ICU MEDICAL INC/DE
Form 10-Q
July 23, 2010
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended: June 30, 2010

or

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

For the transition period from: to

Commission File No.: 0-19974

ICU MEDICAL, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**33-0022692**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

951 Calle Amanecer, San Clemente, California	**92673**
(Address of principal executive offices)	(Zip Code)

(949) 366-2183

(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 x No o

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 x No o

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 o	Accelerated filer x
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date:

Class	**Outstanding at July 12, 2010**
Common	13,450,526

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

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ICU Medical, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

(Amounts in thousands, except per share data)

	June 30, 2010 (unaudited)	December 31, 2009 (1)
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 57,602	$ 51,248
Investment securities	25,472	56,887
Cash, cash equivalents and investment securities	83,074	108,135
Accounts receivable, net of allowance for doubtful accounts of $393 at June 30, 2010 and $324 at December 31, 2009	48,745	47,777
Inventories	41,158	41,327
Prepaid income taxes	781	1,994
Prepaid expenses and other current assets	6,389	5,462
Deferred income taxes	4,178	3,243
Total current assets	184,325	207,938
PROPERTY AND EQUIPMENT, net	80,548	77,449
PROPERTY HELD FOR SALE		940
GOODWILL	1,478	1,478
INTANGIBLE ASSETS, net	15,816	16,782
DEFERRED INCOME TAXES	3,651	3,710
INCOME TAXES RECEIVABLE	856	856
	$ 286,674	$ 309,153
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 17,483	$ 18,423
Accrued liabilities	13,747	12,884
Deferred revenue	106	2,389
Total current liabilities	31,336	33,696
DEFERRED INCOME TAXES	5,698	5,698
INCOME TAX LIABILITY	4,754	4,754
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS EQUITY:		
Convertible preferred stock, $1.00 par value Authorized 500 shares; issued and outstanding none		
Common stock, $0.10 par value Authorized 80,000 shares; issued 14,814 shares at June 30, 2010 and 14,811 shares at December 31, 2009, outstanding 13,451 shares at June 30, 2010 and 14,239 shares at December 31, 2009	1,481	1,481
Additional paid-in capital	55,867	54,357
Treasury stock, at cost 1,363 and 572 shares at June 30, 2010 and December 31, 2009	(47,464)	(19,881)
Retained earnings	239,829	227,861
Accumulated other comprehensive income (loss)	(4,827)	1,187
Total stockholders equity	244,886	265,005
	$ 286,674	$ 309,153

(1) December 31, 2009 balances were derived from audited consolidated financial statements.

The accompanying notes are an integral part of these condensed consolidated financial statements.

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ICU Medical, Inc. and Subsidiaries

Condensed Consolidated Statements of Income

(Amounts in thousands, except per share data)

(unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2010	**2009**	**2010**	**2009**
REVENUES:				
Net sales	$ 68,710	$ 53,282	$ 132,922	$ 107,477
Other	152	117	303	257
TOTAL REVENUE	68,862	53,399	133,225	107,734
COST OF GOODS SOLD	36,735	27,610	74,171	55,379
Gross profit	32,127	25,789	59,054	52,355
OPERATING EXPENSES:				
Selling, general and administrative	19,372	16,503	39,027	31,615
Research and development	952	617	1,870	1,355
Total operating expenses, net	20,324	17,120	40,897	32,970
Income from operations	11,803	8,669	18,157	19,385
OTHER INCOME	63	305	255	623
Income before income taxes	11,866	8,974	18,412	20,008
PROVISION FOR INCOME TAXES	(4,153)	(3,233)	(6,444)	(7,205)
NET INCOME	$ 7,713	$ 5,741	$ 11,968	$ 12,803
NET INCOME PER SHARE				
Basic	$ 0.57	$ 0.39	$ 0.88	$ 0.87
Diluted	$ 0.56	$ 0.38	$ 0.86	$ 0.85
WEIGHTED AVERAGE NUMBER OF SHARES				
Basic	13,469	14,780	13,665	14,758
Diluted	13,657	15,071	13,888	14,975

The accompanying notes are an integral part of these condensed consolidated financial statements.

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ICU Medical, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

(Amounts in thousands)

(unaudited)

	Six months ended June 30,	
	2010	**2009**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$ 11,968	$ 12,803
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	8,602	7,337
Provision for doubtful accounts	97	(84)
Stock compensation	1,668	1,242
Bond premium amortization	947	1,159
Loss on disposal of property and equipment	49	20
Cash provided (used) by changes in operating assets and liabilities, net of assets acquired		
Accounts receivable	(1,970)	11,182
Inventories	(1,423)	(4,668)
Prepaid expenses and other assets	(1,784)	(2,635)
Accounts payable	(1,140)	1,547
Accrued liabilities	1,387	(3,789)
Deferred revenue	(2,283)	
Prepaid and deferred income taxes	1,421	3,682
Net cash provided by operating activities	17,539	27,796
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(11,285)	(6,852)
Proceeds from sale of asset	893	
Business acquisition, net of cash acquired		(5,663)
Change in restricted cash		5,958
Purchases of investment securities	(13,698)	(56,206)
Proceeds from sale of investment securities	44,166	40,423
Net cash provided (used) by investing activities	20,076	(22,340)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	103	1,255
Proceeds from employee stock purchase plan	747	623
Tax benefits from exercise of stock options	58	48
Purchase of treasury stock	(28,648)	(560)
Net cash provided (used) by financing activities	(27,740)	1,366
Effect of exchange rate changes on cash	(3,521)	68
NET INCREASE IN CASH AND CASH EQUIVALENTS	6,354	6,890
CASH AND CASH EQUIVALENTS, beginning of period	51,248	55,696
CASH AND CASH EQUIVALENTS, end of period	$ 57,602	$ 62,586
NON-CASH INVESTING ACTIVITES		
Accrued liabilities for property and equipment	$ 354	$

The accompanying notes are an integral part of these condensed consolidated financial statements.

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ICU Medical, Inc. and Subsidiaries

Condensed Consolidated Statements of Comprehensive Income

(Amounts in thousands)

(unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2010	**2009**	**2010**	**2009**
Net income	$ 7,713	$ 5,741	$ 11,968	$ 12,803
Other comprehensive income (loss), net of tax:				
Foreign currency translation adjustment	(4,507)	881	(6,014)	(6)
Comprehensive income	$ 3,206	$ 6,622	$ 5,954	$ 12,797

The accompanying notes are an integral part of these condensed consolidated financial statements.

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ICU Medical, Inc.

Notes to Condensed Consolidated Financial Statements

Three and Six Months Ended June 30, 2010 and 2009

(Amounts in tables in thousands, except per share data)

(unaudited)

Note 1: Basis of Presentation:

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America and pursuant to the rules and regulations of the Securities and Exchange Commission (SEC) and reflect all adjustments, consisting of only normal recurring adjustments, which are, in the opinion of management, necessary for a fair statement of the consolidated results for the interim periods presented. Results for the interim period are not necessarily indicative of results for the full year. Certain information and footnote disclosures normally included in annual consolidated financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. The condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company s Annual Report on Form 10-K filed with the SEC for the year ended December 31, 2009.

Subsequent to the issuance of the Company s 2009 consolidated financial statements, the Company reclassified $1.2 million of bond premium amortization, a noncash item, from investing activities in the consolidated statement of cash flows for the six months ended June 30, 2009 to a noncash item in cash flows from operating activities as an adjustment to reconcile net income to net cash provided by operating activities. The Company considers this an immaterial reclassification and has changed the 2009 condensed consolidated financial statements.

ICU Medical, Inc. (the Company), a Delaware corporation, operates principally in one business segment engaged in the development, manufacturing and marketing of disposable medical devices. The Company s devices are sold directly or to distributors and medical product manufacturers throughout the United States and internationally. All subsidiaries are wholly or majority owned and included in the consolidated financial statements. All intercompany balances and transactions have been eliminated.

Note 2: New Accounting Pronouncements:

In January 2010, the Financial Accounting Standards Board issued Accounting Standards Update No. 2010-06 for Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements . This Update requires new disclosures for transfers in and out of Level 1 and 2 and activity in Level 3. This Update also clarifies existing disclosures for level of disaggregation and about inputs and valuation techniques. The new disclosures are effective for interim and annual periods beginning after December 15, 2009, except for the Level 3 disclosures, which are effective for fiscal years beginning after December 15, 2010 and for interim periods within those years.

Note 3: Fair Value Measurement:

The Company s investment securities, which are considered available-for-sale and trading, consist principally of certificates of deposit and federal-tax-exempt state and municipal government debt. The Company has $7.3 million of its investment securities as Level 1 assets, which are certificates of deposit with quoted prices in active markets. The Company has $17.4 million of its investment securities as Level 2 assets, which are pre-refunded and non-pre-refunded municipal securities and have observable inputs. The Company has $0.8 million invested in one auction rate security as a Level 3 asset due to the unobservable inputs caused by the lack of liquidity. The valuation of this security was based on quotes received from our brokers derived from their internal models combined with internally developed discount factors. In determining a discount factor for each auction rate security, the model weights various factors, including assessments of credit quality, duration, insurance wraps, discount rates, overall capital market liquidity and comparable securities, if any. They are carried at fair value.

The following table provides the assets and liabilities carried at fair value measured on a recurring basis as of June 30, 2010:

			Fair value measurements at June 30, 2010 using					
		Total carrying value at June 30, 2010		Quoted prices in active markets for identical assets (level 1)		Significant other observable inputs (level 2)		Significant unobservable inputs (level 3)
Available for sale securities	$	24,722	$	7,273	$	17,449	$	
Trading securities		750						750
	$	25,472	$	7,273	$	17,449	$	750

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The following tables summarize the change in the fair values for Level 3 items for the quarter ended June 30, 2010:

Level 3 changes in fair value (pre-tax):

	Three months ended June 30, 2010	Six months ended June 30, 2010
Beginning balance	$ 900	$ 900
Transfer into Level 3		
Sales	(150)	(150)
Unrealized holding loss, included in other comprehensive income		
Ending balance	$ 750	$ 750

The Company has an agreement in place with UBS AG (UBS) that permits the Company to require UBS to purchase the Company s auction rate securities at par value plus accrued interest. As of June 30, 2010, the Company has $0.8 million in one auction rate security. There was no change in the market value of the Company s auction rate security in the quarter ended June 30, 2010.

Note 4: Inventories:

Inventories consisted of the following:

	June 30, 2010	December 31, 2009
Raw material	$ 21,032	$ 16,268
Work in process	2,812	2,711
Finished goods	17,314	22,348
Total	$ 41,158	$ 41,327

Note 5: Property and Equipment:

Property and equipment consisted of the following:

	June 30, 2010	December 31, 2009
Machinery and equipment	$ 59,065	$ 57,966
Land, building and building improvements	50,408	50,200
Molds	20,309	18,939
Computer equipment and software	13,060	12,196
Furniture and fixtures	1,843	1,928

Construction in progress		14,610		9,565
Total property and equipment, cost		159,295		150,794
Accumulated depreciation		(78,747)		(73,345)
Net property and equipment	$	80,548	$	77,449

Note 6: Net Income Per Share:

Net income per share is computed by dividing net income by the weighted average number of common shares outstanding. Diluted net income per share is computed by dividing net income by the weighted average number of common shares outstanding plus dilutive securities. Dilutive securities are outstanding common stock options (excluding stock options with an exercise price in excess of the average market value for the period), less the number of shares that could have been purchased with the proceeds from the exercise of the options, using the treasury stock method. Options that are anti-dilutive because their exercise price exceeded the average market price of the common stock for the period approximated 922,000 and 267,000 for the three months ended June 30, 2010 and 2009, respectively and 748,000 and 679,000 for the six months ended June 30, 2010, respectively.

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The following table presents the calculation of net earnings per common share (EPS) basic and diluted

	Three months ended June 30,		Six months ended June 30,	
	2010	2009	2010	2009
Net income	$ 7,713	$ 5,741	$ 11,968	$ 12,803
Weighted average number of common shares outstanding (for basic calculation)	13,469	14,780	13,665	14,758
Dilutive securities	188	291	223	217
Weighted average common and common equivalent shares outstanding (for diluted calculation)	13,657	15,071	13,888	14,975
EPS basic	$ 0.57	$ 0.39	$ 0.88	$ 0.87
EPS diluted	$ 0.56	$ 0.38	$ 0.86	$ 0.85

Note 7: Income Taxes:

Income taxes were accrued at an estimated annual effective tax rate of 35% in the first half of 2010 compared to 36% in the first half of 2009. The effective tax rate differs from that computed at the federal statutory rate of 35% principally because of the effect of foreign and state income taxes, tax credits, tax exempt income and deductions for domestic production activities.

Note 8: Major Customer:

The Company had revenues equal to 10% or more of total revenues from one customer, Hospira, Inc. Such revenues were 41% and 63% of total revenue for the three months ended June 30, 2010 and 2009, respectively, and 40% and 67% for the six months ended June 30, 2010 and 2009, respectively. As of June 30, 2010 and December 31, 2009, the Company had accounts receivable from Hospira of 35% and 37%, of consolidated accounts receivable, respectively.

Note 9: Treasury Stock:

The Company had a common stock purchase plan, authorized by its board of directors, to purchase up to $55.0 million of its common stock which was completed in the quarter ended June 30, 2010. The Company purchased $4.7 million and $28.6 million of its common stock in the three and six months ended June 30, 2010, respectively.

In July 2010, the Company s board of directors approved a new common stock purchase plan to purchase up to $40.0 million of its common stock.

Note 10: Commitments and Contingencies:

The Company is from time to time involved in various other legal proceedings, most of which are routine litigation, in the normal course of business. In the opinion of management, the resolution of the other legal proceedings in which the Company is involved will not likely have a material adverse impact on the Company s financial position or results of operations.

In the normal course of business, the Company has agreed to indemnify officers and directors of the Company to the maximum extent permitted under Delaware law and to indemnify customers as to certain intellectual property matters related to sales of the Company s products. There is no maximum limit on the indemnification that may be required under these agreements. The Company has never incurred, nor do we expect to incur, any liability for indemnification.

Pursuant to the Asset Purchase Agreement with Hospira, the Company agreed to indemnify Hospira and its affiliates from certain liabilities arising out of (i) inaccuracies of the Company s representations and breaches of the Company s warranties; (ii) defaults of the Company s covenants or obligations; (iii) certain assumed obligations and (iv) use of the acquired assets after the date of closing. Most of Hospira s rights to indemnification will terminate eighteen months after the closing of the transaction on August 31, 2009, except for liabilities arising out of certain provisions of the asset purchase agreement and liabilities for which notice was previously provided. Notwithstanding the foregoing, the Company is not obligated to indemnify Hospira for any liabilities for which Hospira is obligated to indemnify us or our affiliates under our Manufacturing, Commercialization and Development Agreement with Hospira, Inc., dated March 1, 2005 (the MCDA).

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

We are a leader in the development, manufacture and sale of proprietary, disposable medical connection systems for use in vascular therapy applications. Our devices are designed to protect patients from catheter related bloodstream infections and healthcare workers from exposure to diseases through accidental needlesticks or hazardous drugs. We are also a leader in the production of custom infusion sets and we incorporate our proprietary products into many of those custom infusion sets. In addition, we are a significant manufacturer of critical care medical devices, including catheters, angiography kits and cardiac monitoring systems.

Business Overview

Until the late 1990s, our primary emphasis in product development, sales and marketing was disposable medical connectors for use in I.V. therapy, and our principal product was the CLAVE. In the late 1990s, we commenced a transition from a product-centered company to an innovative, fast, efficient, low-cost manufacturer of custom infusion sets, using processes that we believe can be readily applied to a variety of disposable medical devices. This strategy has enabled us to capture revenue on the entire I.V. delivery system, and not just a component of the system. We have furthered this effort to include all of our proprietary devices beyond the CLAVE.

One strategy has been to acquire new product lines. For example, in August 2009, we purchased the commercial rights and physical assets of Hospira s critical care product line, which resulted in our control over all aspects of the critical care product line, including production, sales, marketing, customer contracting and distribution. We had previously manufactured for sale, exclusively to Hospira, the critical care products. Hospira retained commercial responsibility for the products that we manufactured, including sales to end customers, marketing, pricing, distribution, customer contracts, customer service and billing. We had little ability to directly influence Hospira s sales and marketing efforts, and our sales under this arrangement were subject to fluctuations over which we had little control. The purchase of Hospira s critical care line has resulted in an increase in direct sales and sales to independent distributors but a decrease in sales to Hospira. There is no assurance that we will be successful in finding future acquisition opportunities or integrating these new product lines into our existing business.

Another strategy for reducing our dependence on our current proprietary products has been to introduce new products. We have introduced a new line of oncology products including the Spiros male lure connector device, the Genie vial access device and ancillary products specifically designed for chemotherapy. We can provide no assurance that we will be able to successfully manufacture market and sell these new products.

We are also expanding our custom products business through increased sales to medical product manufacturers, independent distributors and through direct sales to the end users of our product. These expansions include our 2008 agreement with Premier, the extension of the term of our agreement with MedAssets and our recent entry into an agreement with Novation of all our critical care products. Each of these organizations is a U.S. healthcare purchasing network. Custom products, which include custom infusion, custom oncology and custom critical care products, accounted for approximately $43.7 million or 33% of total revenue in the first half of 2010 and $78.6 million or 34% of total revenue in 2009. We expect increases in sales of custom infusion sets, custom critical care and custom oncology products and expect that these products will be of increasing importance to us in future years. We expect continued growth in 2010 in our CLAVE products in the U.S., but at a modest growth rate. We also potentially face substantial increases in competition in our CLAVE business. Therefore, we are focusing on increasing product development, acquisition, sales and marketing efforts to custom products and other products that lend themselves to customization and new products in the U.S. and international markets.

Our largest customer is Hospira. Our relationship with Hospira has been and will continue to be of singular importance to our growth. We currently manufacture custom infusion sets for sale by Hospira and jointly promote the products under the name SetSource. Additionally, as discussed above, prior to our acquisition of its critical care line, we previously manufactured Hospira s critical care products. In the first half of 2010 and the years ended 2009 and 2008, our revenues from worldwide sales to Hospira were 40%, 53% and 69%, respectively, of total revenues. Although we can provide no assurances, as a result of our purchase of Hospira s critical care product line, we expect the percentage of revenues from sales to Hospira will continue to decrease because we now sell critical care products directly to the distributor or end user instead of to Hospira. However, we expect revenues from sales of CLAVE products, custom infusion sets and new products to Hospira to remain a significant percentage of our revenues. Hospira has a significant share of the I.V. set market in the U.S. and provides us access to that market, and we expect that Hospira will be important to our growth for CLAVE, custom infusion sets, and our other products worldwide.

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We believe that achievement of our growth objectives worldwide will require increased efforts by us in sales and marketing and product development; however, there is no assurance that we will be successful in implementing our growth strategy. The custom products market is small, when compared to the larger market of standard products, and we could encounter customer resistance to custom products. Further, we could encounter increased competition as other companies see opportunity in this market. Product development or acquisition efforts may not succeed, and even if we do develop or acquire additional products, there is no assurance that we will achieve profitable sales of such products. An adverse change in our relationship with Hospira, or a deterioration of Hospira s position in the market, could have an adverse effect on us. Increased expenditures for sales and marketing and product acquisition and development may not yield desired results when expected, or at all. While we have taken steps to control these risks, there are certain risks that may be outside of our control, and there is no assurance that steps we have taken will succeed.

The following table sets forth, for the periods indicated, total revenues by product as a percentage of total revenues:

	Three months ended June 30,		Six months ended June 30,		Fiscal Year Ended	
Product Line	**2010**	**2009**	**2010**	**2009**	**2009**	**2008**
CLAVE	34%	40%	35%	39%	37%	39%
Custom products	34%	34%	33%	34%	34%	34%
Standard critical care	20%	15%	20%	16%	18%	17%
Standard oncology products	3%	2%	3%	2%	2%	1%
Other product/other revenue	9%	9%	9%	9%	9%	9%
Total	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**

We sell our I.V. administration products to independent distributors, direct sales and through agreements with Hospira and certain other medical product manufacturers. Most independent distributors handle the full line of our I.V. administration products. We sell our I.V. administration and oncology products under two agreements with Hospira. Under a 1995 agreement, Hospira purchases CLAVE products, principally bulk, non-sterile connectors, oncology products and the CLC2000. Under a 2001 agreement, we sell custom infusion sets to Hospira under a program referred to as SetSource. Our 1995 and 2001 agreements with Hospira provide Hospira with conditional exclusive and nonexclusive rights to distribute all existing ICU Medical products worldwide with terms that extend to 2014. We sell invasive monitoring and angiography to independent distributors and through direct sales. We also sell certain other products to a number of other medical product manufacturers.

We believe that as healthcare providers continue to either consolidate or join major buying organizations, the success of our products will depend, in part, on our ability, either independently or through strategic relationships such as our Hospira relationship, to secure long-term contracts with large healthcare providers and major buying organizations. As a result of this marketing and distribution strategy we derive most of our revenues from a relatively small number of distributors and manufacturers. The loss of a strategic relationship with a customer or a decline in demand for a manufacturing customer s products could have a material adverse effect on our operating results.

We have an ongoing effort to increase systems capabilities, improve manufacturing efficiency, reduce labor costs, reduce time needed to produce an order, and minimize investment in inventory. These include the use of automated assembly equipment for new and existing products and use of larger molds and molding machines. In 2006, we centralized our proprietary molding in Salt Lake City and expanded our production facility in Mexico, which took over the majority of our manual assembly previously done in Salt Lake City. In July 2010, we began an additional expansion of our production facility in Mexico that will be completed in 2010. In July 2009, we purchased land in Slovakia and in the third quarter of 2009, we started construction of an assembly plant that will serve our European product distribution. We expect this plant to be operational in late 2010. We may establish additional production facilities outside the U.S. There is no assurance that we will achieve success in establishing manufacturing facilities outside the U.S.

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We distribute products through three distribution channels. Product revenues for each distribution channel were as follows:

	Three months ended June 30,		Six months ended June 30,		Fiscal Year Ended	
Channel	**2010**	**2009**	**2010**	**2009**	**2009**	**2008**
Medical product manufacturers	40%	61%	39%	64%	50%	67%
Independent domestic distributors / direct sales	36%	20%	37%	17%	29%	18%
International distributors /direct sales	24%	19%	24%	19%	21%	15%
Total	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**

Sales to international customers do not include bulk CLAVE products sold to Hospira in the U.S. but subsequently used in products exported by Hospira. Those sales are included in sales to medical product manufacturers. Other sales to Hospira for destinations outside the U.S. are included in sales to international customers.

With the completion of our purchase of the commercial rights and the physical assets of Hospira s critical care line in August 2009, we began selling critical care products in September 2009 to domestic and international distributors and through direct domestic and international sales instead of to Hospira. As a result, we expect to continue to see a shift in sales from medical product manufacturers to domestic and international distributors and direct sales.

Quarter-to-quarter and six month to six month comparisons: We present summarized income statement data in Part I, Item 1- Financial Statements. The following table shows, for the year ended December 31, 2009 and the three and six months ended 2010 and 2009, the percentages of each income statement caption in relation to total revenues.

	Fiscal Year	Three months ended June 30,		Six months ended June 30,	
	2009	**2010**	**2009**	**2010**	**2009**
Total revenues	100%	100%	100%	100%	100%
Gross margin	47%	47%	48%	44%	49%
Selling, general and administrative expenses	30%	28%	31%	29%	30%
Research and development expenses	1%	2%	1%	1%	1%
Total operating expenses	31%	30%	32%	30%	31%
Income from operations	16%	17%	16%	14%	18%
Other income	1%	0%	1%	0%	1%
Income before income taxes	17%	17%	17%	14%	19%
Income taxes	5%	6%	6%	5%	7%
Net income	12%	11%	11		