

STAAR SURGICAL CO
Form 10-Q
May 03, 2013

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: March 29, 2013

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

(State or other jurisdiction of (I.R.S. Employer

incorporation or organization) 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
(Do not check if a smaller reporting company)

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

The registrant has 36,746,714 shares of common stock, par value \$0.01 per share, issued and outstanding as of April 30, 2013.

STAAR SURGICAL COMPANY

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

	March 29, 2013	December 28, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	\$19,243	\$21,675
Accounts receivable trade, net	8,607	8,543
Inventories, net	11,010	11,673
Prepays, deposits and other current assets	2,744	2,183
Total current assets	41,604	44,074
Property, plant and equipment, net	6,184	5,439
Intangible assets, net	1,858	2,142
Goodwill	1,786	1,786
Deferred income taxes	188	187
Other assets	1,038	1,131
Total assets	\$52,658	\$54,759
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Line of credit	\$5,300	\$5,850
Accounts payable	3,663	5,129
Deferred income taxes	440	439
Obligations under capital leases	701	829
Other current liabilities	5,075	5,702
Total current liabilities	15,179	17,949
Obligations under capital leases	346	488
Deferred income taxes	892	885
Asset retirement obligations	646	707
Pension liability	2,946	2,988
Total liabilities	20,009	23,017
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Common stock, \$0.01 par value; 60,000 shares authorized; 36,432 and 36,423 shares issued and outstanding at March 29, 2013 and December 28, 2012	364	364

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Additional paid-in capital	163,361	162,251
Accumulated other comprehensive income	905	1,580
Accumulated deficit	(131,981)	(132,453)
Total stockholders' equity	32,649	31,742
Total liabilities and stockholders' equity	\$52,658	\$54,759

See accompanying notes to the condensed consolidated financial statements.

STAAR SURGICAL COMPANY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended	
	March 29, 2013	March 30, 2012
Net sales	\$18,001	\$15,509
Cost of sales	5,347	4,607
Gross profit	12,654	10,902
General and administrative	3,958	3,860
Marketing and selling	5,286	4,663
Research and development	1,366	1,546
Medical device tax	59	—
Other general and administrative expenses	901	555
Operating income	1,084	278
Other income (expense):		
Interest income	35	—
Interest expense	(83)	(95)
Gain (loss) on foreign currency transactions	(341)	67
Other income, net	90	214
Total other income (expense), net	(299)	186
Income before provision for income taxes	785	464
Provision for income taxes	314	232
Net income	\$471	\$232
Net income per share – basic	\$0.01	\$0.01
Net income per share – diluted	\$0.01	\$0.01
Weighted average shares outstanding – basic	36,427	36,071
Weighted average shares outstanding – diluted	37,418	38,420

See accompanying notes to the condensed consolidated financial statements.

STAAR SURGICAL COMPANY

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands, except par value amounts)

(Unaudited)

	Three Months Ended	
	March 29, 2013	March 30, 2012
Net income	\$471	\$232
Other comprehensive loss:		
Foreign currency translation	(664)	(518)
Pension liability adjustment	(11)	(12)
Other comprehensive loss	(675)	(530)
Comprehensive loss	\$(204)	\$(298)

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended	
	March 29, 2013	March 30, 2012
Cash flows from operating activities:		
Net income	\$471	\$232
Adjustments to reconcile net income to net cash used in operating activities:		
Depreciation of property and equipment	369	317
Amortization of intangibles	117	175
Deferred income taxes	7	57
Fair value adjustment of warrant	(27)	14
Gain on disposal of property and equipment	(28)	—
Change in net pension liability	58	72
Stock-based compensation expense	1,034	687
Accretion of asset retirement obligation	5	—
Other	27	40
Changes in working capital:		
Accounts receivable	(322)	556
Inventories	288	(432)
Prepays, deposits and other current assets	(581)	(665)
Accounts payable	(1,328)	(1,100)
Other current liabilities	(522)	(390)
Net cash used in operating activities	(432)	(437)
Cash flows from investing activities:		
Release of restricted cash	—	129
Acquisition of property and equipment	(1,218)	(287)
Net cash used in investing activities	(1,218)	(158)
Cash flows from financing activities:		
Repayment of capital lease obligations	(242)	(195)
Proceeds from exercise of stock options	23	837
Net cash (used in) provided by financing activities	(219)	642
Effect of exchange rate changes on cash and cash equivalents	(563)	(184)
Decrease in cash and cash equivalents	(2,432)	(137)

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Cash and cash equivalents, at beginning of the period	21,675	16,582
Cash and cash equivalents, at end of the period	\$19,243	\$16,445

See accompanying notes to the condensed consolidated financial statements.

STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 29, 2013

(Unaudited)

Note 1 — Basis of Presentation and Significant Accounting Policies

The consolidated financial statements of the Company present the financial position, results of operations, and cash flows of STAAR Surgical Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities Exchange Commission. In accordance with those rules and regulations certain information and footnote disclosures normally included in comprehensive financial statements have been condensed or omitted pursuant to such rules and regulations. The consolidated balance sheet as of December 28, 2012 derives from the audited financial statements at that date, but does not include all the information and footnotes required by GAAP. These financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 28, 2012.

The condensed consolidated financial statements for the three months ended March 29, 2013 and March 30, 2012, 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. The results of operations for the three months ended March 29, 2013 and March 30, 2012 are not necessarily indicative of the results to be expected for any other interim period or for the entire year.

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

Note 2 — Inventories

Inventories, net are stated at the lower of cost, determined on a first-in, first-out basis, or market and consisted of the following (in thousands):

	March 29, 2013	December 28, 2012
Raw materials and purchased parts	\$2,109	\$ 1,946
Work-in-process	1,698	1,318
Finished goods	7,817	8,945
	11,624	12,209
Less: inventory reserves	614	536
	\$11,010	\$ 11,673

Note 3 — Prepaids, Deposits, and Other Current Assets

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

	March 29, 2013	December 28, 2012
Prepaid vendors	\$1,073	\$ 1,044
Prepaid insurance	742	628
Value added tax (VAT) receivable	393	307
Other current assets	536	204
	\$2,744	\$ 2,183

STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 29, 2013

(Unaudited)

Note 4 — Property, Plant and Equipment

Property, plant and equipment consisted of the following (in thousands):

	March 29, 2013	December 28, 2012
Machinery and equipment	\$ 14,375	\$ 14,734
Furniture and fixtures	4,598	3,483
Leasehold improvements	5,480	5,281
	24,453	23,498
Less: accumulated depreciation	18,269	18,059
	\$ 6,184	\$ 5,439

Note 5 – Amortizable Intangible Assets

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

	March 29, 2013			December 28, 2012		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Amortized intangible assets:						
Patents and licenses	\$ 10,712	(9,914)) \$ 798	\$ 10,786	\$ (9,875)) \$ 911
Customer relationships	1,663	(873)) 790	1,835	(917)) 918
Developed technology	1,056	(786)) 270	1,166	(853)) 313

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Recognized actuarial loss (gain)	5	(1)
	\$ 136	\$ 131

STAAR SURGICAL COMPANY**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****March 29, 2013****(Unaudited)**

During the three months ended March 29, 2013 and March 30, 2012, the Company made cash contributions totaling approximately \$59,000 and \$68,000 to its Swiss pension plan and expects to make additional cash contributions totaling approximately \$176,000 during the remainder of 2013. The Company is not required to and does not make contributions to its Japan pension plan.

Note 8 — Basic and Diluted Income Per Share

The following table sets forth the computation of basic and diluted net income per share (in thousands except per share amounts):

	Three Months Ended	
	March 29, 2013	March 30, 2012
Numerator:		
Net income	\$471	\$232
Denominator:		
Weighted average common shares and denominator for basic calculation:		
Weighted average common shares outstanding	36,660	36,237
Less: Unvested restricted stock	(233)	(166)
Denominator for basic calculation	36,427	36,071
Weighted average effects of dilutive equity-based compensation awards:		
Stock options	522	1,442
Warrants	400	907
Restricted stock	69	—

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Denominator for diluted calculation	37,418	38,420
Net income per share – basic	\$0.01	\$0.01
Net income per share – diluted	\$0.01	\$0.01

The following tables sets forth (in thousands) the weighted average number of options to purchase shares of common stock and restricted stock, which were not included in the calculation of diluted per share amounts because the effects would be anti-dilutive.

	Three Months Ended	
	March 29, 2013	March 30, 2012
Options	2,035	231
Restricted stock	98	167
	2,133	398

Note 9 — Geographic and Product Data

The Company markets and sells its products in over 60 countries and has manufacturing sites in the United States, Switzerland and Japan. Other than the United States, Japan, Korea, China, and Spain the Company does not conduct business in any country in which its sales exceed 5% of consolidated sales. Sales are attributed to countries based on location of customers. The composition of the Company's net sales to unaffiliated customers is set forth below (in thousands):

STAAR SURGICAL COMPANY**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****March 29, 2013****(Unaudited)**

	Three Months Ended	
	March 29, 2013	March 30, 2012
United States	\$3,240	\$3,174
Japan	4,739	3,857
Korea	2,035	1,903
China	2,071	2,106
Spain	1,291	510
Other	4,625	3,959
Total	\$18,001	\$15,509

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 implantable Collamer lenses ("ICLs") used in refractive surgery and intraocular lenses ("IOLs") used in cataract surgery. The composition of the Company's net sales by product line is as follows (in thousands):

	Three Months Ended	
	March 29, 2013	March 30, 2012
ICLs	\$10,631	\$8,605
IOLs	6,347	6,358
Core products	16,978	14,963
Other Surgical Products	1,023	546
Total	\$18,001	\$15,509

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

Note 10 — Stock-Based Compensation

The cost that has been charged against income for stock-based compensation is set forth below (in thousands):

	Three Months	
	Ended	
	March	March
	29,	30,
	2013	2012
ASC 718 expense	\$821	\$ 521
Restricted stock expense	188	127
Consultant compensation	25	39
Total	\$1,034	\$ 687

Stock Option Plans

The Amended and Restated 2003 Omnibus Equity Incentive Plan (“the Plan”) provides for various forms of stock-based incentives. To date, of the available forms of awards under the Plan, the Company has granted only stock options, restricted stock, unrestricted share grants, and may grant in the future performance contingent shares. Options under the plan are granted at fair market value on the date of grant, become exercisable over a three year period, or as determined by the Board of Directors, and expire over periods not exceeding 10 years from the date of grant. Certain option and share awards provide for accelerated vesting if there is a change in control (as defined in the Plan). Pursuant to the Plan, options for 3,830,779 shares were outstanding at March 29, 2013 with exercise prices ranging between \$0.95 and \$11.02 per share. Restricted stock grants under the Plan generally vest over a period of one, three or four years. There were 309,500 shares of restricted stock outstanding at March 29, 2013. As of March 29, 2013, there were 274,035 shares authorized and available for grants under the Plan.

STAAR SURGICAL COMPANY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 29, 2013

(Unaudited)

Assumptions

The fair value of each option award is estimated on the date of grant using a Black-Scholes option valuation model applying the assumptions noted in the following table. Expected volatilities are based on historical volatility of the Company's stock. The Company uses historical data to estimate option exercise and employee termination behavior. The expected term of options granted is derived from the historical exercise activity over the past 15 years, and represents the period of time that options granted are expected to be outstanding. The Company has calculated a 9.92% estimated forfeiture rate used in the model for fiscal year 2013 option grants based on historical forfeiture experience. The risk-free rate is based on the U.S. Treasury yield curve corresponding to the expected term at the time of the grant.

	Three Months Ended	
	March 29, 2013	March 30, 2012
Expected dividend yield	0%	0%
Expected volatility	73.44%	79.64%
Risk-free interest rate	0.61%	0.84%
Expected term (in years)	4.12	5.21

A summary of option activity under the Plan as of March 29, 2013 is presented below:

	Options Shares (000's)	Restricted Shares (000's)	Warrants Shares (000's)
Outstanding at December 28, 2012	3,376	205	1,470
Granted	470	105	—
Exercised	(9)	—	—
Forfeited or expired	(6)	—	(70)

Outstanding at March 29, 2013	3,831	310	1,400
Exercisable at March 29, 2013	2,495	—	1,400

Note 11 — Manufacturing Consolidation Project and Tax Strategy

Since 2011 the Company devoted significant resources to two initiatives: a project to consolidate global manufacturing and product development as part of a strategy to optimize its global organization for tax purposes. The goal of both of these strategies is to continue the Company’s improvement in gross profit margin by reducing costs and to position the Company for future growth. STAAR currently manufactures its products in four facilities worldwide. It has developed a plan to substantially complete its consolidation of manufacturing in a single site at its Monrovia, California location by the end of 2013, which is expected subsequently to yield significant savings in cost of goods and to lower its global administrative and regulatory costs and reduce income taxes. Based on our efforts, we expect our effective tax rate to decline from approximately 50% in 2012 to 40% in 2013.

The Company expects these initiatives to cost approximately \$6 million over a three-year period, of which it has incurred approximately \$4.6 million to date. These expenses are included in “other general and administrative expenses” in consolidated statement of income for the period ended March 29, 2013. Expenses consisted of professional fees to advisors and consultants, travel, salaries and severance accrual. The Company expects to spend approximately \$2.5 million in manufacturing consolidation expenses in 2013.

A summary of the activity for these initiatives is presented below as of March 29, 2013 (in thousands):

STAAR SURGICAL COMPANY**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****March 29, 2013****(Unaudited)**

	Termination Benefits	Other Associated Costs	Total
Liability at December 28, 2012	\$ 504	\$ 293	\$797
Costs incurred and charged to expense	\$ 113	\$ 788	\$901
Cash payments	\$ —	\$ (258)) \$(258)
Liability at March 29, 2013	\$ 617	\$ 823	\$1,440
Total costs incurred to date	\$ 1,013	\$ 3,584	\$4,597
Total costs expected to be incurred	\$ 1,410	\$ 4,590	\$6,000

Note 12 — New Accounting Pronouncements

During the three months ended March 29, 2013, there were no new accounting pronouncements that would have a material effect on our unaudited condensed consolidated financial statements. For a description of recent accounting pronouncements relevant to us, please refer “Recent Accounting Pronouncements” included in Note 1 of our Annual Report on Form 10-K for the year ended December 28, 2012.

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 our Annual Report on Form 10-K for the fiscal year ended December 28, 2012. 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 (“we,” “us,” the “Company,” and “STAAR”) designs, develops, manufactures and sells implantable lenses for the eye and injector devices used to deliver these lenses into the eye through a small incision. We are the world’s leading manufacturer of intraocular lenses used in corrective or “refractive” surgery, and we also make lenses for use in surgery to treat cataracts. All of the lenses we make are foldable, which allows the surgeon to insert them into the eye through a small incision during minimally invasive surgery. Refractive surgery is performed to treat the type of visual disorders that have traditionally been corrected using eyeglasses or contact lenses. We refer to our lenses used in refractive surgery as “implantable Collamer® lenses” or “ICLs” and market them under the Visian® brand name. The field of refractive surgery includes both lens-based procedures, using products like the Visian ICL®, and laser-based procedures like LASIK. Successful refractive surgery can correct common vision disorders such as myopia, hyperopia and astigmatism. Astigmatism is a condition that causes blurred vision when an irregular shape of the cornea prevents light from focusing properly on the retina. Cataract surgery is a common outpatient procedure where the eye’s natural lens that has become cloudy with age is removed and replaced with an artificial lens called an intraocular lens (IOL) to restore the patient’s vision.

STAAR Surgical Company, Visian®, Collamer®, STAARVISC®, Elastimide®, nanoFLEX® nanoPOINT®, CentraFLOW™, AquaPORT™, Epiphany® 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.

Products

A detailed description of STAAR's business appears in our Annual Report on Form 10-K for the fiscal year ended December 28, 2012, along with a glossary explaining many of the specialized terms used in describing our products and our business. We recommend that readers unfamiliar with STAAR refer to that description.

ICLs - Implantable Collamer Lenses for Refractive Surgery. Sales of refractive lenses make up over half of our total sales. Made from our proprietary biocompatible Collamer material, highlights STAAR's family of Visian ICL products are as follows:

The Visian ICL treats refractive disorders such as myopia (near-sightedness) and hyperopia (far-sightedness). STAAR began selling the Visian ICL outside the U.S. in 1996 and inside the U.S. in 2006.

The Visian Toric ICL®, or TICL®, treats myopic and hyperopic patients with astigmatism. STAAR has been selling the Visian TICL outside the U.S. since 2002. STAAR remains in dialogue with the FDA regarding its PMA Supplement submission seeking approval to sell the TICL in the U.S. This matter is further discussed below under, "Status of Regulatory Submission."

STAAR currently sells globally several versions of the Visian ICL and Visian TICL globally; the original V4, the V4b, which expands the population of eligible patients to individuals in the lower diopter range (from -3.0 to +3.0), and the V4c, which includes the proprietary CentraFLOW technology (a port in the center of the myopic ICL and TICL) that eliminates the need for a peripheral iridectomy or iridotomy procedure prior to implanting the ICL.

STAAR's goal is to position the Visian ICL and TICL products throughout the world as primary choices for refractive surgery.

IOLs - Intraocular Lenses for Cataract Surgery. Our range of foldable IOLs for patients undergoing cataract surgery includes the following:

Aspheric IOLs, available in single-piece and three-piece designs made from (i) Collamer, STAAR's proprietary biocompatible collagen copolymer lens material and (ii) from silicone. Aspheric IOLs are designed to improve the patient's quality of vision when compared to earlier spherical IOL designs. The three piece aspheric silicone lens is available in the U.S. and is sold preloaded in certain markets outside of the U.S. The Collamer three piece lens is only marketed and sold in the U.S.

The nanoFLEX IOL, a single-piece Collamer aspheric IOL that can be implanted through a micro-incision with a single-use disposable nanoPOINT injector system is available in the U.S and territories that accept the CE Mark.

The Preloaded Injector, a three-piece silicone or acrylic IOL preloaded into a single-use disposable injector is currently available outside the U.S. The acrylic IOL Preloaded Injector uses an acrylic lens sourced from another manufacturer. The KS-SP, a single-piece preloaded acrylic IOL that can be implanted through a micro-incision with a single-use disposable injector system is available in Japan and on a limited basis in Europe. The third party supplier of acrylic lenses is unable to meet STAAR's demand for the new KS IOL products, thus the company experienced approximately \$900,000 in backorders from its European customers. We are seeking alternative suppliers but cannot predict whether our efforts will prove successful.

STAAR Toric IOL is a single piece silicone toric IOL, used in cataract surgery to treat preexisting astigmatism and is currently only marketed in the U.S. A Collamer version of our toric IOL –nanoFLEX Toric has CE mark approval.

Because most cataract patients are elderly, government agencies or government sponsored entities generally pay the cost of IOLs in our major markets, including the U.S. As a result, cataract procedure volumes will likely remain relatively stable even under adverse conditions in the general economy. However, changes in reimbursement policy under these agencies and entities can reduce our selling prices or reduce the volume of cataract procedures.

Other Surgical Products. We also sell other instruments, devices, and equipment used in cataract or refractive surgery, which we either manufacture or have manufactured for us. However, we have been deemphasizing these products since 2009 because of their lower overall gross profit margins.

Operations

STAAR operates its global administrative headquarters and a manufacturing facility in Monrovia, California, and also maintains manufacturing facilities in Nidau, Switzerland, Chiba Prefecture, Japan, and Aliso Viejo, California.

STAAR is implementing a project to consolidate its manufacturing into a single site at its Monrovia, California location by the end of 2013, which we expect to yield significant savings in cost of goods, lower our global administrative and regulatory costs and reduce income taxes. During the first quarter of 2013, all non-sterile silicone IOLs for Japan were manufactured in the U.S. The Company shipped the first Visian ICLs manufactured in the U.S. during the first quarter of 2013 to approved markets outside the U.S. This project, which is subject to significant risks, is further described under Note 12, “*Manufacturing Consolidation Project and Tax Strategy.*”

Strategy and Key Operational Metrics

STAAR’s strategy is to be valued as a leading global provider of innovative intraocular lens system technologies. STAAR employs a commercialization strategy that focuses on achieving sustainable profitable growth.

STAAR’s key operational metrics for 2013 are guided by two principal strategic goals: to achieve and maintain profitability and to lay the groundwork for further growth. In pursuit of these goals, STAAR has aligned its business initiatives during 2013 along four key operational metrics it uses to gauge its success during the year. Those metrics are as follows:

· Increase total revenue by 8% to 10%.

- As discussed below in “*Results of Operations*,” our total revenue increased by 16% in the first quarter of 2013.

Increase gross profit margins by 250 basis points for the full year.

- As discussed below in “*Results of Operations*,” our gross profit increased by 90 basis points in the first quarter of 2013 compared to full year 2012, and 250 basis points improvement when compared to fourth quarter of 2012.

Achieve profitability in each quarter of 2013.

- As discussed below in “*Results of Operations*,” we achieved net income of \$0.5 million in the first quarter of 2013.

· Manage the manufacturing consolidation with no material disruption to customer supply requirements or quality.

- The Company’s consolidation efforts are proceeding according to plans and the Company expects this to continue during the remainder of 2013.

Other Highlights

In the first quarter of 2013, ICLs grew in ten of our eleven targeted markets by 25%, with particular strength in Europe and the Middle East. The effect of foreign currency exchange, particularly the strength of the Japanese Yen compared to the U.S. Dollar, reduced total sales by \$750,000 during the first quarter of 2013. We expect this trend to continue during the second quarter of 2013. We also reported a \$1,034,000 charge for stock-based compensation. Seventy thousand warrants issued on March 21, 2007 to Broadwood Partners, L.P., expired on March 21, 2013, and were unexercised.

With the transition to a direct sales model in Spain, sales grew in Spain by 156%. As part of our early transition to a direct distribution model in Spain, we made \$422,000 in payments to our former distributor. These payments ended in the first quarter of 2013 and will not impact expenses during the remainder of 2013. Backorders of our preloaded acrylic IOLs in Europe were \$900,000 due to demand for our KS-SP and KS-X products and the supply constraints we continue to experience from a third party supplier. This backorder position is expected to continue to limit IOL sales for the entire year and we are evaluating potential options to meet this demand. STAAR continues its manufacturing consolidation efforts in the first quarter of 2013 in preparation of transferring Swiss and Japanese manufacturing activities to our Monrovia facility. Last year, as part of our manufacturing consolidation plan, we

expanded into approximately 26,000 square feet of space contiguous to our Monrovia headquarters. In the first quarter of 2013, we incurred \$550,000 in costs and we expect to spend an additional \$264,000 during the remainder of 2013 to complete the build-out of this leased real property. Also, the Company launched the nanoFlex Toric IOL for Europe. In compliance with the Affordable Care Act, in the first quarter of 2013, the Company recorded \$59,000 in Medical Device Excise Tax expense. On April 11, 2013, an FDA inspector performed an inspection of our Aliso Viejo, California facility. There were no findings issued on a Form 483 and the inspector indicated that we would receive a 'no action indicated' report.

Status of Regulatory Submissions. Regarding our PMA Supplement submission to the FDA seeking approval for the TICL, by a letter dated April 30, 2012 the FDA rejected our most recent proposed approach to respond to the FDA's concerns regarding timing of follow-up visits for certain patients in the study cohort at certain sites. On November 15, 2012, STAAR submitted to the FDA (1) clinical data showing no statistical difference in the clinical outcomes with or without the patient data that was obtained outside the study windows, (2) engineering data regarding the lens design, and (3) a validation report for the Toric ICL power calculation software. STAAR remains in dialogue with the agency regarding our PMA Supplement, and has responded to a series of questions from the FDA in the first quarter of 2013. STAAR cannot predict when, or if, the FDA will grant approval of the TICL for use in the United States.

On October 9, 2012, STAAR submitted to the FDA a 180 day PMA Supplement regarding the V4c version of the Visian ICL. On February 12, 2013, in response to a request by the FDA, we submitted a Pre-Submission for the PMA Supplement. The FDA expects to respond to our proposal by the end of May 2013 due to an administrative oversight at the FDA. We'll continue to seek approval for our key products in our target markets.

Critical Accounting Policies

This Management's Discussion and Analysis of Financial Condition and Results of Operations discusses and analyzes data in our unaudited Condensed Consolidated Financial Statements, which we have prepared in accordance with U.S. generally accepted accounting principles. 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 conditions may differ from our assumptions and actual results may differ from our estimates.

An accounting policy is deemed critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, if different estimates reasonably could have been used, or if changes in the estimate that are reasonably likely to occur could materially impact the financial statements. Management believes that there have been no significant changes during the three months ended March 29, 2013 to the items that we disclosed as our critical accounting policies and estimates in Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the fiscal year ended December 28, 2012.

Results of Operations

The following table shows the percentage of our total sales represented by the specific items listed in our statements of operations for the periods indicated, and the percentage by which these items increased or decreased over the prior period.

	Percentage of Net Sales for Three Months		Percentage Change for Three Months	
	March 29, 2013	March 30, 2012	2013 vs. 2012	
Net sales	100.0%	100.0%	16.1	%

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Cost of sales	29.7	29.7	16.1	
Gross profit	70.3	70.3	16.1	
General and administrative	22.0	24.8	2.5	
Marketing and selling	29.4	30.1	13.4	
Research and development	7.6	10.0	(11.6))
Medical device tax	0.3	—	—	*
Other general and administrative expenses	5.0	3.6	62.3	
	64.3	68.5	8.9	
Operating income	6.0	1.8	—	*
Other income (expense), net	(1.7)	1.2	—	*
Income before provision for income taxes	4.3	3.0	69.2	
Provision for income taxes	1.7	1.5	35.3	
Net income	2.6	% 1.5	% —	*

* Denotes change is greater than $\pm 100\%$.

Net Sales

	Three Months Ended		Percentage Change for Three Months	
	March 29, 2013	March 30, 2012	2013 vs. 2012	
Net sales	\$18,001	\$15,509	16.1	%
ICL	10,631	8,605	23.5	
IOL	6,347	6,358	(0.2))
Other	1,023	546	87.4	

Net sales for the three months ended March 29, 2013 were \$18.0 million, an increase of 16.1% compared with \$15.5 million reported during the same period of 2012. Changes in currency had a \$0.7 million unfavorable impact on net sales for the first quarter of 2013.

Total ICL sales for the three months ended March 29, 2013 were \$10.6 million, an increase of 23.5% compared with \$8.6 million reported during the same period of 2012. The increase in ICL sales is due to increased sales in the Company's three geographic regions, Europe, Middle East, Africa and Latin America (EMEA), Asia Pacific (APAC) and North America. Sales in EMEA grew 59%, led by Spain which grew 156% and the Middle East, which grew 94%. Sales in APAC and North America each grew 11%, led by growth in the U.S. +11%, India +22%, Japan +14%, China and Korea (each +7%). ICL volume increased 18% and average selling prices (ASPs) increased 5%. The mix of ICL (59%) versus TICL (41%) was unchanged from the same prior year period. ICL sales represented 59.1% and 55.5% of the sales, respectively, for the three months ended March 29, 2013 and March 30, 2012.

Total IOL sales for the three months ended March 29, 2013 were \$6.3 million, a decrease of 0.2% compared with \$6.4 million reported during the same period of 2012. Although sales of our Preloaded acrylic IOL grew 84%, this growth was offset by decreased sales of Preloaded Silicone and Collamer IOLs. IOL sales were negatively impacted due to approximately \$900,000 in backorders from the Company's acrylic IOL supplier and the negative effect of foreign currency exchange which totaled \$646,000. IOL sales represented 35.3% and 41.0% of total net sales respectively, for the three months ended March 29, 2013 and March 30, 2012.

Other product sales for the three months ended March 29, 2013 were \$1.0 million, an increase of 87.4% compared with the \$0.5 million reported during the same period of 2012. This increase was due to increased sales of acrylic preloaded injectors parts to the Company's acrylic lens supplier to support the buildup of acrylic preloaded product supply.

Gross Profit

	Three Months Ended		Percentage Change for Three Months	
	March 29, 2013	March 30, 2012	2013 vs. 2013	
Gross Profit	\$12,654	\$10,902	16.1	%
Gross Profit Margin	70.3 %	70.3 %		

Gross profit for the first quarter was \$12.7 million, or 70.3% of revenue, compared with \$10.9 million, or 70.3% of revenue, in the prior year period. Gross margin expansion was limited primarily by a large increase in very low margin IOL injector systems sales to a third party supplier for the buildup of their acrylic preloaded product supply, which appears in Other Product sales category. The increase in sales of injector parts negatively impacted margins by approximately 170 basis points.

General and Administrative

	Three Months Ended		Percentage Change for Three Months	
	March 29, 2013	March 30, 2012	2013 vs. 2012	
General and Administrative	\$3,958	\$3,860	2.5	%
Percentage of Sales	22.0 %	24.8 %		

General and administrative expenses for the quarter were \$4.0 million, an increase of 2.5% when compared with \$3.9 million reported last year. The increase is due primarily to an increase in stock based compensation expense. General and administrative expenses were favorably impacted by foreign currency exchange by approximately \$70,000.

Marketing and Selling

	Three Months Ended		Percentage Change for Three Months	
	March 29, 2013	March 30, 2012	2013 vs. 2012	
Marketing and Selling	\$5,286	\$4,663	13.4	%
Percentage of Sales	29.4 %	30.1 %		

Marketing and selling expenses for the quarter were \$5.3 million, an increase of 13.4% when compared with \$4.7 million reported last year. The increase is due primarily to increased expense associated with direct distribution transition in Spain and increased headcount globally. Transitional expenses in Spain, which totaled \$442,000 for the quarter, ended at the beginning of March 2013. Marketing and selling expenses were favorably impacted by foreign currency exchange by approximately \$197,000.

Research and Development

	Three Months Ended		Percentage Change for Three Months	
	March 29, 2013	March 30, 2012	2013 vs. 2012	
Research and Development	\$1,366	\$1,546	(11.6)%
Percentage of Sales	7.6 %	10.0 %		

Research and development expense for the quarter were \$1.4 million, a decrease of 11.6% when compared with \$1.5 million reported last year. The decrease was primarily due to transfer of activities from Japan to the US which resulted in improved efficiencies. Research and development expenses were favorably impacted by foreign currency exchange by approximately \$27,000.

Other General and Administrative Expenses

	Three Months Ended		Percentage Change for Three Months
	March 29, 2013	March 30, 2012	2013 vs. 2012
Other General and Administrative Expenses	\$0.9	\$ 0.6	62.3
Percentage of Sales	5.0%	3.6 %	

Other general and administrative expenses for the quarter were \$0.9 million, compared with \$0.6 million reported last year. The increase is due to costs associated with the wind up of manufacturing operations in Japan which should significantly decrease in the remaining months of the year, particularly in the second half. The Company expects to incur a total of approximately \$2.5 million in manufacturing consolidation expenses in 2013. Other general and administrative expenses were favorably impacted by foreign currency exchange by approximately \$57,000.

Other Income, (Expense) Net

	Three Months Ended		Percentage Change for Three Months
	March 29, 2013	March 30, 2012	2012 vs. 2011
Other Income (Expense), Net	\$(0.3)	\$ 0.2	—*

* Denotes change is greater than $\pm 100\%$.

Other expense, for the quarter was \$0.3 million compared to other income of \$0.2 million in the first quarter of 2012. The year over year change in other income (expense), net for both periods is due to foreign currency exchange loss recorded in first quarter of 2013 compared to foreign currency exchange gain reported last year, and a decrease in other income resulting from the release of escrow funds in 2012 related to the sale of our former German distributor.

Liquidity and Capital Resources

STAAR's liquidity requirements arise from the funding of our working capital needs, primarily inventory and accounts receivable. Our primary sources for working capital and capital expenditures are cash flows from operating activities, proceeds from the exercise of stock options, and borrowings under our credit facilities. 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 STAAR's cash flow. In addition, any abnormal product returns or pricing adjustments may also affect our short-term funding.

STAAR believes its current cash balances, coupled with cash flow from operating activities will be sufficient to meet its working capital requirements for the foreseeable future, including the estimated \$6 million cost associated with the manufacturing consolidation plan previously discussed by us and further described in Note 11, "*Manufacturing Consolidation Project and Tax Strategy*." If the need for financing arises, STAAR cannot assure that it will be available on acceptable terms, if at all. STAAR's Japanese and Swiss subsidiaries have bank lines of credit in place for working capital purpose, but STAAR does not maintain such a credit line in the U.S.

STAAR's cash balances have steadily increased over the last two years. To the extent STAAR's cash balances exceed levels needed for working capital and as a cushion for unforeseen demands, STAAR intends to invest its cash in expanding and improving its business. It does not anticipate paying dividends from its earnings for the foreseeable future.

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

As of March 29, 2013 and December 28, 2012, respectively, STAAR had \$19.2 million and \$21.7 million, of cash and cash equivalents.

Net cash used in operating activities was \$0.4 million for the three months ended March 29, 2013 and March 30, 2012 and consisted of net income of \$0.5 million, plus \$1.6 million in non-cash items, offset by \$2.5 million decrease in working capital for the three months ended March 29, 2013.

Net cash used in investing activities was \$1.2 million for the three months ended March 29, 2013, compared to \$0.2 million in net cash provided by investing activities for the three months ended March 30, 2012. Net cash used in investing activities was mainly due to \$1.2 million in acquisition of property, plant and equipment.

Net cash used by financing activities was \$0.2 million for the three months ended March 29, 2013, compared with \$0.6 million in net cash provided by financing activities for the three months ended March 30, 2012. The decrease in cash financing activities was due to decrease in proceeds from exercise of stock options.

Credit Facilities, Contractual Obligations and Commitments

Accrued Termination Benefits for Manufacturing Consolidations Project

The Company has accrued \$0.6 million as of March 29, 2013 in termination benefit costs in connection with its manufacturing consolidation project. The accrual represents STAAR's current best estimate of the termination benefits that will be paid to the eligible employees.

Lines of Credit

The Company's wholly owned Japanese subsidiary, STAAR Japan, has an agreement, as amended on December 28, 2012, with Mizuho Bank, which provides for borrowings of up to 500,000,000 Yen (approximately \$5.3 million based on the rate of exchange on March 29, 2013), at an interest rate equal to the Tokyo short-term prime interest rate (approximately 1.475% as of March 29, 2013). The Company had 500,000,000 Yen outstanding on the line of credit as of March 29, 2013 and December 28, 2012 (approximately \$5.3 million and \$5.8 million based on the foreign currency exchange rates on March 29, 2013 and December 28, 2012). As of March 29, 2013 there were no available borrowings under the line.

In August 2010, the Company's wholly-owned Swiss subsidiary, STAAR Surgical AG, entered into a credit agreement with Credit Suisse (the "Bank"). The credit agreement provides for borrowings of up to 1,000,000 Swiss Francs (approximately \$1.1 million at the rate of exchange on March 29, 2013), to be used for working capital purposes. There were no borrowings outstanding as of March 29, 2013 and the full amount of the line was available for borrowing.

Covenant Compliance

The Company is in compliance with the covenants of its credit facilities as of the date of this report.

Capital Lease Obligations

STAAR leases certain property, plant, and equipment under non-cancelable capital lease agreements. These leases vary in amount, duration, and rates.

Estimated future minimum payments under capital lease obligations were as follows (in thousands):

Fiscal Year	March 29, 2013	December 28, 2012
2013	\$635	\$ 916
2014	313	318
2015	146	152
2016	7	8
Thereafter	—	—
Total minimum lease payments	\$1,101	\$ 1,394
Less: interest	(54)	(77)
Total lease obligation	\$1,047	\$ 1,317
Current	\$701	\$ 829
Long-term	\$346	\$ 488

Off-Balance Sheet Arrangements

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

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

There have been no material changes in the Company's qualitative and quantitative market risk since the disclosure in the Company's Annual Report on Form 10-K for the year ended December 28, 2012.

ITEM 4. *CONTROLS AND PROCEDURES*

Disclosure Controls and Procedures

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our CEO and CFO, of the effectiveness of the design and operation of the disclosure controls and procedures of STAAR Surgical Company and its subsidiaries (the "Company"). Based on that evaluation, our CEO and CFO concluded, as of the end of the period covered by this quarterly report on Form 10-Q, that our disclosure controls and procedures were effective. For purposes of this statement, the term "disclosure controls and procedures" means controls and other procedures of the Company that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act (15 U.S.C. 78a et seq.) is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

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.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended March 29, 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

Our short and long-term success is subject to many factors that are beyond our control. Investors and prospective investors should consider carefully the following risk factors, in addition to other information contained in this report and the risks and uncertainties described in “Part I—Item 1A—Risk Factors” of the Company’s Form 10-K for the fiscal year ended December 28, 2012. Such risks and uncertainties could materially adversely affect our business, financial condition or operating results.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

Not Applicable.

ITEM 6. EXHIBITS

3.1 Certificate of Incorporation, as amended to date.(1)

3.2 By-laws, as amended to date.(2)

†4.2 1991 Stock Option Plan of STAAR Surgical Company.(4)

†4.3 1998 STAAR Surgical Company Stock Plan, adopted April 17, 1998.(5)

- 4.4 Form of Certificate for Common Stock, par value \$0.01 per share.(6)
†4.5 Amended and Restated 2003 Omnibus Equity Incentive Plan, and form of Option Grant and Stock Option Agreement.(3)
- 31.1 Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *
- 31.2 Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *
- 32.1 Certification Pursuant to 18 U.S.C. Section 1350, Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *
- 101 Financial statements from the quarterly report on Form 10-Q of STAAR Surgical Company for the quarter ended September 28, 2012, formatted in XBRL, are filed herewith and include: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Consolidated Statements of Comprehensive Income, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) the Notes to Condensed Consolidated Financial Statements tagged as blocks of text. *

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- (1) Incorporated by reference to the Company's Annual Report on Form 10-K for the fiscal year ended December 28, 2007, as filed with the Commission on March 12, 2008.
- (2) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Commission on May 23, 2006.
- (3) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for quarter ended July 2, 2010, filed with the Commission on August 11, 2010.
- (4) 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.
- (5) 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.
- (6) 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.

Filed herewith.

*

Management contract or compensatory plan or arrangement.

†

SIGNATURES

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

STAAR SURGICAL COMPANY

Date: May 3, 2013 By: /s/ DEBORAH ANDREWS
Deborah Andrews

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