

STAAR SURGICAL CO  
Form 10-Q  
November 04, 2008

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

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Form 10-Q

(Mark One)

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
**For the quarterly period ended: September 26, 2008**
- Or
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
**For the transition period from        to**

**Commission file number: 0-11634**

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**STAAR SURGICAL COMPANY**

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

**Delaware**  
*(State or other jurisdiction of  
incorporation or organization)*

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer     Accelerated filer     Non-accelerated filer     Smaller reporting company

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(Do not check if a smaller  
reporting company)

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

The registrant has 29,496,494 shares of common stock, par value \$0.01 per share, issued and outstanding as of November 4, 2008.

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**STAAR SURGICAL COMPANY****INDEX**

	PAGE NUMBER
<b>PART I – FINANCIAL INFORMATION</b>	
Item 1.	Financial Statements (Unaudited).
	Condensed Consolidated Balance Sheets – September 26, 2008 and December 28, 2007. 1
	Condensed Consolidated Statements of Operations – Three and Nine Months Ended September 26, 2008 and September 28, 2007. 2
	Condensed Consolidated Statements of Cash Flows – Nine Months Ended September 26, 2008 and September 28, 2007. 3
	Notes to the Condensed Consolidated Financial Statements. 4
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations. 18
Item 3.	Quantitative and Qualitative Disclosures About Market Risk. 34
Item 4.	Controls and Procedures. 34
<b>PART II – OTHER INFORMATION</b>	
Item 1.	Legal Proceedings. 35
Item 1A.	Risk Factors. 35
Item 6.	Exhibits. 37
Signatures	38

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

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

	September 26, 2008	December 28, 2007
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 6,697	\$ 10,895
Short-term investments – restricted	—	150
Accounts receivable, net	10,076	6,898
Inventories	15,821	12,741
Prepays, deposits and other current assets	1,962	1,610
Total current assets	34,556	32,294
Property, plant and equipment, net	5,921	5,772
Intangible assets, net	6,383	3,959
Goodwill	7,773	7,534
Advance payment for acquisition of Canon Staar	—	4,000
Other assets	1,028	620
Total assets	\$ 55,661	\$ 54,179
<b>LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Line of credit	\$ 1,880	\$ —
Accounts payable	6,363	4,823
Obligations under capital leases – current	896	822
Deferred income taxes – current	105	102
Other current liabilities	6,932	5,541
Total current liabilities	16,176	11,288
Note payable – long-term, net of discount	4,346	4,166
Obligations under capital leases – long-term	1,184	1,311
Deferred income taxes – long-term	690	570
Other long-term liabilities	1,715	619
Total liabilities	24,111	17,954
Commitments and contingencies (Note 14)		
Series A redeemable convertible preferred stock, \$0.01 par value; 10,000 shares authorized, 1,700 and no shares issued and outstanding at September 26, 2008 and December 28, 2007; respectively. Liquidation value \$6,800.	6,764	—
Stockholders' equity:		

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Common stock, \$0.01 par value; 60,000 shares authorized; issued and outstanding 29,496 at September 26, 2008 and 29,488 at December 28, 2007	295	295
Additional paid-in capital	138,450	137,075
Accumulated other comprehensive income	2,472	1,551
Accumulated deficit	(116,431)	(102,696)
Total stockholders' equity	24,786	36,225
Total liabilities, redeemable convertible preferred stock and stockholders' equity	\$ 55,661	\$ 54,179

*See accompanying notes to the condensed consolidated financial statements.*

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

	Three Months Ended		Nine Months Ended	
	September 26, 2008	September 28, 2007	September 26, 2008	September 28, 2007
Net sales	\$ 18,112	\$ 13,629	\$ 56,737	\$ 43,478
Cost of sales	7,654	6,859	26,990	22,176
Gross profit	10,458	6,770	29,747	21,302
General and administrative	3,480	2,868	11,441	9,581
Marketing and selling	6,514	5,775	20,627	17,223
Research and development	1,890	1,743	5,965	4,987
Loss on settlement of pre-existing distribution arrangement	—	—	3,850	—
Operating loss	(1,426)	(3,616)	(12,136)	(10,489)
Other income (expense):				
Equity in operations of joint venture	—	(365)	—	(280)
Interest income	47	134	138	322
Interest expense	(222)	(128)	(645)	(445)
Loss on foreign currency exchange	(473)	(94)	(329)	(118)
Other (expense), net	63	44	130	(359)
Other expense, net	(585)	(409)	(706)	(880)
Loss before provision (benefit) for income taxes	(2,011)	(4,025)	(12,842)	(11,369)
Provision (benefit) for income taxes	239	(195)	893	339
Net loss	\$ (2,250)	\$ (3,830)	\$ (13,735)	\$ (11,708)
Loss per share – basic and diluted	\$ (0.08)	\$ (0.13)	\$ (0.47)	\$ (0.42)
Weighted average shares outstanding – basic and diluted	29,490	29,374	29,489	27,993

*See accompanying notes to the condensed consolidated financial statements.*

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

	<b>Nine Months Ended</b>	
	<b>September 26, 2008</b>	<b>September 28, 2007</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (13,735)	\$ (11,708)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation of property, plant and equipment	2,055	1,463
Amortization of intangible assets	625	361
Amortization of discount	180	17
Loss on extinguishment of note payable	—	233
Fair value adjustment of warrant	60	(148)
Loss on disposal of property and equipment	89	150
Equity in operations of joint venture	—	280
Stock-based compensation expense	1,195	1,074
Loss on settlement of pre-existing distribution arrangement	3,850	—
Other	106	107
<b>Changes in working capital, net of effects from purchase of Canon Staar:</b>		
Accounts receivable	(2,482)	630
Inventories	1,613	(242)
Prepays, deposits and other current assets	434	(677)
Accounts payable	(1,892)	(636)
Other current liabilities	665	583
Net cash used in operating activities	(7,237)	(8,513)
<b>Cash flows from investing activities:</b>		
Cash acquired in acquisition of Canon Staar, net of acquisition costs	2,215	—
Acquisition of property, plant and equipment	(802)	(368)
Proceeds from sale of property, plant, and equipment	100	12
Dividend received from joint venture	—	117
Net change in other assets	149	6
Net cash provided by (used in) investing activities	1,662	(233)
<b>Cash flows from financing activities:</b>		
Borrowings under notes payable	—	4,000
Repayment of notes payable	—	(4,000)
Borrowings under lines of credit	3,760	1,812
Repayment of lines of credit	(1,880)	(3,610)
Repayment of capital lease lines of credit	(762)	(444)
Net proceeds from public sale of equity securities	—	16,613
Proceeds from the exercise of stock options	40	584
Net cash provided by financing activities	1,158	14,955
Effect of exchange rate changes on cash and cash equivalents	219	229
(Decrease) increase in cash and cash equivalents	(4,198)	6,438

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Cash and cash equivalents, at beginning of the period	10,895	7,758
Cash and cash equivalents, at end of the period	\$ 6,697	\$ 14,196

*See accompanying notes to the condensed consolidated financial statements.*



**STAAR SURGICAL COMPANY**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**September 26, 2008**  
**(Unaudited)**

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

The condensed balance sheet as of December 28, 2007 included in this report, which has been derived from audited financial statements, and the accompanying unaudited interim condensed consolidated financial statements, have been prepared in accordance with accounting principles generally accepted in the U.S. for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities Exchange Commission. Accordingly, they do not include all the information and footnotes required by accounting principles generally accepted in the U.S. for complete financial statements. The condensed consolidated financial statements for the three and nine months ended September 26, 2008 and September 28, 2007, in the opinion of management, include all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the Company's 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 28, 2007.

The results of operations for the three and nine months ended September 26, 2008 and September 28, 2007 are not necessarily indicative of the results to be expected for any other interim period or for the entire year.

Each of the Company's reporting periods ends on the Friday nearest to the quarter ending date and generally consists of 13 weeks. Unless the context indicates otherwise "we," "us," the "Company," and "STAAR" refer to STAAR Surgical Company and its consolidated subsidiaries.

*Prior Year Reclassifications*

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

*New Accounting Pronouncements*

In October 2008, the Financial Accounting Standards Board ("FASB") issued FSP No. FAS 157-3, "Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active" ("FSP No. FAS 157-3"), which clarifies the application of SFAS No. 157 in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. The FSP is effective upon issuance, including prior periods for which financial statements have not been issued. Revisions resulting from a change in the valuation technique or its application should be accounted for as a change in accounting estimate following the guidance in SFAS No. 154, "Accounting Changes and Error Corrections" ("SFAS No. 154"). However, the disclosure provisions in SFAS No. 154 for a change in accounting estimate are not required for revisions resulting from a change in valuation technique or its application. This FSP is effective in the Company's fourth quarter of fiscal year 2008. The Company is assessing the impact of this FSP however, management does not believe that the adoption of this FSP will have a material effect on the Company's consolidated financial position and results of operations.

**Note 2 — Acquisition of STAAR Japan**

On December 29, 2007 (the "Closing Date"), during STAAR's 2008 fiscal year, STAAR acquired the remaining 50% of the shares of Canon Staar Co., Inc. ("Canon Staar") that had been owned previously by Canon Inc. and Canon

Marketing Japan Inc. (“Canon Marketing” and, collectively with Canon Inc., the “Canon companies”). In the transaction (the “Acquisition”), STAAR obtained 100% ownership of Canon Staar, which was renamed STAAR Japan, Inc. (“STAAR Japan”) as of the acquisition date. Prior to the Acquisition, Canon Staar was a joint venture owned 50% by STAAR and 50% by the Canon companies and operating under a Joint Venture Agreement since 1988. STAAR accounted for its investment in Canon Staar as an equity method investor. As of the closing date of the Acquisition, STAAR Japan became a wholly owned subsidiary of STAAR, and its financial information was included in STAAR’s consolidated financial statements as of that date. The functional currency of STAAR Japan is the local currency, the Japanese yen. In accordance with SFAS No. 52, “Foreign Currency Translation,” for purposes of consolidation with the Company, assets and liabilities of STAAR Japan have been translated at rates of exchange in effect at the end of the period, except for the acquisition date translation of the assets acquired and liabilities assumed, which were translated using the exchange rate in effect at the closing date of the Acquisition. Sales and expenses of STAAR Japan were translated at the weighted average of exchange rates in effect during the three and nine months ended September 26, 2008. The resulting translation gains and losses are included in accumulated other comprehensive income on the condensed consolidated balance sheet as of September 26, 2008.

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

STAAR Japan's business consists of designing, manufacturing and selling IOLs and injector systems, all of which are sold as integrated Preloaded Injectors. STAAR Japan is also currently seeking approval from the Japanese regulatory authorities to market in Japan STAAR's Visian ICL, Collamer IOL and the AquaFlow Device for treatment of glaucoma.

Through the acquisition STAAR seeks to achieve the following goals:

- to better exploit the Japanese market for STAAR's technology and the worldwide market for the Preloaded Injector technology through greater control of distribution;
- to re-acquire control of worldwide exclusive rights to STAAR's technology, especially the ICL and Collamer IOL, previously licensed to the joint venture on a worldwide non-exclusive basis;
- to eliminate the risk that Canon Staar could become a competitor of STAAR, especially after a change in control of STAAR;
- to increase access to the Preloaded Injector technology; and
- to develop a more effective global R&D strategy by leveraging the combined technical resources in Japan and the U.S. and taking advantage of STAAR Japan's proven expertise in injector design.

The aggregate consideration paid for the acquisition to the Canon companies was as follows (in thousands):

Fair value of redeemable, convertible preferred stock issued by STAAR as consideration for Canon Staar common shares purchased (see Note 11)	\$ 6,800
Cash consideration for Canon Staar common shares purchased	4,000
Transaction costs	1,000
Total acquisition consideration	\$ 11,800

STAAR paid approximately 60% of the total consideration by issuing 1.7 million shares of redeemable, convertible preferred stock on the Closing Date. The fair value of the convertible preferred stock was determined by a valuation of the instrument with the assistance of an appraiser (see Note 11). In addition, STAAR paid the remaining 40% of the total consideration in cash, which was placed on deposit with the Canon companies just prior to the Closing Date and included in STAAR's non-current assets on its consolidated balance sheet as of fiscal year ended December 28, 2007. Application of the \$4.0 million deposit to the purchase price was subject to numerous closing conditions and the deposit was to be fully refunded by the Canon companies if those conditions were not met. Upon completion of the Acquisition on the Closing Date, the deposited funds were credited to the Canon companies as part of the total consideration paid by STAAR. STAAR also incurred and paid approximately \$1 million in direct transaction and related costs.

The Acquisition was accounted for as a "step-acquisition" under EITF Abstracts, Topic No. D-84, "Accounting for Subsequent Investments in an Investee After Suspension of Equity Method Loss Recognition When an Investor Increases Its Ownership Interest from Significant Influence to Control through a Market Purchase of Voting Securities" (Topic No. D-84) and the provisions of SFAS No. 141, "Business Combinations". The following table summarizes the estimated fair values of the assets acquired and liabilities assumed on December 29, 2007 (in thousands):

<b>December 29,</b>	
<b>2007</b>	<b>Useful Lives (years)</b>

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Cash	\$	3,018	
Accounts receivable		500	
Inventories		4,252	
Prepaid expenses and other current assets		464	
Property, plant and equipment		728	
<b>Intangible assets:</b>			
Customer relationships		1,389	10
Developed technology		882	3 - 10
Patents		601	17 - 21
Total intangible assets		2,872	
Deposits and other long-term assets		715	
Total assets acquired		12,549	
<b>Current liabilities</b>			
Net pension liability		(771)	
Deferred income taxes		(245)	
Other long-term liabilities		(79)	
Total liabilities assumed		(4,599)	
Net assets acquired		7,950	
<b>Loss on settlement of pre-existing distribution arrangement</b>			
		3,850	
Total acquisition consideration	\$	11,800	

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

Among the assets of Canon Staar acquired in the Acquisition was cash in the amount of approximately \$3 million, which was reduced by \$803,000 in transaction costs paid during the nine months ended September 26, 2008. The remaining \$2.2 million of net cash obtained in the acquisition is included in STAAR's consolidated statements of cash flows under investing activities for the nine months ended September 26, 2008.

In determining the final purchase price allocation, STAAR considered, among other factors, its intentions for the use of the acquired assets, historical demand for STAAR Japan's products, estimates of future demand for those products, current selling prices of inventories (less estimated costs of completion, disposal and normal profit), developed technologies incorporated in its products, customer relationships, the revenue generating potential of patents and lives of patents. The fair value of intangible assets was primarily based on the income approach. The rate used to discount the net cash flows to their present values was a 10.5% weighted average cost of capital for the business as a whole, and from 12.5% to 14.0% for the individual intangible assets depending on the risk associated with the assets' potential to generate revenue and its projected remaining useful economic life. The weighted average cost of capital was determined after consideration of market rates of return on debt and equity capital of comparable companies, the weighted average return on invested capital and the risk associated with achieving forecast sales related to technology and assets acquired from STAAR Japan. Property, plant and equipment net book value was evaluated at approximate fair value on the acquisition date due to the nature and relative age of the assets acquired. The intangible assets and property, plant and equipment are being amortized and depreciated based on the pattern in which the economic benefits of these assets are being utilized, using the straight-line method. There was no goodwill recorded in the Acquisition because the fair value of the net assets acquired exceeded the price paid in the Acquisition by approximately \$4 million, net of deferred income taxes. This excess amount was allocated on a pro rata basis to offset against the initially determined fair value of intangible assets and property, plant and equipment.

In connection with the Acquisition, STAAR also assumed the net pension liability under STAAR Japan's noncontributory defined benefit pension plan covering substantially all of the permanent, full-time employees of STAAR Japan (see Note 9). Other liabilities assumed by STAAR in the Acquisition mainly consisted of current trade payables and accrued liabilities and estimated deferred tax liabilities, representing the differences between the assigned values and the tax bases of the assets and liabilities recognized in the Acquisition.

In connection with the Acquisition, the material terms of the Joint Venture Agreement and other documents governing the joint venture were terminated. This included the termination of the distribution arrangement of Canon Staar under which Canon Marketing had the exclusive right to distribute Canon Staar's products in Japan prior to the Acquisition. Under the provisions of EITF Abstracts Issue No. 04-1 (EITF 04-1), "Accounting for Preexisting Relationships between the Parties to a Business Combination," in a business combination between two parties that had a pre-existing relationship, that relationship should be evaluated to determine whether a settlement of that relationship exists. Any such settlement requires accounting separate from the business combination. As a result of such an assessment under EITF 04-1, STAAR Japan recorded an approximate \$3.9 million loss at the close of the Acquisition, which is included in operating loss of STAAR's consolidated statements of operations during the nine months ended September 26, 2008. This loss represents the portion of the consideration paid by STAAR for the Acquisition that was deemed to represent the settlement amount of the pre-existing relationship between Canon Staar and the Canon companies, in particular for the termination of the distribution arrangement that, when compared to a comparable at-market arrangement as of the closing date, was deemed unfavorable to STAAR. The amount of the loss was determined using the discounted incremental cash flows income method from the distribution arrangement and a discount rate of 12%.

Because the Acquisition was completed on the first day of STAAR's fiscal year 2008, the results of STAAR Japan are included in the consolidated financial statements of STAAR beginning in the first quarter of the fiscal year. The following table summarizes unaudited pro forma financial information assuming the Acquisition had occurred on

December 30, 2006, in the corresponding period of the fiscal year immediately preceding the Acquisition, that is, as if the Acquisition was completed on STAAR's first day of fiscal year 2007. This unaudited pro forma financial information does not necessarily represent what would have occurred if the transaction had taken place on December 30, 2006, and should not be taken as representative of STAAR's future consolidated results of operations or financial position. STAAR also expects to realize operating synergies. These synergies will come from offering more products across more geographic areas, consolidating manufacturing at optimal sites, and anticipated reduced costs in logistics, marketing, and administration. The pro forma information does not reflect these potential expenses and synergies.

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

(In thousands, except per share amount)	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 28, 2007</b>		<b>September 28, 2007</b>	
Net sales	\$	14,490	\$	48,026
Net loss	\$	(5,738)	\$	(13,868)
Loss per share – basic and diluted	\$	(0.20)	\$	(0.50)

At the close of the Acquisition, the Canon companies and STAAR entered into a Current Employees Secondment Agreement under which Canon Marketing agreed for a term of two years to lease certain employees who had served as officers of Canon Staar to STAAR Japan to serve in the same capacities after the acquisition. STAAR Japan is required to make monthly payments to Canon Marketing for the services provided by the seconded employees in an amount equal to the costs of the employees' salaries and benefits ("fee") as calculated by Canon Marketing, however, the fee may not exceed 69 million Japanese Yen (approximately \$649,000 based on the rate of exchange on September 26, 2008) per annum in the aggregate. Similarly, Canon Marketing and STAAR entered into a New Employees Secondment Agreement under which Canon Marketing agreed for a term of one year to lease to STAAR Japan certain employees who previously conducted the IOL distribution business of Canon Marketing. STAAR Japan is required to make monthly payments to the Canon companies for the services provided by the seconded employees in an amount equal to the costs of the employees' salaries and benefits as calculated by Canon Marketing, however, the fee may not exceed 190 million Japanese Yen (approximately \$1.8 million based on the rate of exchange on September 26, 2008) per annum in the aggregate.

**Note 3 — Short-Term Investments-Restricted**

As of December 28, 2007, the Company's short-term investments consisted of a three-month Certificate of Deposit with a 4.5% interest rate. The short-term investments were used to collateralize capital leases funded under a lease line of credit with Mazuma Capital Corporation. The short-term investments were classified as held to maturity, carried at amortized cost and approximated fair value. During the third quarter of 2008 the Mazuma capital leases were paid off and therefore the restricted cash balance as of September 26, 2008 is zero.

**Note 4 — 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):

	<b>September 26,</b>		<b>December 28,</b>	
	<b>2008</b>		<b>2007</b>	
Raw materials and purchased parts	\$	1,314	\$	914
Work-in-process		2,383		2,035
Finished goods		12,124		9,792
	\$	15,821	\$	12,741

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

**Note 5 — Prepaids, Deposits, and Other Current Assets**

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

	<b>September 26, 2008</b>	<b>December 28, 2007</b>
Prepaids and deposits	\$ 748	\$ 1,330
Other current assets	1,214	280
	<b>\$ 1,962</b>	<b>\$ 1,610</b>

**Note 6 – Intangible Assets, Net**

Intangible assets consisted of the following (in thousands):

	<b>September 26, 2008</b>			<b>December 28, 2007</b>		
	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Net</b>	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Net</b>
Amortized intangible assets:						
Patents and licenses	\$ 12,127	\$ (7,917)	\$ 4,210	\$ 11,489	\$ (7,530)	\$ 3,959
Customer relationships	1,474	(111)	1,363	—	—	—
Developed technology	937	(127)	810	—	—	—
<b>Total</b>	<b>\$ 14,538</b>	<b>\$ (8,155)</b>	<b>\$ 6,383</b>	<b>\$ 11,489</b>	<b>\$ (7,530)</b>	<b>\$ 3,959</b>

During 2008, the Company acquired intangible assets through the acquisition of the remaining interest in STAAR Japan, Inc. (See Note 2). As of September 26, 2008 the gross carrying amount of the intangible assets acquired through the acquisition had increased by \$177,000 as a result of changes in the exchange rate.

**Note 7 – Other Current Liabilities**

Other current liabilities consisted of the following (in thousands):

	<b>September 26, 2008</b>	<b>December 28, 2007</b>
Accrued salaries and wages	\$ 2,983	\$ 1,910
Commissions due to outside sales representatives	438	544
Accrued audit expenses	510	542
Accounts receivable credit balances	568	516
Accrued income taxes	752	363
Accrued insurance	139	334
Accrued legal expenses	243	141
Other*	1,299	1,191



\$ 6,932 \$ 5,541

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\* No item in “other” above exceeds 5% of total current liabilities.

**Note 8 – Goodwill**

The change in the carrying amount of goodwill for the nine months ended September 26, 2008 is due to the effect of foreign currency translation.

8

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**STAAR SURGICAL COMPANY AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

**Note 9 – Employee Benefits**

The Company has historically maintained a passive pension plan (the “Swiss Plan”) covering employees of its Swiss subsidiary. This plan was previously classified and accounted for as a defined contribution plan. Based on new guidance obtained in the fourth quarter of fiscal 2007 from the Swiss Auditing Chamber’s Auditing Practice Committee and its Accounting Practice Committee with respect to a change in Swiss pension law, the Company concluded that the features of the Swiss Plan now conform to the features of a defined benefit plan. As a result, the Company adopted the recognition and disclosure requirements of Statement of Financial Accounting Standards (“SFAS”) No. 158, “Employers’ Accounting for Defined Benefit Pension and Other Postretirement Plans,” an amendment of SFAS Nos. 87, 88, 106 and 132R (“SFAS 158”) on October 1, 2007.

In connection with the Company’s acquisition of the remaining interest in STAAR Japan, Inc., STAAR assumed the net pension liability under STAAR Japan’s noncontributory defined benefit pension plan substantially covering all of the employees of STAAR Japan. STAAR Japan adopted the recognition and disclosure requirements of Statement of Financial Accounting Standards (“SFAS”) No. 158, “Employers’ Accounting for Defined Benefit Pension and Other Postretirement Plans,” an amendment of SFAS Nos. 87, 88, 106 and 132R (“SFAS 158”) on December 29, 2007.

The following table summarizes the components of net periodic pension cost recorded for the Company’s defined benefit plans (in thousands):

	<b>Three Months Ended September 26, 2008</b>	<b>Nine Months Ended September 26, 2008</b>
Service cost	\$ 100	\$ 301
Interest cost	37	108
Expected return on plan assets	(32)	(93)
Amortization of unrecognized transition obligation or asset	5	16
Amount of gain recognized due to a settlement or curtailment	(3)	(10)
Recognized actuarial loss	6	18
	<b>\$ 113</b>	<b>\$ 340</b>

During the nine months ended September 26, 2008, the Company made cash contributions totaling approximately \$292,000 to its defined benefit pension plans. The Company expects to make additional cash contributions totaling approximately \$14,000 to its defined benefit pension plans during 2008.

**Note 10 — Credit Facilities***Broadwood Promissory Notes*

On December 14, 2007, the Company borrowed \$5 million from Broadwood Partners, L.P. (“Broadwood”), a stockholder in the Company, pursuant to a Senior Promissory Note (the “Note”) between the Company and Broadwood. The borrowed funds were used to finance the cash consideration and related transaction costs in the Company’s purchase of the remaining interests of the Canon companies in its Canon Staar Co., Inc. joint venture. The Note has a term of three years and bears interest at a rate of 7% per annum, increasing to 20% per annum if there is a default. The

Note is not secured by any collateral, may be pre-paid by the Company at any time without penalty, and is not subject to covenants based on financial performance or financial condition (except for insolvency). The Note provides that, with certain exceptions, the Company will not incur indebtedness senior to or at parity with its indebtedness under the Note without the consent of Broadwood. Based on representations made by Broadwood in the Promissory Note, on the date of the transaction Broadwood beneficially owned 4,396,231 shares of the Company's common stock, comprising 15% of the Company's common stock as of December 14, 2007. Based on publicly available information filed by Broadwood, Neal Bradsher, President of Broadwood Partners, L.P., may have been deemed to beneficially own all of the 4,396,231 shares. As additional consideration for the loan, the Company also entered into a Warrant Agreement with Broadwood (See Note 15). In accordance with Accounting Principles Board ("APB") Opinion No. 14, "Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants," the total \$5 million proceeds were allocated to the December 2007 Warrant and Note based on their relative fair values, approximating \$842,000 and \$4.2 million on the issuance date, respectively. The \$842,000 was treated as an additional discount on the loan and is being amortized using the effective interest method over the life of the loan (See Note 15).

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

*Capital Lease Agreements*

The Company's lease agreement with Farnam Street Financial, Inc. ("Farnam"), as amended on October 9, 2006, provides 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 that item's lease term, 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 fiscal year 2008. The terms of this new schedule conform to the amended agreement dated October 9, 2006. Approximately \$300,000 borrowings related to future purchases are available under this facility as of September 26, 2008.

*Lines of Credit*

The Company's German subsidiary, Domilens, entered into a credit agreement on August 30, 2005. The credit agreement provides for borrowings of up to 100,000 EUR (\$147,000 at the rate of exchange on September 26, 2008), at a rate of 8.5% per annum and does not have a termination date. The credit agreement is automatically renewed on an annual basis based on the same terms. The credit agreement may be terminated by the lender in accordance with its general terms and conditions. The credit facility is not collateralized. There were no borrowings outstanding as of September 26, 2008 and December 28, 2007 and the full amount of the line was available for borrowing as of September 26, 2008.

The Company's Japanese subsidiary, STAAR Japan, has an agreement with Mizuho Bank providing borrowings of up to 400,000,000 Japanese Yen (approximately \$3.8 million based on the rate of exchange on September 26, 2008), at an interest rate equal to the Tokyo short-term prime interest rate (approximately 1.875% as of September 26, 2008) and terminates on April 20, 2009, but may be renewed annually. The credit agreement may be terminated by the lender in accordance with its general terms and conditions. The credit facility is not collateralized. As of September 26, 2008 the Company had 200,000,000 Japanese Yen outstanding on the line of credit (approximately \$1.9 million based on the rate of exchange on September 26, 2008).

*Covenant Compliance*

The Company was in compliance with the covenants of these credit facilities as of September 26, 2008.

**Note 11 — Redeemable, Convertible Preferred Stock**

Under its Certificate of Incorporation the Company has had 10,000,000 shares of "blank check" preferred stock, which the Board of Directors is authorized to issue with such rights, preferences and privileges as the Board may determine. On October 22, 2007, the Board approved the designation of 1,700,000 shares of the preferred stock as Series A Redeemable Convertible Preferred Stock ("Preferred Stock") to be issued in connection with the acquisition of the 50% interest in Canon Staar Co., Inc. which was consummated on December 29, 2007 (see Note 2). On December 29, 2007, the Company issued the 1,700,000 shares of Preferred Stock to the Canon companies as partial consideration for their shares of Canon Staar Co., Inc. at an estimated fair value of \$4.00 per share, or \$6.8 million in the aggregate.

The Preferred Stock is redeemable by the Company at any time on or after the first anniversary of the issuance date at a price of \$4.00 per share plus any accrued or declared but unpaid dividends ("Redemption Price"). The holders of the Preferred Stock have a right, exercisable at any time on or after the third anniversary of the issuance date by a majority vote of the Preferred Stock holders, to require the Company to redeem the Preferred Stock at the Redemption Price.

The Preferred Stock is convertible into shares of the Company's common stock at any time after the issuance date at a one-to-one conversion ratio that is adjustable only for stock splits, combinations, subdivisions, dividends or recapitalizations ("Conversion Ratio"). On the fifth anniversary of the issuance date, the Preferred Stock expires and each share of Preferred Stock will be automatically converted to common stock of the Company at the Conversion Ratio.

The fair value of the Preferred Stock was determined on the issuance date by the Company with the assistance of a valuation specialist using the Binomial Tree option valuation model. This model considers the Preferred Stock to be a derivative asset of the Company's common stock where the preferred stockholder has options to choose certain payoffs that maximize returns and therefore maximize the value of the preferred stock. The payoff available to the preferred stockholder is contingent on the future market value of the Company's common stock. Therefore the model, based on certain significant management assumptions, analyzes various payoff patterns for different possible paths that might be followed by the common stock price over the life of the Preferred Stock until the automatic conversion on the fifth anniversary of the issuance date.

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

The significant assumptions used in the valuation were as follows:

Average common stock price*	\$ 3.12
Expected volatility	67.4%
Expected dividend yield	0%
Risk-free interest rate	3.43%
Issuer's call price per share	\$ 4.00
Redemption price per share	\$ 4.00

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\* Average common stock price used in the valuation represents the average closing market price per share of the Company's common stock a few days before and after the announcement date of the Canon Staar acquisition.

The Company filed and secured effectiveness of a registration statement with the SEC for the public resale of the common stock issuable upon conversion of the Preferred Stock and must maintain effectiveness for the remainder of the two-year period following issuance, subject to permitted suspensions of thirty days up to twice a year under specified circumstances. Other than such permitted suspensions, if the Company fails to keep the registration statement effective for the two-year period, as the holders' sole remedy the Company will be obligated to issue an additional 30,000 shares of common stock to the holders for each calendar month that the Company does not meet this effectiveness requirement ("Penalty Shares"). The Company does not consider the issuance of any Penalty Shares to be likely.

The rights, preferences and privileges of the Preferred Stock are specified in a Certificate of Designation that the Company filed with the Delaware Secretary of State on December 24, 2007. The Preferred Stock does not have voting rights in the election of directors or any other matter, except as may be required under the Delaware General Corporation. However, the Company cannot, without the consent of at least two-thirds of the holders of the Preferred Stock, authorize or issue any other equity security senior to or at parity with the Preferred Stock as to dividend, conversion or redemption rights or liquidation preferences.

The Preferred Stock has the right to participate equally, on an as-converted basis, in any dividend or distribution paid to the common stockholders.

On or prior to the effective date of certain change in control or liquidation events of the Company specified in the Certificate of Designation, the Preferred Stock is redeemable at the option of the holder at the Redemption Price; however, the holder will continue to have the right to convert the Preferred Stock into common stock of the Company until the close of the second business day prior to the effective date of such an event.

In the event of a liquidation of the Company, as defined in the Certificate of Designation, the Preferred Stockholders have a right to receive a distribution equal to the Redemption Price prior to the distribution of any funds to the common stockholders. After payment of the Redemption Price the Preferred Stockholders do not participate in the distribution of the remaining proceeds of the liquidation, which will be distributed to the common stockholders. However, until the effective date of any such liquidation, each Preferred Stockholder may convert its shares to

common stock of the Company and participate in the proceeds of the liquidation to be paid to common stockholders in lieu of the Redemption Price.

On a liquidation or change in control of the Company, if a Preferred Stockholder does not make a timely election to either receive the Redemption Price or convert the Preferred shares to common stock, the Certificate of Designation provides that the Preferred Stockholder will be deemed to have elected the higher in value of the two alternatives, to be calculated as provided in the Certificate of Designation.

Because after the third anniversary of issuance the Preferred Stock is redeemable at the option of the holders, which is not within the control of the Company, the Company has presented the Preferred Stock in the mezzanine section of the consolidated balance sheet in accordance with the provisions of EITF Abstracts, Topic No. D-98 (“Topic D-98”), “Classification and Measurement of Redeemable Securities.” Because the Preferred Stock fair value recorded on the issuance date approximates the redemption price, no further accretion will be required by the Company to redemption value and no subsequent revaluation will be necessary so long as the Preferred Stock is still considered a temporary equity instrument. However, issuance and registration costs of approximately \$48,000 were incurred related to the Preferred Stock, which were offset against the fair value of the Preferred Stock on the issuance date and are being accreted to the redemption value using the interest method with a corresponding charge to Additional Paid-In Capital over a three-year period.

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

**Note 12 — Stockholders' Equity**

The consolidated interim condensed 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 issuances of common stock on both net income and the weighted number of shares outstanding. Potential issuances of common stock include outstanding stock options, warrants issued to Broadwood and 1,700,000 shares issuable on conversion of the Series A Preferred Stock. Because the Company was in a loss position, potential common shares of 5,744,991 and 5,992,624 for the three and nine months ended September 26, 2008, respectively, and 3,682,298 and 3,403,004 for the three and nine months ended September 28, 2007, respectively, were excluded from the computation as the shares would have had an anti-dilutive effect.

*Comprehensive loss*

The components of comprehensive loss are as follows (in thousands):

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 26, 2008</b>	<b>September 28, 2007</b>	<b>September 26, 2008</b>	<b>September 28, 2007</b>
Net loss	\$ (2,250)	\$ (3,830)	\$ (13,735)	\$ (11,708)
Minimum pension liability adjustment	(51)	—	(58)	—
Foreign currency translation adjustment	(416)	512	979	655
Total comprehensive loss	\$ (2,717)	\$ (3,318)	\$ (12,814)	\$ (11,053)

**Note 13 — 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, Japan and Switzerland. Other than the United States, Germany, Japan, and Korea, the Company does not sell products 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):

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 26, 2008</b>	<b>September 28, 2007</b>	<b>September 26, 2008</b>	<b>September 28, 2007</b>
United States	\$ 4,746	\$ 4,739	\$ 14,468	\$ 14,991
Germany	5,844	5,742	19,260	17,471
Japan	3,127	103	9,608	282
Korea	1,137	262	2,777	1,791
Other	3,258	2,783	10,624	8,943
Total	\$ 18,112	\$ 13,629	\$ 56,737	\$ 43,478



One hundred percent 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):

12

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**STAAR SURGICAL COMPANY AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

	Three Months Ended		Nine Months Ended	
	September 26, 2008	September 28, 2007	September 26, 2008	September 28, 2007
Cataract	\$ 12,913	\$ 10,100	\$ 41,270	\$ 31,956
Refractive	5,085	3,396	14,994	11,059
Glaucoma	114	133	473	463
Total	\$ 18,112	\$ 13,629	\$ 56,737	\$ 43,478

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 14 — Commitments and Contingencies**

*Litigation*

*Moody v. STAAR Surgical Company; Parallax Medical Systems, Inc. v. STAAR Surgical Company* (California Superior Court, County of Orange, Cases No. 07CC10132 and 07CC10136). 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.

On December 7, 2007 STAAR filed a general denial of the Parallax and Moody claims along with cross-complaints against Parallax and Moody for breach of contract and for misappropriation of trade secrets. STAAR believes that the Parallax and Moody claims are without merit. It also believes that its cross complaints are well founded. Nevertheless, the outcome of litigation is never certain and the possibility that the plaintiffs will recover under their claims, or that STAAR will not recover on its cross-complaints, cannot be eliminated at this time. Motions for summary adjudication in the Parallax case by both STAAR and the plaintiff have been denied, and the case is expected to be tried before a jury in the fourth quarter of 2008. If STAAR does not succeed in obtaining dismissal of all of Moody's claims through motions for summary adjudication, remaining issues of fact in that case are also likely to be determined by a jury in early 2009. Jury trials add uncertainty as to the outcome in these cases and the potential for damages. STAAR has not reserved funds against a negative outcome in the lawsuits. Costs of defending these lawsuits have been substantial, and even if STAAR prevails legal fees are likely to be unrecoverable. An unexpected negative outcome in these cases or litigation costs that are greater than anticipated could result in material harm to STAAR's business.

In addition to the lawsuits discussed above, STAAR is from time to time subject to various claims and legal proceedings arising out of the normal course of its business. These claims and legal proceedings relate to contractual rights and obligations, employment matters, and claims of product liability. STAAR maintains insurance coverage for product liability claims. While the Company does not believe that any of the claims known is likely to have a material adverse effect on its financial condition or results of operations, new claims or unexpected results of existing claims

could lead to significant financial harm.

**Note 15 — 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” (“Opinion”) 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 price and the market price on the date of grant. The Company has elected to apply the Modified Prospective Application (“MPA”) in its implementation of SFAS No. 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.

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

As of September 26, 2008, 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 26, 2008	September 28, 2007	September 26, 2008	September 28, 2007
SFAS 123R expense	\$ 265	\$ 349	\$ 937	\$ 1,033
Restricted stock expense	53	21	186	118
Consultant compensation	52	—	72	15
Total	\$ 370	\$ 370	\$ 1,195	\$ 1,166

There was no net 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 \$63,000 and \$151,000 of SFAS No. 123R compensation to inventory during the three and nine months ended September 26, 2008, and \$43,000 and \$122,000, respectively during the three and nine months ended September 28, 2007, and recognizes those amounts as expense through Cost of Sales as the inventory is sold.

#### *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 has been increased as necessary to provide that 2% of the total shares of common stock outstanding on the immediately preceding December 31 would be reserved for issuance, up to a maximum of 1,586,371 additional shares, and a maximum total of 6,500,000 shares issuable under the 2003 Plan and all of the Restated Plans incorporated in it. The 6,500,000 maximum shares were reached on January 1, 2007, and no additional shares will be available for issuance as incentives to employees without stockholder approval. Shares subject to grants under the 2003 Omnibus Plan that lapse or terminate in accordance with their terms become available for new grants under the 2003 Omnibus Plan. As of September 26, 2008, 833,049 shares were authorized and available for grants under the 2003 Omnibus Plan. 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, restricted stock and unrestricted share grants. 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). Pursuant to the plan, options for 2,678,000 shares were outstanding at September 26, 2008 with exercise prices ranging between \$2.21 and \$10.99 per share. Restricted stock grants under the 2003 Plan generally vest over a period of one, three or four years. There were 35,000 shares of restricted stock grants outstanding at September 26, 2008.

In fiscal year 2000, the Board of Directors approved the Stock Option Plan and Agreement for the Company’s Chief Executive Officer (now President of International) 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 26, 2008, 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 349,000 were outstanding at September 26, 2008 with exercise prices ranging between \$3.350 and \$13.625 per share. No further awards may be made under this plan.

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

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 45,000 shares were outstanding at September 26, 2008 with an exercise price of \$1.70 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 26, 2008 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 26, 2008 with exercise prices ranging between \$9.375 and \$10.63.

*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. Options granted with a three-year vesting life during the three and nine months ended September 26, 2008 had an expected term of 5.5 years derived from historical exercise and termination activity. The Company has calculated a 9.73% estimated forfeiture rate used in the model for fiscal year 2008 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 26, 2008	September 28, 2007	September 28, 2008	September 28, 2007
Expected dividend yield	0%	0%	0%	0%
Expected volatility	62.48%	68.87%	61.85%	69.43%
Risk-free interest rate	3.15%	5.10%	2.96%	4.70%
Expected term (in years)	5.5	5.4	5.5	5.4 & 5.5

A summary of option activity under the Plans as of September 26, 2008 is presented below:

Options	Shares (000's)	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term	Aggregate Intrinsic Value (000's)
Outstanding at December 28, 2007	3,717	\$ 6.70		

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Granted	641	2.48		
Exercised	(10)	3.95		
Forfeited or expired	(661)	6.39		
Outstanding at September 26, 2008	3,687	\$ 6.03	6.06	\$ 1,905
Exercisable at September 26, 2008	2,549	\$ 7.02	4.82	\$ 584

The weighted-average grant-date fair value of options granted during the nine months ended September 26, 2008 was \$1.51. The total fair value of options vested during nine months ended September 26, 2008 and September 28, 2007 was \$1,544,000 and \$1,307,000, respectively. The total intrinsic value of options exercised during the nine months ended September 26, 2008 and September 28, 2007 was \$13,000 and \$0.

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

A summary of the status of the Company's non-vested shares as of September 26, 2008 and changes during the period is presented below:

<b>Nonvested Shares</b>	<b>Shares (000's)</b>	<b>Weighted- Average Grant Date Fair Value</b>
Nonvested at December 28, 2007	1,055	\$ 5.18
Granted	641	1.51
Vested	(496)	3.11
Forfeited	(62)	2.40
Nonvested at September 26, 2008	1,138	\$ 2.36

As of September 26, 2008, there was \$1.9 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plans. That cost is expected to be recognized over a weighted-average period of 1.88 years.

*Broadwood Warrants*

On March 21, 2007, STAAR entered into a loan arrangement with Broadwood Partners, L.P. ("Broadwood"), a stockholder in the Company. Pursuant to a Promissory Note (the "March 2007 Note") between STAAR and Broadwood, STAAR borrowed \$4 million from Broadwood. The loan was subsequently repaid on June 27, 2007.

As additional consideration for the loan, STAAR also entered into a Warrant Agreement (the "March 2007 Warrant Agreement") with Broadwood granting the right to purchase up to 70,000 shares of STAAR's common stock at an exercise price of \$6.00 per share, exercisable for a period of six years, with additional warrants issuable quarterly to Broadwood if the March 2007 Note remained outstanding after June 30, 2007. Due to the repayment of the March 2007 Note on June 27, 2007, no additional warrants are issuable to Broadwood by STAAR under that note. The warrant agreement also provides that STAAR will register the shares issuable on exercise of the warrant for resale with the SEC. On May 1, 2008, the registration statement for the warrant shares was declared effective, but STAAR is required to maintain its effectiveness. Accordingly, in accordance with the provisions of 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"), the warrant instrument is accounted for as a liability because the Company is required to assume that a warrant exercised when registration requirements have not been satisfied may be settled in cash. The warrant instrument liability must be revalued at each reporting period with changes in fair value being reflected in the condensed consolidated statements of operations. STAAR used the Black-Scholes valuation model to estimate the warrant's fair value as of and subsequent to the issuance date. As of March 21, 2007 the fair value of the warrant liability approximated \$250,000 with the residual amount of the total \$4 million in proceeds, or \$3.75 million being allocated to the March 2007 Note. The \$250,000 was treated as an additional discount on the loan and the unamortized balance of \$215,000 was written off and included in other expenses, net, when the loan was paid off in June 2007. The fair value of the warrant approximated \$128,000 as of September 26, 2008 and \$68,000 as of December 28, 2007 with the change in value of \$60,000 recorded in other income for the nine months ended September 26, 2008.

The Company estimated the fair value of the warrant on September 26, 2008 and December 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 common stock. The expected life of the warrant is determined by the amount of time remaining on the original six-year term of the agreement as of the valuation date. 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.

	<b>As of September 26, 2008</b>	<b>As of December 28, 2007</b>
Expected dividends	0%	0%
Expected volatility	58.2%	62.5%
Risk-free rate	3.05%	3.77%
Remaining life (in years)	4.50	5.25

On December 14, 2007 STAAR entered into a new loan arrangement with Broadwood, which as noted above is a stockholder of the Company. Pursuant to a Senior Promissory Note (the "December 2007 Note") between STAAR and Broadwood, STAAR borrowed \$5 million from Broadwood (See Note 10). As additional consideration for the loan, the Company also entered into a Warrant Agreement with Broadwood (the "December 2007 Warrant Agreement") granting Broadwood the right to purchase up to 700,000 shares of common stock at an exercise price of \$4.00 per share, exercisable for a period of six years. The December 2007 Note also provides that if any indebtedness remains outstanding under the Note on June 29, 2009, the Company will issue additional warrants on the same terms as set forth in the December 2007 Warrant Agreement in a number equal to 700,000 times the percentage of the original \$5 million principal that remains outstanding. The December 2007 Warrant Agreement also provides that the Company will register for resale with the Securities Exchange Commission ("SEC") the 700,000 shares issuable on exercise of the December 2007 Warrant, and the up to 700,000 shares that may be issuable under additional warrants if indebtedness remains outstanding on the Note on June 29, 2009. The Company filed and secured effectiveness of a registration statement covering resale of the shares. If the registration statement is not kept effective by the Company and the lapse exceeds permitted suspensions, the Company is obligated to issue additional 30,000 warrants per month for each month that the Company remains non-compliant with the registration requirement through the term of the warrants as the sole remedy to the warrant holder. The Company does not believe there is any liability incurred associated with not complying with the registration requirement and therefore no liability was accrued as of September 26, 2008 and December 28, 2007. The December 2007 Warrant Agreement has been accounted for as an equity instrument in accordance with the provisions of EITF 00-19.

**STAAR SURGICAL COMPANY AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

The fair value of the warrant was estimated on the December 14, 2007 issuance date using a Black-Scholes option valuation model applying the assumptions noted in the following table.

	<b>As of December 14, 2007</b>
Expected dividends	0%
Expected volatility	67.3%
Risk-free rate	3.88%
Remaining life (in years)	6.0

**Note 16 — Supplemental Disclosure of Cash Flow Information**

Interest and income taxes paid for the nine months ended were as follows (in thousands):

	<b>September 26, 2008</b>	<b>September 28, 2007</b>
Interest paid	\$ 382	\$ 392
Income taxes paid, net of refunds	1,005	570

The Company's non-cash investing and financing activities for the nine months ended were as follows (in thousands):

	<b>September 26, 2008</b>	<b>September 28, 2007</b>
<b>Non-cash investing and financing activities:</b>		
Acquisition of Canon Staar	\$ 7,147	\$ —
Applied 2007 advance payment on acquisition of Canon Staar	(4,000)	—
Applied 2007 deferred acquisition costs	(197)	—
Assets obtained by capital lease	606	1,034
Issuance of preferred stock	6,800	—
Issuance and registration costs of preferred stock included in accounts payable and accrued liabilities	(17)	—

## **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 for the fiscal year ended December 28, 2007 under the heading "Risk Factors." The Company undertakes no obligation to update these forward-looking statements that may be made to reflect events or circumstances after the date of this report or to reflect actual outcomes.

The following discussion should be read in conjunction with the Company’s interim condensed financial statements and the related notes provided under “Item 1— Financial Statements” above.

### **Overview**

STAAR Surgical Company develops, manufactures and sells visual implants and other innovative ophthalmic products to improve or correct the vision of patients with cataracts and refractive conditions. We manufacture products in the U.S., Switzerland and Japan and distribute our products worldwide.

Originally incorporated in California in 1982, STAAR Surgical Company reincorporated in Delaware in 1986. Unless the context indicates otherwise “we,” “us,” the “Company,” and “STAAR” refer to STAAR Surgical Company and its consolidated subsidiaries.

STAAR Surgical Company, Visian™, Collamer®, STAARVISC®, Elastimide®, SonicWAVE™ and AquaFlow™ are trademarks or registered trademarks of STAAR in the U.S. and other countries. Collamer® is the brand name for STAAR’s proprietary collagen copolymer lens material.

### **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.* The majority of our revenue is generated by manufacturing and selling foldable intraocular lenses, known as IOLs, and related products for cataract surgery. A foldable IOL is a prosthetic lens used to replace a cataract patient’s natural lens after it has been extracted in minimally invasive small incision cataract surgery. STAAR makes IOLs out of silicone and out of Collamer®, STAAR’s proprietary biocompatible collagen copolymer lens material. STAAR’s IOLs are available in both three-piece and one-piece designs. Over the years, we have expanded our range of products for use in cataract surgery to include the following:

- Aspheric Collamer and silicone IOLs, designed to provide a clearer image than traditional spherical designs;
  - The silicone Toric IOL, used in cataract surgery to reduce preexisting astigmatism;
- The Preloaded Injector, a three-piece silicone or acrylic IOL preloaded into a single-use disposable injector;

• STAARVISC™ II, a viscoelastic material which is used as a tissue protective lubricant and to maintain the shape of the eye during surgery;

• Cruise Control, a disposable filter that allows for a faster, cleaner phacoemulsification procedure and is compatible with all phacoemulsification equipment utilizing Venturi and peristaltic pump technologies.

We also sell other instruments, devices and equipment that we manufacture or that are manufactured by others in the ophthalmic industry. In general, these products complement STAAR's proprietary product range and allow us to compete more effectively.

18

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*Refractive Surgery.* Manufacturing and selling lenses for refractive surgery is an increasingly important source of revenue for STAAR. We have used our proprietary biocompatible Collamer material to develop and manufacture the Implantable Collamer Lens, or ICL. STAAR's VISIAN™ ICL and VISIAN™ Toric ICL, or TICL™, treat refractive disorders such as myopia (near-sightedness), hyperopia (far-sightedness) and astigmatism. These disorders of vision affect a large proportion of the population. Unlike the IOL, which replaces a cataract patient's cloudy lens, these products are designed to work with the patient's natural lens to correct refractive disorders. The surgeon implants the foldable Visian lens through a tiny incision, generally under local anesthesia. STAAR began selling the Visian ICL outside the U.S. in 1996 and inside the U.S. in 2006. STAAR began selling the Visian TICL outside the U.S. in 2002. These products are sold in more than 40 countries. STAAR's goal is to establish the position of the ICL and TICL throughout the world as one of the primary choices for refractive surgery.

*Distribution.* STAAR's wholly owned subsidiary, Domilens Vertrieb fuer medizinische Produkte GmbH ("Domilens") is a leading distributor of ophthalmic products in Germany. Products sold by Domilens include implantable lenses, related surgical equipment, consumables and other supplies. Domilens sells custom surgical kits that incorporate a surgeon's preferred supplies and consumables in a single ready-to-use package, and services phacoemulsification and other surgical equipment. In addition to distributing and servicing products of third party manufacturers, Domilens distributes STAAR's Visian ICL and TICL, IOLs, and Preloaded Injectors.

### *Operations*

STAAR has significant operations both within and outside the U.S. Revenue from activities outside the U.S. accounted for 75% of our total revenues in the nine months of 2008 and 66% of our total revenues in the first nine months of 2007. 66% of the increase in the share of our revenue derived from outside the U.S. results from the acquisition of the remaining interests in our Japanese joint venture in early fiscal 2008. Prior to that time none of the Japanese company's revenues was included in our consolidated financial statements. STAAR's principal business units and their operations are as follows:

*United States.* STAAR operates its global administrative headquarters and a manufacturing facility in Monrovia, California. The Monrovia manufacturing facility principally makes Collamer and silicone IOLs and injector systems for IOLs and ICLs. STAAR also manufactures the Collamer material in the U.S.

*Switzerland.* STAAR operates an administrative and manufacturing facility in Nidau, Switzerland under its wholly owned subsidiary, STAAR Surgical AG. The Nidau manufacturing facility makes all of STAAR's ICLs and TICLs and also manufactures Collamer IOLs and the AquaFlow™ Collagen Glaucoma Drainage Device. STAAR Surgical AG handles distribution and other administrative affairs for Europe and other territories outside North America and Japan.

*Japan.* STAAR completed the acquisition of the remaining 50% interest in its joint venture Canon Staar, Co., Inc. during the first quarter of 2008, following which the entity's name was changed to STAAR Japan, Inc. ("STAAR Japan"). Through this new wholly owned subsidiary, STAAR operates an administrative facility in Tokyo, Japan and a manufacturing facility in Ichikawa City. All of STAAR's preloaded injectors are manufactured at the Ichikawa City facility. STAAR Japan is also currently seeking approval from the Japanese regulatory authorities to market in Japan STAAR's Visian ICL, Collamer IOL and AquaFlow Device.

*Germany.* Domilens, a wholly owned subsidiary of STAAR Surgical AG, operates its distribution business at facilities in Hamburg, Germany.

The global nature of STAAR's business operations subjects it to risks, including the effect of changes in currency exchange rates, differences in laws, including laws protecting intellectual property and regulating medical devices, political risks and the challenge of managing foreign subsidiaries. These risks are discussed in our Annual Report on

Form 10-K for the fiscal year ended December 28, 2007 under Item 1.A – Risk Factors, under the headings “*The global nature of our business may result in fluctuations and declines in our sales and profits*” and “*The success of our international operations depends on our successfully managing our foreign subsidiaries.*”

***Strategy***

STAAR is currently focusing on the following four strategic goals:

- improving cash flow;
- increasing U.S. sales by reversing the decline in cataract sales and improving the growth of refractive sales;
- successfully integrating STAAR Japan; and

- maintaining and expanding international growth rates.

*Strategic Goal 1: Improve cash flow.* STAAR used \$7.2 million of cash in operations during the nine months of 2008 and \$8.5 million of cash in the first nine months of 2007. Approximately \$2.9 million of the total cash used in operating activities in 2008 was used by STAAR Japan in assuming the IOL distribution business acquired from Canon Marketing Japan, Inc. and for payments on inventory purchased from Canon Marketing. STAAR seeks to reduce its use of cash both by cutting costs and by increasing U.S. revenue and profit margin. Our strategy to increase U.S. revenue and profit margin is discussed in detail under *Strategic Goal 2*.

While STAAR's international operations have generally generated cash or been cash flow neutral in recent periods, losses from U.S. operations have been the principal cause of cash use on a consolidated basis. To reduce these losses, STAAR implemented cost cutting measures in the third fiscal quarter of 2007 and during the first nine months of 2008, including targeted reductions in the U.S. workforce. Beginning in December 2007, STAAR began a process to closely rationalize and evaluate its spending levels. This evaluation has identified opportunities by which STAAR seeks to save approximately \$3.5 million in annualized costs in the U.S. These initiatives include streamlining STAAR's U.S. organization by reducing spending levels in all areas of the business, renegotiating or eliminating certain obligations, and eliminating all executive bonus opportunities until STAAR showed positive trends toward achieving profitability. During the first nine months of 2008 these reductions have totaled \$2.9 million and STAAR expects to meet or exceed its \$3.5 million target in the U.S. for the full year 2008. However, while STAAR has achieved these reductions in its U.S. operations, the reductions have been offset, in part, by the need to increase expenses outside the U.S. to support its 42% international refractive sales growth. STAAR exited the third quarter of 2008 with \$6.7 million in cash and cash equivalents, compared with \$10.9 million at the end of fiscal year 2007.

STAAR believes its cash management plans are achievable and continues to seek ways to reduce spending; however, STAAR cannot provide assurance that it will achieve the level of intended savings. STAAR's cash management plans depend on increases in U.S. sales of high-margin refractive products as well as improvements in revenue generated by U.S. sales of cataract products. During the third quarter of 2008, STAAR experienced an increase of 22% in U.S. sales of refractive products over the third quarter of 2007; however, although the rate of decline has slowed, U.S. sales of cataract products declined by 6% over the third quarter of 2007 and decreased 8% over the second quarter of 2008. If new cataract product introductions by STAAR do not generate significant additional revenues, STAAR may be required to more significantly reduce spending in its U.S. operations.

*Strategic Goal 2: Increase U.S. sales by reversing the decline in cataract sales and improving the growth of refractive sales.* In fiscal year 2007 STAAR experienced a flat rate of growth in U.S. refractive sales and a decrease of 16% in U.S. cataract sales over fiscal year 2006. To reverse these trends STAAR has significantly modified its U.S. selling strategy and is continuing its efforts to introduce improved and enhanced products that will compete better in the marketplace. As described in greater detail below, U.S. refractive sales have already shown resumed growth during the nine months of 2008.

*Refractive sales.* 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 Visian 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.

During the first nine months of 2008 STAAR's U.S. sales of Visian ICLs increased 24% over the first nine months of 2007 and decreased by 9% over the second quarter of 2008. STAAR believes this represents a trend to resumed growth in U.S. refractive sales following 2007 sales levels that did not grow beyond those reached in the first year of introduction. STAAR believes that the following are among the factors that may have contributed to improved Visian

ICL sales in 2008:

- increasing use of the ICL by a number of surgeons among STAAR's established U.S. customers as they have gained experience with the product and become more skilled at identifying, attracting and supporting those patients most likely to benefit from the ICL;
- increased patient awareness of the ICL as a result of favorable mass media exposure for the ICL;
- a change in marketing focus as STAAR, in its third year of ICL marketing in the U.S., has shifted from increasing its overall customer base to devoting more attention to identifying and supporting those surgical practices that show potential for significant repeat business through a professional commitment to the ICL technology; and

20

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- greater stability and focus in STAAR's refractive sales force following its reorganization in the second half of 2007.

To achieve its plans, STAAR will need not only to sustain, but to increase this rate of growth. STAAR believes that such an increase is achievable because, among other things, the favorable media coverage for the ICL and the implementation of STAAR's revised marketing approach had only begun to have their effect late in the first quarter or early in the second quarter. For example, a segment of the NBC News *Today* show featuring a successful live ICL surgery, aired on March 5, 2008, and a segment featuring use of ICL aired on the CBS "Early Show" August 8, 2008. Those shows and similar local television news segments resulted in increased consumer interest in ICL, as measured by web traffic and inquiries received on web sites maintained by STAAR and by the surgeons involved. STAAR's ICL Growth Program, which is part of its revised marketing approach, was announced in April 2008, and on April 22, 2008 held the first of nine webinars hosted by ICL surgeon Dr. Brian Boxer Wachler designed to help refractive physicians build their Visian ICL practices.

Notwithstanding the increasing Visian ICL sales in 2008, STAAR will continue to face challenges in marketing the ICL in the U.S., including the following:

- the U.S. refractive surgery market has been dominated by corneal laser-based techniques, which unlike the Visian ICL are already well known to potential refractive patients;
- other newly introduced surgical products will continue to compete with the Visian ICL for the attention of surgeons seeking to add new, high value surgical products, in particular multifocal and accommodating IOLs;
- the expected recession will likely reduce U.S. consumers' discretionary spending, including spending on elective procedures like refractive surgery;
- the U.S. economic downturn has reduced LASIK volumes and thereby reduced the number of patients to whom ICL is offered;
- negative publicity about complications of LASIK could reduce interest in all refractive surgical procedures; and
- FDA approval of the TICL, which STAAR sells in international markets for treating patients severely affected by both myopia and astigmatism, has been delayed.

Refractive surgery is an elective procedure generally not covered by health insurance. Patients must pay for the procedure, frequently through installment financing arrangements. Some makers of lasers for refractive surgery have reduced their U.S. sales projections for 2008 because worsening general economic conditions are expected to reduce demand for laser vision correction. As of the date of this filing, sales of the Visian ICL have not been similarly affected and have continued to grow during 2008 despite a general economic downturn and forecasts for global recession. However, STAAR cannot assure that U.S. Visian ICL sales will be unaffected by a deep or prolonged recession in the U.S.

On April 25, 2008, the FDA Ophthalmic Devices Panel held a public meeting to discuss issues of medical complications and customer satisfaction following refractive surgery. While the panel also discussed phakic IOLs such as the Visian ICL, most of its discussions centered on LASIK and testimony regarding customer dissatisfaction following LASIK surgery. The Panel recommended enhanced patient warnings of possible complications for LASIK and created a task force to study methods of better identifying those patients who are more likely to have an unsatisfactory outcome from laser vision correction. The proceedings of the Panel were widely reported in the U.S. While it is difficult to assess precisely the impact of the panel hearings on patient attitudes or the recommendations of practicing surgeons, it is possible that reduced demand for laser eye surgery observed in 2008 was caused in part by concerns regarding complications and potential patient dissatisfaction. Patient concerns about LASIK could increase

interest in the Visian ICL as an alternative for patients who have a greater risk of complications from LASIK. The fact that the Visian ICL is removable if a patient is dissatisfied with the outcome may also be appealing to some patients with new concerns about risks of refractive surgery. However, the negative publicity concerning LASIK could decrease patient interest in all refractive surgery, including Visian ICL. Because nearly all candidates for refractive surgery can achieve acceptable vision through the use of spectacles or contact lenses, for most patients the decision to have refractive surgery is a lifestyle choice that depends on high confidence in achieving a satisfactory outcome.

STAAR's TICL corrects both myopia and astigmatism, and has been shown to be highly effective in treating individuals severely affected by these conditions. When STAAR has introduced the TICL in international markets it has generally experienced rapid growth, and the TICL may also lead to increased ICL sales by introducing more patients and physicians to the ICL technology. STAAR has applied for approval of the TICL in the U.S., but the FDA has suspended review of the application pending resolution of concerns regarding STAAR's oversight of the TICL clinical study. This agency action, and STAAR's progress in resolving it, is discussed below under the caption "*Other Highlights: Medical Device Regulatory Compliance, Clinical Oversight and TICL Approval.*" Based on experience in international markets, STAAR believes that U.S. sales of the ICL will increase even if TICL approval continues to be delayed. Nevertheless, STAAR believes that approval and introduction of the TICL would significantly enhance refractive sales in the U.S. Obtaining approval remains a part of STAAR's long-term strategy.

*Cataract Sales.* For several years STAAR has experienced a decline in U.S. market share of cataract products.. U.S. cataract product sales declined 10% during the first nine months of 2008 compared with the same period of 2007 and 14% during the first nine months of 2007 compared with the same period of 2006. Factors contributing to long term decline in U.S. cataract sales include the slow pace of cataract product improvement and enhancement during a period when we devoted most of our research and development resources to introducing the ICL and to resolving the regulatory and compliance issues raised by the FDA. This long-term trend was intensified in 2007 by disruption in STAAR's independent sales force when STAAR elected not to renew its last two contracts with regional manufacturer's representatives, in the third quarter of 2007. In addition the trend was exacerbated by STAAR's lagging behind its competitors in the introduction of IOLs with advanced aspheric optics, and by the entry of Alcon as a competitor in the Toric IOL market.

STAAR's strategy to achieve profitability in its U.S. cataract business is to rationalize its cataract product offering around its higher value products, including recently introduced products and products planned for introduction in the near future. This has included aspheric optics across all IOL platforms, approval of higher reimbursement from Medicare for these lenses, improved delivery systems for Collamer IOLs to broaden their appeal and preloaded delivery systems for silicone lenses. Successful implementation of this strategy is subject to risks, including the risk of delays in developing new products or securing regulatory approval.

STAAR's initiatives to enhance its cataract product line have resulted in the following recent developments:

- The introduction of STAAR's aspheric three-piece Collamer IOL in April 2007;
- The introduction of STAAR's aspheric three-piece silicone IOL November 2007;
- The April 2008 introduction of the nanoPOINT™ injector, which delivers STAAR's single piece Collamer IOL through a 2.2 mm incision;
- The grant of New Technology IOL ("NTIOL") status for the aspheric three-piece Collamer IOL in March, 2008;
- The grant of NTIOL status for the aspheric single-piece Collamer IOL and the aspheric three-piece silicone IOL in July, 2008.

The addition of aspheric optics to STAAR's IOL designs has been a primary focus of STAAR's recent development efforts. Aspheric IOLs use advanced optical designs intended to provide a clearer image than traditional spherical lenses, especially in low light, which has led to significant market share gains for aspheric designs. In recognition of these advantages the Centers for Medicare and Medicaid Services ("CMS") will grant NTIOL status to aspheric IOLs that can demonstrate improved visual performance over conventional IOLs, allowing an extra \$50 reimbursement per lens implanted in an ASC (ambulatory surgical center). Because the overwhelming majority of IOL purchases in the U.S. are implanted at ASCs and reimbursed through Medicare, NTIOL status will significantly increase STAAR's

margin on qualifying lenses.

All of STAAR's aspheric lenses feature a proprietary optical design (patent pending) that is optimized for the naturally curved surface of the retina and certain other anatomical features of the human eye, and provides outstanding image quality even if decentered.

22

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STAAR intends to continue to focus on the following projects designed to make our cataract product offering more competitive:

- developing a Collamer Toric IOL to complement our pioneering silicone Toric IOL and better compete with the Alcon acrylic Toric IOL;
- The introduction of an aspheric single-piece Collamer IOL, which brings advanced aspheric optics to the micro-incision nanoPOINT platform;
  - introduction of an all new injector system for the three-piece Collamer IOL; and
  - Adapting our proprietary Preloaded Injector system for our new silicone aspheric IOLs.

STAAR's development efforts aim to realize the full market potential for Collamer IOLs by improving lens delivery systems and differentiating STAAR's silicone IOL offering through the Preloaded Injector. The majority of IOLs sold by STAAR in the U.S. are made of silicone, which was the original material used for foldable IOLs. However, physician preferences in the U.S. have strongly shifted to acrylic IOLs which currently account for an approximately 72% share of the U.S. IOL market. STAAR believes that its Collamer lenses have outstanding optical qualities and superior biocompatibility, and should be capable of competing with any of our competitor's acrylic lens products in the advanced material sector. In addition, increasing use of the ICL, which relies on the outstanding optical properties of Collamer, has also introduced the advantages of the Collamer material to a growing number of surgeons. However, growth of the Collamer IOL market has been limited by the difficulty of perfecting delivery systems for the soft Collamer material. Although acrylic lenses do not have the same level of optical performance in the eye as Collamer and often introduce glare or glistenings into the visual field, the stiffness and toughness of the acrylic material makes design of delivery systems simpler. STAAR has a number of development projects in place intended to make Collamer lenses easier to deliver and broaden customer appeal. The nanoPOINT injector system, which delivers the one-piece Collamer IOL through a 2.2 mm incision, was the first of these projects to reach market and was launched in April 2008.

While the U.S. market share for silicone IOLS has been slowly declining overall, a significant number of surgeons continue to select silicone lenses for their patients. STAAR believes that its recently introduced aspheric, three-piece silicone IOL offers outstanding optical performance and with its recently granted NTIOL status could enable STAAR to retain or possibly increase its market share within the silicone IOL sector, especially if STAAR's efforts are successful in securing FDA approval to make it available in a Preloaded Injector.

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. Until 2006 only STAAR sold Toric IOLs in the U.S. because CMS allows cataract patients receiving reimbursement to pay a premium for the correction of pre-existing astigmatism, while Medicare provides the customary reimbursement for cataract surgery, Toric IOLs can be sold at a higher price and higher profit margin than standard IOLs. CMS also permits the patient to separately remunerate the surgeon for the significant additional services needed to prescribe and implant a lens with toric correction for astigmatism. The increased revenues and profit margin originally expected by STAAR as a result of the CMS ruling have, to date, not been realized because of the introduction of a competing acrylic toric IOL by Alcon Laboratories. In particular, STAAR believes that in 2007 a number of customers who previously had purchased STAAR's Toric IOL but had otherwise been customers of Alcon's ophthalmic products, converted to use of the Alcon Toric IOL. STAAR also believes that the U.S. economic recession has reduced the demand for premium IOLs that require a significant contribution to the purchase price by the patient. STAAR believes that its planned introduction of a collamer-based Toric IOL will be essential to regaining market share in this technology.

STAAR believes that it has continued to face a challenge in marketing its products in the U.S. as a result of Warning Letters, Form 483 Inspectional Observations and other correspondence received from the FDA between December 29, 2003 and July 5, 2005, which indicated that the FDA deemed STAAR's Monrovia, California facility to be violating the FDA's Quality System Regulations and Medical Device Reporting regulations, warning of possible enforcement action and suspending approval of Class III medical devices to which the violations related. STAAR believes that it has resolved the issues giving rise to those agency actions to the satisfaction of the FDA staff. Nevertheless, STAAR believes that it has not yet fully overcome the reputational harm caused by the FDA's past findings of compliance deficiencies, which may continue to present a challenge in increasing U.S. product sales. In the opinion of STAAR's management, the June 26, 2007 warning letter from the Bioresearch Monitoring Program of the FDA Office of Regulatory Affairs ("BIMO") and the integrity hold placed on STAAR's clinical activities by the Office of Device Evaluation, although they concern STAAR's oversight of clinical activities rather than its quality systems, have perpetuated the reputational harm resulting from the earlier FDA actions, and made it more difficult for STAAR to regain its former market share.

STAAR comprehensively reorganized its U.S. sales force in the latter part of 2007 and early 2008. STAAR now directly employs its regional sales managers. At the local level STAAR continues to rely chiefly on independent sales representatives to promote sales and demonstrate products. STAAR believes that its reorganized sales force will position the company to capitalize on enhancements to its cataract product line intended to make the line more competitive.

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, managing independent local sales representatives, competing with much larger companies and overcoming reputational harm from the FDA's findings of compliance deficiencies. We cannot assure that this strategy will ultimately be successful.

*Strategic Goal 3: Successfully integrate STAAR Japan.* Early in fiscal year 2008 STAAR completed the acquisition of the remaining interests in its Japan-based joint venture, Canon Staar Co., Inc. ("Canon Staar"). Canon, Inc. and its affiliated marketing company, Canon Marketing Japan Inc. ("Canon Marketing") collectively owned 50% of Canon Staar prior to the closing of the acquisition on December 29, 2007, and STAAR owned the other 50%. Following the closing of this transaction (the "Acquisition") on December 29, 2007, Canon Staar became a wholly owned subsidiary of STAAR operating under the name "STAAR Japan, Inc."

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. Its current business consists of manufacturing and selling the Preloaded Injector. It has also been working to secure approval from Japanese regulatory authorities to sell the ICL, Collamer IOLs and AquaFlow Collagen Glaucoma Drainage Device in Japan. Canon Staar recorded worldwide sales of \$8.1 million in fiscal year 2007.

Although STAAR participated as a shareholder and had appointees serve as directors in the oversight of Canon Staar over its approximately twenty-year history, STAAR and its officers were not involved in day-to-day management of the joint venture. In completing the acquisition STAAR relied on the completeness and accuracy of the information provided during pre-closing due diligence. As a result, integrating STAAR Japan with STAAR faces some of the same challenges typically faced by the acquirer of an unrelated company.

When comparing STAAR Japan's financial performance in the first three quarters of 2008, investors should be aware that rules of purchase accounting and other effects of the acquisition affected results, especially in the first quarter. The financial impact of the STAAR Japan acquisition on STAAR recognized in the first fiscal quarter of 2008 includes approximately \$3.9 million in non-cash charges relating to the settlement loss on pre-existing arrangements and \$1.5 million in charges to cost of goods sold as a result of rules of purchase accounting that require acquired inventory to be written up in value, reducing reported margins until that inventory is sold off. The full amount of the stepped-up inventory was sold off in the first fiscal quarter of 2008.

Through the acquisition STAAR seeks to achieve the following goals:

- to better exploit the Japanese market for STAAR's technology and the worldwide market for the Preloaded Injector technology through greater control of distribution;
- to re-acquire control of world-wide exclusive rights to STAAR's technology, especially the ICL and Collamer IOL, previously licensed to the joint venture;
- to eliminate the risk that Canon Staar could become a competitor of STAAR, especially after a change in control of STAAR;

- to increase access to the Preloaded Injector technology; and
- to develop a more effective global R&D strategy by leveraging the combined technical resources in Japan and the U.S. and taking advantage of STAAR Japan's proven expertise in injector design.



*Control of Distribution.* Canon Marketing has been the exclusive distributor of Canon Staar products in Japan throughout the joint venture's history. While the Canon companies are a global leader in optics, Canon Staar's IOLs have been the only surgical product of the Canon companies and represented an insignificant portion of their total business. As a smaller company exclusively focused on ophthalmic implants, STAAR believes that it will be better positioned to exploit the value of the products developed and manufactured for the Japanese market by STAAR Japan. In addition, STAAR's Switzerland subsidiary has already served as Canon Staar's distributor for Preloaded Injectors in Europe and Australia and (on a non-exclusive basis) in China. STAAR believes distribution of Preloaded Injectors outside Japan can yield greater sales in the future, in particular following the 2007 introduction of an acrylic Preloaded Injector.

The cataract market in Japan is one of the world's largest, and enjoys high average selling prices. Mean myopia rates in Japan also make it an attractive market for refractive surgery. While Canon Staar experienced losses in 2007, it has historically earned modest profits and higher gross margins than STAAR's world-wide average. In addition, by absorbing the distribution business previously operated by Canon Marketing, STAAR expects to add substantially all of the distributor's historical margins to STAAR Japan's gross margin. Accordingly, STAAR believes that the acquisition of the Canon companies' interests in Canon Staar could lead to long-term improvements if control of distribution leads to better marketing and increased sales.

*Re-acquisition of World-Wide Exclusive Rights to STAAR Technology.* In 1988, pursuant to the Canon Staar Joint Venture Agreement and a Technical Assistance and License Agreement ("TALA"), STAAR granted to Canon Staar an irrevocable, exclusive right to make, have made and sell products using its technology in Japan, and an irrevocable, non-exclusive license to sell products using our technology in the rest of the world. Under a 2001 Settlement Agreement STAAR also granted to 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 and Japan. The TALA covered not only the license and transfer to Canon Staar of STAAR's intellectual property in existence at the time the joint venture was formed, but all intellectual property STAAR might develop in the future. As a result of these licenses, Canon Staar had the ability to become a worldwide competitor of STAAR using STAAR's own technology. In addition, the worldwide non-exclusive rights held by Canon Staar limited STAAR's ability to exploit the value of its own intellectual property through license agreements, because they prevented STAAR from granting any another company exclusive rights in any territory or assigning all rights under any of its patents. Accordingly, STAAR believes the reacquisition of the rights granted under the TALA and the 2001 Settlement Agreement is of significant value to STAAR and its shareholders.

*Eliminate the risk that Canon Staar could become a competitor of STAAR, especially after a change in control of STAAR.* Prior to the acquisition, if STAAR had entered into a merger or other reorganization, had been acquired or was subject of a take-over attempt or experienced other events of default under the Joint Venture Agreement, the Canon companies would have had the right to acquire STAAR's interest in Canon Staar at book value. (Book value of STAAR's 50% interest in Canon Staar was approximately \$2.3 million as of December 28, 2007). STAAR believes that book value would not have represented the fair value of its interest in the joint venture, especially because following the purchase of its interests by the Canon Companies, STAAR would lose its rights under the Joint Venture Agreement to control the worldwide exploitation of STAAR's technology in competition with STAAR. STAAR also believes that elimination of this risk has greatly enhanced its opportunity to enter into strategic transactions that may benefit its stockholders.

*Increase Access to the Preloaded Injector Technology.* Canon Staar introduced the world's first Preloaded Injector in 2003, and STAAR believes that Canon Staar remains a leader in this technology. Foldable IOLs are typically stored and shipped in an unfolded state, and then folded just before surgery to ensure that they quickly resume their proper shape on implantation. As a result, designing an effective Preloaded Injector involves many challenges. Among other things, it requires the engineering of an injector that is mechanically sound but also safe as a long-term container for the IOL, that can reliably fold the lens for delivery, smoothly compress and deliver the lens through a small incision,

typically less than 3 mm in width, then release the lens in a safe and predictable manner. In the course of developing the first practical preloaded injector Canon Staar filed patents on various innovations in Japan, the U.S. and elsewhere in the world. These are among the 33 patents of Canon Staar acquired in the acquisition. All rights under these patents were held exclusively by Canon Staar, with no express license for use by STAAR or any other company (except a limited license to Nidek Inc. in connection with distributing the acrylic Preloaded Injector).

While STAAR has many injector patents of its own, as a result of past transactions or disputes, it entered into cross licenses or covenants not to sue covering existing injector technology with the other major U.S. ophthalmic companies, Alcon, Advanced Medical Optics (“AMO”) and Bausch & Lomb. STAAR believes the existing patents acquired in the acquisition of Canon Staar will not be subject to those agreements. STAAR believes that in addition to securing its own access to Preloaded Injector technology these patents enhance STAAR’s proprietary position in the technology vis-à-vis its competitors.

*Develop a more effective global R&D strategy by combining STAAR Japan’s proven expertise in injector design with STAAR’s expertise in ophthalmic lenses and materials.* Both STAAR and Canon Staar have devoted substantial resources to R&D. Through working with the joint venture STAAR believes that the Japanese and U.S. R&D teams have complementary skills. For example, although STAAR first developed and patented the concept of a preloaded injector and experimented with its design, it was Canon Staar’s R&D staff that developed the first practical working model. STAAR believes that the complementary talents of the U.S. and Japan teams will provide opportunities for greater synergies and efficiencies and the development of new products that could continue STAAR’s tradition of innovation.

As in any acquisition, the integration of STAAR Japan will present STAAR with a number of challenges, including, but not limited to, the following:

- the risk that STAAR may not successfully integrate the former Canon Staar business or its employees into its overall business,
  - the risk that key employees of STAAR Japan may leave,
- the risk that removal of the Canon name from STAAR Japan and its products may reduce its goodwill or the acceptance of its products,
  - the risk that STAAR Japan 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 accurately assess the projections of management of STAAR Japan,
  - the risk that Japanese regulators may not approve the sale of the ICL or Collamer IOLs,
  - 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,
- the risk that STAAR's need to rely on the completeness and accuracy of information provided by the sellers during STAAR's investigation of the STAAR Japan business prevented discovery of material problems, and
- the risk that STAAR Japan may find financing for its operations or for additional working capital purposes difficult to maintain on reasonable terms, if at all.

In the period immediately following the closing of the acquisition, STAAR has seen no negative impact on sales from ceasing use of the Canon name or operating as a company independent of Canon, but STAAR cautions that it is too early to definitively determine that no negative effects of this change will emerge in the future.

Because of the strategic importance of the STAAR Japan business to STAAR, and the risks to realizing the full value of the transaction listed above STAAR has been devoting significant resources to completing the integration of STAAR Japan in 2008. Failure to successfully integrate STAAR Japan could significantly harm STAAR and its business.

*Strategic Goal 4: Maintain and expand international growth rates.* STAAR's revenue from international markets has grown steadily in recent periods. During the nine months of 2008, this growth primarily resulted from the STAAR Japan acquisition, increased sales of ICL and TICL and the effect of changes in currency.

The ICL and TICL are sold in more than 40 countries. International refractive sales have continued at a steady rate of growth, increasing approximately 40% in 2007 and 42% in the first three quarters of 2008. 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. STAAR received approval for the ICL in China on July 31, 2006 and received approval of the TICL and Hyperopic ICL in China in March 2008. We also continue to seek new approvals for the ICL and TICL in other countries, including Japan and Taiwan, and expanded indications in countries where they are already approved, but the timing of such approvals is at the discretion of the local authorities.

Domilens Vertrieb fuer medizinische Produkte GmbH is a leading distributor of ophthalmic products in Germany. Products sold by Domilens include implantable lenses, related surgical equipment, consumables and other supplies. Domilens sells custom surgical kits that incorporate a surgeon's preferred supplies and consumables in a single ready-to-use package, and services phacoemulsification and other surgical equipment made by third parties. In addition to distributing and servicing products of third party manufacturers, Domilens distributes STAAR's refractive products and Preloaded Injectors. Domilens sales in the first three quarters of 2008 were \$19.3 million, an increase of \$1.8 million over the comparable period of 2007, but this increase was a result of favorable changes in currency. Domilens generated total sales of \$23.7 during fiscal year 2007. During 2007 STAAR's efforts to further integrate Domilens resulted in a significant increase in ICL and TICL sales in Germany, where STAAR believes its market potential remains significantly unrealized. STAAR intends to foster resumed growth at Domilens by encouraging the continuation of its historically successful customer-focused business model as a distributor, and by working to further develop Domilens as platform for selling STAAR's own higher value proprietary products. Domilens will begin selling in Germany the acrylic Preloaded Injector jointly developed by STAAR Japan and Nidek, Inc. in the fourth quarter of 2008, STAAR believes this product will provide opportunities to expand STAAR's presence in international cataract surgery. STAAR Japan's silicone Preloaded Injectors are sold in Japan, China, Europe and Australia, among other countries. STAAR believes the convenience and reliability of the Preloaded Injector can yield further growth in international markets.

### ***Other Highlights***

*Medical Device Regulatory Compliance, Clinical Oversight and TICL Approval.* STAAR's ability to develop, manufacture and distribute its products depends heavily on maintaining good standing with the FDA and other regulatory agencies. STAAR believes that it is substantially in compliance with the FDA's Quality System Regulations and Medical Device Reporting regulations. STAAR has invested significant resources in maintaining regulatory compliance and expects to continue to do so in the future.

STAAR's business activities as a sponsor of biomedical research are subject to review by the Bioresearch Monitoring Program of the FDA Office of Regulatory Affairs ("BIMO"). Following STAAR's submission of a Pre-Market Approval application (PMA) supplement for the TICL to the FDA on April 28, 2006, BIMO conducted an inspection of STAAR's clinical study procedures, practices, and documentation related to the TICL between February 15 and March 14, 2007. At the close of the inspection, STAAR received eight inspectional observations on Form 483, to which it responded on April 5, 2007. Notwithstanding the response, on June 26, 2007 the FDA's BIMO branch issued a Warning Letter to STAAR noting four areas of noncompliance observed during the BIMO inspection. STAAR provided its written response to the Warning Letter to the FDA on July 31, 2007.

On August 3, 2007 STAAR received a letter from the FDA Office of Device Evaluation ("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 same deficiencies cited in the June 26, 2007 Warning Letter from the BIMO Branch, and other deficiencies noted in an audit of a clinical study site, ODE requested that STAAR engage a 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 third party auditor has completed its inspections, has reviewed and certified the amended clinical data that is the source for the data to be included in the resubmission of the TICL application, and has completed its audit report on STAAR's quality systems related to clinical oversight. The audit report of the TICL clinical data and the clinical quality systems audit report have been provided to the FDA for its examination in connection with the data integrity hold. After the FDA releases the audit reports to STAAR, STAAR will ensure that its corrective actions already underway are aligned with the audit findings, and will prepare and implement a corrective action plan for any new findings. If the FDA agrees with the corrective action plan, then an inspection by the local office will be scheduled. If the results of the inspection are satisfactory, the inspector will forward a report to FDA headquarters and it is expected that the FDA would then lift the integrity hold. STAAR cannot assure investors that its 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.

### ***Other Recent Highlights***

*Competition with Multifocal IOLs.* The U.S. IOL market continues to be affected by sales of multifocal and accommodating lenses resulting from a ruling of the Centers for Medicare and Medicaid Services ("CMS"). The ruling permits Medicare-covered cataract patients to receive more highly priced multifocal or accommodating IOLs (sometimes referred to as "presbyopic lenses") by paying only the additional cost of the lens and surgical procedure while still receiving reimbursement for the basic cost of cataract surgery and a monofocal IOL. This has increased the number of patients to whom surgeons offer the alternative of the higher-priced lenses. Presbyopic lenses will likely continue to claim a significant share of the US cataract market, and STAAR does not currently offer a lens of this type.

*Dual Payment for Toric IOLs.* The CMS has also ruled that a Medicare patient receiving a cataract lens that also corrects astigmatism, such as STAAR's Toric IOL, may be reimbursed by Medicare for the basic cost of the surgery and pay only the additional costs of the premium lens and specialized surgical procedure. While this ruling permits

STAAR to increase the average selling price of its silicone Toric IOL, STAAR has seen revenue from this product line decline as a result of market share lost following Alcon's introduction of an acrylic Toric IOL. STAAR is seeking FDA approval for a Toric IOL based on its Collamer single-piece IOL, which it believes will better compete with the Alcon Toric IOL and enable STAAR to benefit from dual payment under the CMS ruling. In particular, STAAR believes that the bioadhesive qualities of Collamer will provide an exceptionally stable platform for correction of astigmatism, which depends on correct angular positioning of the lens. In addition, STAAR plans to supply the nanoPOINT injector for use with the Collamer Toric IOL. Because larger incisions can themselves create astigmatism, STAAR believes a 2.2 millimeter incision for its Collamer Toric IOL will provide a competitive advantage. STAAR cautions that FDA approval of any product may be delayed or denied, and even if approved it cannot be assured that the Collamer Toric IOL will gain sufficient sales to materially improve the results of STAAR's U.S. cataract business.

*Foreign Currency Fluctuations.* Our products are sold in approximately 50 countries. During the third quarter of fiscal year 2008, sales from international operations represented 75% of total sales. The results of operations and the financial position of certain of our foreign 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. During the three and nine months ended September 26, 2008, changes in currency exchange rates had a \$0.5 million and \$2.4 million favorable impact on net sales, respectively.

### ***New Accounting Pronouncements***

In October 2008, the Financial Accounting Standards Board (“FASB”) issued FSP No. FAS 157-3, “Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active” (“FSP No. FAS 157-3”), which clarifies the application of SFAS No. 157 in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. The FSP is effective upon issuance, including prior periods for which financial statements have not been issued. Revisions resulting from a change in the valuation technique or its application should be accounted for as a change in accounting estimate following the guidance in SFAS No. 154, “Accounting Changes and Error Corrections” (“SFAS No. 154”). However, the disclosure provisions in SFAS No. 154 for a change in accounting estimate are not required for revisions resulting from a change in valuation technique or its application. This FSP is effective in the Company’s fourth quarter of fiscal year 2008. The Company is assessing the impact of this FSP. However, management does not believe that the adoption of this FSP will have a material effect on the Company’s consolidated financial position and results of operations.

### **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 nine months ended September 26, 2008 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 28, 2007.

## 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 Net Sales for Three Months		Percentage Change for Three Months	Percentage of Net Sales for Nine Months		Percentage Change for Nine Months
	September 26, 2008	September 28, 2007	vs. 2007	September 26, 2008	September 28, 2007	vs. 2007
Net sales	100.0%	100.0%	32.9%	100.0%	100.0%	30.5%
Cost of sales	42.3	50.3	11.6	47.6	51.0	21.7
Gross profit	57.7	49.7	54.5	52.4	49.0	39.6
General and administrative	19.2	21.0	21.3	20.2	22.0	19.4
Marketing and selling	36.0	42.4	12.8	36.4	39.6	19.8
Research and development	10.4	12.8	8.4	10.5	11.5	19.6
Loss on settlement of pre-existing distribution arrangement	—	—	—	6.8	—	—*
Operating loss	65.6	76.2	14.4	73.9	73.1	31.7
Other expense, net	(7.9)	(26.5)	(60.6)	(21.5)	(24.1)	15.7
Other expense, net	(3.2)	(3.0)	43.0	(1.2)	(2.0)	(19.8)
Loss before provision for income taxes	(11.1)	(29.5)	(50.0)	(22.7)	(26.1)	13.0
Provision (benefit) for income taxes	1.3	(1.4)	222.6	1.6	0.8	163.4
Net loss	(12.4)%	(28.1)%	(41.3)	(24.3)%	(26.9)%	17.3

\* Denotes change is greater than 100%

In comparing results of operations for the three months and nine months ended September 26, 2008 with prior periods, readers should be aware that results for these periods have been significantly affected by the acquisition of the remaining interests in STAAR Japan, including both non-recurring charges resulting from the accounting treatment of the transaction and the consolidation of the results of STAAR Japan from the first quarter of 2008 forward. On the December 29, 2007, closing date of the acquisition, STAAR Japan became a wholly owned subsidiary of STAAR, and its financial information was included in the Company's consolidated financial statements as of that date. As a result of the acquisition, the Company's net sales and expenses have increased significantly compared to 2007. Additionally, the Company, during the first quarter of 2008, recorded an approximate \$3.9 million loss on settlement of pre-existing distribution arrangement and a \$1.5 million increase to cost of sales resulting from the sales of inventory that had a stepped-up basis required under GAAP which have significantly contributed to the Company's operating loss. Note 2 of the Notes to the Condensed Consolidated Financial Statements of STAAR provide details on the accounting for the STAAR Japan acquisition.

### Net Sales



Net sales for the three and nine months ended September 26, 2008 increased 31% and 30% to \$18.1 million and \$56.7 million, respectively, compared with \$13.6 million and \$43.5 million reported for the for the same periods of 2007. Changes in currency accounted for \$542,000 and \$2.4 million, respectively, and STAAR Japan sales accounted for \$2.9 million and \$9.1 million, respectively, of the increase in sales for the three and nine months ended September 26, 2008.

International sales for the third quarter of 2008 were \$13.4 million, an increase of 50% compared with \$8.9 million reported for the same period of 2007. The increase in international sales for the quarter is due primarily to the inclusion of STAAR Japan sales and the effect of currency (both described above) and a 63% increase in refractive product sales resulting from increased sales of ICLs and TICLs.

International sales for the nine months of 2008 were \$42.2 million, an increase of 48% compared with \$28.5 million reported in the same period of 2007. The increase in international sales for nine months is due primarily to the inclusion of STAAR Japan sales and the effect of currency (both described above), and a 42% increase in refractive product sales resulting from increased sales of ICLs and TICLs.

U.S. net sales of \$4.7 million for third quarter of 2008 were essentially unchanged compared with the third quarter of 2007. During the third quarter of 2008, refractive product sales increased due to a 24% increase in sales of ICLs. Increased sales of refractive products were largely offset by a 6% decrease in cataract product sales. The decline in cataract product sales was due to a decrease in sales of non-aspheric silicone and collamer IOLs and Toric IOLs, partially offset by an increase in sales of aspheric IOLs and other cataract products.

U.S. net sales for the nine months of 2008 decreased approximately 4% to \$14.5 million compared with the first nine months of 2007 mainly due to a \$1.1 million (10%) decrease in cataract product sales, partially offset by a \$0.7 million (21%) increase in refractive product sales.

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

Gross profit margin for the three and nine months ended September 26, 2008 was 57.7% and 52.4% compared with 49.7% and 49.0% for the three and nine months ended September 28, 2007, respectively. The increase for both periods was primarily due to increased sales of ICLs in the U.S., TICL sales internationally and Japan cataract product sales which yield higher average selling prices than in other countries. Gross margin, during the first nine months of 2008, was reduced by non-cash charges recorded when the inventory acquired in the STAAR Japan acquisition was stepped up in value in accordance with purchase accounting rules and sold during the first quarter of 2008.

### ***General and administrative***

General and administrative expenses for the three and nine months ended September 26, 2008 were \$3.5 million and \$11.4 million, respectively, compared with \$2.9 million and \$9.6 million reported for the for the three and nine months ended September 28, 2007, respectively. The increase for the three and nine months ended September 26, 2008 was primarily due to incremental costs of STAAR Japan of \$0.9 million and \$2.6 million, respectively, and increased costs in Europe, partially offset by decreased costs in the U.S.

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

Marketing and selling expenses for the three and nine months ended September 26, 2008 increased by 13% and 20% to \$6.5 million and \$20.6 million, respectively, compared with \$5.8 million and \$17.2 million reported for the three and nine months ended September 28, 2007. Changes in currency accounted for \$0.2 million and \$0.9 million, respectively, and the incremental costs of STAAR Japan accounted for \$0.8 million and \$2.9 million, of the increase in marketing and selling costs for the quarter and year-to-date periods. Additionally, spending increased outside of Japan to drive continued sales growth internationally. The increase in marketing and selling expenses was partially offset by decreased commissions and promotional activities in the U.S.

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

Research and development expenses, including regulatory and clinical expenses increased 8% to \$1.9 million in the third quarter of 2008, compared with \$1.7 million reported for the third quarter of 2007, and increased 20% in the first nine months of 2008 to \$6.0 million compared with \$5.0 million reported for the first nine months of 2007. The increases for the three and nine months of 2008 were primarily due to incremental costs of STAAR Japan of \$0.5 million and \$1.5 million, respectively, partially offset by cost reductions in the U.S.

### ***Loss on Settlement of Pre-existing Distribution Arrangement***

In connection with the Company's acquisition of STAAR Japan, the Company recorded a \$3.9 million loss at the close of the Acquisition (first quarter of fiscal 2008). This loss represents the portion of the consideration paid by STAAR for the Acquisition that was deemed to represent the settlement amount of the preexisting relationship between Canon

Staar and the Canon companies, in particular for the termination of the pre-existing distribution arrangement that was deemed unfavorable to STAAR Japan and to STAAR when compared to a comparable, at-market arrangement as of the December 29, 2007 closing date.

**Liquidity and Capital Resources**

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

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As of September 26, 2008 and December 28, 2007, the Company had \$6.7 million and \$10.9 million, respectively, of cash and cash equivalents.

Net cash used in operating activities was \$7.2 million for the nine months ended September 26, 2008, compared with \$8.5 million for the nine months ended September 28, 2007. The \$7.2 million used for operating activities for the first nine months of 2008 included \$3.0 million used by STAAR Japan in the first two quarters of 2008 as STAAR Japan began selling direct versus through a distributor. STAAR Japan effectively had no receivables at the end of 2007 and had to use existing cash balances for working capital purposes until it generated cash from sales. STAAR Japan's days sales outstanding "DSO" is approximately 69 days on average, indicating they did not start receiving cash from direct sales until the end of the first quarter and as a result utilized much of their cash on hand. During the third quarter of 2008, STAAR Japan generated a small amount of cash from operations.

Net cash provided by investing activities was \$1.7 million for the nine months ended September 26, 2008 compared with net cash of \$0.2 million used in investing activities for the nine months ended September 28, 2007. Cash acquired in connection with the acquisition of STAAR Japan was approximately \$2.2 million, net of \$0.8 million in transactions costs paid during the nine months ended September 26, 2008. The total consideration for the STAAR Japan acquisition was \$11.8 million. Approximately 60% of the total consideration was settled by issuing redeemable, convertible preferred stock on the closing date and the remaining 40% of the total consideration was paid in cash, which was advanced to the Canon companies just prior to the closing date and included in STAAR's non-current assets on its consolidated balance sheet as of the end of fiscal year 2007. Upon completion of the Acquisition on the closing date, the advance payment was credited to the Canon companies as part of the total consideration paid by STAAR.

Net cash provided by financing activities was \$1.2 million for the nine months ended September 26, 2008 compared to \$15.0 million for the nine months ended September 28, 2007. Net cash provided by financing activities in the nine months of 2008 resulted primarily from borrowings on the STAAR Japan revolving line of credit, offset by principal payments of capital lease obligations. Net cash provided by financing activities in the nine months of 2007 included \$16.6 million in net proceeds from the public offering of 3.6 million shares of common stock and \$0.6 million from proceeds related to stock option exercises, offset by the net \$1.8 million repayment of lines of credit and principal payments of capital lease obligations.

As of September 26, 2008, the Company had a current ratio of 2.1:1, net working capital of \$18.4 million and net equity of \$31.6 million (including Preferred Stock) compared to December 28, 2007 when the Company's current ratio was 2.9:1, its net working capital was \$21.0 million, and its net equity was \$36.2 million.

While the Company's international business generates positive cash flow and represents approximately 75% of consolidated net sales, the Company has reported losses on a consolidated basis for several years due to a number of factors, including eroding sales of cataract products in the U.S. and FDA compliance issues that consumed additional resources while delaying the introduction of new products in the U.S. market. During these years the Company has secured additional capital to sustain operations through private and public sales of equity securities.

The Company believes that its best prospect for returning its U.S. and consolidated operations to profitability is through the growth in sales of the ICL in the U.S. and cost reduction efforts, combined with continued growth in international markets. At the same time the Company seeks to develop and introduce products in the U.S. cataract market to stop further erosion of its market share, increase gross profit margins and resume growth in that sector. Nevertheless, success of these strategies is not assured and, even if successful, the Company is not likely to achieve positive cash flow on a consolidated annual basis during fiscal 2008.

The Company believes that based on current cash balances, combined with expected cash from international operations, it currently has sufficient cash to meet its funding requirements at least through the third quarter of 2009. Although the Company has no current specific plans to obtain additional capital, given its history of losses and

negative cash flows, it is possible that the Company will find it necessary to supplement these sources of capital with additional financing to sustain operations.

If our losses continue, we risk defaulting on the terms of our credit facilities or having them terminated. Our limited borrowing capacity could cause a shortfall in working capital or prevent us from making expenditures to expand or enhance our business. A default on any of our credit facilities could cause our long term obligations to be accelerated, make further borrowing difficult and more expensive and jeopardize our ability to continue operations.

If the Company is unable to rely solely on existing debt financing and is unable to obtain additional debt financing, the Company may find it necessary to raise additional capital in the future through the sale of equity or debt securities; however, there can be no assurance that such financing will be available at acceptable terms, if at all. To the extent any such financings involve the issuance of equity securities (or securities convertible into or exchangeable for equity securities), existing stockholders could experience dilution.

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

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

### ***Financial Position***

As a result of the acquisition of STAAR Japan during the first quarter of STAAR's fiscal year 2008, STAAR acquired net assets having a value of approximately \$7.9 million, which is the total purchase price of \$11.8 million less the \$3.9 million loss on settlement of a pre-existing distribution arrangement. The \$7.9 million net assets acquired were allocated among the various assets acquired and liabilities assumed on STAAR's balance sheet based on estimated fair values of the date of acquisition of STAAR Japan. Note 2 of the Notes to the Condensed Consolidated Financial Statements of STAAR provide details on the estimated fair values of the assets acquired and liabilities assumed.

Accounts receivable at September 26, 2008 increased \$3.2 million relative to December 28, 2007. The increase in accounts receivable relates primarily to the inclusion of STAAR Japan. DSO was 51 days at September 26, 2008 compared to 40 days at December 28, 2007. The increase in DSO days at September 26, 2008 was primarily due to the inclusion of STAAR Japan's results beginning as of the first quarterly period of fiscal 2008. The Company expects to maintain DSO within a range of 45 to 50 days during the remaining course of the 2008 fiscal year.

Inventories at September 26, 2008 increased \$3.1 million relative to December 28, 2007. The increase in inventories relates primarily to the inclusion of STAAR Japan.

Prepaid expenses, deposits and other current assets at September 26, 2008 increased \$0.4 million to \$2.0 million, as compared to \$1.6 million at December 28, 2007. The increase was primarily due to increases at the Switzerland and Germany subsidiaries.

Accounts payable at September 26, 2008 increased \$1.5 million to \$6.4 million, as compared to \$4.8 million at December 28, 2007. The increase was primarily due to the inclusion of STAAR Japan's accounts payable of approximately \$1.9 million offset by decreases in accounts payable in the U.S.

### ***Credit Facilities, Contractual Obligations and Commitments***

#### ***Redeemable, Convertible Preferred Stock***

On December 29, 2007, the Company issued 1,700,000 shares of Series A Redeemable Convertible Preferred Stock ("Preferred Stock") to the Canon companies as partial consideration for their 50% interest in Canon Staar Co., Inc. (see Note 2).

The Preferred Stock is redeemable by the Company at any time on or after the first anniversary of the issuance date at a price of \$4.00 per share plus any accrued or declared but unpaid dividends (“Redemption Price”). The holders of the Preferred Stock have a right, exercisable at any time on or after the third anniversary of the issuance date by a majority vote of the Preferred Stock holders, to require the Company to redeem the Preferred Stock at the Redemption Price. Because after the third anniversary of issuance the Preferred Stock is redeemable at the option of the holders, which is not within the control of the Company, the aggregate \$6.8 million Redemption Price of the Preferred Stock is presented in the mezzanine section of the consolidated balance sheet.

The Preferred Stock is convertible into shares of the Company's common stock at any time after the issuance date at a one-to-one conversion ratio that is adjustable only for stock splits, combinations, subdivisions, dividends or recapitalizations ("Conversion Ratio"). On the fifth anniversary of the issuance date, each share of Preferred Stock will expire and be automatically converted to common stock of the Company at the Conversion Ratio. Once a share of Preferred Stock is converted to common stock the holder's right to redeem the Preferred Stock is extinguished.

#### *Broadwood Promissory Notes*

On March 21, 2007, STAAR entered into a loan arrangement with Broadwood Partners, L.P. ("Broadwood"). Pursuant to a Promissory Note (the "March 2007 Note") between STAAR and Broadwood, Broadwood loaned \$4 million to STAAR. The March 2007 Note was repaid by STAAR on June 27, 2007. As additional consideration for the loan, STAAR also entered into a Warrant Agreement (the "March 2007 Warrant Agreement") as further described in Note 15 of the Notes to the Condensed Consolidated Financial Statements of STAAR.

On December 14, 2007, the Company borrowed \$5 million from Broadwood Partners, L.P. pursuant to a Senior Promissory Note (the "Note") between the Company and Broadwood. The borrowed funds were used to finance the cash consideration and related transaction costs in the Company's purchase of the remaining interests of the Canon companies in its Canon Staar Co., Inc. joint venture. The Note has a term of three years and bears interest at a rate of 7% per annum, increasing to 20% per annum if there is a default. The Note is not secured by any collateral, may be pre-paid by the Company at any time without penalty, and is not subject to covenants based on financial performance or financial condition (except for insolvency). The Note provides that, with certain exceptions, the Company will not incur indebtedness senior to or at parity with its indebtedness under the Note without the consent of Broadwood. Based on representations made by Broadwood in the Promissory Note, on the date of the transaction Broadwood beneficially owned 4,396,231 shares of the Company's common stock, comprising 15% of the Company's common stock as of December 14, 2007. Based on publicly available information filed by Broadwood, Neal Bradsher, President of Broadwood Partners, L.P., may have been deemed to beneficially own all of the 4,396,231 shares. As additional consideration for the loan, STAAR also entered into a Warrant Agreement (the "December 2007 Warrant Agreement") as further described in Note 15 of the Notes to the Condensed Consolidated Financial Statements of STAAR.

#### *Lines of Credit*

The Company's German subsidiary, Domilens, entered into a credit agreement on August 30, 2005. The credit agreement provides for borrowings of up to 100,000 EUR (\$147,000 at the rate of exchange on September 26, 2008), at a rate of 8.5% per annum and does not have a termination date. The credit agreement has been automatically renewed on an annual basis based on the same terms. The credit agreement may be terminated by the lender in accordance with its general terms and conditions. The credit facility is not collateralized. There were no borrowings outstanding as of September 26, 2008 and December 28, 2007 and the full amount of the line was available for borrowing as of September 26, 2008.

The Company's Japanese subsidiary, STAAR Japan, has an agreement with Mizuho Bank providing borrowings of up to 400,000,000 Japanese Yen (approximately \$3.8 million based on the rate of exchange on September 26, 2008), at an interest rate equal to the Tokyo short-term prime interest rate (approximately 1.875% as of September 26, 2008) that terminates on April 20, 2009, but may be renewed annually. The credit facility is not collateralized. As of September 26, 2008 the Company had 200,000,000 Japanese Yen outstanding on the line of credit (approximately \$1.9 million based on the rate of exchange on September 26, 2008).

#### *Lease Agreements*



The Company's lease agreement with Farnam Street Financial, Inc. ("Farnam"), as amended on October 9, 2006, provides 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 that item's lease term, 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 fiscal year 2008. The terms of this new schedule conform to the amended agreement dated October 9, 2006. Approximately \$300,000 borrowings related to future purchases are available under this facility as of September 26, 2008.

### *STAAR Japan Secondment Agreements*

At the close of the Acquisition by STAAR of the remaining shares of Canon Staar, the Canon companies and STAAR entered into a Current Employees Secondment Agreement under which Canon Marketing agreed for a term of two years to lease certain employees who had served as officers of Canon STAAR to STAAR Japan to serve in the same capacities after the acquisition. STAAR Japan is required to make monthly payments to Canon Marketing for the services provided by the seconded employees in an amount equal to the costs of the employees' salaries and benefits ("fee") as calculated by Canon Marketing; however, the fee may not exceed 69 million Japanese Yen (approximately \$649,000 based on the rate of exchange on September 26, 2008) per annum in the aggregate. Similarly, Canon Marketing and STAAR entered into a New Employees Secondment Agreement under which Canon Marketing agreed to lease to STAAR Japan for a term of one year certain employees who previously conducted the IOL distribution business of Canon Marketing. STAAR Japan is required to make monthly payments to the Canon companies for the services provided by the seconded employees in an amount equal to the costs of the employees' salaries and benefits as calculated by Canon, however, the fee may not exceed 190 million Japanese Yen (approximately \$1.8 million based on the rate of exchange on September 26, 2008) per annum in the aggregate.

### **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 28, 2007.

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

#### **Disclosure Controls and Procedures**

Our management, with the participation of the CEO and the CFO, evaluated the effectiveness of our disclosure controls and procedures as required by Exchange Act Rule 13a-15(b) as of the end of the period covered by this report. Based on that evaluation, the CEO and the CFO have concluded that our disclosure controls and procedures (as defined in Exchange Act Rule 13a – 15e) are effective.

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 or 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.

**Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting during the nine months ended September 26, 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, other than as necessary to complete the extension of our controls and procedures to STAAR Japan.

34

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## **PART II – OTHER INFORMATION**

### **ITEM 1.**

### **LEGAL PROCEEDINGS**

*Moody v. STAAR Surgical Company; Parallax Medical Systems, Inc. v. STAAR Surgical Company* (California Superior Court, County of Orange, Cases No. 07CC10132 and 07CC10136). 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.

On December 7, 2007 STAAR filed a general denial of the Parallax and Moody claims along with cross-complaints against Parallax and Moody for breach of contract and for misappropriation of trade secrets. STAAR believes that the Parallax and Moody claims are without merit. It also believes that its cross complaints are well founded. Nevertheless, the outcome of litigation is never certain and the possibility that the plaintiffs will recover under their claims, or that STAAR will not recover on its cross-complaints, cannot be eliminated at this time. Motions for summary adjudication in the Parallax case by both STAAR and the plaintiff have been denied, and the case is expected to be tried before a jury in the fourth quarter of 2008. If STAAR does not succeed in obtaining dismissal of all of Moody's claims through motions for summary adjudication, remaining issues of fact in that case are also likely to be determined by a jury in early 2009. Jury trials add uncertainty as to the outcome in these cases and the potential for damages. STAAR has not reserved funds against a negative outcome in the lawsuits. Costs of defending these lawsuits have been substantial, and even if STAAR prevails legal fees are likely to be unrecoverable. An unexpected negative outcome in these cases or litigation costs that are greater than anticipated could result in material harm to STAAR's business.

In addition to the lawsuits discussed above, STAAR is from time to time subject to various claims and legal proceedings arising out of the normal course of its business. These claims and legal proceedings relate to contractual rights and obligations, employment matters, and claims of product liability. STAAR maintains insurance coverage for product liability claims. While the Company does not believe that any of the claims known is likely to have a material adverse effect on its financial condition or results of operations, new claims or unexpected results of existing claims could lead to significant financial harm.

### **ITEM 1A.**

### **RISK FACTORS**

There have been no material changes to the risk factors disclosed in Item 1A of Part 1 of our Annual Report on Form 10-K for the fiscal year ended December 28, 2007, except for the following:

#### ***Global recession could reduce sales of our refractive products.***

Refractive surgery is an elective procedure generally not covered by health insurance. Patients must pay for the procedure, frequently through installment financing arrangements, and they can defer the choice to have refractive surgery if they do not feel confident that they can comfortably pay for it under current economic conditions. STAAR's competitors have reported that the economic downturn in the U.S. has significantly reduced demand for LASIK refractive correction in the second and third quarters of 2008. While Visian ICL sales have continued to grow, the rate of growth might have been higher under better economic conditions, and STAAR faces the risk that a predicted global recession, if severe or prolonged, could further restrict Visian ICL sales growth. Because the Visian ICL is STAAR's

fastest growing and highest margin product, restricted growth, could materially harm STAAR's business.

Because cataracts generally affect the elderly, most sales of IOLs and other products used in cataract surgery are reimbursed by government entities worldwide. Accordingly, these sales are generally unaffected by economic downturns or recessions. However, a severe or prolonged global recession could cause STAAR's customers to slow their payments. If STAAR's customers face financial difficulty, they could further slow or default in payment, increasing our collection risk.

***Negative publicity concerning complications of laser eye surgery could reduce the demand for our refractive products as well.***

On April 25, 2008, the FDA Ophthalmic Devices Panel held a public meeting to discuss issues of medical complications and customer satisfaction following refractive surgery, which received wide publicity in the United States. The panel discussion and resulting publicity have broadened public awareness of the potential complications of refractive surgery and potential patient dissatisfaction, in particular as a result of LASIK and other corneal laser-based procedures. Concerns about complications of refractive laser eye surgery could encourage more patients and doctors to select the Visian ICL as an alternative. However, negative publicity concerning LASIK could decrease patient interest in all refractive surgery, including Visian ICL. Depending on the nature and severity of future negative publicity about refractive surgery, the growth of ICL sales in the U.S. could be limited or sales could decline as a result. Because nearly all candidates for refractive surgery can achieve acceptable vision through the use of spectacles or contact lenses, for most patients the decision to have refractive surgery is a lifestyle choice that depends on high confidence in achieving a satisfactory outcome.

***Legal costs may be material.***

STAAR has incurred increased expenses for legal fees, such as fees related to the defense of the lawsuits by former regional manufacturers' representatives and STAAR's related cross-complaints that are described in Item 1 of Part III of this Report. While STAAR maintains insurance coverage for a number of litigation risks, including the cost of defending product liability claims, such insurance does not cover those lawsuits or some other types of commercial disputes. The defense of litigation, including fees of external legal counsel, expert witnesses and related costs, is expensive and may be difficult to project accurately. In general, such costs are unrecoverable even if STAAR ultimately prevails in litigation, and could represent a significant portion of STAAR's limited capital resources. To defend lawsuits, STAAR also finds it necessary to divert officers and other employees from their normal business functions to gather evidence, give testimony and otherwise support litigation efforts. Higher than expected costs of litigation could reach levels that materially reduce the amount of capital available for STAAR to pursue its business strategies.

STAAR may also in the future find it necessary to file lawsuits to recover damages or protect its interests. The cost of such litigation could also be significant and unrecoverable, which may also deter STAAR from aggressively pursuing even legitimate claims.

**ITEM 6. EXHIBITS**

**Exhibits**

- 3.1 Certificate of Incorporation, as amended to date.(1)
- 3.2 By-laws, as amended to date.(2)
- 4.1 Certificate of Designation of Series A Convertible Preferred Stock.(1)
- 4.2 1991 Stock Option Plan of STAAR Surgical Company(3)
- 4.3 1998 STAAR Surgical Company Stock Plan, adopted April 17, 1998(4)
- 4.4 Form of Certificate for Common Stock, par value \$0.01 per share(5)
- 4.5 2003 Omnibus Equity Incentive Plan and form of Option Grant and Stock Option Agreement(6)
- 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 to the Company's Annual Report on Form 10-K for the fiscal year ended December 28, 2007, as filed with the Commission on March 12, 2008.

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

(3) Incorporated by reference to the Company's Registration Statement on Form S-8, File No. 033-76404, as filed with the Commission on March 11, 1994.

(4) Incorporated by reference to the Company's Proxy Statement for its Annual Meeting of Stockholders held on May 29, 1998, filed with the Commission on May 1, 1998.

(5) Incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the Company's Registration Statement on Form 8-A/A, as filed with the Commission on April 18, 2003.

(6) Incorporated by reference to the Company's Proxy Statement for its Annual Meeting of Stockholders held on June 18, 2003, as filed with the Commission on May 19, 2003.

(\*)

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 4, 2008

By:

/s/ DEBORAH ANDREWS  
**Deborah Andrews**

**Chief Financial Officer**  
**(on behalf of the Registrant and as**  
**its**  
**principal financial officer)**