

STAAR SURGICAL CO  
Form 10-Q  
August 12, 2009

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

**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: July 3, 2009**

**Or**

☐

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

**For the transition period from to**

**Commission file number: 0-11634**

**STAAR SURGICAL COMPANY**

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

Delaware

95-3797439

STAAR SURGICAL COMPANY

(State or other jurisdiction of  
Incorporation or organization)

(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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). 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  
(Don 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 34,700,235 shares of common stock, par value \$0.01 per share, issued and outstanding as of August 10, 2009.

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

	July 3, 2009	January 2, 2009
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 5,754	\$ 4,992
Restricted cash	7,341	
Short-term investments restricted		179
Accounts receivable trade, net	9,411	8,422
Inventories	15,672	16,668
Prepays, deposits and other current assets	1,876	2,009
Total current assets	40,054	32,270
Property, plant and equipment, net	5,378	5,974
Intangible assets, net	5,051	5,611
Goodwill	7,711	7,538
Other assets	1,132	1,189
Total assets	\$ 59,326	\$ 52,582
<b>LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 5,553	\$ 6,626
Line of credit	2,704	2,200
Deferred income taxes current	282	282
Obligations under capital leases current	1,046	989
Other current liabilities	11,627	11,366
Total current liabilities	21,212	21,463
Note payable long-term, net of discount	4,276	4,414
Obligations under capital leases long-term	1,182	1,335
Deferred income taxes long-term	828	897
Other long-term liabilities	1,769	1,678
Total liabilities	29,267	29,787
Commitments, contingencies and subsequent events (Note 13)		
Series A redeemable convertible preferred stock, \$0.01 par value; 10,000 shares authorized; 1,700 shares issued and outstanding at July 3, 2009 and January 2, 2009, respectively. Liquidation value \$6,800.	6,776	6,768

Stockholders' equity:

Common stock, \$0.01 par value; 60,000 shares authorized; issued and outstanding 34,693 at July 3, 2009 and 29,503 at January 2, 2009	347	295
Additional paid-in capital	148,992	138,811
Accumulated other comprehensive income	2,585	2,812
Accumulated deficit	(128,641 )	(125,891 )
Total stockholders' equity	23,283	16,027
Total liabilities, redeemable convertible preferred stock and stockholders' equity	\$ 59,326	\$ 52,582

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

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

	Three Months Ended		Six Months Ended	
	July 3, 2009	June 27, 2008	July 3, 2009	June 27, 2008
Net sales	\$19,117	\$20,665	\$37,400	\$38,625
Cost of sales	8,453	9,131	16,397	19,336
Gross profit	10,664	11,534	21,003	19,289
General and administrative	3,855	3,520	8,137	7,961
Marketing and selling	6,032	7,646	11,811	14,113
Research and development	1,441	2,357	2,853	4,075
Loss on settlement of pre-existing distribution arrangement				3,850
Operating loss	(664 )	(1,989 )	(1,798 )	(10,710 )
Other income (expense):				
Interest income	5	63	8	91
Interest expense	(399 )	(222 )	(632 )	(423 )
Gain on foreign currency transactions	122	16	197	144
Other income (expense), net	128	(17 )	191	67
Other expense, net	(144 )	(160 )	(236 )	(121 )
Loss before provision for income taxes	(808 )	(2,149 )	(2,034 )	(10,831 )
Provision for income taxes	280	396	716	654
Net loss	\$(1,088 )	\$(2,545 )	\$(2,750 )	\$(11,485 )
Loss per share basic and diluted	\$(0.04 )	\$(0.09 )	\$(0.09 )	\$(0.39 )
Weighted average shares outstanding basic and diluted	30,911	29,488	30,276	29,488

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

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# STAAR SURGICAL COMPANY

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)  
(Unaudited)

	Six Months Ended	
	July 3, 2009	June 27, 2008
Cash flows from operating activities:		
Net loss	\$ (2,750 )	\$ (11,485 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	1,156	1,340
Amortization of intangibles	390	418
Amortization of discount	152	118
Fair value adjustment of warrant	8	2
Loss on disposal of property and equipment	29	84
Change in net pension liability	106	56
Stock-based compensation expense	902	825
Loss on settlement of pre-existing distribution arrangement		3,850
Other	112	(130 )
Changes in working capital, net of business acquisition:		
Accounts receivable	(1,173 )	(2,716 )
Inventories	937	2,034
Prepaids, deposits and other current assets	381	(487 )
Accounts payable	(645 )	(753 )
Other current liabilities	233	714
Net cash used in operating activities	(162 )	(6,130 )
Cash flows from investing activities:		
Cash acquired in acquisition of Canon Staar, net of acquisition costs		2,511
Restricted cash	(7,341 )	
Acquisition of property and equipment	(256 )	(415 )
Proceeds from sale of short-term investments restricted		79
Proceeds from sale of property and equipment	81	89
Net change in other assets	5	(63 )
Net cash (used in) provided by investing activities	(7,511 )	2,201
Cash flows from financing activities:		
Net proceeds from public sale of equity securities	8,548	
Borrowings under line of credit	630	3,800
Repayment under line of credit		(1,900 )
Repayment of capital lease lines of credit	(559 )	(419 )
Net cash provided by financing activities	8,619	1,481
Effect of exchange rate changes on cash and cash equivalents	(184 )	404

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Increase (decrease) in cash and cash equivalents	762	(2,044 )
Cash and cash equivalents, at beginning of the period	4,992	10,895
Cash and cash equivalents, at end of the period	\$ 5,754	\$ 8,851

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



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**STAAR SURGICAL COMPANY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL  
STATEMENTS**

**July 3, 2009  
(Unaudited)**

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

The condensed balance sheet as of January 2, 2009 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 six months ended July 3, 2009 and June 27, 2008, 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 January 2, 2009.

The results of operations for the three and six months ended July 3, 2009 and June 27, 2008 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 calendar 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.

The accompanying unaudited interim condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the liquidation of liabilities in the normal course of business.

**Going Concern**

In the Company's audited consolidated financial statements for the fiscal year ended January 2, 2009, the report of the Company's independent registered public accounting firm included an explanatory paragraph indicating that substantial doubt exists about STAAR's ability to continue as a going concern. STAAR's management believes that during and after the second fiscal quarter it has made progress towards the goal of overcoming this doubt. The developments that have enhanced management's confidence in STAAR's ability to continue as a going concern are discussed in detail in *Management's Discussion and Analysis of Financial Condition and Results of Operations* under the caption *Liquidity and Capital Resources*. They include the following:

improved cash flows from operations and continued cost reduction efforts  
the completion of a registered direct public offering yielding total cash proceeds of \$8.5 million;  
the use of proceeds from that offering to post a \$7.3 million deposit in connection with the \$4.9 million adverse judgment in the *Parallax* case, resolving the Company's largest current unfunded cash obligation;  
the Company's general trend of increasing gross profit margins  
the Company's success in securing key regulatory approvals and prospects for future approvals;  
the recent removal of the integrity hold put in place by the FDA on August 3, 2007

On May 11, 2009, final judgment was entered in the case *Parallax Medical Systems, Inc. v. STAAR Surgical Company*, confirming a \$4.9 million jury verdict against STAAR. The adverse judgment, and STAAR's need to obtain a surety bond or post a deposit in the amount of 150% of the judgment amount to stay enforcement during appeal, were among the principal factors that STAAR believes gave rise to substantial doubt regarding STAAR's ability to continue as a going concern. At the time of the final judgment, STAAR lacked the cash resources to pay such amounts. However, prior to the expiration of the temporary stay STAAR

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**STAAR SURGICAL COMPANY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL  
STATEMENTS**

**July 3, 2009**

**(Unaudited)**

**Note 1 Basis of Presentation and Significant Accounting  
Policies (continued)**

completed the offering and deposited approximately \$7.3 million in proceeds into a restricted account to assure payment of the judgment, thereby staying any enforcement of the judgment pending appeal (see Notes 2 and 13.) The \$4.9 million judgment liability related to the Parallax judgment must be paid (along with 10% per annum in post-judgment interest and approximately \$56,000 in reimbursement of trial related costs) if STAAR's appeal is unsuccessful. The judgment was accrued in fiscal year 2008 and cash exceeding the amount of the judgment has been placed in a restricted account with the Superior Court of California, County of Orange, exclusively for the purpose of satisfying the judgment. Accordingly, the *Parallax* judgment does not have a material effect on STAAR's future liquidity or availability of cash resources for its business.

Another lawsuit similar to the *Parallax* case, *Scott C. Moody, Inc. v. STAAR Surgical Company*, is currently scheduled for trial in the Superior Court of California, County of Orange, on October 19, 2009 and could result in further significant liability. Because no two courts or trials are identical, the outcome of the Moody case cannot be predicted and STAAR cannot estimate the amount or range of loss, if any, in the event of an unfavorable outcome. STAAR believes its cash resources are sufficient to vigorously defend the *Moody* case. However, a material adverse judgment in *Moody* could exceed STAAR's available cash resources.

As STAAR posted the deposit and obtained an amendment curing any default that may have occurred as a result of the *Parallax* judgment, STAAR's obligation under the Broadwood Promissory Note, which is due on December 14, 2010, net of the related discount, has been reclassified from current indebtedness as of the first quarter ended April 3, 2009 to noncurrent indebtedness in STAAR's consolidated balance sheet as of July 3, 2009 (see Note 9).

STAAR has a history of losses, its business is subject to numerous risks and contingencies and it cannot assure investors that its cash needs will not again exceed the level of cash generated by operations. Future obligations and liabilities that could exceed STAAR's current cash reserves include the following:

the \$5 million principal indebtedness under the Senior Secured Promissory Note held by Broadwood Partners, L.P., which becomes due on December 14, 2010 and accrues interest at a rate of 20% per annum; the possibility of a material adverse judgment in the case *Scott Moody v. STAAR Surgical Company*, scheduled for trial on October 19, 2009.

In addition, the holders of 1.7 million shares of outstanding Series A Redeemable, Convertible Preferred Stock have the right to redeem the stock at a price of \$4.00 per share, or \$6.8 million in aggregate, beginning on December 29, 2010, to the extent the Company has funds available to redeem the shares in accordance with the Delaware General

Corporation Law (see Note 10).

If the Company's need for cash exceeds available resources, the Company may be required to seek additional financing through the sale of debt and/or equity securities. The Company cannot assure that such financing will be available at acceptable terms, if at all, and an inability to secure additional and adequate financing could jeopardize the Company's ability to continue as a going concern.

### **New Accounting Pronouncements**

On June 29, 2009, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 168 (SFAS No. 168), *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles (as amended)*. The *FASB Accounting Standards Codification*<sup>TM</sup> ( Codification ) will become the source of authoritative U.S. generally accepted accounting principles (GAAP) recognized by the FASB to be applied by nongovernmental entities. Rules and interpretive releases of the Securities and Exchange Commission (SEC) under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. Content contained in the SEC Sections of the Codification is provided for convenience and relates only to SEC registrants. The SEC Sections are not the authoritative

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**STAAR SURGICAL COMPANY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL  
STATEMENTS**

**July 3, 2009  
(Unaudited)**

**Note 1 Basis of Presentation and Significant Accounting  
Policies (continued)**

sources of such content and do not contain the entire population of SEC rules, regulations, interpretive releases, and staff guidance. Content in the SEC Sections is expected to change over time, and there may be delays between SEC and staff changes to guidance and Accounting Standards Updates. The Codification does not replace or affect guidance issued by the SEC or its staff for public entities in their filings with the SEC. On the effective date of this Statement, the Codification will supersede all then-existing non-SEC accounting and reporting standards. All other nongrandfathered non-SEC accounting literature not included in the Codification will become nonauthoritative. This Statement is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The Codification will be effective for the Company's third quarter ending October 2, 2009 and authoritative references to current applicable GAAP in the Company's filings and other documents, as necessary, will be made using the relevant sections of the Codification.

On June 12, 2009, the FASB issued SFAS No. 167, *Amendments to FASB Interpretation No. 46(R) (as amended)*. FASB's objective in issuing this Statement is to improve financial reporting by enterprises involved with variable interest entities. FASB undertook this project to address (1) the effects on certain provisions of FASB Interpretation No. 46 (revised December 2003), *Consolidation of Variable Interest Entities*, as a result of the elimination of the qualifying special-purpose entity concept in FASB Statement No. 166, *Accounting for Transfers of Financial Assets*, and (2) constituent concerns about the application of certain key provisions of Interpretation 46(R), including those in which the accounting and disclosures under the Interpretation do not always provide timely and useful information about an enterprise's involvement in a variable interest entity. This Statement shall be effective as of the beginning of each reporting entity's first annual reporting period that begins after November 15, 2009, for interim periods within that first annual reporting period, and for interim and annual reporting periods thereafter. Earlier application is prohibited. The Company does not believe that the provisions of this Statement, when effective, will result in a significant impact to its consolidated financial statements.

On June 12, 2009, the FASB issued SFAS No. 166, *Accounting for Transfers of Financial Assets (as amended)*. The FASB's objective in issuing this Statement is to improve the relevance, representational faithfulness, and comparability of the information that a reporting entity provides in its financial statements about a transfer of financial assets; the effects of a transfer on its financial position, financial performance, and cash flows; and a transferor's continuing involvement, if any, in transferred financial assets. The Board undertook this project to address (1) practices that have developed since the issuance of FASB Statement No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities*, that are not consistent with the original intent and key requirements of that Statement and (2) concerns of financial statement users that many of the financial assets (and related obligations) that

have been derecognized should continue to be reported in the financial statements of transferors. This Statement must be applied as of the beginning of each reporting entity's first annual reporting period that begins after November 15, 2009, for interim periods within that first annual reporting period and for interim and annual reporting periods thereafter. Earlier application is prohibited. The Company does not believe that the provisions of this Statement, when effective, will result in a significant impact to its consolidated financial statements.

On May 28, 2009, the FASB issued SFAS No. 165, *Subsequent Events (as amended)*. The objective of this Statement is to establish general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. In particular, this Statement sets forth:

- (1) The period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements,

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**STAAR SURGICAL COMPANY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL  
STATEMENTS**

**July 3, 2009  
(Unaudited)**

**Note 1 Basis of Presentation and Significant Accounting  
Policies (continued)**

- (2) The circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements,
- (3) The disclosures that an entity should make about events or transactions that occurred after the balance sheet date. This Statement should not result in significant changes in the subsequent events that an entity reports either through recognition or disclosure in its financial statements. This Statement introduces the concept of financial statements being *available to be issued*. It requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for that date, that is, whether that date represents the date the financial statements were issued or were available to be issued. This disclosure should alert all users of financial statements that an entity has not evaluated subsequent events after that date in the set of financial statements being presented. An entity should apply the requirements of this Statement to interim or annual financial periods ending after June 15, 2009. Therefore, in accordance with this Statement, the Company deems these consolidated financial statements to be issued as of the date of filing of this report and the Company has evaluated subsequent events through that date.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements - An Amendment of ARB No. 51*. SFAS No. 160 establishes accounting and reporting standards for the non-controlling interest in a subsidiary. SFAS No. 160 also requires that a retained noncontrolling interest upon the deconsolidation of a subsidiary be initially measured at its fair value. Upon adoption of SFAS No. 160, the Company is required to report its noncontrolling interests as a separate component of stockholders' equity and to present net income allocable to the noncontrolling interests and net income attributable to the stockholders of the Company separately in its consolidated statements of operations. SFAS No. 160 requires retroactive adoption of the presentation and disclosure requirements for existing minority interests. All other requirements of SFAS No. 160 shall be applied prospectively. SFAS No. 160 became effective for the Company at the beginning of its 2009 fiscal year and the adoption of this standard did not have a material impact on its consolidated financial statements.

**Note 2 Restricted Cash**

On June 22, 2009, the Company posted a \$7.3 million deposit with the Superior Court of California, County of Orange, required as a deposit of 150% of the *Parallax* judgment amount while the *Parallax* judgment is on appeal (see Note 13). The Court maintains full control of, and access to the deposit, including the ultimate disbursement of any and all amounts, plus interest, depending on the final outcome of the *Parallax* appeal or settlement, if any. The Company has no access to these funds and limited information as to their investment status. The Court will pay 1.5%

interest per annum on the deposit, which will be reinvested into the deposit account by the Court and subject to the same restrictions as the principal amount. The Company has classified this restricted cash deposit as a current asset commensurate with the *Parallax* judgment being included in other current liabilities in the consolidated balance sheets (see Notes 7 and 13). Once the *Parallax* appeal is final and the amount to be paid, if any, is known, the Company will liquidate the deposit held by the Court and depending on the final judgment amount the Company may or may not use the funds from the deposit to pay the judgment. Therefore, the Company considers this deposit to be akin to a purchase of a temporary investment with the Court and any activity in this account from its inception to liquidation will be included as investing cash outflows and inflows in the Company's consolidated statements of cash flows.

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

Short-term investments at January 2, 2009 consisted of an original maturity four-month Certificate of Deposit at 7.5% held by our subsidiary in Australia, which matured in February 2009.



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**STAAR SURGICAL COMPANY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**July 3, 2009  
(Unaudited)**

**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):

	July 3, 2009	January 2, 2009
Raw materials and purchased parts	\$ 1,701	\$ 1,462
Work-in-process	2,741	3,028
Finished goods	11,230	12,178
	\$ 15,672	\$ 16,668

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

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

	July 3, 2009	January 2, 2009
Prepaids and deposits	\$ 1,216	\$ 1,703
Other current assets*	660	306
	\$ 1,876	\$ 2,009

\* No item in other current assets above exceeds 5% of total current assets.

**Note 6 Goodwill and Other Intangible Assets**

Amortizable intangible assets consisted of the following (in thousands):

	July 3, 2009			January 2, 2009		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Amortized intangible assets:						

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Patents and licenses	\$ 10,698	\$ (7,788 )	\$ 2,910	\$ 10,739	\$ (7,578 )	\$ 3,161
Customer relationships	1,631	(245 )	1,386	1,725	(172 )	1,553
Developed technology	1,037	(282 )	755	1,096	(199 )	897
Total	\$ 13,366	\$ (8,315 )	\$ 5,051	\$ 13,560	\$ (7,949 )	\$ 5,611

As of July 3, 2009 the gross carrying amount of the amortizable intangible assets had decreased by \$194,000 as a result of changes in the foreign currency exchange rates. The change in the carrying amount of goodwill presented on the accompanying consolidated balance sheets is also due to the effects of foreign currency translation.

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**STAAR SURGICAL COMPANY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**July 3, 2009  
(Unaudited)**

**Note 7 Other Current Liabilities**

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

	July 3, 2009	January 2, 2009
Accrued salaries and wages	\$ 2,185	\$ 2,467
Commissions due to outside sales representatives	265	395
Accrued audit fees	365	413
Customer credit balances	584	546
Accrued income taxes	986	486
Accrued legal	268	383
Accrued insurance	183	380
Accrued legal judgment including interest	5,057	4,900
Other*	1,734	1,396
	\$ 11,627	\$ 11,366

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

**Note 8 Employee Benefits**

The Company has historically maintained a passive pension plan (the Swiss Plan) covering employees of its Swiss subsidiary, which has been accounted for as a defined benefit plan under the provisions 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).

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 (Japan Plan) substantially covering all of the employees of STAAR Japan. STAAR Japan accounts for the Japan Plan under the requirements of SFAS 158.

The following table summarizes the components of net periodic pension cost recorded in general and administrative expenses for the Company's defined benefit plans (in thousands):

	Three Months Ended July 3, 2009	Three Months Ended June 27, 2008	Six Months Ended July 3, 2009	Six Months Ended June 27, 2008
Service cost	\$ 135	\$ 104	\$ 273	\$ 201
Interest cost	33	38	66	71
Expected return on plan assets	(24 )	(34 )	(48 )	(61 )
Amortization of unrecognized transition obligation or asset	6	5	12	11
Amount of gain recognized due to a settlement or curtailment	(4 )	(3 )	(9 )	(7 )
Recognized actuarial loss	8	7	16	12
	\$ 154	\$ 117	\$ 310	\$ 227

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**STAAR SURGICAL COMPANY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL  
STATEMENTS**

**July 3, 2009  
(Unaudited)**

**Note 8 Employee Benefits (continued)**

During the six months ended July 3, 2009 and June 27, 2008, the Company made cash contributions totaling approximately \$168,000 and \$228,000 to its defined benefit pension plans. The Company expects to make additional cash contributions totaling approximately \$168,000 to its defined benefit pension plans during the remainder of 2009.

**Note 9 Note Payable and Lines of Credit**

**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 between the Company and Broadwood, with a scheduled maturity of December 14, 2010. On April 2, 2009, after preliminary judgment was entered in the *Parallax* case, Broadwood and STAAR entered into a Temporary Waiver Agreement with respect to any event of default that may occur, or may be deemed to have occurred, under the Note as a result of the judgment. In consideration of the Temporary Waiver Agreement, STAAR agreed to amend the Senior Promissory Note to grant to Broadwood a security interest in substantially all of STAAR's assets to secure STAAR's obligations under the original Senior Promissory Note. To effectuate this grant of a security interest, as of April 13, 2009, the Company and Broadwood entered into an Amended and Restated Senior Secured Promissory Note (the Note ) and Security Agreement. All other key terms of the Note remained unchanged. The Temporary Waiver Agreement provided that if the Company secured a stay of enforcement of judgment prior to June 23, 2009 (the expiration date of a temporary stay granted by the Court), no default was deemed to have occurred with respect to the judgment. On June 24, 2009, following the timely posting of the deposit and satisfaction of the provisions of the Temporary Waiver, Broadwood and STAAR again amended the Note by replacing the Temporary Waiver with a provision stating that because the Company secured a stay of enforcement of judgment until the completion of the appeal by posting the required deposit with the Court, any default resulting from the *Parallax* judgment is deemed to be cured. Broadwood is entitled to receive interest at the rate of 20% per annum beginning on June 23, 2009, as would have been applicable in the event a default had occurred under the original terms of the Note. However, this rate may be lowered to 7% if the Company fully satisfies the *Parallax* judgment and fully resolves all other then outstanding and undecided material litigation of the Company. The Note may be pre-paid by the Company at any time without penalty, with prior notice, 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 initial 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. Based on publicly available information, as of June 23, 2009, Broadwood beneficially owned 6,028,638 shares of the Company's common stock comprising approximately 17.4% of the Company's issued and outstanding common stock.

As additional consideration for the loan, on December 14, 2007, the Company also entered into a Warrant Agreement with Broadwood (the December 2007 Warrant Agreement) granting 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 remained outstanding under the Note on June 1, 2009, the Company would 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. On June 1, 2009, as the entire \$5 million was outstanding, the Company issued an additional 700,000 warrants to Broadwood, which the Company has valued at approximately \$290,000 and included as additional paid-in capital in the consolidated balance sheet upon issuance. The

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(Unaudited)****Note 9    Note Payable and Lines of Credit    (continued)**

December 2007 Warrant Agreement also provides that the Company will register the shares issuable upon exercise of the warrants with the Securities Exchange Commission ( SEC ). The Company filed and secured effectiveness of a registration statement covering resale of the shares. If the Company fails to keep the registration statement effective and the lapse exceeds permitted suspensions, as the holder's sole remedy, the Company will be obligated to issue an additional 30,000 warrants for each month that the Company does not meet this effectiveness requirement through the term of the warrants ( Penalty Warrants ) (a maximum of approximately 2,130,000 warrants issuable as of July 3, 2009 under an assumed noncompliance as of that date). The Company does not consider the issuance of Penalty Warrants likely. The December 2007 Warrant Agreement has been accounted for as an equity instrument in accordance with the provisions of EITF 00-19. Additionally, 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 and the June 1, 2009 additional warrants valued at \$290,000 were treated as an additional discount on the loan and are being amortized using the effective interest method over the life of the loan (which approximates an effective interest rate of 32% per annum as of July 3, 2009, assuming the 20% cash interest rate is maintained throughout the life of the Note).

The fair value of the warrants was estimated on the December 14, 2007 and the June 1, 2009 issuance dates using a Black-Scholes option valuation model applying the assumptions noted in the following table.

	As of December 14, 2007	As of June 1, 2009
Common stock price per share	\$ 2.63	\$ 1.01
Expected dividends	0 %	0 %
Expected volatility	67.3 %	74.4 %
Risk-free rate	3.88 %	3.28 %
Remaining life (in years)	6.0	6.0

The Company adopted SFAS No. 157, *Fair Value Measurements*, on January 3, 2009. SFAS No. 157 defines fair value, establishes a three-level valuation hierarchy for disclosures of fair value measurement and enhances disclosure requirements for fair value measures. The three levels are defined as follows:

Level 1 Inputs to the valuation methodology are quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 Inputs to the valuation methodology include quoted prices for similar assets and liabilities in active markets, and inputs that are observable for the assets or liability, either directly or indirectly, for substantially the full term of the financial instruments.

Level 3 Inputs to the valuation methodology are unobservable; that reflect management's own assumptions about the assumptions market participants would make and significant to the fair value.

The warrants issued on June 1, 2009, are valued using Level 2 inputs.

### **Capital Lease Agreement**

The Company's lease agreement with Farnam Street Financial, Inc. ( Farnam ), as amended on October 9, 2006, provided for purchases of up to \$1,500,000 of property, plant and equipment. In accordance with the requirements of SFAS 13 Accounting for Leases, purchases under this facility are accounted for as capital leases and generally have a thirty-month to 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



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**Note 9    Note Payable and Lines of Credit    (continued)**

agreed-upon fair value. On April 1, 2007, the Company signed an additional leasing schedule with Farnam, which provided for additional purchases of \$800,000 during 2008. The terms of this new schedule conform to the amended agreement dated October 9, 2006. There are no remaining borrowings available under the agreement.

**Lines of Credit**

The Company's German subsidiary, Domilens, entered into a credit agreement on May 4, 2009 with Postbank. The credit agreement provides for borrowings of up to 500,000 EUR (\$704,000 at the rate of exchange on July 3, 2009), at a rate of 7.25% per annum. 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 and contains certain restrictions regarding payment of dividends or providing loans to the Company or other consolidated subsidiaries. There were no borrowings outstanding as of July 3, 2009 and January 2, 2009 and the full amount of the line was available for borrowing as of July 3, 2009.

The Company's Japanese subsidiary, STAAR Japan, has an agreement, as amended on June 30, 2009, with Mizuho Bank which provides for borrowings of up to 300,000,000 Japanese Yen (approximately \$3.1 million based on the rate of exchange on July 3, 2009), at an interest rate equal to the Tokyo short-term prime interest rate (approximately 1.475% as of July 3, 2009) plus 1.125% and terminates on April 20, 2010, but may be renewed annually. The credit facility is not collateralized. The Company had 260,000,000 and 200,000,000 Japanese Yen outstanding on the line of credit as of July 3, 2009 and January 2, 2009, (approximately \$2.7 million and \$2.2 million based on the foreign exchange rates on July 3, 2009 and January 2, 2009, respectively).

**Covenant Compliance**

Among the events of default in the Note held by Broadwood Partners, L.P. is any judgment in excess of \$500,000 against the Company that shall remain unpaid. On April 2, 2009, after preliminary judgment was entered, Broadwood and STAAR entered into a Temporary Waiver Agreement with respect to any event of default that may occur, or may be deemed to have occurred, under the Note as a result of the *Parallax* judgment. On June 24, 2009, following the posting of the deposit and satisfaction of the provisions of the Temporary Waiver, Broadwood and STAAR again amended the Note by replacing the Temporary Waiver with a provision stating that because the Company secured a stay of enforcement of Judgment until the completion of the appeal by posting the required deposit with the Court, any default resulting from the *Parallax* judgment is deemed to be cured. As such, STAAR's obligation under the Note, which is due on December 14, 2010, net of the related discount, has been reclassified from current indebtedness as of

the first quarter ended April 3, 2009 to noncurrent indebtedness in STAAR's consolidated balance sheet as of July 3, 2009.

The Company is in compliance with covenants of the Note, the capital lease agreement and the lines of credit as of July 3, 2009.

## **Note 10 Redeemable, Convertible Preferred Stock**

Under its Certificate of Incorporation the Company has 10,000,000 shares of blank check preferred stock that 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. 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.

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**Note 10 Redeemable, Convertible Preferred Stock (continued)**

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 (December 29, 2010) of the issuance date by a majority vote of the Preferred Stock holders with at least 30-days written notice, to require the Company to redeem the Preferred Stock at the Redemption Price. However, if the redemption right is exercised by the Preferred Stock holders, in no event is the Company required to pay the redemption price if the Company is insolvent or if payment would cause the Company to become insolvent, in accordance with the Delaware General Corporation Law.

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.

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

\* 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

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**Note 10 Redeemable, Convertible Preferred Stock (continued)**

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 of 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 the liquidation, each Preferred Stockholder may convert their shares to common stock of the Company and participate in the proceeds of the liquidation to be paid to Common stockholders in lieu of any liquidation preference.

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 will be accreted to the redemption value using the interest method with a corresponding charge to Additional Paid-In Capital

over a three-year period.

## Note 11 Stockholders Equity

On June 17, 2009, the Company completed a public offering (the Offering ) of 4,555,319 shares of Common stock to institutional investors at the previous day's closing market price of \$1.88 per share, raising \$8.5 million in aggregate, net of approximately \$16,000 issuance costs. No warrants or other financial instruments were issued in the Offering. The Offering resulted in an increase in the par value of Common Stock of \$46,000, with the remainder of the proceeds being recorded as additional paid-in capital on the issuance date. The primary purpose of the Offering was to provide the funds necessary to post a deposit with the Superior Court of California, County of Orange, in connection with the Company's *Parallax* judgment while the case is on appeal (see Notes 2 and 13).

On February 20, 2009, the Company issued 246,764 shares of Company common stock to certain of its attorneys at the closing market price of \$1.72 per share, or approximately \$425,000, in lieu of cash for previously incurred legal services related to the *Parallax* case.

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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 6,588,822 and 6,494,218 for the three and six months ended July 3, 2009, respectively, and 6,121,511 and 6,164,266 for the three and six months ended June 27, 2008, 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):

	Three Months Ended		Six Months Ended	
	July 3, 2009	June 27, 2008	July 3, 2009	June 27, 2008
Net loss	\$ (1,088 )	\$ (2,545 )	\$ (2,750 )	\$ (11,485 )
Minimum pension liability adjustment	(1 )	(9 )	(2 )	(7 )
Foreign currency translation adjustment	818	(528 )	(225 )	1,395
Total comprehensive loss	\$ (271 )	\$ (3,082 )	\$ (2,977 )	\$ (10,097 )

**Note 12 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 South Korea, no country in which the Company conducts business has sales that exceed 5% of the Company's 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, Japan, South Korea, and other locations for each year, is set forth below

(in thousands):

	Three Months Ended		Six Months Ended	
	July 3, 2009	June 27, 2008	July 3, 2009	June 27, 2008
United States	\$ 4,153	\$ 5,198	\$ 8,391	\$ 9,722
Germany	5,959	6,976	12,084	13,416
Japan	3,856	3,529	7,556	6,481
Korea	1,615	890	2,601	1,640
Other	3,534	4,072	6,768	7,366
Total	\$ 19,117	\$ 20,665	\$ 37,400	\$ 38,625

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

	Three Months Ended		Six Months Ended	
	July 3, 2009	June 27, 2008	July 3, 2009	June 27, 2008
IOLs	\$ 8,510	\$ 8,738	\$ 16,656	\$ 16,686
ICLs	5,652	5,405	10,717	9,684
Other Surgical Products	4,955	6,522	10,027	12,255
Total	\$ 19,117	\$ 20,665	\$ 37,400	\$ 38,625

The Company sells its products internationally, which subjects the Company to several potential risks, including fluctuating foreign currency exchange rates, regulation of fund transfers by foreign governments, United States and foreign export and import duties and tariffs, and political instability.

**Note 13 Commitments and Contingencies****Litigation and Claims**

*Parallax Medical Systems, Inc. v. STAAR Surgical Company* (California Superior Court, County of Orange, Case No. 07CC10136). Final judgment in this case was rendered on May 11, 2009, in accordance with a March 2, 2009 jury verdict awarding approximately \$2.2 million in actual damages and \$2.7 million in punitive damages to Parallax Medical Systems, Inc. Parallax is a former independent regional manufacturer's representative ( RMR ) of STAAR. Parallax promoted sales of STAAR products in the southeastern region of the U.S. under a contract that expired on July 31, 2007. Parallax originally filed its complaint against STAAR on September 21, 2007, claiming, among other things, that STAAR interfered with Parallax's prospective economic advantage when it informed a regional IOL distributor that Parallax had a covenant restricting the sale of competing products, and that STAAR interfered with Parallax's contracts when STAAR caused some of its current or former subcontractors to enter into new agreements to represent STAAR products. STAAR filed a cross-complaint alleging breach of contract and misappropriation of trade secrets; the jury found in favor of *Parallax* on the cross-complaint. The complaint sought \$48 million in actual

damages and unspecified punitive damages.

Final judgment was rendered following a hearing on principal post-trial motions on May 8, 2009. On May 15, 2009, the Court ruled in favor of the Company by disallowing *Parallax*'s motion for legal fees in the amount of approximately \$314,000 related to its defense of STAAR's cross complaint. In this ruling, the Court ruled that the Plaintiff is not entitled to legal fees in this case. On July 14, 2009, the Court in part granted STAAR's motion to strike or reduce Parallax's claim for approximately \$109,000 in trial related costs, of which approximately \$56,000 was awarded to Parallax, which will be added to the judgment with payment subject to the pending appeal. If STAAR's appeal is unsuccessful, post-judgment interest at a rate of 10% per annum will also be payable.

STAAR believes that the *Parallax* case was incorrectly decided as to liability, the amount of compensatory damages and the appropriateness and amount of punitive damages, and intends to vigorously appeal the outcome of this case. On June 22, 2009, the Company deposited \$7.3 million into a restricted account with the Court to assure payment of the judgment, thereby staying any enforcement of the judgment pending the appeal.

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**Note 13 Commitments and Contingencies (continued)**

*Moody v. STAAR Surgical Company*; (California Superior Court, County of Orange, Case No. 07CC10132). Scott C. Moody, Inc., also a former RMR of STAAR, filed a complaint against STAAR on the same day that *Parallax* filed its complaint. Moody promoted sales of STAAR products in the southwestern region of the U.S., under a contract that, like *Parallax*’s, expired on July 31, 2007. Like *Parallax*, *Moody* claims that STAAR interfered with *Moody*’s prospective economic advantage when it informed a regional IOL distributor that Moody had a covenant restricting the sale of competing products. The complaint seeks \$32 million in actual damages and unspecified punitive damages. STAAR has filed a cross-complaint alleging breach of contract and misappropriation of trade secrets.

The *Moody* case is currently scheduled to be tried before a jury on October 19, 2009. STAAR believes that the evidence to be presented in *Moody* does not support liability for interference with prospective business advantage or interference with *Moody*’s contracts with former subcontractors, and does not support damages at a level that is material to STAAR. However, the *Parallax* and *Moody* cases have many facts in common; the plaintiff in *Moody* alleges that the same conduct of STAAR interfered with its prospective business advantage, and *Moody* will also be tried before a jury. The *Moody* plaintiff has also indicated it will seek punitive damages. But because no two courts or trials are identical, the outcome of the *Moody* case cannot be predicted. In particular, important factual differences exist between the two cases, it is possible that the *Moody* court will permit different evidence or arguments to be presented at trial, and the outcome of jury trials is inherently uncertain. On May 4, 2009, STAAR retained new counsel for the *Moody* case following the appointment of its former lead counsel to a judgeship on the California Superior Court. On July 1, 2009, STAAR filed a motion for summary judgment in the case based on additional defenses, and on July 2, 2009 STAAR filed a motion to amend its answer to the *Moody* complaint to raise additional defenses.

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 14 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 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.

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As of July 3, 2009, the Company has multiple share-based compensation plans. 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		Six Months Ended	
	July 3, 2009	June 27, 2008	July 3, 2009	June 27, 2008
SFAS 123R expense	\$ 220	\$ 308	\$ 496	\$ 672
Common stock issued to employees	1		288	
Restricted stock expense	53	59	119	133
Consultant compensation	20	20	(1 )	20
Total	\$ 294	\$ 387	\$ 902	\$ 825

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 \$21,000 and \$54,000 of SFAS No. 123R compensation to inventory for the three and six months ended July 3, 2009, and \$39,000 and \$88,000, respectively, for the three and six months ended June 27, 2008, and recognizes those amounts as expense under in 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 ). As of July 3, 2009, there were 32,580 shares 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 2,671,501 shares were outstanding at July 3, 2009 with exercise prices ranging between \$0.95 and \$8.80 per share. Restricted stock grants under the 2003 Plan generally vest over a period of one,

three or four years. There were 53,722 shares of restricted stock outstanding at July 3, 2009.

In fiscal year 2000, the Board of Directors approved the Stock Option Plan and Agreement for the Company's Chief Executive Officer authorizing the granting of options to purchase common stock or awards of common stock. Pursuant to this plan, options for 500,000 were outstanding at July 3, 2009, 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. Pursuant to the plan, options for 485,633 were outstanding at July 3, 2009 with exercise prices ranging between \$3.350 and \$13.625 per share. No further awards may be made under this plan.

In fiscal year 1995, the Company adopted the 1995 Consultant Stock Plan, authorizing the granting of options to purchase common stock or awards of common stock. Pursuant to this plan, options for 45,000 shares were outstanding at July 3, 2009 with an exercise price of \$1.70 per share. No further awards may be made under this plan.

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Under provisions of the Company's 1991 Stock Option Plan, 2.0 million shares were reserved for issuance. Pursuant to this plan, options for 60,000 shares were outstanding at July 3, 2009 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 30,000 shares were outstanding at July 3, 2009 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 six months ended July 3, 2009 and had an expected term of 5.50 years derived from historical exercise and termination activity. The Company has calculated a 10.0% estimated forfeiture rate used in the model for fiscal year 2009 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				Six Months Ended			
	July 3, 2009		June 27, 2008		July 3, 2009		June 27, 2008	
Expected dividend yield	0	%	0	%	0	%	0	%
Expected volatility	79.06	%	60.87	%	73.43	%	61.82	%
Risk-free interest rate	2.66	%	3.07	%	1.89	%	2.94	%
Expected term (in years)	5.5		5.5		5.5		5.5	

A summary of option activity under the Plans as of July 3, 2009 is presented below:

Options	Shares (000 s)	Weighted- Average	Weighted- Average	Aggregate Intrinsic
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		Exercise Price	Remaining Contractual Term	Value (000 s)
Outstanding at January 2, 2009	3,854	\$ 5.80		
Granted	195	1.49		
Exercised				
Forfeited or expired	(257 )	7.44		
Outstanding at July 3, 2009	3,792	\$ 5.47	5.62	\$
Exercisable at July 3, 2009	2,963	\$ 6.15	4.77	\$

The weighted-average grant-date fair value of options granted during the six months ended July 3, 2009 was \$1.07 per option. The total fair value of options vested during the six months ended July 3, 2009 and June 27, 2008 was \$983,000 and \$1,330,000, respectively. There were no options exercised in the six months ended July 3, 2009 and June 27, 2008.



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**STAAR SURGICAL COMPANY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**July 3, 2009  
(Unaudited)**

**Note 14 Stock-Based Compensation (continued)**

A summary of the status of the Company's non-vested shares as of July 3, 2009 and changes during the period is presented below:

Nonvested Shares	Shares (000 s)	Weighted- Average Grant Date Fair Value
Nonvested at January 2, 2009	1,092	\$ 2.25
Granted	195	1.07
Vested	(415 )	2.36
Forfeited	(43 )	1.91
Nonvested at July 3, 2009	829	\$ 1.88

As of July 3, 2009, there was \$1.1 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 1.44 years.

**Note 15 Supplemental Disclosure of Cash Flow Information**

Interest paid was \$132,000 and \$115,000 for the six months ended July 3, 2009 and June 27, 2008, respectively. Income taxes paid amounted to approximately \$318,000 and \$630,000 for the six months ended July 3, 2009 and June 27, 2008, respectively.

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

	July 3, 2009	June 27, 2008
Non-cash investing and financing activities:		
Acquisition of Canon Staar	\$	\$ 7,147
Applied 2007 advance payment on acquisition of Canon Staar		(4,000 )
Applied 2007 deferred acquisition costs		(197 )
Acquisition costs in accounts payable and accrued liabilities		296

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Assets obtained by capital lease	479	460
Issuance of common stock to attorneys for legal services performed	425	
Warrants issued to Broadwood	290	
Issuance of preferred stock		6,800
Issuance and registration costs of preferred stock included in accounts payable and accrued liabilities		(48 )

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## **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 we believe that the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risks and STAAR 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 STAAR. These factors include, without limitation, those described in this report and in our Annual Report on Form 10-K for the fiscal year ended January 2, 2009 under the heading *Risk Factors*. STAAR undertakes no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes.

The following discussion should be read in conjunction with STAAR'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®, nanoFLEX™, nanoPOINT™, Epiphany™, 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**

#### **Intraocular lenses**

We generate a substantial portion of our revenue by manufacturing and selling foldable intraocular lenses, known as IOLs, and related products for cataract surgery. STAAR pioneered the foldable IOL, a flexible prosthetic lens used to replace a cataract patient's natural lens after it has been extracted in minimally invasive small incision cataract extraction. STAAR makes IOLs out of silicone and out of our proprietary Collamer lens material. STAAR's IOLs are available in both three-piece and one-piece designs. STAAR's range of IOLs includes the following:

three-piece IOLs, available in silicone or Collamer;

single-piece IOLs, available in silicone or Collamer;

The silicone Toric IOL, used in cataract surgery to treat preexisting astigmatism; and

The Preloaded Injector, a silicone or acrylic IOL preloaded into a single-use disposable injector, which is currently available outside the U.S.

Most of STAAR's IOLs sold worldwide feature aspheric optics, an advanced design intended to provide a clearer image than traditional spherical lenses, especially in low light. STAAR has developed a proprietary aspheric design (patent pending) that is optimized for the naturally curved surface of the retina and certain other anatomical features of the human eye, and that provides outstanding image quality even if accidentally moved off center.

Because the majority of cataract patients are elderly and qualify for Medicare, most of STAAR's U.S. cataract revenue derives indirectly from reimbursement payments by the Center for Medicaid and Medicare Services, or CMS. CMS has granted to STAAR's aspheric lenses New Technology Intraocular Lens status,

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which provides an additional \$50 reimbursement to doctors or hospitals that use these lenses in ambulatory surgical centers, enabling STAAR to increase the average selling price for these lenses.

Outside the U.S. as well, government agencies or government sponsored entities generally pay the cost of IOLs for cataract patients. As a result, STAAR believes that IOL revenues are likely to remain relatively stable even under adverse conditions in the general economy.

Sales of IOLs during the three and six months ended July 3, 2009 were \$8.5 million and \$16.7 million and represent approximately 45% of total net sales.

### **Visian ICL**

Manufacturing and selling lenses used in refractive surgery is an increasingly important source of revenue for STAAR. We have used our proprietary biocompatible Collamer material to develop and manufacture implantable Collamer lenses, or ICLs. 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 50 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.

ICL sales internationally increased by 12% in the second quarter as compared to the same period in the prior year while in the U.S. sales declined 15% due to the continued decline of refractive procedures in the U.S. during 2009. Despite the current decline in refractive procedures the ICL has grown in market share in each of the top ten refractive markets. Refractive surgery is an elective procedure generally not covered by health insurance. Patients must pay for the procedure, frequently through installment financing arrangements. Patients can defer the choice to have refractive surgery if they lack the disposable income to pay for it, they do not feel their income is secure, or they cannot obtain credit. As a result, if the current recession continues it may reduce sales of ICLs.

Sales of ICLs during the three and six months ended July 3, 2009 were \$5.7 million and \$10.7 million and represent approximately 29% of total net sales.

### **Other surgical products**

We offer a number of other products used in ophthalmic surgery that complement our IOL and Visian ICL product lines. We market STAARVISC II, a viscoelastic material which is used as a protective lubricant and to maintain the shape of the eye during surgery. We also manufacture Cruise Control™, a single-use disposable filter used in phacoemulsification, which is the process of removing a cataract patient's cloudy lens through a small incision using ultrasound and suction. Cruise Control allows for a faster, cleaner phacoemulsification procedure and is compatible with all phacoemulsification equipment. We also make the AquaFlow Collagen Glaucoma Drainage Device, an implantable device used for the surgical treatment of glaucoma. We also sell other instruments, devices and equipment that we manufacture or that others in the ophthalmic industry manufacture.

Sales of other surgical products during the three and six months ended July 3, 2009 were \$5.0 million and \$10.0 million and represent approximately 26% of total net sales.



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### **Operations**

STAAR has significant operations both within and outside the U.S., and receives the majority of its revenue from its activities outside the U.S. 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. STAAR Surgical AG handles distribution and other administrative affairs for Europe and other territories outside North America and Japan.

*Japan.* Through its wholly owned subsidiary, STAAR Japan, Inc., STAAR maintains executive offices and distribution facilities in Shin-Urayasu, 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 and TICL, Collamer IOL and AquaFlow Device.

*Germany.* STAAR's wholly owned subsidiary, Domilens Vertrieb Für Medizinische Produkte GmbH, is headquartered in Hamburg, 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. Domilens distributes and services products of third party manufacturers and distributes STAAR's ICLs, IOLs, and Preloaded Injectors.

The global nature of STAAR's business operations subjects it to risks, including the effect of changes in currency foreign exchange rates, differences in laws, including laws that protect intellectual property or regulate 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 January 2, 2009 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**

During 2009, STAAR is focused on the following five strategic operational goals:

- to improve cash flow;
- to increase gross profit margin;
- to continue cost reduction efforts;
- to secure key regulatory approvals;
- to increase the ICL's share of the refractive market in key territories.

*Improve cash flow.* For several years STAAR has not generated enough cash to sustain its operations and has relied on financing activity to supplement cash from operations. Through a combination of cost cutting and enhanced product mix STAAR has reduced its use of cash significantly in recent periods. In the second quarter of 2009, STAAR achieved a positive cash flow from operations as a result of these efforts. If recent trends continue, STAAR expects to generate positive cash flows from operations for the remainder of 2009. While STAAR's ultimate goal is to achieve profitability, achievement of positive cash flow this quarter was an important milestone for the Company, and if it continues will enhance STAAR's ability to obtain financing on favorable terms, and will permit STAAR to further invest in expansion of its business.





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STAAR generated \$286,000 of cash from operations during the second quarter of 2009 and used \$162,000 of cash in operations during the six months of fiscal year 2009 compared to \$2.8 million of cash used during the second quarter of 2008 and \$6.1 million of cash used for the six months of fiscal year 2008. The improved cash flow in the second quarter continues a trend established in fiscal year 2008, when STAAR used \$3.4 million of cash in operations in the first quarter of 2008 and \$8.2 million of cash used during fiscal year 2008. Approximately \$3.2 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 further improve cash flow by cutting costs and increasing profit margins, which are separately discussed in greater detail below. STAAR's cost-cutting efforts in the U.S., described in greater detail under the heading *Continue Cost Reduction Efforts* yielded savings in operating expenses during the second quarter of 2009 of approximately \$1.8 million, or 27%, when compared to the second quarter of 2008. For the first six months of 2009, these savings in the U.S. were \$2.7 million, or 21%, when compared to the first six months of 2008.

During fiscal year 2008 and early 2009 STAAR's cash flow has been negatively affected by the cost of defending two lawsuits brought by former independent regional manufacturer's representatives. On March 2, 2009, in the first of these cases (*Parallax*), a jury rendered a verdict against STAAR for a total of \$4.9 million in actual and punitive damages and on May 11, 2009, the court entered final judgment in that amount. On June 22, 2009, the Company posted with the court a \$7.3 million deposit required to stay enforcement of the judgment while it is on appeal. The Court will maintain complete control of and access to this deposit, including the final disbursement of any and all amounts upon the final outcome of the *Parallax* appeal or prior settlement, if any. See *Liquidity and Capital Resources* below.

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. Factors affecting the success of STAAR's cash management plans include the outcome of the *Moody* trial and our degree of success in increasing the amount of cash generated by our business through increased sales and improved profit margins.

*Increase gross profit margins.* U.S. IOL sales revenue has continued to decline, but the rate of decline has slowed as STAAR has begun replacing older lens designs with higher priced NTIOL lenses. In the second quarter of 2009, U.S. IOL sales were relatively flat compared to the same quarter in the prior year and sequentially IOL sales increased approximately 8%, while in the first quarter of 2009 U.S. IOL sales declined 8% year-over-year and the rate of decline was 16% in 2008 and 20% in 2007. If our new IOL product introductions are successful, U.S. IOL sales may resume growing in 2009, but if this does not occur, STAAR may find it necessary to reduce spending in its U.S. operations more deeply.

While expanded market share and increased gross revenue remain key goals, STAAR believes that it can achieve profitability even at modest growth levels by increasing its profit margin through the following means:

*Increasing ICL sales as a percentage of STAAR's overall product mix.* ICLs and TICLs generally yield high margins and are STAAR's most profitable products. ICLs continue to represent the fastest growing product line of STAAR's business and are the largest contributor to enhanced profit margins. Bringing ICL and TICL to new markets, and expanding market share in existing markets, will improve STAAR's profitability. This initiative is described in greater detail under *Other Highlights* *ICL Sales* below.

*Shifting to higher value IOLs.* In 2007 and 2008 STAAR began converting its U.S. IOL product offering from lower value spherical products to newer aspheric designs that are eligible for enhanced CMS reimbursement as NTIOLs. STAAR has now added aspheric optics to all of its IOL platforms. While STAAR hopes to regain lost U.S. IOL market share through new product introductions, the enhanced profitability of these designs should significantly

improve the performance of the U.S. IOL business even if market share gains are minimal. As a result of the conversion of STAAR's silicone product offering to NTIOL lenses, STAAR's silicone IOL sales increased 19% in the second quarter year-over-year, and were up 9% for the first six

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months of 2009. With the third quarter launch of nanoFLEX™, a one-piece Collamer NTIOL that can be delivered through a 2.2 mm incision using STAAR's nanoPOINT™ injector, and launch of the Epiphany™ injector for the three-piece Collamer NTIOL, STAAR believes that similar gains may be achievable in the Collamer IOL sector. In addition, STAAR believes it can significantly improve gross margins in 2009 through continued growth in sales of its preloaded IOL offering, especially in Japan, where selling prices for IOLs are relatively high.

*Improve product mix and pricing of other surgical products.* STAAR distributes a variety of complimentary products used in ophthalmic surgery as a service to its customers. In an effort to improve margins of other surgical products, STAAR is reviewing all pricing to determine if products are priced appropriately and is discontinuing product lines with lower than average margins.

*Implement Centers of Excellence Program.* STAAR believes that it has an opportunity to reduce costs while continuing its history of innovation by rationalizing its business among its worldwide operations through its Centers of Excellence program. The first initiative in this area has begun in 2009, as STAAR begins making its U.S. facility the center of excellence for optical design and manufacturing of IOLs and Japan the center of excellence for design and manufacturing of delivery systems. By moving all IOL manufacturing to STAAR's Monrovia facility STAAR expects to significantly reduce costs by increasing volume without significantly increasing fixed costs. Similarly, the transfer of delivery system development and manufacturing to Japan is expected to lead to cost savings and a greater focus on STAAR Japan's more advanced lens injector designs. STAAR expects to see margin expansion in 2010 as a consequence.

*Continue Cost Reduction Efforts.* While STAAR's international operations, outside of Japan, 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, including targeted reductions in the U.S. workforce. Beginning in December 2007, STAAR began a process to closely rationalize and evaluate its spending levels. These initiatives included 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 second quarter of 2009, operating expenses declined \$2.2 million from the second quarter of 2008, mainly due to decreases in marketing and selling and research and development expenses; for the first six months of 2009, operating expenses have declined \$7.2 million compared to the first six months of 2008, however, this decline partly reflects \$3.8 million in acquisition costs related to STAAR Japan that we incurred in 2008. The reduction in expense was nevertheless significant and continued the trend established in 2008, when STAAR achieved a \$4.5 million reduction in U.S. annual operating expenses over the prior year. STAAR continues to seek to identify opportunities for savings in its global operations.

*Secure Key Regulatory Approvals.* Regulatory approvals of high margin products in significant markets can yield rapid growth in sales and improvements in profitability. The principal approvals pursued by STAAR at this time are the U.S. approval of the TICL and the approval of ICL and TICL in Japan.

STAAR's TICL corrects both myopia and astigmatism, and has been shown to be highly effective in treating individuals affected by both 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 making the product family a more complete solution that physicians can offer to patients. STAAR has applied for approval of the TICL in the U.S., but the FDA had suspended review of the application pending resolution of concerns regarding STAAR's oversight of the TICL clinical study. On July 21, 2009 the FDA informed STAAR that this integrity hold had been removed. Although the removal of the integrity hold should not be construed as approval of any conditions that may be found in the future, nor should it be construed as clearance to market the Visian Toric ICL, the removal of the integrity hold enables the FDA to resume scientific review of the STAAR application for the Toric Implantable Collamer Lens (TICL(TM)) for Myopic/ Astigmatic patients. This agency action, and STAAR's progress is discussed below under the caption *Other*



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*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 generally increase over time 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.

In June 2009, STAAR received CE Mark approval for its KS-X Preloaded Hydrophobic Acrylic Injector for use in minimally invasive cataract surgical procedures. The CE Mark allows STAAR to market this foldable intraocular (IOL) KS-X lens delivery system in the European Union as well as other countries that recognize the CE Mark.

STAAR has been offering the KS-X system, which mates a preloaded delivery system manufactured by STAAR Japan with an independently sourced acrylic lens, in the Japanese market for two years. The STAAR system enables lens delivery into the eye through a 2.8 millimeter incision and is compatible with the most commonly used small incision cataract extraction procedures. It is the only preloaded lens delivery system in the world that provides single or bi-manual injection options in one single design, allowing for the smoothest IOL injection methods compared with traditional delivery systems. First shipments of the product in key European and Australian markets began in late June. STAAR's preloaded injectors are not approved for sale in the U.S.

In addition, on June 11, 2009, the FDA granted 510(k) clearance for the Company's Epiphany Injector System for use with the Affinity Collamer Three-Piece NTIOL and the Elastimide Silicone NTIOL. The Epiphany is a manually loaded version of STAAR's preloaded injector designed for smooth, controlled delivery of the three-piece Collamer IOL. It is the first insertion device available in the U.S. using injector technology developed at STAAR Japan and will pave the way for the future introduction of a preloaded injector for the U.S. market. Epiphany has been designed to combine both ease of use with controlled delivery. The Epiphany injector system is intended for single use and offers the flexibility of either twist or push insertion techniques—a unique feature of STAAR's IOL delivery systems. First shipments of the product began in July with full release to the market in the August timeframe.

Approval of ICL and TICL by Japanese regulators is pending. Like other Asian countries, Japan has a high mean rate of myopia, which is often accompanied by astigmatism. As a result STAAR believes that the Japanese market for ICL and TICL is promising. STAAR Japan's preloaded IOL injectors have established a presence in the Japanese cataract IOL market that could also help establish a market for the Collamer IOL.

*Increase the ICL's Share of the Refractive Market in Key Territories.* While the ICL and TICL are approved for sale in over 50 countries, a smaller group of countries where we have achieved significant sales volume and market share yields the bulk of our ICL and TICL sales revenue. STAAR currently views the following as its key markets for the ICL and TICL:

United States  
China  
Germany  
India  
Korea  
Spain  
Latin America

To date, the highest penetration rate achieved by STAAR for ICL and TICL within any particular refractive surgery market has exceeded 5% but is less than 10%. STAAR believes it has the opportunity to achieve significant profits if it can achieve a 5% or greater penetration rate in all of its key markets, and during 2009 will concentrate its international sales efforts on key markets to achieve that goal.



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***Other Highlights***

*U.S. ICL Sales.* We consider ICL sales growth in the U.S. market to be essential because of the size of the U.S. refractive surgery market and the perceived worldwide 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.

Visian ICL sales in the U.S. were relatively flat in the first six months of 2009 compared to prior year, and grew 18% in 2008 when compared to 2007 levels.

STAAR believes that the continued global recession represents the largest challenge to increased growth in U.S. ICL sales. Refractive surgery is an elective procedure generally not covered by health insurance. Patients must pay for the procedure, frequently through installment financing arrangements. Overall ICL sales grew during 2008 but were relatively flat in the first six months of 2009 compared to the same period in 2008. However, quarter over quarter, STAAR has seen a 15% decline, and sequentially to the first quarter of 2009 a 10% decline which we believe is due to significantly lower volume of patients seeking refractive surgery, which reduces the number of patients to whom the ICL is offered. While ICL sales have been much more resistant to the recession than laser-based procedures, if severe recession conditions continue for a prolonged period, ICL sales may decline further until consumer spending levels begin to recover. STAAR believes that its share of the U.S. refractive market has grown during the past years, which will position the ICL for strong sales growth when conditions improve.

Other challenges to sustained growth in U.S. Visian ICL sales include the following:

the U.S. refractive surgery market has been dominated by corneal laser-based techniques, which continue to be better known than the Visian ICL among 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;

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.

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, STAAR believes the negative publicity concerning LASIK has decreased 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 makes the ICL available to selected surgeons only after completion of a training program that includes

proctoring of selected supervised surgeries. STAAR believes that this carefully guided method of product release is essential to help ensure the consistent quality of patient outcomes and the high levels of patient satisfaction needed to establish wide acceptance of the ICL as a primary choice for refractive surgery.



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*U.S. IOL Sales* For several years STAAR has experienced a decline in U.S. market share of IOLs. The rate of decline has slowed as STAAR has begun replacing older lens designs with higher priced NTIOL lenses. In the second quarter of 2009, U.S. IOL sales were flat compared to the second quarter of 2008, while the rate of decline was 16% in 2008 and 20% in 2007. Factors contributing to long-term decline in U.S. IOL sales include the slow pace of 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 was unable to reach a new contract 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. IOL business is to rationalize its 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 IOL 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 introduction of the nanoFLEX™ aspheric single-piece Collamer IOL in the second quarter of 2009, which brings advanced aspheric optics to the micro-incision nanoPOINT platform; and
- the launch of the Epiphany injector for the Collamer three-piece lens in the third quarter of 2009 which brings smoother and more controlled delivery to one of STAAR's most advanced lenses and paves the way for U.S. introduction of the silicone preloaded injector.

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 majority of IOL purchases in the U.S. are implanted at ASCs and reimbursed through Medicare, NTIOL status significantly increases STAAR's potential margin on qualifying lenses.

All of STAAR's aspheric lenses sold in the U.S. 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.

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

Complete the development of the Collamer Toric IOL to complement our pioneering silicone Toric IOL and better compete with the Alcon acrylic Toric IOL. The Collamer Toric IOL should provide a product with advanced optic materials and rotational stability to provide superior outcomes for cataract patients with astigmatism.

Gain approval for a preloaded silicone IOL injector system in the U.S.

Develop a preloaded injector system for our Collamer IOLs.

Continue to study the accommodating properties of our Collamer single piece IOL to determine the possible submission of claims that the lens offers patients less spectacle dependence or accommodation.

STAAR cautions that the successful development and introduction of new products is subject to risks and uncertainties, including the risk of unexpected delays and, in some cases, prior approval of regulatory authorities.

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. Physician preferences in the U.S. have shifted to some degree toward acrylic IOLs though currently silicone IOLs still account for approximately 25% 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 glistening into the visual field, the stiffness and toughness of the acrylic material makes design of delivery systems simpler. STAAR has completed 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. In addition the launch of the Epiphany injector for the Collamer three-piece lens in the third quarter of 2009 brings smoother and more controlled delivery to one of STAAR's most advanced lenses.

Over the past several years surgeons implanting the Collamer Single Piece IOL have reported that their cataract patients have better than expected near vision. In late 2008 STAAR, organized the Collamer Accommodating Study Team or CAST. The CAST consists of eight prominent physicians across the U.S. The CAST physicians are implanting the recently launched Collamer Aspheric Single Piece IOL (nanoFLEX) and are checking both near and intermediate vision approximately one month post operation. STAAR believes the feedback received thus far is encouraging. It indicates that nanoFLEX achieves better near vision than that of any conventional IOL where STAAR has comparative data. The feedback also appears to indicate that nanoFLEX achieves near vision better than some presbyopia correcting IOLs that have been studied and approaches that of others that are already on the market. The team will continue to study this data. STAAR cautions that the CAST results are preliminary and that no data has been submitted to the FDA regarding near vision performance of the nanoFLEX. Until broader and more systematic clinical research is performed STAAR cannot determine if a claim of accommodation or reduced spectacle dependence for nanoFLEX is likely to be approved. Information about CAST is provided in this report for the information of investors only, and is not intended as a recommendation to physicians or their patients regarding indications for the use of any STAAR product.

While the market share of silicone IOLs has been slowly declining overall, a significant number of surgeons continue to select silicone lenses for their patients. Among U.S. IOL sales, STAAR believes that its recently introduced

aspheric, three-piece silicone IOL offers outstanding optical performance and with its

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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. In this regard, the improved silicone IOL sales in the second quarter of 2009 are encouraging.

We have developed and currently market 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.

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.

*Reorganization of U.S. Sales Force.* 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 on independent sales representatives as well as employees 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.

*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. Based on the results of the FDA inspections of STAAR's Monrovia, California facilities between 2005 and 2009, STAAR believes that it is substantially in compliance with the FDA's Quality System Regulations and Medical Device Reporting regulations. The recent lifting of the integrity hold placed on STAAR's clinical activities by the Office of Device Evaluation similarly indicates that STAAR's corrective actions have brought its oversight of clinical activities substantially into compliance. Notwithstanding its success in overcoming past concerns regarding its quality systems, 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, including the June 26, 2007 warning letter from the Bioresearch Monitoring Program of the FDA Office of Regulatory Affairs (BIMO). STAAR has invested significant resources in maintaining regulatory compliance and expects to continue to do so in the future. STAAR believes that U.S. approval of the TICL, if granted, and continued evidence of good standing with the FDA will reduce and may eventually eliminate the reputational harm caused by past agency actions.

### **Status of TICL Submission.**

STAAR submitted a Pre-Market Approval Application (PMA) supplement for the TICL to the FDA on April 28, 2006. The FDA's consideration of the application was suspended on August 3, 2007, when the FDA notified STAAR that it would place the application on integrity hold. On July 21, 2009, the FDA notified STAAR that as a result of

various corrective actions the integrity hold had been removed and that consideration of the TICL application would resume.

The integrity hold resulted from inspectional observations made by the Bioresearch Monitoring Program of the FDA Office of Regulatory Affairs ( BIMO ) during an inspection related to the TICL conducted between February 15 and March 14, 2007. BIMO inspections are part of a program designed to ensure that data and information contained in certain requests for FDA approval are scientifically valid and accurate. Another objective of the program is to ensure that human subjects are protected from undue hazard or risk during the course of scientific investigations. STAAR responded to the eight inspectional observations issued

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by BIMO 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. While the past procedural violations noted in the Warning Letter are serious in nature and required comprehensive corrective and preventative actions, the Company does not believe that these nonconformities undermine the scientific validity and accuracy of its clinical data, or that human subjects were subjected to undue hazard or risk.

On August 3, 2007 STAAR received a letter from the FDA Office of Device Evaluation ( ODE ) notifying STAAR that the review of the TICL application would be placed on integrity hold (i.e., halted) until STAAR completed specified actions establishing the integrity and reliability of the clinical data under the TICL application and the robustness of STAAR's clinical trial procedures and systems. Noting the same deficiencies cited in the June 26, 2007 Warning Letter from BIMO, and other deficiencies noted in an audit of a clinical study site, ODE requested that STAAR engage an independent third party auditor to conduct an audit of patient records along with a clinical systems audit to ensure accuracy and completeness of data before resubmitting the application.

The findings from the third party auditor were submitted to FDA in two audit reports, dated October 8, 2008 and December 15, 2008. In response to questions from the FDA the December 15, 2008 report was revised and resubmitted by the third party auditor on March 13, 2009. Once the last of the reports was released to STAAR on May 6, 2009, STAAR completed a corrective action plan to address the findings of the third party auditor as reported to FDA and ensure that it is aligned with all of the auditor's filings. While STAAR had anticipated that the FDA would perform an inspection to verify the implementation of the corrective action plan, no inspection was required, and on July 21, 2009 the FDA removed the integrity hold. STAAR will now be permitted to resubmit the clinical data for the TICL application, as certified by the third party auditor, and FDA will resume substantive review of the TICL data. STAAR cannot assure investors that renewed consideration will result in approval by the ODE, or that the scope of requested TICL approval, if granted, would not be limited by the FDA.

In releasing the integrity hold, the FDA noted that for a period of two years it will require STAAR to obtain certification from an independent third party auditor for some of its filings.

## **Financing Strategy**

STAAR has reported losses and negative cash flows on a consolidated basis over the last several years, primarily as a result of losses in the U.S. IOL business. During this period STAAR has raised additional funds to support operations through sales of equity and debt securities. As cash flow improved in recent periods, STAAR has sought to avoid further financings and to operate exclusively on self-generated cash. This strategy was challenged in the first quarter of 2009, when cash reserves were drawn down to low levels, positive cash flow had not yet been achieved, and the Company suffered an adverse litigation judgment in the amount of \$4.9 million. At the time the judgment became final, STAAR did not have adequate cash or cash equivalents either to satisfy the judgment or to deposit 150% of the judgment amount with the court to obtain a stay of enforcement of the judgment while the appeal was pending.

On June 17, 2009, the Company completed a registered direct public offering (the Offering ) with certain existing institutional investors, raising a total of \$8.5 million in cash by issuing 4.6 million shares of Company's common stock. The proceeds were primarily applied to posting the required \$7.3 million deposit with the Superior Court of California, County of Orange, while the Parallax verdict is on appeal. On June 22, 2009, following the receipt of proceeds from the Offering, STAAR timely posted this deposit with the Court just before the expiration of a temporary stay of enforcement that had been granted by the court.

Other recent financing activity includes the December 14, 2007 borrowing by STAAR of \$5 million from Broadwood Partners, L.P., at an interest rate of 7% per annum, primarily to fund the acquisition of STAAR's remaining interest in the Canon Staar Joint Venture. On April 2, 2009, after preliminary judgment was entered in the *Parallax* case, Broadwood and the Company entered into a Temporary Waiver Agreement with respect to any event of default that may occur, or may be deemed to have occurred, under the Broadwood note as a result of the judgment. In consideration of the Temporary Waiver Agreement, STAAR agreed to amend the Original Note to grant to Broadwood a security interest in substantially all of STAAR's assets to secure STAAR's obligations under the Original Note. To effectuate this grant of a security interest, as of April 13,

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2009, the Company and Broadwood entered into an Amended and Restated Senior Secured Promissory Note and Security Agreement. The Temporary Waiver Agreement had provided that no such default was deemed to have occurred until June 23, 2009, when a temporary stay of judgment expired.

On June 24, 2009, following the posting of the deposit and satisfaction of conditions of the Temporary Waiver, Broadwood and STAAR again amended the Note by replacing the Temporary Waiver with a provision stating that because the Company secured a stay of enforcement of judgment until the completion of the appeal by posting the required deposit with the Court, any default that may have otherwise resulted from the *Parallax* judgment is cured. Broadwood is entitled to receive interest at the rate of 20% per annum beginning on June 23, 2009, as would have been applicable in the event a default had occurred under the original terms of the Note. However, this rate may be lowered to 7% if the Company fully satisfies the *Parallax* judgment or finally resolves all then outstanding and undecided material litigation.

STAAR believes its cash resources are sufficient to vigorously defend the *Moody* case. However, a material adverse judgment in *Moody* could exceed STAAR's available cash resources. Accordingly, STAAR may need to seek additional equity and/or debt financing and to explore other financing options to meet its need for working capital in the near term. STAAR may also seek new capital to expand its business or fund efforts to improve efficiency. However, STAAR does not expect to require significant new capital to support operations if its initiatives for cash management and improved profitability continue in line with present trends.

STAAR's need for working capital, and the terms on which financing may be available, will depend in part on its degree of success in achieving and maintaining positive cash flow and earnings through the strategies described above under the caption *Strategy*. STAAR cannot assure that such financing will be available at acceptable terms, if at all, if the need arises.

## **New Accounting Pronouncements**

On June 29, 2009, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 168 (SFAS No. 168), *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles (as amended)*. The *FASB Accounting Standards Codification*<sup>TM</sup> (Codification) will become the source of authoritative U.S. generally accepted accounting principles (GAAP) recognized by the FASB to be applied by nongovernmental entities. Rules and interpretive releases of the Securities and Exchange Commission (SEC) under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. Content contained in the SEC Sections of the Codification is provided for convenience and relates only to SEC registrants. The SEC Sections are not the authoritative sources of such content and do not contain the entire population of SEC rules, regulations, interpretive releases, and staff guidance. Content in the SEC Sections is expected to change over time, and there may be delays between SEC and staff changes to guidance and Accounting Standards Updates. The Codification does not replace or affect guidance issued by the SEC or its staff for public entities in their filings with the SEC. On the effective date of this Statement, the Codification will supersede all then-existing non-SEC accounting and reporting standards. All other nongrandfathered non-SEC accounting literature not included in the Codification will become nonauthoritative. This Statement is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The Codification will be effective for us in the third quarter ending October 2, 2009 and authoritative references to current applicable GAAP in our filings and other documents, as necessary, will be made using the relevant sections of the Codification.

On June 12, 2009, the FASB issued SFAS No. 167, *Amendments to FASB Interpretation No. 46(R) (as amended)*. FASB's objective in issuing this Statement is to improve financial reporting by enterprises involved with variable



interest entities. FASB undertook this project to address (1) the effects on certain provisions of FASB Interpretation No. 46 (revised December 2003), *Consolidation of Variable Interest Entities*, as a result of the elimination of the qualifying special-purpose entity concept in FASB Statement No. 166, *Accounting for Transfers of Financial Assets*, and (2) constituent concerns about the application of certain key provisions of Interpretation 46(R), including those in which the accounting and disclosures under the Interpretation do not always provide timely and useful information about an enterprise's involvement in a variable interest entity. This Statement shall be effective as of the beginning of each reporting entity's first annual reporting period that begins after November 15, 2009, for interim periods within that first annual reporting period, and for

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interim and annual reporting periods thereafter. Earlier application is prohibited. We do not believe that the provisions of this Statement, when effective, will result in a significant impact to our consolidated financial statements.

On June 12, 2009, the FASB issued SFAS No. 166, *Accounting for Transfers of Financial Assets (as amended)*. The FASB's objective in issuing this Statement is to improve the relevance, representational faithfulness, and comparability of the information that a reporting entity provides in its financial statements about a transfer of financial assets; the effects of a transfer on its financial position, financial performance, and cash flows; and a transferor's continuing involvement, if any, in transferred financial assets. The Board undertook this project to address (1) practices that have developed since the issuance of FASB Statement No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities*, that are not consistent with the original intent and key requirements of that Statement and (2) concerns of financial statement users that many of the financial assets (and related obligations) that have been derecognized should continue to be reported in the financial statements of transferors. This Statement must be applied as of the beginning of each reporting entity's first annual reporting period that begins after November 15, 2009, for interim periods within that first annual reporting period and for interim and annual reporting periods thereafter. Earlier application is prohibited. We do not believe that the provisions of this Statement, when effective, will result in a significant impact to our consolidated financial statements.

On May 28, 2009, the FASB issued SFAS No. 165, *Subsequent Events (as amended)*. The objective of this Statement is to establish general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. In particular, this Statement sets forth:

1. The period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements,
  2. The circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements,
  3. The disclosures that an entity should make about events or transactions that occurred after the balance sheet date.
- This Statement should not result in significant changes in the subsequent events that an entity reports either through recognition or disclosure in its financial statements. This Statement introduces the concept of financial statements being *available to be issued*. It requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for that date, that is, whether that date represents the date the financial statements were issued or were available to be issued. This disclosure should alert all users of financial statements that an entity has not evaluated subsequent events after that date in the set of financial statements being presented. An entity should apply the requirements of this Statement to interim or annual financial periods ending after June 15, 2009. Therefore, in accordance with this Statement, we deem these consolidated financial statements to be issued as of the date of filing of this report and we have evaluated subsequent events through that date.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements - An Amendment of ARB No. 51*. SFAS No. 160 establishes accounting and reporting standards for the non-controlling interest in a subsidiary. SFAS No. 160 also requires that a retained noncontrolling interest upon the deconsolidation of a subsidiary be initially measured at its fair value. Upon adoption of SFAS No. 160, the registrant is required to report its noncontrolling interests as a separate component of stockholders' equity and to present net income allocable to the noncontrolling interests and net income attributable to the stockholders of the company separately in its consolidated statements of operations. SFAS No. 160 requires retroactive adoption of the presentation and disclosure requirements for existing minority interests. All other requirements of SFAS No. 160 shall be applied prospectively. SFAS No. 160 became effective for us at the beginning of our 2009 fiscal year and the adoption of this standard did not have a material impact on our consolidated financial statements.



TABLE OF CONTENTS**Critical Accounting Policies**

Management's Discussion and Analysis of Financial Condition and Results of Operations are based on our unaudited Condensed Consolidated 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 six months ended July 3, 2009 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 January 2, 2009.

**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 Six Months		Percentage Change for Six Months
	July 3, 2009	June 27, 2008	2009 vs. 2008	July 3, 2009	June 27, 2008	2009 vs. 2008
Net sales	100.0%	100.0%	(7.5 )%	100.0%	100.0%	(3.2 )%
Cost of sales	44.2	44.2	(7.4 )	43.8	50.1	(15.2 )
Gross profit	55.8	55.8	(7.5 )	56.2	49.9	8.9
General and administrative	20.2	17.0	9.5	21.8	20.5	2.2
Marketing and selling	31.6	37.0	(21.1 )	31.6	36.5	(16.3 )
Research and development	7.5	11.4	(38.9 )	7.6	10.6	(30.0 )
Loss on settlement of pre-existing distribution arrangement					10.0	(100.0)
	59.3	65.4	(16.2 )	61.0	77.6	(24.0 )
Operating loss	(3.5 )	(9.6 )	(66.6 )	(4.8 )	(27.7 )	(83.2 )
Other expense, net	(0.8 )	(0.8 )	(10.0 )	(0.6 )	(0.3 )	95.0
Loss before provision for income taxes	(4.3 )	(10.4 )	(62.4 )	(5.4 )	(28.0 )	(81.2 )
Provision for income taxes	1.5	1.9	(29.3 )	1.9	1.7	9.5

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Net loss (5.8 )% (12.3 )% (57.2 ) (7.3 )% (29.7 )% (76.1 )

In comparing results of operations for the six months ended July 3, 2009 with six months ended June 27, 2008, readers should be aware that results for fiscal 2008 were 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 beginning in the first quarter of 2008. Material charges significantly contributing to the Company's net loss in 2008 in connection with the

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acquisition were an approximate \$3.9 million loss on settlement of a 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.

### **Net Sales**

Net sales for the three and six months ended July 3, 2009 were \$19.1 million and \$37.4 million, a decrease of approximately 7.5% and 3.2%, respectively, compared with \$20.7 million and \$38.6 million for the three and six months ended June 27, 2008. The decrease in net sales was due mainly to a decrease in sales of other surgical products and the negative effect of currency. Changes in currency had a \$0.7 million and \$1.3 million unfavorable impact on net sales for the three and six months of 2009 primarily due to the weaker Euro compared to the U.S. Dollar.

U.S. sales for the three and six months ended July 3, 2009 were \$4.1 million and \$8.4 million, a decrease of 20.1% and 13.7%, respectively, compared with \$5.2 million and \$9.7 million reported for the three and six months ended June 27, 2008. The primary reason for the decrease in both periods is a significant decrease in other product sales as a result of the de-emphasis of low margin non-IOL/ICL products. U.S. ICL sales decreased 15% in the second quarter of 2008 and were up 1.8% year to date. STAAR believes the decline in ICL sales for the quarter results from the continued decrease in the number of refractive procedures performed in the U.S. as a result of economic recession.

U.S. IOL sales for the three and six months ended July 3, 2009 decreased 1% and 4.7%. The rate of decline has slowed significantly from the levels of 2008 and 2007, which STAAR believes resulted from its introduction of new products.

International sales for the for the three and six months ended July 3, 2009 were \$15.0 million and \$29.0 million, down 3.3% compared with \$15.5 million reported in the second quarter of 2008 and up 0.4% compared with the first six months of 2008. During the quarter and year to date periods, international Visian ICL sales grew to \$4.4 million and \$8.1 million, a 12% and 14% increase compared to the \$4.0 million and \$7.1 million reported in the same periods of 2008. The sales increase in 2009 is due to a significant increase in volume, partially offset by lower average selling prices in Korea and the negative effect of foreign exchange rates. International IOL sales decreased approximately 3.2% to \$6.2 million for the current quarter from \$6.4 million compared to the same quarter in the prior year but increased 1.6% over the first six months of 2008. Unit volume in both periods increased, but the effect of higher volumes was negatively impacted by lower average selling prices ( ASPs ) and the effect of foreign exchange. Other products decreased 15% to \$4.4 million from \$5.1 million reported in the second quarter of 2008 and decreased 10.9% to \$8.7 million from the \$9.8 million reported in the first six months of 2008. Other product sales decreased as a result of STAAR's decision to de-emphasize low margin non-IOL/ICL products and also due to the negative effect of foreign exchange.

### **Gross Profit Margin**

Gross profit margin for the second quarter was approximately 56%, unchanged compared with same quarter in the prior year. During the period the favorable effect of increased volumes and product mix was offset by lower average selling prices on IOLs and ICLs, and the unfavorable effect of foreign exchange and higher unit costs due to decreased manufacturing volume as part of an effort to reduce inventories. Gross profit for the first six months of 2009 was \$21.0 million, or 56% of net sales, compared with \$19.3 million, or 50% of net sales in the prior year period. Gross profit for the first six months of 2008 reflected the negative impact of a \$1.5 million purchase accounting charge associated with the step-up of inventory in the STAAR Japan acquisition.

## General and Administrative

General and administrative (G&A) expenses for the quarter were \$3.9 million, an increase of 10% when compared with \$3.5 million last year due to certain reclassifications to research and development expense made by STAAR Japan in the second quarter of 2008 post acquisition to conform to STAAR's presentation resulting in lower than normal G&A for that quarter. In the U.S., G&A expenses decreased by approximately 10.7% due to lower legal fees and insurance costs in the current quarter compared to the second quarter of 2008. G&A expenses for the first six months of 2009 totaled \$8.1 million as compared with \$8.0 million for the same period one year ago. The increase in G&A expenses is due to certain reclassifications to research and development expense made by STAAR Japan in 2008 described above for the quarter.

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### **Marketing and Selling**

Marketing and selling expenses for the second quarter of 2009 decreased approximately \$1.6 million to \$6.0 million as compared with \$7.6 million in the same period in 2008. This 21% decrease was due to decreased salaries, travel, consulting fees, promotional activities and commissions particularly in the U.S. For the first six months of 2009, marketing and selling expenses were \$11.8 million, down \$2.3 million or 16%, from \$14.1 million reported for the first six months of 2008. The decrease in marketing and selling expenses is due to general cost reductions implemented globally.

### **Research and Development**

Research and development expenses for the second quarter of 2009 were \$1.4 million, a 39% decline compared with the second quarter of 2008 due to decreased salaries, consulting fees and general cost containment efforts. For the six months ended July 3, 2009, research and development expenses were \$2.9 million, down \$1.2 million or 30%, compared with \$4.1 million for the first six months of 2008. The decrease in research and development expenses is due to general cost reductions implemented globally.

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

In connection with the Company's acquisition of STAAR Japan, the Company recorded an approximate \$3.9 million loss at the close of the acquisition on December 29, 2007, the first quarter of 2008, which has a negative impact on the total operating loss for the six months ended June 27, 2008 as compared with the same period in 2009. This loss represents the portion of the consideration paid by STAAR for the Acquisition that was deemed to represent the amount paid to settle the pre-existing 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**

#### **Going Concern**

In the Company's audited consolidated financial statements for the fiscal year ended January 2, 2009, the report of the Company's independent registered public accounting firm included an explanatory paragraph indicating that substantial doubt exists about STAAR's ability to continue as a going concern. STAAR's management believes that during the current second fiscal quarter it made progress towards the goal of overcoming this doubt. Developments that have improved our liquidity after the filing of our Form 10-K include the following:

*Improved cash flow from operations and continued cost reduction efforts.* STAAR's cost-cutting efforts have reduced its cash used in operating activities, and in the second quarter of 2009 STAAR achieved positive cash flows from operations for the three months ended July 3, 2009. If recent operating trends continue, STAAR may generate positive cash flow from operations during the remaining two quarters of 2009.

*Significant financing activity.* On June 17, 2009, the Company successfully completed a public offering of 4.6 million shares of common stock (the Offering), raising approximately \$8.5 million from institutional investors. No warrants or other financial instruments were issued in the Offering. The primary purpose of the Offering was to provide the funds necessary to post a deposit in connection with the \$4.9 adverse judgment in the *Parallax* case while the case is on appeal. By providing funds for the deposit (and to pay the *Parallax* judgment if appeal is unsuccessful) and for the defense of the *Moody* case, the Offering resolved concerns about the largest unfunded cash obligation currently facing



the Company as well as the *Moody* defense costs. As a result of the deposit, any default that may be deemed to have occurred was cured under the amended and restated Senior Secured Promissory Note held by Broadwood Partners, L.P.

*Increasing gross profit margins.* As noted above, STAAR has experienced a general increase in gross profit margins in recent periods. While gross profit margins were flat in the second quarter compared to the first, management expects gross profit margins to resume growth due to a number

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of factors, including the increase in ICLS and TICLS as a percentage of our global product mix, the conversion of our U.S. IOL product line to more highly reimbursed NTIOLs, and improvements in operating efficiency expected to result from our Centers of Excellence Program.

*Key regulatory approvals.* During the second quarter STAAR received CE Mark approval for its KS-X Preloaded Hydrophobic Acrylic Injector, received FDA 510(k) clearance for the Epiphany Injector System, and received approval from the Japanese regulatory authorities for sale of the KS-Ni silicone Preloaded Injector system in Japan. In addition, STAAR has two pending regulatory approvals that could materially improve sales: U.S. FDA approval of the TICL, and Japanese approval of the ICL and TICL. Although the timing of the regulatory approval is never certain, the Company believes approval of these products could be granted in 2009.

*Removal of Integrity Hold.* On July 21, 2009, the FDA Division of Bioresearch Monitoring informed the Company that the restrictions of the integrity hold put in place by the FDA on August 3, 2007 have been removed. While removal of the integrity hold does not constitute clearance to market the Visian Toric ICL, it enables the FDA to resume scientific review of the STAAR application for the TICL and reopens the pathway for STAAR to seek future FDA approvals requiring submissions of clinical data to the agency.

On May 11, 2009, final judgment was entered in the case *Parallax Medical Systems, Inc. v. STAAR Surgical Company*, confirming a \$4.9 million jury verdict against STAAR. The adverse judgment, and STAAR's need to obtain a surety bond or post a deposit in the amount of 150% of the judgment to stay enforcement during appeal, were among the principal factors that STAAR believes gave rise to substantial doubt regarding STAAR's ability to continue as a going concern. At the time of the final judgment STAAR lacked the cash resources to pay such amounts. However, prior to the expiration of the temporary stay STAAR completed the Offering and deposited approximately \$7.3 million in proceeds into a restricted account to assure payment of the judgment, thereby staying any enforcement of the judgment pending appeal. The \$4.9 million liability related to the *Parallax* judgment, which must be paid (along with 10% per annum in post-judgment interest and approximately \$56,000 in trial related costs) if STAAR's appeal is unsuccessful, was accrued in fiscal year 2008 and cash exceeding the amount of the judgment has been placed in a restricted account with the Court exclusively for the purpose of satisfying the judgment. Accordingly, the judgment does not have a material effect on STAAR's future liquidity or availability of cash resources for its business.

Another lawsuit similar to the *Parallax* case, *Scott C. Moody, Inc. v. STAAR Surgical Company*, is currently scheduled for trial in the Superior Court of California, County of Orange, on October 19, 2009 and could result in further significant liability. Because no two courts or trials are identical, the outcome of the Moody case cannot be predicted and STAAR cannot estimate the amount or range of loss, if any, in the event of an unfavorable outcome. STAAR believes its cash resources are sufficient to vigorously defend the *Moody* case. However, a material adverse judgment in *Moody* would likely exceed STAAR's available cash resources.

STAAR has a history of losses, its business is subject to numerous risks and contingencies and it cannot assure investors that its cash needs will not again exceed the level of cash generated by operations. Future obligations and liabilities that could exceed STAAR's current cash reserves include the following:

the \$5 million principal indebtedness under the Senior Secured Promissory Note held by Broadwood Partners, L.P., which becomes due on December 14, 2010 and accrues interest at a rate of 20% per annum;  
the possibility of a material adverse judgment in the case *Scott Moody v. STAAR Surgical Company*, scheduled for trial on October 19, 2009.

In addition, the holders of 1.7 million shares of outstanding Series A Redeemable, Convertible Preferred Stock have the right to redeem the stock at a price of \$4.00 per share, or \$6.8 million in aggregate, beginning on December 29, 2010, to the extent the Company has funds available to redeem the shares in accordance with the Delaware General Corporation Law.



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If the Company's need for cash exceeds available resources, the Company may be required to seek additional financing through the sale of debt or equity securities. The Company cannot assure that such financing will be available at acceptable terms, if at all, and an inability to secure additional and adequate financing could jeopardize the Company's ability to continue as a going concern.

### **Overview of Changes in Cash and Cash Equivalents and Other Working Capital Accounts.**

As of July 3, 2009 and January 2, 2009, we had \$5.8 million and \$5.0 million, respectively, of cash and cash equivalents.

Net cash provided by operating activities was \$0.3 million for the three months ended July 3, 2009, compared with cash used of \$2.8 million for the three months ended June 27, 2008. For the first six months of 2009, we used cash in operations of \$0.2 million compared with \$6.1 million used in the first six months of 2008. Approximately \$2.5 million of the total cash used in operating activities in the first quarter of 2008 was used by STAAR Japan in assuming distribution from Canon Marketing and for payments on inventory purchased from Canon Marketing.

Net cash used in investing activities was \$7.5 million for the six months ended July 3, 2009, compared to \$2.2 million cash provided by investing activities for the six months ended June 27, 2008. On June 22, 2009, we posted a \$7.3 million deposit with the Superior Court of California, County of Orange, to obtain a stay of enforcement of the *Parallax* judgment while it is under appeal. These funds are restricted and the Court maintains full access to and control of the deposit until the final outcome of the *Parallax* appeal is known or a settlement is reached, whichever occurs first. The Court will pay us 1.5% per annum interest on the deposit, which will be reinvested by the Court into this restricted account and, as with the principal amount deposited, we will not have any access to the earned interest and limited information about its investment status as well. For the six months ended June 27, 2008, net cash provided by investing activities includes the \$2.5 million of cash acquired in connection with the December 29, 2007 acquisition of STAAR Japan, net of acquisition costs.

Net cash provided by financing activities was \$8.6 million for the six months ended July 3, 2009 compared to \$1.5 million for the six months ended June 27, 2008. On June 17, 2009, we completed a Common Stock offering to certain institutional investors by issuing 4.6 million shares of our stock for aggregate proceeds of \$8.5 million, net of issuance costs. We also borrowed an additional \$0.6 million from our Japanese line of credit, offset by capital lease principal repayments of \$0.6 million. For the six months ended June 27, 2008, our net borrowings from our line of credit were \$1.9 million offset by capital lease principal repayments of \$0.4 million.

Accounts receivable at July 3, 2009 increased \$1.0 million relative to January 2, 2009. Days sales outstanding ( DSO ) were 44 days at July 3, 2009 compared to 45 days at June 27, 2008. We expect to maintain DSO within a range of 40 to 45 days during the course of the 2009 fiscal year.

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

#### **Credit Facilities**

As detailed below, we have credit facilities with different lenders to support operations in the U.S., Germany and Japan.

### **Broadwood Promissory Note**

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 between the Company and Broadwood, with a scheduled maturity of December 14, 2010. On April 2, 2009, after preliminary judgment was entered in the *Parallax* case, Broadwood and STAAR entered into a Temporary Waiver Agreement with respect to any event of default that may occur, or may be deemed to have occurred, under the Note as a result of the judgment. In consideration of the Temporary Waiver Agreement, STAAR agreed to amend the Senior Promissory Note to grant to Broadwood a security interest in substantially all of STAAR's assets to secure STAAR's obligations under the original Senior Promissory Note. To effectuate this grant of a security interest, as of April 13, 2009, the Company and Broadwood entered into an Amended and Restated Senior Secured Promissory Note (the Note ) and Security Agreement. All other key terms of the Note remained unchanged.

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The Temporary Waiver Agreement provided that if the Company secured a stay of enforcement of judgment prior to June 23, 2009 (the expiration date of a temporary stay granted by the Court), no default was deemed to have occurred with respect to the judgment. On June 24, 2009, following the timely posting of the deposit and satisfaction of the provisions of the Temporary Waiver, Broadwood and STAAR again amended the Note by replacing the Temporary Waiver with a provision stating that because the Company secured a stay of enforcement of judgment until the completion of the appeal by posting the required deposit with the Court, any default resulting from the *Parallax* judgment is deemed to be cured. Broadwood is entitled to receive interest at the rate of 20% per annum beginning on June 23, 2009 as would have been applicable in the event a default had occurred under the original terms of the Note. However, this rate may be lowered to 7% if the Company fully satisfies the *Parallax* judgment and fully resolves all other then outstanding and undecided material litigation of the Company. The Note may be pre-paid by the Company at any time without penalty, with prior notice, 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.

As additional consideration for the loan, on December 14, 2007, we also entered into a Warrant Agreement with Broadwood (the December 2007 Warrant Agreement ) granting the right to purchase up to 700,000 shares of our 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 remained outstanding under the Note on June 1, 2009, we would 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. On June 1, 2009, as the entire \$5 million was outstanding, we issued an additional 700,000 warrants to Broadwood valued at approximately \$290,000. The December 2007 Warrant Agreement also provides that we will register the shares issuable upon exercise of the warrants with the Securities Exchange Commission ( SEC ). We have filed and secured effectiveness of a registration statement covering resale of the shares. If we fail to keep the registration statement effective and the lapse exceeds permitted suspensions, as the holder s sole remedy, we will be obligated to issue an additional 30,000 warrants for each month that we do not meet this effectiveness requirement through the term of the warrants ( Penalty Warrants ) (a maximum of approximately 2,130,000 warrants issuable as of July 3, 2009 under an assumed noncompliance as of that date). We do not consider the issuance of Penalty Warrants as likely.

### **Capital Lease Agreement**

The Company s lease agreement with Farnam Street Financial, Inc. ( Farnam ), as amended on October 9, 2006, provided for purchases of up to \$1,500,000 of property, plant and equipment. In accordance with the requirements of SFAS 13 Accounting for Leases, purchases under this facility are accounted for as capital leases and generally have a thirty-month to 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-upon fair value. On April 1, 2007, the Company signed an additional leasing schedule with Farnam, which provided for additional purchases of \$800,000 during 2008. The terms of this new schedule conform to the amended agreement dated October 9, 2006. There are no remaining borrowings available under the agreement.

### **Lines of Credit**

The Company s German subsidiary, Domilens, entered into a credit agreement on May 4, 2009 with Postbank. The credit agreement provides for borrowings of up to 500,000 EUR (\$704,000 at the rate of exchange on July 3, 2009), at a rate of 7.25% per annum. 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 and contains certain restrictions regarding payment of dividends or providing loans to the Company or other consolidated subsidiaries. There were no borrowings outstanding as of July 3, 2009 and

January 2, 2009 and the full amount of the line was available for borrowing as of July 3, 2009.

The Company's Japanese subsidiary, STAAR Japan, has an agreement, as amended on June 30, 2009, with Mizuho Bank which provides for borrowings of up to 300,000,000 Japanese Yen (approximately \$3.1 million based on the rate of exchange on July 3, 2009), at an interest rate equal to the Tokyo short-term prime interest rate (approximately 1.475% as of July 3, 2009) plus 1.125% and terminates on April 20, 2010,

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but may be renewed annually. The credit facility is not collateralized. The Company had 260,000,000 and 200,000,000 Japanese Yen outstanding on the line of credit as of July 3, 2009 and January 2, 2009, (approximately \$2.7 million and \$2.2 million based on the foreign exchange rates on July 3, 2009 and January 2, 2009, respectively).

### **Covenant Compliance**

Among the events of default in the Note held by Broadwood Partners, L.P. is any judgment in excess of \$500,000 against the Company that shall remain unpaid. On April 2, 2009, after preliminary judgment was entered, Broadwood and STAAR entered into a Temporary Waiver Agreement with respect to any event of default that may occur, or may be deemed to have occurred, under the Note as a result of the *Parallax* judgment. On June 24, 2009, following the posting of the deposit and satisfaction of the provisions of the Temporary Waiver, Broadwood and STAAR again amended the Note by replacing the Temporary Waiver with a provision stating that because the Company secured a stay of enforcement of Judgment until the completion of the appeal by posting the required deposit with the Court, any default resulting from the *Parallax* judgment is deemed to be cured. As such, STAAR's obligation under the Note, which is due on December 14, 2010, net of the related discount, has been reclassified from current indebtedness as of the first quarter ended April 3, 2009 to noncurrent indebtedness in STAAR's consolidated balance sheet as of July 3, 2009.

The Company is in compliance with covenants of the Note, the capital lease agreement and the lines of credit as of July 3, 2009.

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

On December 29, 2007, we 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.

The Preferred Stock is redeemable by us 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 us 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 our control, the aggregate \$6.8 million Redemption Price of the Preferred Stock is presented in the mezzanine section of the consolidated balance sheet. However, if the redemption right is exercised by the Preferred Stock holders, in no event is the Company required to pay the redemption price if the Company's capital is impaired or if payment would cause the Company's capital to become impaired, in accordance with the Delaware General Corporation Law.

The Preferred Stock is convertible into shares of our 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 our common stock 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.

Our liquidity requirements arise from the funding of our working capital needs, primarily inventory, work-in-process and accounts receivable. Our 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 our credit facility and proceeds from the sale of our common stock. Any withdrawal of support from its lenders could have serious consequences on our liquidity. Our 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 our cash flows. In addition, any abnormal product returns or pricing adjustments may also affect our 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.

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## **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 our Annual Report on Form 10-K for the year ended January 2, 2009.

## **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 quarter ended July 3, 2009 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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## PART II OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

*Litigation and Claims*

*Parallax Medical Systems, Inc. v. STAAR Surgical Company* (California Superior Court, County of Orange, Case No. 07CC10136). Final judgment in this case was rendered on May 11, 2009, in accordance with a March 2, 2009 jury verdict awarding approximately \$2.2 million in actual damages and \$2.7 million in punitive damages to Parallax Medical Systems, Inc. Parallax is a former independent regional manufacturer's representative (RMR) of STAAR. Parallax promoted sales of STAAR products in the southeastern region of the U.S. under a contract that expired on July 31, 2007. Parallax originally filed its complaint against STAAR on September 21, 2007, claiming, among other things, that STAAR interfered with Parallax's prospective economic advantage when it informed a regional IOL distributor that Parallax had a covenant restricting the sale of competing products, and that STAAR interfered with Parallax's contracts when STAAR caused some of its current or former subcontractors to enter into new agreements to represent STAAR products. STAAR filed a cross-complaint alleging breach of contract and misappropriation of trade secrets; the jury found in favor of *Parallax* on the cross-complaint. The complaint sought \$48 million in actual damages and unspecified punitive damages.

Final judgment was rendered following a hearing on principal post-trial motions on May 8, 2009. On May 15, 2009, the Court ruled in favor of the Company by disallowing *Parallax*'s motion for legal fees in the amount of approximately \$314,000 related to its defense of STAAR's cross complaint. In this ruling, the Court ruled that the Plaintiff is not entitled to legal fees in this case. On July 14, 2009, the Court in part granted STAAR's motion to strike or reduce Parallax's claim for approximately \$109,000 in trial related costs, of which approximately \$56,000 was awarded to Parallax. That amount will be added to the judgment and become payable subject to the pending appeal.

STAAR believes that the *Parallax* case was incorrectly decided as to liability, the amount of compensatory damages and the appropriateness and amount of punitive damages, and intends to vigorously appeal the outcome of this case.

*Moody v. STAAR Surgical Company* (California Superior Court, County of Orange, Case No. 07CC10132). Scott C. Moody, Inc., also a former RMR of STAAR, filed a complaint against STAAR on the same day that *Parallax* filed its complaint. Moody promoted sales of STAAR products in the southwestern region of the U.S., under a contract that, like Parallax's, expired on July 31, 2007. Like Parallax, *Moody* claims that STAAR interfered with *Moody*'s prospective economic advantage when it informed a regional IOL distributor that Moody had a covenant restricting the sale of competing products. The complaint seeks \$32 million in actual damages and unspecified punitive damages. STAAR has filed a cross-complaint alleging breach of contract and misappropriation of trade secrets.

The *Moody* case is currently scheduled to be tried before a jury on October 19, 2009. STAAR believes that the evidence to be presented in *Moody* does not support liability for interference with prospective business advantage or interference with Moody's contracts with former subcontractors, and does not support damages at a level that is material to STAAR. However, the *Parallax* and *Moody* cases have many facts in common; the plaintiff in *Moody* alleges that the same conduct of STAAR interfered with its prospective business advantage, and *Moody* will also be tried before a jury. The *Moody* plaintiff has also indicated it will seek punitive damages. But because no two courts or trials are identical, the outcome of the *Moody* case cannot be predicted. In particular, important factual differences exist between the two cases, it is possible that the *Moody* court will permit different evidence or arguments to be presented at trial, and the outcome of jury trials is inherently uncertain. On May 4, 2009, STAAR retained new counsel for the *Moody* case following the appointment of its former lead counsel to a judgeship on the California

Superior Court. On July 1, 2009, STAAR filed a motion for summary judgment in the case based on additional defenses, and on July 2, 2009 STAAR filed a motion to amend its answer to the *Moody* complaint to raise additional defenses.

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

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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 January 2, 2009, except as follows:

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

STAAR generated cash from operations in the second fiscal quarter of 2009. While management has projected positive cash flow from operations for the remainder of 2009, STAAR has a history of losses, its business is subject to numerous risks and contingencies and it cannot assure investors that its needs will not again exceed the level of cash generated by operations. Future obligations and liabilities that could result in STAAR exceeding its cash reserves include the following:

the \$5 million indebtedness under the Senior Secured Promissory Note held by Broadwood Partners, L.P., which becomes due on December 14, 2010 and accrues interest at a rate of 20% per annum; and the possibility of a material adverse judgment in the case *Scott Moody v. STAAR Surgical Company*, scheduled for trial on October 19, 2009.

In addition, the holders of our 1.7 million shares of outstanding Series A Redeemable, Convertible Preferred Stock have the right to redeem the stock at a price of \$4.00 per share beginning on December 29, 2010. To the extent we have funds available to redeem the shares without impairing our capital we may be required to use those funds to redeem shares of preferred stock.

If our need for cash exceeds our available funds, we may be required to seek additional financing through the sale of debt and/or equity securities. Our ability to raise financing through sales of equity securities depends on general market conditions and the demand for STAAR's common stock. We may be unable to raise adequate capital through sales of equity securities, and if we are able to do so but our stock has a low market price at the time of such sales our existing stockholders could experience substantial dilution. Debt financing may not be available on favorable terms, or at all. An inability to secure additional and adequate financing could jeopardize our ability to continue operations as a going concern.

#### **The global nature of our business may result in significant fluctuations in our results of operations.**

Our products are sold in approximately 50 countries. Sales from international operations make up a significant portion of our business, comprising over 75% of our total net 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 translation risk. In addition, we are exposed to foreign exchange transaction risk because some of our expenses are incurred in a different currency from the currency in which our sales are received. Our most significant currency exposures are to the Euro, the Swiss Franc, the Australian dollar, and the Japanese Yen. The exchange rates between these and other local currencies and the U.S. dollar may fluctuate substantially. We have not attempted to offset our exposure to these risks by investing in derivatives or engaging in other hedging transactions in order to mitigate risk.

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

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rates can make our products more expensive in some foreign markets and reduce our sales. Inflation in emerging markets also makes our products more expensive there and increases the credit risks to which we are exposed.

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

## ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

a. The annual meeting of the stockholders of the Company (the Annual Meeting ) was held on June 11, 2009. 30,103,450 shares of common stock were outstanding on the record date for the Annual Meeting (April 24, 2009) and entitled to vote at the Annual Meeting.

b. At the Annual Meeting, six directors were elected to serve until the annual meeting of stockholders in 2010 and until his successor is duly elected and qualified. The vote was as follows:

	Number of Shares	
	For	Withheld
Don Bailey	26,265,594	1,303,611
Barry Caldwell	27,253,525	315,680
David Bailey	20,473,453	7,095,752
Donald Duffy	26,837,830	731,375
John C. Moore	25,415,083	2,154,122
David Morrison	27,255,060	314,145

c. At the Annual Meeting, a proposal to ratify the appointment of BDO Seidman, LLP as the Company's independent registered public accounting firm for the fiscal year ending January 1, 2010 approved by the stockholders. The vote was as follows:

Number of Shares		
For	Against	Abstain
27,446,853	120,555	1,795

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**ITEM 6. EXHIBITS**

**Exhibits**

Representations, warranties or covenants that may appear in any agreement filed as an exhibit to this report were made solely for the benefit of the parties to that agreement. The parties made those statements for the private purpose of allocating contractual risk, not to establish facts, so the statements may not have been accurate or complete when made. Even if accurate when made, these statements may not be accurate now, and they may have been qualified by schedules or other disclosures that have not been filed with this report. Only the parties to such an agreement are entitled to enforce its representations, warranties or covenants. You should not rely on those statements for any purpose.

- 3.1 Certificate of Incorporation, as amended to date.<sup>(1)</sup>
- 3.2 By-laws, as amended to date.<sup>(2)</sup>
- 4.1 Certificate of Designation of Series A Convertible Preferred Stock.<sup>(1)</sup>
- 4.2 1991 Stock Option Plan of STAAR Surgical Company.<sup>(3)</sup>
- 4.3 1998 STAAR Surgical Company Stock Plan, adopted April 17, 1998.<sup>(4)</sup>
- 4.4 Form of Certificate for Common Stock, par value \$0.01 per share.<sup>(5)</sup>
- 4.5 2003 Omnibus Equity Incentive Plan, as amended, and form of Option Grant and Stock Option Agreement.<sup>(6)</sup>
- 10.72 Amended and Restated Senior Secured Promissory Note between the Company and Broadwood Partners, L.P., dated April 13, 2009.<sup>(7)</sup>
- 10.73 Security Agreement by and between the Company and Broadwood Partners, L.P., dated April 13, 2009.<sup>(7)</sup>
- 10.74 Stock Purchase Agreement.<sup>(8)</sup>
- 10.75 Amendment Agreement between the Company and Broadwood Partners, L.P.<sup>(8)</sup>
- 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.<sup>(\*)</sup>
- 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.<sup>(\*)</sup>
- 32.1 Certification Pursuant to 18 U.S.C. Section 1350, Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.<sup>(\*)</sup>

- (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 Current Report on Form 8-K filed with the Commission on January 8, 2009.
- (7)
- (8)



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Incorporated by reference to the Company's Current Report on Form 8-K filed with the Commission on April 17, 2009.

(8) Incorporated by reference to the Company's current report on Form 8-K filed with the Commission on June 25, 2009.

(\*)

Filed herewith.

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## SIGNATURES

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

STAAR SURGICAL COMPANY

By:

/s/ DEBORAH ANDREWS

Date: August 12, 2009

**Deborah Andrews**

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