease in cash and cash equivalents	$ (4,515)	$ -	$ (4,515)

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.

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 (in thousands):

	September 28, 2007	December 29, 2006
Raw materials and purchased parts	$ 1,011	$ 690
Work-in-process	2,209	1,669
Finished goods	10,569	10,580
	$ 13,789	$ 12,939

Note 4 — Prepaids, Deposits, and Other Current Assets

Prepaids, deposits, and other current assets consisted of the following (in thousands):

	September 28, 2007	December 29, 2006
Prepaids and deposits	$ 2,184	$ 1,455
Other current assets	430	468
	$ 2,614	$ 1,923

Included in prepaids and deposits as of September 28, 2007 is $356,000 of deferred acquisition costs related to the Company's purchase of the remaining 50% interest in the Canon-Staar joint venture as discussed further in Note 11. These deferred costs will be included in the purchase price in determining the total cost of the purchase.

Note 5 — Other Current Liabilities

Other current liabilities consisted of the following at September 28, 2007 and December 29, 2006 (in thousands):

	September 28, 2007	December 29, 2006
Accrued salaries and wages	$ 2,146	$ 1,970
Accrued income taxes	668	831
Accrued commissions	680	781
Payable related to acquisition of minority interest in Australia subsidiary	923	770
Accrued audit expenses	563	517
Accrued insurance	843	484
Other	2,392	2,221
	$ 8,215	$ 7,574

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Note 6 — Stockholders' Equity

The Company completed a public offering of its common stock on May 1, 2007. In the offering, the Company sold 3,600,000 shares of common stock at price to the public of $5 per share, which yielded approximately $16.6 million net proceeds. All shares of the common stock offered by the Company were sold pursuant to a shelf registration statement that was declared effective by the U.S. Securities and Exchange Commission on August 8, 2006, as supplemented by an additional registration statement filed on April 25, 2007, pursuant to Rule 462(b) under the Securities Act of 1933. The public offering included all of the securities available for issuance under STAAR's Form S-3 shelf registration statement.

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 3,682,298 and 3,403,004 for the three and nine months ended September 28, 2007, respectively, and 2,692,151 and 2,579,142 for the three and nine months ended September 29, 2006, respectively, were excluded from the computation as the shares would have had an anti-dilutive effect.

Note 7 — 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 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):

	Three Months Ended		Nine Months Ended	
	September 28, 2007	September 29, 2006	September 28, 2007	September 29, 2006
Sales to unaffiliated customers				
United States	$ 4,739	$ 5,705	$ 14,991	$ 17,080
Germany	5,743	4,969	17,471	15,491
Other	3,147	2,639	11,016	8,940
Total	$ 13,629	$ 13,313	$ 43,478	$ 41,511

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 intraocular lenses ("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):

	Three Months Ended		Nine Months Ended	
	September 28,	September 29,	September 28,	September 29,

	2007	2006	2007	2006
Cataract	$ 10,100	$ 10,249	$ 31,956	$ 32,084
Refractive	3,396	2,901	11,059	8,924
Glaucoma	133	163	463	503
Total	$ 13,629	$ 13,313	$ 43,478	$ 41,511

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 8 — Commitments and Contingencies

Litigation

Moody v. STAAR Surgical Company; Parallax Medical Systems, Inc. v. STAAR Surgical Company. On September 21, 2007, Scott C. Moody, Inc. and Parallax Medical Systems, Inc. filed substantially identical complaints against STAAR in the Superior Court of California, County of Orange. Moody and Parallax are former independent regional manufacturer's representatives ("RMRs") of STAAR whose contracts with STAAR expired on July 31, 2007. They claim, among other things, that STAAR interfered with the plaintiffs' contracts when it caused some of their current or former subcontractors to enter into new agreements to represent STAAR products, and that STAAR interfered with the plaintiffs' prospective economic advantage when it informed a regional IOL distributor that each of the RMR's contracts had a covenant restricting the sale of competing products. Moody claims general and compensatory damages of $32 million and Parallax claims general and compensatory damages of $48 million, and both plaintiffs request punitive damages. At this early stage of the litigation, STAAR is unaware of any facts that substantiate these claims and believes them to be without merit. It intends vigorously to oppose the claims and intends to assert claims for affirmative relief against both plaintiffs. The plaintiffs offer no factual basis for the magnitude of their claims; STAAR believes there is no such basis and that it should not be liable for any amount of damages. Nevertheless, the outcome of litigation is never certain and the possibility that the plaintiffs will recover under their claims cannot be completely eliminated at this time. STAAR has not accrued any expenses related to this matter as of September 28, 2007 based on the fact that the loss, if any, is not probable or estimable.

The Company has asserted its right under the California Code of Civil Procedure to early discovery of any evidence supporting the plaintiffs' claims. In its sworn testimony, Parallax failed to provide evidence that supported the amount of damages claimed. As a result, STAAR continues to believe that Parallax's claims for damages are without merit. STAAR expects to obtain sworn testimony from the other plaintiff in the near future.

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 provided for borrowings of 85% of eligible accounts receivable with a maximum of $3.0 million, carried an interest rate of prime plus 1.5%, and was secured by substantially all of the assets of the Company's U.S. operations. The term of the agreement was three years and it contained certain financial covenants, among others, relating to minimum calculated net worth, net loss, liquidity and restrictions on Company investments or loans to affiliates and investments in capital expenditures. On September 27, 2007 STAAR terminated the facility with Wells Fargo Bank in accordance with the terms of the Credit and Security Agreement.

The Company's lease agreement with Farnam Street Financial, Inc., as amended on October 9, 2006, provided for purchases of up to $1,500,000 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 three-year term. Under the agreement, the Company has the option to purchase any item of the leased property, at the end of the

respective items lease terms, at a mutually agreed fair value. On April 1, 2007, the Company added a new leasing schedule with Farnam under the original agreement, which provides for additional purchases of $800,000 during the next fiscal year. The terms of this new schedule conform to the amended agreement dated October 9, 2006. Approximately $491,000 in borrowings was available under this facility as of September 28, 2007.

Warrant Obligation

On March 21, 2007, STAAR entered into a Warrant Agreement (the "Warrant Agreement") with Broadwood Partners, L.P. ("Broadwood") granting the right to purchase up to 70,000 shares of Common Stock at an exercise price of $6, exercisable for a period of six years. The warrant agreement provided that STAAR will register the stock for resale with the U.S. Securities and Exchange Commission ("SEC").

In accordance with the guidance provided in *Emerging Issues Task Force 00-19 Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock* ("EITF 00-19"), STAAR has determined that the warrant should be accounted for as a liability and must be revalued at each reporting period. STAAR revalued the warrant as of September 28, 2007 using the assumptions noted below and determined the fair value to be $102,000, with the change in value recorded in other expense.

Assumptions

The fair value of the warrant was estimated on September 28, 2007 using a Black-Scholes option valuation model applying the assumptions noted in the following table. Expected volatilities are based on historical volatility of the Company's stock. The expected life of the warrant is determined by the amount of time remaining on the original six year term of the agreement. The risk-free rate for periods within the contractual life of the warrant is based on the U.S. Treasury yield curve in effect at each reporting period.

Expected dividends	0%
Expected volatility	69.37%
Risk-free rate	4.38%
Expected life (in years)	5.5

Note 9 ~~-~~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 28, 2007, 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 is set forth below (in thousands):

	Three Months Ended		Nine Months Ended	
	September 28, 2007	September 29, 2006	September 28, 2007	September 29, 2006
SFAS 123R expense	$ 349	$ 443	$ 1,033	$ 1,250
Restricted stock expense	21	31	118	66
Consultant compensation	--	(76)	15	17
Total	$ 370	$ 398	$ 1,166	$ 1,333

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 $43,000 and $122,000, respectively, of SFAS 123R compensation to inventory for the three and nine months ended September 28, 2007, and $42,000 and $106,000, respectively for the three and nine months ended September 29,

2006.

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 if necessary to provide that 2% of the total shares of common stock outstanding on the immediately preceding December 31 will be reserved for issuance. 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 2,256,002 shares were outstanding at September 28, 2007, with exercise prices ranging between $3.81 and $11.24 per share. There were 49,418 shares of restricted stock outstanding at September 28, 2007.

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 28, 2007, 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 779,033 were outstanding at September 28, 2007, with exercise prices ranging between $2.96 and $13.625 per share. 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 56,700 shares were outstanding at September 28, 2007 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 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 28, 2007, 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 28, 2007, with exercise prices ranging between $9.375 and $10.63.

During the nine months ended September 28, 2007, officers, employees and others exercised 163,233 options from the 1995, 1998, and 2003 stock option plans at prices ranging from $2.96 to $4.88 resulting in net cash proceeds to the Company totaling $584,000.

Assumptions

The fair value of each option award is estimated on the date of grant using a Black-Scholes option valuation model applying 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 has calculated a 9.59% estimated forfeiture rate used in the model for fiscal year 2007 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 28, 2007	September 29, 2006	September 28, 2007	September 29, 2006

Expected dividends	0%	0%	0%	0%
Expected volatility	68.87%	72.11%	69.43%	70.35%
Risk-free rate	5.10%	4.76%	4.70%	4.23%
Expected term (in years)	5.4	5.2	5.4 & 5.5	4.3

A summary of option activity under the Plans as of September 28, 2007 and changes during the period is presented below:

Options	Shares (000's)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value (000's)
Outstanding at December 29, 2006	3,472	$ 5.62		
Granted	535	4.93		
Exercised	(163)	3.57		
Forfeited or expired	(137)	5.70		
Outstanding at September 28, 2007	3,707	$ 6.80	5.76	$ 59
Exercisable at September 28, 2007	2,668	$ 7.28	4.54	$ 59

The total fair value of options vested during the nine months ended September 28, 2007, and September 29, 2006 was $1,307,000 and $1,503,000, respectively. The total intrinsic value of options exercised during the nine months ended September 28, 2007 and September 29, 2006 was $0 and $2,408,000, respectively.

A summary of the status of the Company's nonvested shares as of September 28, 2007 and changes during the period is presented below:

Nonvested Shares	Shares (000's)	Weighted-Average Grant Date Fair Value
Nonvested at December 29, 2006	1,032	$ 3.30
Granted	535	3.13
Vested	(460)	2.84
Forfeited	(68)	3.17
Nonvested at September 28, 2007	1,039	$ 5.56

As of September 28, 2007 there was $2.3 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 2.24 years.

Note 10 — Provision (Benefit) for Income Taxes

During the quarter ended September 28, 2007, the Company reached a settlement with the German Ministry of Finance related to taxes assessed in connection with unreported sales of a company controlled by the former President of Domilens, GmbH. As a result of the settlement, the Company reversed approximately $460,000 in income tax expense originally recorded in the fourth quarter of 2006, based on the best information available to management at that time. This adjustment caused the relationship between income tax provision and pretax accounting income to vary from customary levels during the three and nine months ended September 28, 2007.

Note 11 — Subsequent Events

Canon Staar Joint Venture

On October 25, 2007 STAAR entered into a Share Purchase Agreement (the "Share Purchase Agreement") with Canon Inc. and Canon Marketing Japan Inc. ("Canon Marketing" and collectively "the Canon companies") to acquire all of the Canon companies' interests in Canon Staar and obtain 100% ownership of Canon Staar.

The Share Purchase Agreement provides that the closing will occur on the later of December 28, 2007 or the date on which all conditions to closing are satisfied. At closing STAAR will pay the $4 million cash consideration and 1.7 million shares of Series A Convertible Preferred Stock to the Canon companies, and the Canon companies will deliver all their shares of Canon Staar to STAAR.

The principal agreements among the joint venture parties, including the Technical Assistance and License Agreement between the Company and Canon Staar, will be terminated at Closing.

Each share of Preferred Stock to be issued to the Canon companies will be convertible for five years at the option of the holder into one share of STAAR's common stock and will automatically convert after five years into one share of STAAR's common stock. The Preferred Stock will be redeemable at the option of the holders at a price of $4 per share (plus accrued or declared but unpaid dividends) on the occurrence of a change in control or liquidation of STAAR or at any time after the third anniversary of the issuance date.

STAAR's obligation to complete the transaction is subject to the satisfaction of customary conditions to closing and include the following:

- BDO Sanyu, the auditors of Canon Staar, will perform a review of the financial statements, including balance sheet, for the quarter and nine months ended September 30, 2007 for Canon Staar;
  - an audit by STAAR will have confirmed the inventory of Canon Staar products listed by Canon Marketing;
- STAAR's due diligence will not have discovered any event, action or change that has had or could have a material adverse effect on the business, operations, properties or conditions (financial or otherwise) of Canon Staar, other than with respect to any matter arising in connection with Canon Staar's Bylaws, Rules of Organization, Rules for Job Functions and Rules for the Use of the Application for Approval or Impression of Seal (the "Internal Regulations"); and
- the Japanese Ministry of Health and Welfare will have approved Canon Staar's acting as a seller of products directly to end users.

The Share Purchase Agreement requires STAAR to file with the Securities and Exchange Commission a "shelf" registration statement providing for the public resale of the shares issuable on conversion of the Series A Preferred Stock (the "Conversion Shares") within 30 days after issuance of the Preferred Stock. Subject to customary black-out periods the registration statement will remain in force until the Conversion Shares may be sold freely under Rule 144(k). STAAR will use best efforts to have the registration statement declared effective within 180 days. If it fails to do so, STAAR will issue 30,000 shares of common stock for each month (or part thereof) in which effectiveness has not been obtained, and each month when availability of the registration is suspended (apart from permitted black-out periods) while the obligation to maintain effectiveness is in place.

The Canon companies agree that for a period of three years after the closing they will not directly manage, operate or engage in research, development, manufacture, marketing, sale or distribution of implantable silicone and collagen copolymer intraocular lenses whether phakic or aphakic, whether spheric or aspheric, and insertion devices for such implants and collagen glaucoma wicks (collectively the "Business') or acquire a controlling ownership interest in any entity that manages, operates or engages in the Business (other than conducting research and development activities) in Japan and has aggregate annual sales of products connected with the Business in excess of $1 million.

At the closing STAAR and Canon Marketing will enter into an Inventory Sales Agreement in the form attached to the Share Purchase Agreement (the "Inventory Sales Agreement"), which provides for the repurchase by Canon Staar of all Canon Staar product inventory owned by Canon Marketing (the "Repurchased Inventory"). The Inventory Sales Agreement provides that at the end of each month during the first year after the closing Canon Staar will pay Canon Marketing for the Repurchased Inventory Canon Staar has sold in the preceding month. The price paid to Canon Marketing will be the same price Canon Marketing originally paid Canon Staar for the Repurchased Inventory (the "Original Purchase Price"), except for sales in China of the KS-XI model acrylic Preloaded Injector, for which the price will be 50% of Canon Staar's sales price to the customer. On the first anniversary of the closing Date Canon Staar will pay Canon Marketing the Original Purchase Price for any remaining Repurchased Inventory (except the Model KS-XI) that has not yet been sold by Canon Staar and that has a shelf life through at least October 25, 2009. Canon Staar will continue to pay Canon Marketing for KS-XI inventory only after its sale by Canon Staar. At and

following closing all accounts receivable and accounts payable between Canon Marekting and Canon Staar will be reconciled and any net amount owed by either party will be paid.

At closing Canon Staar and the Canon companies will enter into secondment agreements covering employees of the Canon companies who will work for Canon Staar after the Closing, including employees of Canon Marketing involved in the selling and marketing of Canon Staar products.

At closing releases will be entered into by each of STAAR, the Canon companies and Canon Staar related to the prior conduct of the joint venture and uses of confidential information.

Australian Subsidiary

On November 5, 2007, the Company paid the second and final installment for the purchase of the of the remaining 20% minority interest in its Australian subsidiary, Conceptvision Australia Pty Limited. The payment, in the amount of approximately $972,000 (based on the exchange rate on the payment date), was made pursuant to the terms of the purchase agreement dated May 5, 2004.

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 materially 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 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 interim condensed 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 and refractive conditions. We distribute our products worldwide.

Originally incorporated in California in 1982, STAAR reincorporated in Delaware in 1986. Unless the context indicates otherwise, “we,” “us,” the “Company” and “STAAR” all refer to STAAR Surgical Company and its 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™ line of products designed to surgically correct refractive conditions such as myopia (nearsightedness), hyperopia (farsightedness) and astigmatism.

Intraocular Lenses (IOLs) and Related Cataract Treatment Products. We produce and market a line of foldable IOLs for use in minimally invasive cataract surgical procedures. 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.

We currently manufacture foldable IOLs from both our proprietary Collamer ® and silicone materials. We make IOLs in each of the materials in two different configurations: the single-piece plate haptic design, and the three-piece design where the optic is combined with spring-like Polyimide™ loop haptics. The selection of one style over the other is primarily based on the preference of the ophthalmologist.

In April 2007 we introduced a Collamer three-piece IOL with an aspheric optic, and we are introducing a silicone three-piece IOL with an aspheric optic in November 2007. Aspheric IOLs are intended to improve functional vision, especially at night, by reducing spherical aberration, an optical error that is characteristic of conventional spheric IOL

designs. Since the introduction of aspheric IOLs may surgeons have began selecting them for their patients. However, it has been noted, that their optical performance degrades significantly if the lens moves out of close alignment with the central axis of the eye. STAAR has sought to differentiate its aspheric IOLs tailoring its optic to the natural curvature of the retina, where their visual image is projected. This results in an optic that performs optimally even if decentered or tilted. STAAR is seeking patent protection for this proprietary design.

We have developed and currently market globally the Toric IOL, a toric version of our single-piece silicone IOL, which is specifically designed for cataract patients who also have pre-existing astigmatism. The Toric IOL is the first refractive product we offered in the U.S.

Canon Staar introduced the first preloaded lens injector system in Japan in 2002. In late 2003 we introduced Canon Staar's preloaded lens injector system in international markets. The Preloaded Injector is a silicone or acrylic IOL packaged and shipped in a pre-sterilized, disposiable injector ready for use in cataract surgery. We believe the Preloaded Injector offers surgeons improved convenience and reliability. The Preloaded Injector is not yet available in the U.S. In 2006 Canon Staar began selling in Japan an acrylic-lens-based Preloaded Injector employing a lens supplied by a Japanese ophthalmic company.

During the quarter ended September 28, 2007, sales from IOLs accounted for approximately 40% of total sales compared with approximately 46% in the quarter ended September 29, 2006.

As part of our approach to providing complementary products for use in minimally invasive cataract surgery, we also market STAARVISC II, a viscoelastic material which is used as a protective lubricant and to maintain the shape of the eye during surgery, the STAARSonicWAVE Phacoemulsification System, a medical device system that uses ultrasound to remove a cataract patient’s cloudy lens through a small incision and has low energy and high vacuum characteristics, and Cruise Control, a single-use disposable filter which allows for a faster, cleaner phacoemulsification procedure. We also sell other related instruments, devices, surgical packs and equipment that we manufacture or that are manufactured by others. Sales of other cataract products accounted for approximately 35% of our total sales for the quarter ended September 28, 2007 compared with 31% of total sales for the quarter ended September 29, 2006.

Refractive Correction — Visian ICL. ICLs are implanted into the eye to correct refractive disorders such as 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. The ICL is capable of correcting refractive errors over a wide diopter range.

The ICL is folded and implanted into the eye behind the iris and in front of the natural crystalline lens using minimally invasive surgical techniques similar to implanting an IOL during cataract surgery, except that the natural lens is not removed. 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.

The FDA approved the ICL for myopia for use in the United States on December 22, 2005. The ICL and TICL are approved in countries that require the Conformité Européenne Mark (or CE Mark) Canada, Korea and Singapore. The ICL is also approved in China. Applications are pending for the TICL in China and the ICL and TICL in Australia, and STAAR is working to expand sales of ICLs and TICLs in other countries and will seek additional approvals to the extent necessary. STAAR submitted its application for U.S. approval of the TICL to the FDA in 2006 and is further discussed in the strategy section.

The Hyperopic ICL, for treatment of far-sightedness or hyperopia, is approved for use in countries that require the CE Mark and in Canada, and is currently in clinical trials in the United States.

The ICL is available for myopia in the United States in four lengths and 27 powers for each length, and internationally in four lengths, with 41 powers for each length, and for hyperopia in four lengths, with 37 powers for each length, which equates to 420 inventoried parts. This requires STAAR to carry a significant amount of inventory to meet the customer demand for rapid delivery. The Toric ICL is available for myopia in the same powers and lengths but carries additional parameters of cylinder and axis with 11 and 180 possibilities, respectively. Accordingly, the Toric ICL is generally made to order.

Sales of ICLs (including TICLs) during the quarter ended September 28, 2007 accounted for approximately 24% of our total sales compared with 21% of total sales during the quarter ended September 29, 2006.

Glaucoma Products. Among our other products is the AquaFlow Collagen Glaucoma Drainage Device, an implantable device used for the surgical treatment of glaucoma. Glaucoma is a progressive ocular disease that manifests itself through increased intraocular pressure. The increased pressure may damage the optic disc and decrease the visual field. Untreated, progressive glaucoma can cause blindness. Sales of AquaFlow devices during the quarters ended September 28, 2007 and September 29, 2006 accounted for approximately 1% of our total sales.

Foreign Currency Fluctuations. Our products are sold in approximately 50 countries. Sales from international operations represented 65% of total sales for the quarter ended September 28, 2007. 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.

Strategy

STAAR is currently focusing on the following four strategic goals:

• building the U.S. market for the ICL 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 the restructuring of the sales force; and

• maintaining our focus on regulatory compliance and continuous quality improvement.

Building the U.S. market for the ICL 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. Notwithstanding strong and sustained growth internationally, U.S. market growth 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.

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 28, 2007, 446 surgeons had completed training and certification to implant the ICL. STAAR recognized $1,051,000 of U.S. sales revenue from ICLs for the quarter ended September 28, 2007. ICL sales in the U.S., while profitable, have not grown significantly beyond the levels reached in the first year of introduction. Based on the ICL's penetration of the overall refractive market in significant markets outside the U.S., STAAR believes that its U.S. sales should increase significantly in the future and has modified its U.S. ICL marketing strategy in 2007 in an effort to spur growth.

STAAR's strategy for the U.S. market is to position the ICL technology as one that helps build our customers' total refractive volume through excellent visual outcomes and high levels of patient satisfaction. STAAR makes 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.

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 in refractive surgery centers throughout the U.S. and around the world.

One of STAAR's challenges in building market share for ICL has been its historical dependence on a primarily independent and cataract-focused sales force. To promote sales of its cataract products in the U.S., STAAR has historically relied on a two-tier independent sales force consisting of regional representatives contracted to STAAR ("RMRs") and more local territorial representatives. Each independent representative has received a commission on all of our sales within a specified region, including sales on products we sell into the region without their assistance. The independent representatives have generally borne the responsibility of demonstrating products, including training surgeons in the use of products. Because they have been independent contractors, we had a limited ability to manage and direct these representatives or their employees. In addition, the representatives have been able to represent manufacturers other than STAAR. Although the products of other manufacturers did not compete directly with STAAR's, they did in some instances take time and focus away from selling STAAR's products. These representatives

generally emphasized cataract products and had little experience in selling refractive products like the ICL.

In regions where RMRs had contracts giving them exclusive rights to represent the ICL, STAAR has had to rely on the independent representatives to implement the marketing of the ICL. To support the promotion of ICL sales in these regions, STAAR developed marketing plans under which it assumed the responsibility of training surgeons through a staff of highly trained applications specialists who are direct employees of STAAR. Despite STAAR's taking on the cost and administrative burden of this activity, STAAR was still obligated to pay commissions to the independent representatives on all sales generated in their regions. Beginning in 2006 STAAR also provided at its expense the services of refractive specialists who would assist interested surgeons in evaluating their practices and fully incorporating ICL into the spectrum of refractive treatments offered.

In August 2007 STAAR began a comprehensive restructuring of its U.S. sales model, which concluded with STAAR's election not to renew its last two long-term contracts with regional manufacturers' representatives. STAAR's sales of Visian ICL refractive products in the U.S. will in the future generally be handled by a directly employed sales force specializing in the refractive market. The Company expects this strategy to be more effective and efficient by eliminating the need to pay territory based commissions on ICL sales while also supporting a direct sales staff as the Company has done in the past. It is too early to determine whether this strategy will in fact yield the intended benefits.

To accelerate the U.S. market uptake of the ICL, in the third quarter of 2007 STAAR began handling sales of the ICL through a specialized direct sales force nationwide. Direct sales staff will include STAAR's existing applications specialists (who train surgeons in use of the ICL), refractive specialists (who help integrate ICL into the surgeon's practice) and a newly recruited team of refractive sales managers. The refractive sales managers will orchestrate the commercial effort at a regional level and work with existing certified doctors to build usage rates and to identify additional surgeons based purely on their ICL potential. 15 of the 18 refractive sales force positions have been filled as of the date of this report.

Other members of the current sales team (both employed and independent) will continue to be involved in ICL sales to the extent needed to ensure continuity. However, this group will primarily focus on STAAR's cataract business. This aspect of STAAR's restructuring of its sales force is discussed below under the heading *"Reversing the decline in U.S. market share for our cataract product lines by intensifying selling efforts and renewing and refining our product offering through enhanced R&D."*

The changes discussed above build on the structural changes begun the first quarter of 2007 when STAAR split its Sales and Marketing Department into two separate groups. A principal purpose of the split was to enable the Sales Department to focus on the development of STAAR's direct sales model, which will now be employed for refractive sales nationwide. 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 application (PMA) supplement for the TICL to the FDA on April 28, 2006, and received comments from the Office of Device Evaluation ("ODE") on November 20, 2006 requesting that STAAR submit an amended application. On August 3, 2007 STAAR received a letter from ODE notifying STAAR that the TICL application would be placed on integrity hold until STAAR completed specified actions to the satisfaction of the FDA. Noting the deficiencies cited in a June 26, 2007 Warning Letter from the FDA's Bioresearch Monitoring branch ("BIMO") and in an audit of a clinical study site, ODE requested that STAAR engage an independent third party auditor to conduct an audit of patient records along with a clinical systems audit to ensure accuracy and completeness of data before resubmitting the application. STAAR's independent auditor has completed the first phase of this work, which involved extensive discussions with FDA and the submission of a full project plan to the agency. In early November 2007 the auditor will begin a 100% on-site data inspection, a process estimated to require three months. Following that, the independent auditor will undertake any necessary amendments to clinical data, assess STAAR's clinical quality systems and perform any necessary follow-up actions necessary to confirm the scientific validity of the TICL clinical data through the process outlined by the FDA. The independent auditor will conduct the audit under the oversight of the FDA and STAAR's communications with the auditors will be limited until the project is complete. While STAAR believes these actions, if successful, should enable STAAR to resubmit the TICL application in an approvable form, STAAR cannot assure investors that the results of the independent audit or STAAR's corrective actions will be satisfactory, that ODE will grant approval to the TICL, or that the scope of requested TICL approval, if granted, would not be limited by the FDA.

Generating further growth of the ICL and TICL in international markets. The ICL and TICL are sold in more than 40 countries. International sales of refractive implants have continued at a steady rate of growth, increasing approximately 45% for the quarter ended September 28, 2007. STAAR believes that the international market for its refractive products has the potential for further growth, both through the introduction of the ICL and TICL in new territories and expanded market share in existing territories. 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, but the timing of such approvals are at the discretion of the local authorities.

Reversing the decline in U.S. market share for our 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.

STAAR seeks to reverse the decline in its domestic cataract market share by the introduction of enhanced design IOLs and improved delivery systems. The completion in 2005 of initiatives to revamp STAAR's systems of regulatory compliance and quality management permitted STAAR to shift resources back to product development. In particular, STAAR has focused on the following projects intended to expand and improve our cataract product offering:

- Development of the Afinity(TM) Collamer® Aspheric IOL, a new three-piece Collamer IOL featuring a square edge and an aspheric optic design, which was introduced in April 2007;

- Development of new silicone IOL models featuring the same advanced aspheric optics and a squared edge configuration, launched in November 2007;

- The development of a 2.0 mm micro-incision injector system for its Collamer plate lens late;

- The development of a Toric Collamer plate IOL to complement our pioneering silicone Toric IOL;

- Obtaining from the Centers for Medicare and Medicaid Services “new technology IOL” classification for STAAR’s aspheric Collamer and aspheric silicone lenses, permitting higher reimbursement rates;

- An improved injector system for the three-piece Collamer lens product line;

- Development of a preloaded injector system for our new silicone aspheric IOLs.

STAAR cautions that the successful development and introduction of new products is subject to risks and uncertainties, including the risk of unexpected delays.

As noted above, STAAR elected not to renew the last two RMR contracts between STAAR and RMRs, which covered the southwestern and southeastern U.S. and expired on July 31, 2007, and has undertaken a comprehensive restructuring of its sales organization. In addition to the direct sales force for the ICL discussed above, STAAR is re-organizing the remainder of its existing sales force, both employees and independent representatives, into a separate sales force specializing in the cataract market. STAAR believes this focus will be essential to capitalize on the introductions of new and enhanced products discussed above. STAAR expects to enter into a contract with its one remaining independent RMR, who is not currently under contract, to represent its products and manage territorial representatives in the central eastern seaboard. Elsewhere in the country, directly employed sales managers will supervise both direct and independent local representatives. STAAR may or may not use independent regional managers in the future to oversee local representatives; it intends to adopt a flexible and pragmatic approach on a region by region basis based on results.

STAAR believes its introduction of IOLs with advanced aspheric optics will enhance the market appeal of its cataract product line. In addition, STAAR intends to seek New Technology IOL (“NTIOL”) status for both its silicone and Collamer aspheric IOLs with the Centers for Medicare and Medicaid Services (CMS). CMS will grant NTIOL status, and allow higher reimbursement rates, when an aspheric IOL can demonstrate specifically improved visual performance over conventional IOLs. Because the overwhelming majority of IOL purchases in the U.S. are reimbursed through Medicare, NTIOL status would significantly increase STAAR’s margin on these lenses.

On January 22, 2007, CMS issued a ruling that allows cataract patients receiving reimbursement by Medicare to choose a lens that also corrects astigmatism. Under the ruling, patients may elect to pay a premium for the correction of pre-existing astigmatism, while Medicare provides the customary reimbursement for cataract surgery. STAAR’s Toric IOL is eligible for this dual aspect reimbursement. This change enables STAAR to increase its price and its profit margin, and also permits the surgeon to be remunerated for the significant additional services needed to prescribe and implant a lens with toric correction for astigmatism. STAAR had expected the ruling to increase sales revenue from its Toric IOL, but the entry of STAAR’s largest competitor, Alcon, into the Toric IOL market has initially resulted in a reduction of revenue despite the CMS ruling. STAAR believes this reduction results primarily from Alcon’s much greater penetration of the U.S. ophthalmic market, including surgeons who may have relied on STAAR as the sole source for Toric IOLs only until Alcon made its competing Toric IOL available. In addition, STAAR’s Toric IOL is currently available only as a silicone lens, while many surgeons prefer the acrylic material used

in Alcon's Toric IOL. STAAR believes that its Toric IOL, which has a significant price advantage over Alcon's, should continue to be viable in the expanding market made available by the CMS ruling and is seeking avenues to recover and expand its U.S. market. In addition, STAAR is developing a Collamer-based Toric IOL to better compete with the acrylic alternative.

Reversing the decline in U.S. IOL sales will require STAAR to overcome several short and long-term challenges, including successfully meeting its objectives to develop new and enhanced products, organizing, training and managing a specialized cataract sales force, competing with much larger companies and overcoming reputational harm from the FDA's findings of compliance deficiencies. 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 general quality 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 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.

STAAR's activities as a sponsor of biomedical research are subject to review by the FDA's Bioresearch Monitoring branch. On June 26, 2007, the Company received a Warning Letter from the U.S. Food and Drug Administration ("FDA") citing four areas of noncompliance noted during an inspection by BIMO of the Company's clinical study procedures, practices, and documentation related to the TICL. BIMO conducted the inspection between February 15 and March 14, 2007. The Warning Letter notes deviations from FDA regulations that occurred between 2002 and 2005, which were among eight matters observed in the Inspectional Observations on FDA Form 483 received by the Company on March 14, 2007, and to which STAAR responded on April 5, 2007. STAAR provided its written response to the Warning Letter to the FDA on July 31, 2007. The response detailed revisions by STAAR to enhance key processes and procedures involved in initiating and monitoring clinical studies and a detailed discussion of their intended corrective effect. STAAR reported that all revised procedures had been approved and that all affected internal staff had been trained, and the response included a schedule for the training of external personnel in the enhanced procedures. STAAR believes that it has comprehensively addressed the concerns of the FDA; however, if the FDA does not find the Company's response adequate, further administrative action could follow, including actions that could further delay approval of the TICL or restrict the Corporation as a sponsor of clinical investigations.

BIMO inspections are part of a program designed to ensure that data and information contained in requests for Investigational Device Exemptions (IDE), Premarket Approval (PMA) applications, and Premarket Notification submissions (510k) are scientifically valid and accurate. Another objective of the program is to ensure that human subjects are protected from undue hazard or risk during the course of scientific investigations. While the past procedural violations noted in the Warning Letter are serious in nature and required comprehensive corrective and preventative actions, the Company does not believe that these nonconformities undermine the scientific validity and accuracy of its clinical data, or that human subjects were subjected to undue hazard or risk. However, as noted above, the ODE, with reference largely to the same deficiencies noted in the Warning Letter, has placed STAAR's pending application for approval of the TICL on integrity hold and will require STAAR to establish the accuracy and completeness of the clinical data through an independent audit before further considering the submission.

Financing Strategy

While STAAR's international business generates positive cash flow and 65% of STAAR's revenue, STAAR has reported losses on a consolidated basis over the last 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 the last three years STAAR has secured additional capital to sustain operations through public and private sales of equity securities, exercise of options, the repayment of directors' notes and debt financing.

STAAR's management believes that in the near term its best prospect for achieving profitability in its U.S. and consolidated operations is to significantly increase U.S. sales of the ICL. In the longer term STAAR 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, STAAR is not likely to achieve positive cash flow on a consolidated basis during fiscal 2007 or 2008. In addition, STAAR's cash resources will be affected by the $4 million cash consideration to be paid at the anticipated closing of the Canon Staar buy-out on or soon after December 28, 2007.

STAAR may seek additional debt or equity financing to fund the Canon Staar transactions or other acquisitions or strategic initiatives, provide working capital or expand its business. Because of our history of losses, our ability to obtain adequate financing on satisfactory terms is limited. STAAR's cash resources are discussed in further detail under the caption "Liquidity and Capital Resources" below.

Canon Staar Joint Venture

Pending Buy-Out. STAAR is the 50% owner of a Japan-based joint venture, Canon Staar Co., Inc. ("Canon Staar"), which manufactures the Preloaded Injector, a silicone or acrylic intraocular lens packaged and shipped in a pre-sterilized, disposable injector ready for use in cataract surgery. The co-owners of the joint venture are the Japanese optical company Canon, Inc. and its affiliated marketing company, Canon Marketing Japan Inc. ("Canon Marketing"). On October 25, 2007 STAAR entered into a Share Purchase Agreement (the "Share Purchase Agreement") with Canon Inc. and Canon Marketing (collectively referred to as the "Canon companies") to acquire all of the Canon companies' interests in Canon Staar and obtain 100% ownership of Canon Staar.

The following summary of the Share Purchase Agreement (including the forms of ancillary agreements attached as exhibits) is qualified in its entirety by reference to the Share Purchase Agreement, which has been incorporated by reference to this Quarterly Report.

The Share Purchase Agreement provides that the closing will occur on the later of December 28, 2007 or the date on which all conditions to closing are satisfied. At closing STAAR will pay the $4 million cash consideration and 1.7 million shares of Series A Convertible Preferred Stock to the Canon companies, and the Canon companies will deliver all their shares of Canon Staar to STAAR.

Each share of Preferred Stock to be issued to the Canon companies will be convertible for five years at the option of the holder into one share of STAAR's common stock and will automatically convert after five years into one share of STAAR's common stock. The Preferred Stock will be redeemable at the option of the holders at a price of $4 per share (plus accrued or declared but unpaid dividends) on the occurrence of a change in control or liquidation of STAAR or at any time after the third anniversary of the issuance date. The rights, preferences, privileges and obligations of the Series A Convertible Preferred Stock will be established in a Certificate of Designation attached as an exhibit to the Share Purchase Agreement, and to be filed with the Delaware Secretary of State.

STAAR's obligation to complete the transaction is subject to the satisfaction of customary conditions to closing, which include the following:

- BDO Sanyu, the auditors of Canon Staar, will have provided reviewed financial statements, including balance sheet, for the quarter and nine months ended September 30, 2007 for Canon Staar;
    - an audit by STAAR will have confirmed the inventory of Canon Staar products listed by Canon Marketing;
- STAAR's due diligence will not have discovered any event, action or change that has had or could have a material adverse effect on the business, operations, properties or conditions (financial or otherwise) of Canon Staar, other than with respect to any matter arising in connection with Canon Staar's Bylaws, Rules of Organization, Rules for Job Functions and Rules for the Use of the Application for Approval or Impression of Seal (the "Internal Regulations"); and
- the Japanese Ministry of Health and Welfare will have approved Canon Staar's acting as a seller of products directly to end users.

The Share Purchase Agreement requires STAAR to file with the Securities and Exchange Commission a "shelf" registration statement providing for the public resale of the shares issuable on conversion of the Series A Preferred Stock (the "Conversion Shares") within 30 days after issuance of the Preferred Stock. Subject to customary black-out periods the registration statement will remain in force until the Conversion Shares may be sold freely under Rule 144(k). STAAR will use best efforts to have the registration statement declared effective within 180 days. If it fails to do so, STAAR will issue 30,000 shares of common stock for each month (or partial month) in which effectiveness has not been obtained, and each month when availability of the registration is suspended (apart from permitted black-out periods) while the obligation to maintain effectiveness is in place.

The Canon companies agree that for a period of three years after the closing they will not directly manage, operate or engage in research, development, manufacture, marketing, sale or distribution of implantable silicone and collagen copolymer intraocular lenses whether phakic or aphakic, whether spheric or aspheric, and insertion devices for such implants and collagen glaucoma wicks (collectively the "Business") or acquire a controlling ownership interest in any entity that manages, operates or engages in the Business (other than conducting research and development activities) in Japan and has aggregate annual sales of products connected with the Business in excess of $1 million.

At the closing STAAR and Canon Marketing will enter into an Inventory Sales Agreement in the form attached to the Share Purchase Agreement (the "Inventory Sales Agreement"), which provides for the repurchase by Canon Staar of all Canon Staar product inventory owned by Canon Marketing (the "Repurchased Inventory"). The Inventory Sales Agreement provides that at the end of each month during the first year after the closing Canon Staar will pay Canon Marketing for the Repurchased Inventory Canon Staar has sold in the preceding month. The price paid to Canon Marketing will be the same price Canon Marketing originally paid Canon Staar for the Repurchased Inventory (the "Original Purchase Price"), except for sales in China of the KS-XI model acrylic Preloaded Injector, for which the price will be 50% of Canon Staar's sales price to the customer. On the first anniversary of the closing Date Canon Staar will pay Canon Marketing the Original Purchase Price for any remaining Repurchased Inventory (except the Model KS-XI) that has not yet been sold by Canon Staar and that has a shelf through at least October 25, 2009. Canon Staar will continue to pay Canon Marketing for KS-XI inventory only after its sale by Canon Staar. At and following closing all accounts receivable and accounts payable between Canon Marketing and Canon Staar will be reconciled and any net amount owed by either party will be paid.

At closing Canon Staar and the Canon companies will enter into secondment agreements covering employees of the Canon companies who will work for Canon Staar after the Closing, including employees of Canon Marketing involved in the marketing of Canon Staar products. Also at closing releases will be entered into by each of STAAR, the Canon companies and Canon Staar related to the prior conduct of the joint venture and uses of confidential information.

STAAR's investment in Canon Staar is currently reflected on STAAR's financial statements using the equity method of accounting. Following the buy-out Canon Staar will be a wholly owned subsidiary of STAAR and its results of operations and financial condition will be consolidated with STAAR's for reporting purposes.

Canon Staar Joint Venture - Background STAAR currently owns 50% of Canon Staar and the Canon companies own the remaining 50%. In addition to Canon Staar's current business of manufacturing the Preloaded Injector, Canon Staar is also seeking approval from the Japanese regulatory authorities to market in Japan STAAR's Visian ICL and TICL, Collamer IOL and AquaFlow Device. Canon Staar recorded worldwide sales of $10.4 million in fiscal year 2006. Canon Marketing distributes the Preloaded Injector in Japan, while STAAR's Swiss subsidiary, STAAR AG, distributes the silicone Preloaded Injector in Europe and Australia, and on a non-exclusive basis in China and some other international markets. Canon Staar's silicone-lens-based Preloaded Injector was introduced in Japan in 2002 and internationally in 2003. The acrylic Preloaded Injector, introduced in Japan in 2006, employs a lens supplied by a Japanese ophthalmic company.

Canon Staar was created in 1988 pursuant to a Joint Venture Agreement between STAAR and the Canon companies for the principal purpose of designing, manufacturing, and selling in Japan intraocular lenses and other ophthalmic products. The joint venture agreement provides that Canon Staar will not directly distribute its products but will distribute them worldwide through the Canon companies, STAAR and such other distributors as the Board of Directors of Canon Staar may approve. The terms of any such distribution arrangement must be unanimously approved by the Canon Staar Board.

Several other matters require the unanimous approval of the Canon Staar Board of Directors, including appointment of key officers or directors with specific titles, acquiring or disposing of assets exceeding 20% of Canon Staar's total book value, borrowing in the principal amount of more than 20% of Canon Staar's total book value and granting a lien on any of Canon Staar's assets or contractual rights in excess of 20% of Canon Staar's total book value. STAAR is entitled to appoint, and has appointed, two of the five Canon Staar Board members. The president of Canon Staar is to be appointed, and has been appointed, by STAAR.

The Joint Venture Agreement contains numerous default provisions that give the non-defaulting party the right to acquire the defaulting party's entire interest in Canon Staar at book value. For this purpose, a party is in default under

the Joint Venture Agreement (1) if the party cannot pay its debts or files for bankruptcy or similar protection, or voluntarily or involuntarily liquidates, (2) if the party defaults in its obligations under the Joint Venture Agreement and fails to cure the default within 90 days of receiving notice of default, (3) if the party undergoes a merger, acquisition or sale of substantially all of its assets, (4) if a material change occurs in management of the party, or (5) if any person or entity attempts to acquire all or a substantial portion of the party's capital stock by a tender offer or otherwise, or attempts to acquire a substantial portion of the party's business or assets.

The Joint Venture Agreement provides that the joint venture will be dissolved and its assets liquidated if an event of "force majeure" occurs, such as natural disaster, war, strike or governmental order, and the continuation of the event has a material adverse effect on the operations of Canon Staar. The joint venture will also be dissolved and its assets liquidated if a problem that materially affects Canon Staar or the continuation of its operations is not resolved after six months' negotiation.

In accordance with the Joint Venture Agreement, in 1988 Canon Staar and STAAR entered into a Technical Assistance and Licensing Agreement (the "TALA"), pursuant to which STAAR granted to the joint venture an irrevocable, exclusive license to STAAR's technology to make, have made, use, sell, lease or otherwise dispose of any products in Japan. The Joint Venture Agreement also gives Canon Staar a right of first refusal on any distribution of STAAR's products in Japan, contemplates a Distribution Agreement to cover the resulting arrangement, gives Canon Staar the right to purchase from STAAR manufacturing equipment and tooling necessary to manufacture intraocular lenses, and contemplates a Supply Agreement to cover the resulting arrangement, The Joint Venture Agreement also contemplates that the relevant parties will enter into a Company's Name License Agreement giving Canon Staar a license to use the founding parties' names. To date, the parties have not entered into any such Distribution Agreement, Supply Agreement or Company's Name License Agreement.

Under the TALA, STAAR granted Canon Staar a royalty free, fully paid-up, irrevocable, exclusive license to make, have made, use, sell, lease or otherwise dispose of any products in Japan using or incorporating STAAR's "Licensed Technology." "Licensed Technology" means all intellectual property relating to intraocular lenses, surgical packs, phacoemulsification machines, ophthalmic solutions, other pharmaceuticals and medical equipment, owned or controlled by STAAR as of the date of the TALA or thereafter. Under the TALA, STAAR also granted Canon Staar a royalty-free, fully paid-up, irrevocable, non-exclusive license to use, sell, lease or otherwise dispose of any products in the rest of the world using or incorporating STAAR's "Licensed Technology." The TALA also provides that STAAR will provide the Licensed Technology in written or other tangible form to enable Canon Staar to make, sell and service products and provide training and consulting services in connection with the manufacture of products. In consideration of the licenses and rights granted by STAAR under the TALA, Canon Staar paid STAAR $3 million. The TALA continues in effect until such time as the parties agree to terminate it.

In 2001, the joint venture parties, including Canon Staar, entered into a Settlement Agreement under which they reconfirmed the Joint Venture Agreement and the TALA and STAAR agreed promptly to commence the transfer to Canon Staar under the TALA of all of its new or advanced technology, including technology related to collamer IOL, glaucoma wicks and ICL. In the Settlement Agreement STAAR also granted Canon Staar a royalty free, fully paid-up, perpetual, exclusive license to use STAAR's Licensed Technology to make and have made any products in China and sell such products in Japan and China (subject to STAAR's existing licenses and the existing rights of third parties). The Settlement Agreement also provided that STAAR would enter into a raw material supply agreement covering the supply of raw materials to Canon Staar and would continue to supply raw materials under existing arrangements until execution of the supply agreement. The Settlement Agreement further provided that Canon Marketing would enter into a distribution agreement with Canon Staar governing Canon Marketing's status as Canon Staar's exclusive distributor in Japan. The distribution agreement would provide that the selling prices by Canon Staar of its products to Canon Marketing will be in the range of 50% to 70% of the sales price of the products from Canon Marketing to its end customers through its own sales channel, with the pricing to be reviewed annually and subject to unanimous approval of the Canon Staar Board. The Settlement Agreement provides that until the distribution agreement is executed the Canon Staar will sell its products to Canon Marketing at its then current prices, provided the prices are within the 50-70% range. The parties also settled certain patent disputes. To date, the parties have not entered into the supply agreement or distribution agreement.

At the closing of the pending Canon Staar buy-out, the Joint Venture Agreement, the TALA and the material provisions of the Settlement Agreement will be terminated.

Canon Staar has a single class of capital stock, of which STAAR owns 50%. Accordingly, STAAR is entitled to 50% of any dividends or distributions by Canon Staar and 50% of the proceeds of any liquidation.

The foregoing description of the joint venture agreement, TALA and Settlement Agreement is qualified in its entirety by the full text of such agreements, which have been filed as exhibits or incorporated by reference to this report. The joint venture agreement, TALA and Settlement Agreement are governed by the laws of Japan, and contain provisions

that may be open to different interpretations. Accordingly, these agreements may be interpreted in a manner that may be materially adverse to the interests of STAAR, and any description of these agreements is subject to uncertainty. See "Risk Factors — We have licensed our technology to our joint venture company, which could cause our joint venture company to become a competitor"; and "Risk Factors — Our interest in Canon Staar may be acquired for book value on the occurrence of specified events, including a change in control of STAAR.

Domilens GmbH

Domilens GmbH is a wholly owned indirect subsidiary of STAAR Surgical Company based in Hamburg, Germany. Domilens distributes ophthalmic products made by both STAAR and other manufacturers. During fiscal year 2006 Domilens reported sales of $21.1 million.

During the first quarter of 2007 STAAR learned that the president of of Domilens, Guenther Roepstorff, had misappropriated significant corporate assets. Mr. Roepstorff resigned shortly after the disclosure and STAAR conducted an extensive internal inquiry under the direction of the Audit Committee of STAAR's Board of Directors. The results of this investigation are described in detail in STAAR's Annual Report on Form 10-K for the fiscal year ended December 29, 2006.

The investigation determined that fraudulent activities by Mr. Roepstorff between 2001 through 2006 diverted assets having a book value of approximately $400,000. Based on the investigation, STAAR concluded that the events at Domilens revealed a material weakness in its internal controls over financial reporting, and that increased oversight was necessary to reduce the risk of recurrence.

Foreign Currency Fluctuations. Our products are sold in approximately 50 countries. Sales from international operations represented 65% of total sales for the quarter ended September 28, 2007. 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.

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 there have been no significant changes during the three months ended September 28, 2007 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 29, 2006.

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		*Percentage Change for Three Months*	*Percentage of Total Sales for Nine Months*		*Percentage Change for Nine Months*
	September 28, 2007	September 29, 2006	2007 vs. 2006	September 28, 2007	September 29, 2006	2007 vs. 2006
Sales	100.0%	100.0%	2.4%	100.0%	100.0%	4.7%
Cost of sales	50.3	52.4	(1.7)	51.0	52.7	1.5
Gross profit	49.7	47.6	6.9	49.0	47.3	8.4
General and administrative	21.0	19.5	10.4	22.0	19.5	17.8
Marketing and selling	42.4	38.3	13.5	39.6	37.5	10.3
Research and development	12.8	12.5	4.4	11.5	12.6	(3.8)
Note reserve reversal	0.0	(2.5)	(100.0)	--	(0.8)	(100.0)
Operating loss	(26.5)	(20.2)	34.2	(24.1)	(21.6)	17.2
Total other expense, net	(3.0)	0.8	--	(2.0)	0.2	--
Loss before income taxes	(29.5)	(19.5)	55.4	(26.1)	(21.3)	28.5
Provision (benefit) for income taxes	(1.4)	1.5	--	0.8	1.3	(34.9)
Net loss	(28.1)%	(20.9)%	37.3%	(26.9)%	(22.6)%	25.0%

Net Sales

We generally experience lower sales during the third quarter due to the effect of summer vacations on elective procedures. In particular, because sales activity in Europe drops dramatically in July and August, and European sales have accounted for a greater proportion of our total sales, this seasonal variation in our results has become even more pronouced.

Net sales for the three and nine months ended September 28, 2007 increased 2.4% and 4.7% to $13,629,000 and $43,478,000 compared with the $13,313,000 and $41,511,00 reported for the same periods of 2006. The favorable impact of changes in currency for the three and nine month periods of 2007 was approximately $471,000 and $1,462,000, respectively.

International sales for the third quarter were $8,889,000, up 16.9% compared with $7,608,000 reported in the same period of last year. During the third quarter, international sales of refractive products grew 44.9% to $2,290,000 compared with the $1,581,000 reported for the third quarter of 2006. The increase in refractive product sales is due to increased sales of ICLs and TICLs which represented 97.8% of total refractive sales in international during the third quarter. International cataract sales for the third quarter were $6,532,000, up 9.6% compared with $5,959,000 reported

in the same period of the prior year due to the favorable effect of currency and increased sales of the Company's German subsidiary.

International sales for the first nine months of 2007 were $28,487,000, up 16.6% compared with the same period of 2006. During the first nine months of 2007, international sales of refractive products grew 41.7% to $7,783,000 compared with the $5,492,000 reported for the first nine months of 2006. The increase in refractive product sales is due to increased sales of ICLs and TICLs which represented 98.0% of total refractive sales in international during the period. International cataract sales for the first nine months of 2007 were $20,489,000, up 9.3% compared with $18,742,000 reported for the same period of 2006 due largely to the effect of currency, but also due to favorable effect of currency and increased sales of the Company's German subsidiary.

Total U.S. sales for the third fiscal quarter of 2007 were $4,739,000, down 16.9% compared with $5,705,000 reported in the same period of 2006. Third quarter U.S. refractive product sales decreased 16.2% to $1,106,000, compared with the $1,321,000 reported for the third quarter of 2006. The decrease in refractive product sales is due primarily to decreased sales of ICLs which represented 95.0% of total refractive sales in the U.S. during the quarter and to decreased sales of other refractive products.

Total U.S. sales for the first nine months of 2007 were $14,991,000, down 12.2% compared with $17,080,000 in the same period of 2006. U.S. refractive products sales during the first nine months of 2007 were $3,276,000, down 4.6% compared with the same period of 2006. The decrease in refractive product sales is due to decreased sales of ICLs which represented 94.6% of total refractive sales in the U.S. during the period and to decreased sales of other refractive products. U.S. cataract product sales for the first nine months of 2007 were $11,467,000, down 14.1% compared with $13,341,000 reported for the same period of 2006. The decline in U.S. cataract sales is due, in part, to a shift in market preference from spherical IOLs to aspheric IOLs. The Company introduced its first aspheric IOL made of Collamer during the second quarter and anticipates introducing a silicone aspheric IOL in the fourth quarter of 2007 which should allow the Company to compete more effectively in this market segment. Additionally, the Company believes that disruption in sales activity in the period before two sales representative agreements expired on July 31, 2007 may have had some impact on cataract sales in their regions for both the three and nine month periods of 2007.

Gross Profit Margin

Gross profit margin for the three and nine months ended September 28, 2007 was 49.7% and 49.0%, compared with 47.6% and 47.3% for the three and nine months ended September 29, 2006. The increase in gross profit margin was principally due to an increase in high margin refractive sales.

General and Administrative

General and administrative expenses for the three months ended September 28, 2007 were up 10.4% or $270,000 over the three months ended September 29, 2006 and up 17.8% or $1,446,000 for the same year-to-date period. The increase in general and administrative expenses for the quarter was primarily due to increased international travel associated with increased oversight of foreign subsidiaries and increased bank charges associated with the termination of the Wells Fargo credit line. The increase in general and administrative expenses for the nine month period was primarily due to costs associated with the Domilens investigation, increased international travel associated with increased oversight of foreign subsidiaries, increased bank charges associated with the termination of the Wells Fargo credit line and increased insurance costs.

Marketing and Selling

Marketing and selling expenses for the three months ended September 28, 2007 increased 13.5% or $686,000 compared with the three months ended September 29, 2006 and increased 10.3% or $1,613,000 compared with the nine months ended September 29, 2006. The increase for both periods is primarily due to increased salaries and benefits due to increased headcount globally, the unfavorable effect of currency on expenses, partially offset by decreased U.S. commissions. Marketing and selling expense for the nine month period was also impacted by increased travel costs.

Research and Development

Research and development expenses, including regulatory and clinical expenses, for the third quarter of 2007, increased 4.4% or $73,000 compared with the three months ended September 29, 2006 due to increased salaries and benefits including severance costs. Research and development expenses for the nine months ended September 28, 2007 decreased 3.8% primarily due to lower activity associated with regulatory submissions.

Other Expense

Other expense for the three and nine month periods of 2007 was $409,000 and $880,000, compared with income reported for the same periods in 2006 of $104,000 and $99,000. Other expense increased in both periods due to inventory reserves and sales allowances recorded by the Company's Japanese joint venture in connection with Canon Marketing's decision to discontinue distribution of one of the joint venture's products, increased interest expense from capital lease transactions and foreign exchange losses partially offset by an increase in interest income. For the nine-month period, other expense also increased due to the write-off of deferred financing costs and losses from the extinguishment of the Broadwood Partners L.P. note. These expenses were partially offset by $148,000 fair value adjustment upon revaluation of the Broadwood warrant obligation at September 28, 2007.

Income Tax Provision (Benefit)

During the quarter the Company reached a settlement with the German Ministry of Finance related to taxes assessed in connection with unreported sales of a company controlled by the former President of Domilens, GmbH. As a result of the settlement, the Company reversed approximately $460,000 in income tax expense originally recorded in the fourth quarter of 2006, based on the best information available to management at that time.

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 domestic and foreign lenders, the sales of Common Stock, the repayment of former directors' notes, and the exercise of stock options.

As of September 28, 2007 and December 29, 2006, the Company had $14.2 million and $7.8 million, respectively, of cash and cash equivalents.

Cash used in operating activities was $8.5 million for the nine months ended September 28, 2007 versus $6.9 million for the nine months ended September 29, 2006. The increase in cash used for operating activities was primarily due to payments associated with the Domilens investigation, costs incurred in evaluating financing options, interest expense of the Broadwood note, and increased salaries and travel.

Cash used in investing activities was $0.2 million for the nine months ended September 28, 2007 versus $0.7 million for the nine months ended September 29, 2006. Cash used in investing activities was primarily the result of purchases of property, plant and equipment, the effect of which was partially offset by dividends received from the Company's Japanese joint venture.

Net cash provided by financing activities was $15.0 million for the nine months ended September 28, 2007 versus $2.9 million for the nine months ended September 29, 2006. Cash provided by financing activities for the nine months ended September 28, 2007 principally resulted from $16,613,000 in net proceeds from the private placement of 3,600,000 shares of common stock, partially offset by the repayment of a $1.8 million bank loan.

Accounts receivable at September 28, 2007 decreased $0.6 million relative to December 29, 2006. The decrease in accounts receivable relates primarily to decreased sales. Day's sales outstanding (DSO) were 40 days at September 28, 2007 compared to 39 days at December 29, 2006. The Company expects to maintain DSO within a range of 40 to 45 days during the course of the 2007 fiscal year.

Public Equity Offering

To provide additional working capital, STAAR completed a public offering of its common stock on May 1, 2007. In the offering, STAAR sold 3,600,000 shares of common stock at price to the public of $5 per share, which yielded approximately $16.6 million net proceeds to STAAR. All shares of the common stock offered by STAAR were sold pursuant to a shelf registration statement that was declared effective by the SEC on August 8, 2006 as supplemented by an additional registration statement filed on April 25, 2007 pursuant to Rule 462(b) under the Securities Act of 1933. After the June 20, 2007 repayment of $4 million in indebtedness incurred under a Promissory Note with Broadwood Partners, L.P., which is discussed below, the remaining proceeds of the public offering will be used for working capital and other general corporate purposes. STAAR believes that with the proceeds of the public offering, along with expected cash from operations, it has sufficient cash to meet its funding requirements over the next year. The public offering included all of the securities available for issuance under STAAR's previously filed shelf registration.

STAAR's liquidity requirements arise from the funding of its working capital needs, primarily inventory, work-in-process and accounts receivable. While STAAR's international business generates positive cash flow and represents approximately 66% of consolidated net sales, we have 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. As a result, during recent periods cash flow from operations has not been sufficient to satisfy our need for working capital and STAAR has relied on additional sources, including proceeds of the private placement of equity securities, proceeds of option exercises and borrowings on our lines of credit.

STAAR's management believes that in the near term its best prospect for achieving profitability in its U.S. and consolidated operations is to significantly increase U.S. sales of the ICL. To date, sales growth of ICLs has been slower than expected. In the longer term STAAR 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, STAAR is not likely to achieve positive cash flow on a consolidated basis during fiscal 2007 or 2008.

Credit Facilities

The Company and its subsidiaries have credit facilities with different lenders to support operations in the U.S., 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 provided for borrowings of 85% of eligible accounts receivable with a maximum of $3.0 million, carried an interest rate of prime plus 1.5%, and was secured by substantially all of the assets of the Company's U.S. operations. The term of the agreement was three years and it contained certain financial covenants, among others, relating to minimum calculated net worth, net loss, liquidity and restrictions on Company investments or loans to affiliates and investments in capital expenditures. On September 27, 2007 STAAR terminated the Wells Fargo Bank facility in accordance with the terms of the Credit and Security Agreement.

On March 21, 2007, STAAR entered into a loan arrangement with Broadwood Partners, L.P. ("Broadwood"). The note was fully repaid on June 20, 2007.

As additional consideration for the loan STAAR also entered into a Warrant Agreement (the "Warrant Agreement") with Broadwood granting the right to purchase up to 70,000 shares of Common Stock at an exercise price of $6, exercisable for a period of six years. The warrant agreement provided that STAAR will register the stock for resale with the SEC.

The Company's lease agreement with Farnam Street Financial, Inc., as amended on October 9, 2006, provided for purchases of up to $1,500,000 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 three-year term. Under the agreement, the Company has the option to purchase any item of the leased property, at the end of the respective items lease terms, at a mutually agreed fair value. On April 1, 2007, the Company signed an additional leasing schedule with Farnam, which provides for additional purchases of $800,000 during the next fiscal year. The terms of this new schedule conform to the amended agreement dated October 9, 2006. Approximately $491,000 in borrowings was available under this facility as of September 28, 2007.

The Company's lease agreement with Mazuma Capital Corporation, as amended on August 16, 2006, provided for purchases of up to $301,000 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 was 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 28, 2007, the Company had a certificate of deposit for approximately $150,000 recorded as "short-term investment — restricted" with a 12-month term at a fixed interest rate of 4.5%. The agreement also provides that the Company may elect to purchase any item of the leased property at the end of its lease term for $1. No borrowings were available under this facility as of September 28, 2007.

The Company's German subsidiary, Domilens, entered into a credit agreement at August 30, 2005. The renewed credit agreement provides for borrowings of up to 100,000 EUR ($141,000 at the rate of exchange on September 28, 2007), at a rate of 8.5% per annum and does not have a termination date. The credit agreement may be terminated by the lender in accordance with its general terms and conditions. The credit facility is not secured. There were no borrowings outstanding as of September 28, 2007 and December 29, 2006 and the full amount of the line was available for borrowing as of September 28, 2007. The Company was in compliance with all terms of the agreements as of September 28, 2007.

As of September 28, 2007, the Company had a current ratio of 2.7:1, net working capital of $23.1 million and net equity of $39.1 million compared to December 29, 2006 when the Company's current ratio was 2.0:1, its net working capital was $14.2 million, and its net equity was $31.8 million.

The Company believes through effective cost management it has sufficient cash on hand to finance its current operations through 2008 and into 2009 and has taken measures aimed at reducing the global use of cash to approximately $2.0 million per quarter, or $8.0 million per year. Improvement in US sales, particularly growth in US ICL sales, could improve cash flow further, as could continued growth in international markets which we expect. However, the pending acquisition of the remaining 50% equity interest in Canon Staar will obligate the Company to pay $4.0 million at closing. To conserve existing cash for operations, we may elect to finance all or a portion of the purchase price and costs associated with the acquisition.

The Company's liquidity requirements arise from the funding of its working capital needs, primarily inventory, work-in-process and accounts receivable. In addition, STAAR's cash resources maybe affected by the $4,000,000 cash consideration that will be paid at the anticipated closing of the Canon Staar buy-out on or soon after December 28, 2007. The Company's primary sources for working capital and capital expenditures are cash flow from operations,

which are largely dependent on the success of the ICL, proceeds of the public offering of common stock completed in the second fiscal quarter, and proceeds from option exercises. 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. Given the Company's history of losses and negative cash flows, it is possible that the Company could find it necessary to supplement its sources of capital with additional financing to sustain operations until the Company returns to profitability.

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.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as that term is defined in the rules of the SEC, that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors.

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 29, 2006.

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.

Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

The Company's management, with the participation of the CEO and the 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 and the identification of the material weakness in internal controls over financial reporting described below, the CEO and the CFO concluded that, as of the end of the period covered by this quarterly report on Form 10-Q, the Company's disclosure controls and procedures were not effective.

Internal Control over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Exchange Act Rule 13a-15(f) and for assessing the effectiveness of its internal control over financial reporting. Our internal control system is designed to provide reasonable assurance to our management and Board of Directors regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States.

As discussed in our Annual Report on Form 10-K for the fiscal year ended December 29, 2006, the Audit Committee of the Company's Board of Directors commenced in January 2007 an independent investigation into reports to the Company's management that Guenther Roepstorff, president of Domilens GmbH, a subsidiary of STAAR located in Germany, had admitted to the German Federal Ministry of Finance that without STAAR's knowledge he had diverted

property of Domilens with a book value of approximately $400,000 to a company under his control over a four-year period between 2001 and 2004. Mr. Roepstorff made this admission in connection with an audit conducted by the Ministry in 2006, which examined the financial records of Mr. Roepstorff, Domilens and the company to which he diverted the property, Equimed GmbH (currently known as eyemaxx GmbH), covering the four-year period. During the course of the investigation, the Company found that in addition to the diversions of property admitted by Mr. Roepstorff, payments were made to Mr. Roepstorff disguised as prepayments to suppliers and unauthorized borrowing occurred.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. In connection with the assessment described above, management identified a material weakness as of December 29, 2006 which was discussed in the Company’s Annual Report on Form 10-K filed with the Commission on March 29, 2007. Because the Company’s remediation efforts remained in progress, management identifies the same material weakness as of September 28, 2007, the end of the period covered by this report, as described below:

Failure to design and maintain controls over and in its German subsidiary sufficient to detect and prevent management override and fraud

- *Control Environment* The Company did not maintain an effective control environment because of the following: (a) the Company did not adequately and consistently reinforce the importance of adherence to controls and the Company's code of conduct; (b) the Company failed to institute all elements of an effective program to help prevent and detect fraud by Company employees; and (c) the Company did not maintain effective corporate and regional management oversight and monitoring of operations to detect managements' override of established financial controls and accounting policies, execution of improper transactions and accounting entries to impact revenue and earnings, and reporting of these transactions to the appropriate finance personnel or the Company's independent registered public accounting firm.

Because of the material weakness described above, management concluded that our internal control over financial reporting was not effective. We have been implementing improvements to our internal controls to address the aforementioned material weakness and lack of effectiveness in our disclosure controls and internal controls, and continue to do so. As of the date of this report we have not been able to conclude that the material weakness identified above has been rectified. The Company has taken the following corrective actions:

- obtained the immediate resignation of the president of Domilens GmbH
- hired a new president of Domilens in October 2007
- enhanced monitoring and oversight from STAAR's Swiss and U.S. operations
- held meetings to discuss the Company's Code of Ethics and whistleblower policies with subsidiary employees as a bridge to more formal training
- assigned oversight of corporate compliance programs and training to its corporate legal counsel
- terminated the Director of Finance of our Swiss subsidiary, who was responsible for oversight of financial affairs and internal reporting at Domilens
- hired a new international controller based at Domilens
  re-educated employees in STAAR's Code of Ethics
- enhanced whistleblower program for international operations of STAAR
- reinforced the certification process to emphasize senior manager's accountability for maintaining an ethical environment
- sent a team of managers from the corporate IT and Finance departments to evaluate the adequacy of the controls and procedures at Domilens
- conducted a visit by members of the Audit Committee to Domilens' facility in early August to interview employees, reinforce policies and assess the effectiveness of remedial actions.

There was no change during the fiscal quarter ended September 28, 2007 that has materially affected, or is reasonably likely to materially affect the Company's internal control over financial reporting.

While we continue to devote significant resources to meeting the internal control over financial reporting requirements of the rules adopted by the SEC pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we cannot assure you that the policies and procedures we have adopted and our continued efforts will successfully remediate the material

weakness we have identified and any control deficiencies or material weaknesses that we or our outside auditors may identify before the end of our fiscal year.

Our management, including the CEO and the CFO, do not expect that our disclosure controls and procedures or our internal control over financial reporting will necessarily prevent all fraud and material errors. An internal control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations on all internal control systems, our internal control system can provide only reasonable assurance of achieving its objectives and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of internal control is also based in part upon certain assumptions about the likelihood of future events, and can provide only reasonable, not absolute, assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in circumstances, or the degree of compliance with the policies and procedures may deteriorate.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Moody v. STAAR Surgical Company; Parallax Medical Systems, Inc. v. STAAR Surgical Company. On September 21, 2007, Scott C. Moody, Inc. and Parallax Medical Systems, Inc. filed substantially identical complaints against STAAR in the Superior Court of California, County of Orange. Moody and Parallax are former independent regional manufacturer's representatives ("RMRs") of STAAR whose contracts with STAAR expired on July 31, 2007. They claim, among other things, that STAAR interfered with the plaintiffs' contracts when it caused some of their current or former subcontractors to enter into new agreements to represent STAAR products, and that STAAR interfered with the plaintiffs' prospective economic advantage when it informed a regional IOL distributor that each of the RMR's contracts had a covenant restricting the sale of competing products. Moody claims general and compensatory damages of $32 million and Parallax claims general and compensatory damages of $48 million, and both plaintiffs request punitive damages. At this early stage of the litigation, STAAR is unaware of any facts that substantiate these claims and believes them to be without merit. It intends vigorously to oppose the claims and intends to assert claims for affirmative relief against both plaintiffs. The plaintiffs offer no factual basis for the magnitude of their claims; STAAR believes there is no such basis and that it should not be liable for any amount of damages. Nevertheless, the outcome of litigation is never certain and the possibility that the plaintiffs will recover under their claims cannot be eliminated at this time. STAAR has not reserved funds against a negative outcome in the lawsuits. An unexpected negative outcome in these cases or litigation costs that are much greater than anticipated could result in material harm to STAAR's business.

The Company has asserted its right under the California Code of Civil Procedure to early discovery of any evidence supporting the plaintiffs' claims. In its sworn testimony, Parallax failed to provide evidence that supported the amount of damages claimed. As a result, STAAR continues to believe that Parallax's claims for damages are without merit. STAAR expects to obtain sworn testimony from the other plaintiff in the near future.

The disclosure of the *Moody* and *Parallax* lawsuits in this Item 1 of Part II of its Quarterly Report on Form 10-Q is not intended to imply that these lawsuits, either individually or in aggregate, are material to STAAR.

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

Investment in securities of STAAR Surgical Company involves a high degree of risk. You should carefully consider the risks described below before making a decision to invest in the common stock. These risks are not the only ones we face.

Risks Related to Our Business

We have a history of losses and anticipate future losses.

We have reported losses in each of the last several fiscal years and have an accumulated deficit of $98.4 million as of September 28, 2007. There can be no assurance that we will report net income in any future period.

We have only limited working capital and limited access to financing.

Our cash requirements continue to exceed the level of cash generated by operations and we expect to continue to seek additional resources to support and expand our business, such as debt or equity financing. Because of our history of losses and negative cash flows, our ability to obtain adequate financing on satisfactory terms is limited. 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, and if our stock has a low market price at the time of such sales our existing stockholders could experience substantial dilution. An inability to secure additional financing could prevent the expansion of our business and jeopardize our ability to continue operations.

We may have limited ability to fully use our recorded tax loss carryforwards.

We have accumulated approximately $89.4 million of tax loss carryforwards as of December 29, 2006 to be used in future periods if we become profitable. If we were to experience a significant change in ownership, Internal Revenue Code Section 382 may restrict the future utilization of these tax loss carryforwards even if we become profitable.

FDA compliance issues have harmed our reputation and we expect to devote significant resources to maintaining compliance in the future.

The Office of Compliance of the FDA's Center for Devices and Radiological Health regularly inspects STAAR's facilities to determine whether we are in compliance with the FDA Quality System Regulations relating to such things as manufacturing practices, validation, testing, quality control, product labeling and complaint handling, and in compliance with FDA Medical Device Reporting regulations and other FDA regulations. The FDA also regularly inspects for compliance with regulations governing clinical investigations.

Based on the results of the FDA inspections of STAAR's Monrovia, California facilities in 2005 and 2006, STAAR believes that it is substantially in compliance with the FDA's Quality System Regulations and Medical Device Reporting regulations. However, between December 29, 2003 and July 5, 2005 we received Warning Letters and other correspondence indicating that the FDA found STAAR's Monrovia, California facility in violation of applicable regulations, warning of possible enforcement action and suspending approval of new implantable devices. The FDA's findings of compliance deficiencies during that period harmed our reputation in the ophthalmic industry, affected our product sales and delayed FDA approval of the ICL.

On June 26, 2007 the Company received a Warning Letter from the FDA citing four areas of noncompliance noted by the FDA's Bioresearch Monitoring branch during its inspection of STAAR's clinical study procedures, practices, and documentation related to the TICL. STAAR provided its written response to the Warning Letter to the FDA on July 31, 2007. If the FDA does not find the Company's response adequate, further administrative action could follow, including actions that could restrict STAAR as a sponsor of clinical investigations or preclude approval of the application for approval of the TICL. The deficiencies cited in the Warning Letter have also been cited by the Office of Device Evaluation in a letter placing an integrity hold on the TICL application. While BIMO's oversight covers clinical research, rather than the manufacturing, quality and device reporting issues that have been STAAR's greatest focus in its recent compliance initiatives, STAAR believes that the negative publicity from the BIMO observations and Warning Letter has made it more difficult for STAAR to overcome the harm to its reputation resulting from past FDA proceedings.

STAAR's ability to continue its U.S. business depends on the continuous improvement of its quality systems and its compliance with FDA regulations. Accordingly, for the foreseeable future STAAR's management expects its strategy to include devoting significant resources and attention to those efforts. STAAR cannot ensure that its efforts will be successful. Any failure to demonstrate substantial compliance with FDA regulations can result in enforcement actions that terminate, suspend or severely restrict our ability to continue manufacturing and selling medical devices. Please see the related risks discussed under the headings *"We are subject to extensive government regulation, which increases our costs and could prevent us from selling our products"* and *"We are subject to federal and state regulatory investigations."*

Our strategy to restore profitability in the near term relies on successfully penetrating the U.S. refractive market.

While products to treat cataracts continue to account for the majority of our revenue, we believe that increased income generated by sales of our Visian ICL refractive products, especially in the U.S., presents a near term opportunity for a return to profitability. The FDA approved the Visian ICL for treatment of myopia on December 22, 2005. Selling and marketing the ICL has presented a challenge to our sales and marketing staff and to our independent manufacturers'

representatives. In the U.S. patients who might benefit from the ICL have already been exposed to a great deal of advertising and publicity about laser refractive surgery, but have little if any awareness of the ICL. In addition, established refractive surgeons frequently have large and well developed practices that are oriented entirely toward the delivery of laser procedures. In countries where the ICL has been approved, our sales have grown steadily but slowly, and the U.S. appears to be following this pattern. A surgeon interested in implanting the ICL must first schedule training and certification and invest time in the training process. While STAAR has sufficient resources to make training available to qualified surgeons with minimal delay, the need to undergo training continues to limit the pace at which interested surgeons can begin providing the ICL to their patients. STAAR employs advertising and promotion targeted to potential patients through providers, but has limited resources for these purposes. Failure to successfully market the ICL in the U.S. will delay and may prevent growth and profitability.

FDA Approval of the Toric ICL, which could have a significant U.S. market, may be significantly delayed.

Part of STAAR's strategy to increase U.S. sales of refractive products has been a plan to introduce the Toric ICL, or TICL, a variant of the ICL that corrects both astigmatism and myopia in a single lens and that is marketed outside the U.S. STAAR believes the TICL also has a significant potential market in the U.S. and could accelerate growth of the overall refractive product line. STAAR submitted a premarket approval application (PMA) supplement for the TICL to the FDA on April 28, 2006, and received comments from the Office of Device Evaluation (ODE) on November 20, 2006 requesting that STAAR amend parts of the submission. On August 3, 2007 STAAR received a letter from ODE notifying STAAR that the TICL application would be placed on integrity hold until STAAR completed specified actions to the satisfaction of the FDA, including engaging an independent third party auditor to conduct a 100% data audit of patient records along with a clinical systems audit to ensure accuracy and completeness of data before submitting amendments to the application for the FDA's review. Satisfying the requirements in the August 3 letter will likely delay any approval of the TICL. STAAR has engaged an independent auditor in order to satisfy the requirements of the August 3 letter. An independent audit will delay the approval of the TICL and STAAR cannot ensure that the auditor will ultimately be able to establish to the satisfaction of the FDA the accuracy and completeness of data supporting the TICL Application. If STAAR is required to conduct additional clinical studies, significant further delays and costs would likely result.

Our core domestic business has suffered declining sales, which sales of new products have only begun to offset.

The foldable silicone IOL was once our largest source of sales. Since we introduced the product, however, competitors have introduced IOLs employing a variety of designs and materials. Over the years these products have taken an increasing share of the IOL market, while the market share for STAAR silicone IOLs has decreased. In particular, many surgeons now choose lenses made of acrylic material rather than silicone for their typical patients. In addition, our competitors have begun to offer multifocal or accommodating lenses that claim to reduce the need for cataract patients to use reading glasses; the market for these "presbyopic" lenses is expected to grow as a segment of the cataract market. Our newer line of IOLs made of our proprietary biocompatible Collamer material, while intended to reverse the trend of declining domestic cataract product sales, may not permit us to recover the market share lost over the last several years.

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

In many countries where STAAR sells its products, doctors, including ophthalmologists, 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 affects sales of our products. For example, in fiscal year 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. Such problems could occur again in Germany or other regions and, 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.

Our sales are subject to significant seasonal variation.

We generally experience lower sales during the third quarter due to the effect of summer vacations on elective procedures. In particular, because sales activity in Europe drops dramatically in July and August, and European sales have recently accounted for a greater proportion of our total sales, this seasonal variation in our results has become even more pronounced.

We may lose customers or sales as the result of the restructuring of our sales force and the non-renewal of agreements with regional manufacturers' representatives.

In August 2007 STAAR began a comprehensive restructuring of its U.S. sales model and moved away from its historical reliance on independent regional manufacturers' representatives to promote sales of its products. This coincides with STAAR's election not to renew its last two long-term contracts with regional manufacturer's representatives, which covered the southwestern and southeastern U.S. and expired on July 31, 2007. STAAR is organizing a direct sales force to sell its Visian ICL refractive products, and a mixed direct/independent sales force to sell cataract products. This transition results in a number of risks to STAAR and its business, including the following:

- In the regions affected by contracts STAAR elected not to renew, a number of independent representatives will cease selling STAAR products. Customers, in particular long-time customers for cataract products, may not transfer their loyalty to STAAR's new representatives.

- Customers may be lost due to lack of service while replacement representatives are recruited and trained.

- Newly recruited sales representatives may initially be less familiar with our products and our customer base, and accordingly be less effective, than the representatives they replace.

- STAAR's restructured refractive sales force will be subject to the risks of direct sales, including the need to recruit and retain key personnel to establish and maintain customer relationships and manage local representatives.

- If we do not properly implement the transition to our new sales model, we could lose customers, our U.S. refractive sales may fail to grow or decline and our U.S. cataract sales may continue to decline.

Product recalls have been costly and may be so in the future.

Medical devices must be manufactured to the highest standards and tolerances, and often incorporate newly developed technology. From time to time defects or technical flaws in our products may not come to light until after the products are sold or consigned. In those circumstances, we have previously made voluntary recalls of our products. Similar recalls could take place again. We may also be subject to recalls initiated by manufacturers of products we distribute. Courts or regulators can also impose mandatory recalls on us, even if we believe our products are safe and effective. Recalls can result in lost sales of the recalled products themselves, and can result in further lost sales while replacement products are manufactured, especially if the replacements must be redesigned. If recalled products have already been implanted, we may bear some or all of the cost of corrective surgery. Recalls may also damage our professional reputation and the reputation of our products. The inconvenience caused by recalls and related interruptions in supply, and the damage to our reputation, could cause professionals to discontinue using our products.

We could experience losses due to product liability claims.

We have been subject to product liability claims in the past and continue to be so. Our third-party product liability insurance coverage has become more expensive and difficult to procure. Product liability claims against us may exceed the coverage limits of our insurance policies or cause us to record a loss in excess of our deductible. A product liability claim in excess of applicable insurance could have a material adverse effect on our business, financial condition and results of operations. Even if any product liability loss is covered by an insurance policy, these policies have retentions or deductibles that provide that we will not receive insurance proceeds until the losses incurred exceed the amount of those retentions or deductibles. To the extent that any losses are below these retentions or deductibles, we will be responsible for paying these losses. The payment of retentions or deductibles for a significant amount of claims could have a material adverse effect on our business, financial condition, and results of operations.

Any product liability claim would divert managerial and financial resources and could harm our reputation with customers. We cannot assure you that we will not have product liability claims in the future or that such claims would not have a material adverse effect on our business.

We compete with much larger companies.

Our competitors, including Alcon, Advanced Medical Optics and Bausch & Lomb, have much greater financial resources than we do and some of them have large international markets for a full suite of ophthalmic products. Their greater resources for research, development and marketing, and their greater capacity to offer comprehensive products and equipment to providers, make it difficult for us to compete. We have lost significant market share to some of our competitors.

Most of our products have single-site manufacturing approvals, exposing us to risks of business interruption.

We manufacture all of our products either at our facilities in California or at our facility in Switzerland. Most of our products are approved for manufacturing only at one of these sites. Before we can use a second manufacturing site for

an implantable device we must obtain the approval of regulatory authorities. Because this process is expensive, we have generally not sought approvals needed to manufacture at an additional site. If a natural disaster, fire, or other serious business interruption struck one of our manufacturing facilities, it could take a significant amount of time to validate a second site and replace lost product. We could lose customers to competitors, thereby reducing sales, profitability and market share.

The global nature of our business may result in fluctuations and declines in our sales and profits.

Our products are sold in approximately 50 countries. Sales from international operations make up a significant portion of our total sales. For the three months ended September 28, 2007, sales from international operations were 65% of our total sales. The results of operations and the financial position of certain of our offshore 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 translation risk. In addition, we are exposed to transaction risk because some of our expenses are incurred in a different currency from the currency in which our sales are received. Our most significant currency exposures are to the Euro, the Swiss Franc, and the Australian dollar. The exchange rates between these and other local currencies and the U.S. dollar may fluctuate substantially. We have not attempted to offset our exposure to these risks by investing in derivatives or engaging in other hedging transactions.

Economic, social and political conditions, laws, practices and local customs vary widely among the countries in which we sell our products. Our operations outside of the U.S. are subject to a number of risks and potential costs, including lower profit margins, less stringent protection of intellectual property and economic, political and social uncertainty in some countries, especially in emerging markets. Our continued success as a global company depends, in part, on our ability to develop and implement policies and strategies that are effective in anticipating and managing these and other risks in the countries where we do business. These and other risks may have a material adverse effect on our operations in any particular country and on our business as a whole. We price some of our products in U.S. dollars, and as a result changes in exchange rates can make our products more expensive in some offshore markets and reduce our sales. Inflation in emerging markets also makes our products more expensive there and increases the credit risks to which we are exposed.

The success of our international operations depends on our successfully managing our foreign subsidiaries.

We conduct most of our international business through wholly owned subsidiaries. Managing distant subsidiaries and fully integrating them into STAAR's business is challenging. While STAAR seeks to integrate its foreign subsidiaries fully into its operations, direct supervision of every aspect of their operations is impossible, and as a result STAAR relies on its local managers and staff. Cultural factors and language differences can result in misunderstandings among internationally dispersed personnel. These risks will increase when the Canon Staar joint venture becomes a wholly owned subsidiary of STAAR at the completion of the pending buy-out. The risk that unauthorized conduct may go undetected will always be greater in foreign subsidiaries. For example, in early 2007 STAAR learned that the president of its German sales subsidiary, Domilens GmbH, had misappropriated corporate assets. Some countries may also have laws or cultural factors that make it difficult to impose uniform standards and practices. For example, while STAAR's Code of Ethics requires all employees to certify they are not aware of code violations by others, German legal counsel has advised STAAR that in Germany it cannot legally compel ordinary employees (that is, non-supervisors) to notify STAAR of breaches by others. STAAR believes the absence of such a requirement in its Code of Ethics for German employees is a risk inherent to doing business in Germany that may be mitigated, but not entirely eliminated, by other controls.

We obtain some of the components of our products from a single source, and an interruption in the supply of those components could reduce our sales.

We obtain some of the components for our products from a single source. For example, only one supplier produces our viscoelastic product. The loss or interruption of any of these suppliers could increase costs, reducing our sales and profitability, or harm our customer relations by delaying product deliveries. Even when substitute suppliers are available, the need to certify regulatory compliance and quality standards of substitute suppliers could cause significant delays in production and a material reduction in our sales. Even when secondary sources are available, the failure of one of our suppliers could be the result of an unforeseen industry-wide problem, or the failure of our supplier could create an industry-wide shortage affecting secondary suppliers as well.

Our activities involve hazardous materials and emissions and may subject us to environmental liability.

Our manufacturing, research and development practices involve the use of hazardous materials. We are subject to federal, state and local laws and regulations in the various jurisdictions in which we have operations governing the use, manufacturing, storage, handling and disposal of these materials and certain waste products. We cannot completely eliminate the risk of accidental contamination or injury from these materials. Remedial environmental actions could require us to incur substantial unexpected costs, which would materially and adversely affect our results of operations. If we were involved in a major environmental accident or found to be in substantial non-compliance with applicable environmental laws, we could be held liable for damages or penalized with fines.

We risk losses through litigation.

From time to time we are party 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. While 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, new claims or unexpected results of existing claims could lead to significant financial harm.

We depend on key employees.

We depend on the continued service of our senior management and other key employees. The loss of a key employee could hurt our business. We could be particularly hurt if any key employee or employees went to work for competitors. Our future success depends on our ability to identify, attract, train, motivate and retain other highly skilled personnel. Failure to do so may adversely affect our results.

We have licensed our technology to our joint venture company, which could cause our joint venture company to become a competitor.

We have granted to our Japanese joint venture, Canon Staar Co. Inc., an irrevocable, exclusive license to make, have made and sell products using our technology in Japan. We have also granted Canon Staar an irrevocable, exclusive license to make and have made products using our technology in China and to sell such products made in China in China and Japan. In addition, we have granted Canon Staar an irrevocable, non-exclusive license to sell products using our technology in the rest of the world. It is the intent of the Joint Venture Agreement that products be marketed indirectly through Canon, Inc., Canon Marketing Japan Inc., their subsidiaries, STAAR, and other distributors that the Canon Staar Board approves. The grant of such licenses and rights under STAAR's technology may result in Canon Staar becoming a competitor of STAAR, which could materially reduce STAAR's revenues and profits. If the pending buy-out of the Canon companies' interests in Canon Staar does not close as expected, STAAR will remain subject to these risks. See *"Management's Discussion and Analysis of Financial Condition and Results of Operations — Canon Staar Joint Venture."*

Our interest in Canon Staar may be acquired for book value on the occurrence of specified events, including a change in control of STAAR.

If STAAR becomes insolvent or enters bankruptcy, dissolves, enters into a merger or other reorganization, is the subject of a take-over attempt or experiences other events of default under the joint venture agreement, the other joint venture partners will have the right to acquire STAAR's interest in Canon Staar at book value. Book value of STAAR's 50% interest in Canon Staar was $3.6 million as of December 31, 2006. Book value may not represent the fair value of STAAR's interest in Canon Staar, and depending on the future condition of Canon Staar's business it may represent only a small fraction of fair value. STAAR's interest in Canon Staar is valued in Japanese yen and its value in U.S. dollars may vary significantly with fluctuations in currency exchange rates. If the pending buy-out of the Canon companies' interests in Canon Staar does not close as expected, STAAR will remain subject to these risks. See *"Management's Discussion and Analysis of Financial Condition and Results of Operations — Canon Staar Joint Venture."*

Our pending purchase of the Canon companies' interests in the joint venture is subject to closing conditions and to integration challenges.

On October 25, 2007 STAAR entered into a Share Purchase Agreement with Canon Inc. and Canon Marketing Japan Inc. to acquire all of the Canon companies' interests in the Canon Staar joint venture. The Share Purchase Agreement is subject to numerous risks and uncertainties, including the following:

- the need of the parties to satisfy contractual conditions before the Share Purchase Agreement may close,

- the risk that STAAR may elect to close the transaction even if some conditions are not met or it discovers negative information about Canon Staar prior to closing,

- the risk that STAAR may not successfully integrate the Canon Staar business or its employees into its overall business,

- the risk that key employees of Canon Staar may leave after closing,

- the risk that removal of the Canon name from Canon Staar and its products may reduce its goodwill or the acceptance of its products,

- the risk that Canon Staar may not sustain current or prior sales levels or achieve projected levels,

- the risk that STAAR's limited access to information has limited its ability to assess the projections provided to STAAR by Canon Staar's management,

- the risk that Japanese regulators may not approve the sale of the ICL or Collamer,

- the risk of operating a foreign subsidiary with limited direct oversight, the risk that applying U.S. accounting standards and controls and procedures over financial reporting may be more difficult, more expensive or more time-consuming than anticipated,

- STAAR's need to rely on the completeness and accuracy of information provided during its investigation of Canon Staar's business, and

- the risk that financing for the transaction or for additional working capital purposes may be more difficult to obtain than anticipated and may not be available on reasonable terms, if at all.

Changes in accounting standards could affect our financial results.

The accounting rules applicable to public companies like STAAR are subject to frequent revision. Future changes in accounting standards could require us to change the way we calculate income, expense or balance sheet data, which could result in significant change to our reported results of operation or financial condition.

We are subject to international tax laws that could affect our financial results.

STAAR conducts international operations through its subsidiaries. Tax laws affecting international operations are highly complex and subject to change. STAAR’s payment of income tax in the different countries where it operates depends in part on internal settlement prices and administrative charges among STAAR and its subsidiaries. These arrangements require judgments by STAAR and are subject to risk that tax authorities will disagree with those judgments and impose additional taxes, penalties or interest on STAAR. In addition, transactions that STAAR has arranged in light of current tax rules could have unforeseeable negative consequences if tax rules change.

If we suffer loss to our facilities due to catastrophe, our operations could be seriously harmed.

We depend on the continuing operation of our manufacturing facilities in California and Switzerland, which have little redundancy or overlap among their activities. Our facilities are subject to catastrophic loss due to fire, flood, earthquake, terrorism or other natural or man-made disasters. Our California facilities are in areas where earthquakes could cause catastrophic loss. If any of these facilities were to experience a catastrophic loss, it could disrupt our operations, delay production, shipments and revenue and result in large expenses to repair or replace the facility. Our insurance for property damage and business interruption may not be sufficient to cover any particular loss, and we do not carry insurance or reserve funds for interruptions or potential losses arising from earthquakes or terrorism.

If we are unable to protect our information systems against data corruption, cyber-based attacks or network security breaches, our operations could be disrupted.

We are significantly dependent on information technology networks and systems, including the Internet, to process, transmit and store electronic information. In particular, we depend on our information technology infrastructure for electronic communications among our locations around the world and between our personnel and our subsidiaries, customers, and suppliers. Security breaches of this infrastructure can create system disruptions, shutdowns or unauthorized disclosure of confidential information. If we are unable to prevent such security breaches, our operations could be disrupted or we may suffer financial damage or loss because of lost or misappropriated information.

Risks Related to the Ophthalmic Products Industry

If we fail to keep pace with advances in our industry or fail to persuade physicians to adopt the new products we introduce, customers may not buy our products and our sales may decline.

Constant development of new technologies and techniques, frequent new product introductions and strong price competition characterize the ophthalmic industry. The first company to introduce a new product or technique to market usually gains a significant competitive advantage. Our future growth depends, in part, on our ability to develop products to treat diseases and disorders of the eye that are more effective, safer, or incorporate emerging technologies better than our competitors' products. Sales of our existing products may decline rapidly if one of our competitors introduces a superior product, or if we announce a new product of our own. If we fail to make sufficient investments in research and development or if we focus on technologies that do not lead to better products, our current and planned products could be surpassed by more effective or advanced products. In addition, we must manufacture these products economically and market them successfully by persuading a sufficient number of eye-care professionals to use them. For example, glaucoma requires ongoing treatment over a long period; thus, many doctors are reluctant to switch a patient to a new treatment if the patient's current treatment for glaucoma remains effective. This has been a challenge in selling our AquaFlow Device.

Resources devoted to research and development may not yield new products that achieve commercial success.

We spent 11.5% of our sales on research and development during the nine months ended September 28, 2007, and we expect to spend approximately 10% for this purpose in future periods. Development of new implantable technology, from discovery through testing and registration to initial product launch, is expensive and typically takes from three to seven years. Because of the complexities and uncertainties of ophthalmic research and development, products we are currently developing may not complete the development process or obtain the regulatory approvals required for us to market the products successfully. Any of the products currently under development may fail to become commercially successful.

Changes in reimbursement for our products by third-party payors could reduce sales of our products or make them less profitable.

Many of our products, in particular IOLs and products related to the treatment of glaucoma, are used in procedures that are typically covered by health insurance, HMO plans, Medicare, Medicaid, or other governmental sponsored programs in the U.S. and Europe. Third party payors in both government and the private sector continue to seek to manage costs by restricting the types of procedures they reimburse to those viewed as most cost-effective and by capping or reducing reimbursement rates. Whether they limit reimbursement prices for our products or limit the surgical fees for a procedure that uses our products, these policies can reduce the sales volume of our reimbursed products, their selling prices or both. In some countries government agencies control costs by limiting the number of surgical procedures they will reimburse. For example, a recent reduction in the number of authorized cataract procedures in Germany has affected the sales of our German subsidiary, Domilens. Similar changes could occur in our other markets. The U.S. Congress has considered legislative proposals that would significantly change the system of public and private health care reimbursement, and will likely consider such changes again in the future. We are not able to predict whether new legislation or changes in regulations will take effect at the state or federal level, but if enacted these changes could significantly and adversely affect our business.

We are subject to extensive government regulation, which increases our costs and could prevent us from selling our products.

STAAR is regulated by regional, national, state and local agencies, including the Food and Drug Administration, the Department of Justice, the Federal Trade Commission, the Office of the Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies, as well as governmental authorities in those foreign countries in which we manufacture or distribute products. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal and state statutes and regulations govern the research, development, manufacturing and commercial activities relating to medical devices, including their pre-clinical and clinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information and promotion. We are also subject to government regulation over the prices we charge and the rebates we offer to customers. Complying with government regulation substantially increases the cost of developing, manufacturing and selling our products.

In the U.S., we must obtain approval from the FDA for each product that we market. Competing in the ophthalmic products industry requires us to introduce new or improved products and processes continuously, and to submit these to the FDA for approval. Obtaining FDA approval is a long and expensive process, and approval is never certain. In addition, our operations are subject to periodic inspection by the FDA and international regulators. An unfavorable outcome in an FDA inspection may result in the FDA ordering changes in our business practices or taking other enforcement action, which could be costly and severely harm our business.

Our new products could take a significantly longer time than we expect to gain regulatory approval and may never gain approval. If a regulatory authority delays approval of a potentially significant product, the potential sales of the

product and its value to us can be substantially reduced. Even if the FDA or another regulatory agency approves a product, the approval may limit the indicated uses of the product, or may otherwise limit our ability to promote, sell and distribute the product, or may require post-marketing studies. If we cannot obtain timely regulatory approval of our new products, or if the approval is too narrow, we will not be able to market these products, which would eliminate or reduce our potential sales and earnings.

Regulatory investigations and allegations, whether or not they lead to enforcement action, can materially harm our business and our reputation.

Failure to comply with the requirements of the FDA or other regulators can result in civil and criminal fines, the recall of products, the total or partial suspension of manufacture or distribution, seizure of products, injunctions, whistleblower lawsuits, failure to obtain approval of pending product applications, withdrawal of existing product approvals, exclusion from participation in government healthcare programs and other sanctions. Any threatened or actual government enforcement action can also generate adverse publicity and require us to divert substantial resources from more productive uses in our business. Enforcement actions could affect our ability to distribute our products commercially and could materially harm our business.

From time to time STAAR is subject to formal and informal inquiries by regulatory agencies, which could lead to investigations or enforcement actions. Even when an inquiry results in no evidence of wrongdoing, is inconclusive or is otherwise not pursued, the agency generally is not required to notify STAAR of its findings and may not inform STAAR that the inquiry has been terminated.

As a result of widespread concern about backdating of stock options and similar conduct among U.S. public companies, during 2006 and early 2007 STAAR conducted an investigation of its practices from 1993 to the present in granting stock options to employees, directors and consultants. STAAR's investigation did not find evidence of fraud, deliberate backdating or similar practices. The investigation did uncover evidence of frequent administrative errors and delays, which STAAR investigated further and determined, would not have a material effect on its historical financial statements, either individually or in aggregate. STAAR believes that its investigation, while limited in scope, was reasonably designed to detect fraud and backdating and determine any material effect on its financial statements. However, STAAR cannot ensure that a more exhaustive investigation would not find additional errors or irregularities in option granting practices, the effect of which could be material.

STAAR maintains a hotline for employees to report any violation of laws, regulations or company policies anonymously, which is intended to permit STAAR to identify and remedy improper conduct. Nevertheless, present or former employees may elect to bring complaints to regulators and enforcement agencies. The relevant agency will generally be obligated to investigate such complaints to assess their validity and obtain evidence of any violation that may have occurred. Even without a finding of misconduct, negative publicity about investigations or allegations of misconduct could harm our reputation with professionals and the market for our common stock. Responding to investigations can be costly, time-consuming and disruptive to our business.

We depend on proprietary technologies, but may not be able to protect our intellectual property rights adequately.

We rely on contractual provisions, confidentiality procedures and patent, trademark, copyright and trade secrecy laws to protect the proprietary aspects of our technology. These legal measures afford limited protection and may not prevent our competitors from gaining access to our intellectual property and proprietary information. Any of our patents may be challenged, invalidated, circumvented or rendered unenforceable. Any of our pending patent applications may fail to result in an issued patent or fail to provide meaningful protection against competitors or competitive technologies. Litigation may be necessary to enforce our intellectual property rights, to protect our trade secrets and to determine the validity and scope of our proprietary rights. Any litigation could result in substantial expense, may reduce our profits and may not adequately protect our intellectual property rights.

In addition, we may be exposed to future litigation by third parties based on claims that our products infringe their intellectual property rights. This risk is exacerbated by the fact that the validity and breadth of claims covered by patents in our industry may involve complex legal issues that are open to dispute. Any litigation or claims against us, whether or not successful, could result in substantial costs and harm our reputation. Intellectual property litigation or claims could force us to do one or more of the following:

- cease selling or using any of our products that incorporate the challenged intellectual property, which would adversely affect our sales;

- negotiate a license from the holder of the intellectual property right alleged to have been infringed, which license may not be available on reasonable terms, if at all; or

- redesign our products to avoid infringing the intellectual property rights of a third party, which may be costly and time-consuming or impossible to accomplish.

We may not successfully develop and launch replacements for our products that lose patent protection.

Most of our products are covered by patents that, if valid, give us a degree of market exclusivity during the term of the patent. We have also earned revenue in the past by licensing some of our patented technology to other ophthalmic companies. The legal life of a patent in the U.S. is 20 years from application. Patents covering our products will expire from this year through the next 20 years. Upon patent expiration, our competitors may introduce products using the same technology. As a result of this possible increase in competition, we may need to reduce our prices to maintain sales of our products, which would make them less profitable. If we fail to develop and successfully launch new products prior to the expiration of patents for our existing products, our sales and profits with respect to those products could decline significantly. We may not be able to develop and successfully launch more advanced replacement products before these and other patents expire.

Risks Related to Ownership of Our Common Stock

Our charter documents and contractual obligations could delay or prevent an acquisition or sale of our company.

Our Certificate of Incorporation empowers the Board of Directors to establish and issue a class of preferred stock, and to determine the rights, preferences and privileges of the preferred stock. These provisions give the Board of Directors the ability to deter, discourage or make more difficult a change in control of our company, even if such a change in control could be deemed in the interest of our stockholders or if such a change in control would provide our stockholders with a substantial premium for their shares over the then-prevailing market price for the common stock. Our contractual obligations, including with respect to Canon Staar, could discourage a potential acquisition of our company. Our bylaws contain other provisions that could have an anti-takeover effect, including the following:

· stockholders have limited ability to remove directors;

· stockholders cannot act by written consent;

· stockholders cannot call a special meeting of stockholders; and

· stockholders must give advance notice to nominate directors.

Anti-takeover provisions of Delaware law could delay or prevent an acquisition of our company.

We are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock or preventing changes in our management.

The market price of our common stock is likely to be volatile.

Our stock price has fluctuated widely, ranging from $2.75 to $8.64 during the twelve month period ended September 28, 2007. Our stock price will likely continue to fluctuate in response to factors such as quarterly variations in operating results, operating results that vary from the expectations of securities analysts and investors, changes in financial estimates, changes in market valuations of competitors, announcements by us or our competitors of a material nature, additions or departures of key personnel, future sales of Common Stock and stock volume fluctuations. Also, general political and economic conditions such as recession or interest rate fluctuations may adversely affect the market price of our stock.

Future sales of our common stock could reduce our stock price.

Our Board of Directors could issue additional shares of common or preferred stock to raise additional capital or for other corporate purposes without stockholder approval. In addition, the Board of Directors could designate and sell a class of preferred stock with preferential rights over the common stock with respect to dividends or other distributions. Sales of common or preferred stock could dilute the interest of existing stockholders and reduce the market price of our common stock. Even in the absence of such sales, the perception among investors that additional sales of equity securities may take place could reduce the market price of our common stock.

ITEM 6. EXHIBITS

Exhibits

3.1	Certificate of Incorporation, as amended to date.(1)
3.2	By-laws, as amended to date.(1)
10.65	Share Purchase Agreement dated October 25, 2007 by and between Canon Marketing Japan Inc. and Canon Inc. as Sellers and the Company as Buyer.(2)
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.(*)

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

(2) Incorporated by reference to Exhibit 10.65 to the Company's Current Report on Form 8-K filed with the Commission on October 31, 2007.

(*) Filed herewith.

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

Date: November 7, 2007

By: /s/ DEBORAH ANDREWS
Deborah Andrews

Chief Financial Officer
(on behalf of the Registrant and as its chief accounting officer)