

ICU MEDICAL INC/DE  
Form 10-Q  
October 22, 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: September 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)

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

**33-0022692**  
(I.R.S. Employer  
Identification No.)

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

**92673**  
(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 ☒ 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 ☐  
(Do not check if a smaller reporting company)

Smaller reporting company ☐

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

**Class**  
Common

**Outstanding at October 10, 2010**  
13,591,805

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

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**ICU Medical, Inc. and Subsidiaries**

## Condensed Consolidated Balance Sheets

(Amounts in thousands, except per share data)

	September 30, 2010 (unaudited)	December 31, 2009 (1)
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 65,671	\$ 51,248
Investment securities	16,225	56,887
Cash, cash equivalents and investment securities	81,896	108,135
Accounts receivable, net of allowance for doubtful accounts of \$522 at September 30, 2010 and \$324 at December 31, 2009	55,796	47,777
Inventories	43,625	41,327
Prepaid income taxes	2,994	1,994
Prepaid expenses and other current assets	6,748	5,462
Deferred income taxes	4,307	3,243
Total current assets	195,366	207,938
PROPERTY AND EQUIPMENT, net	83,777	77,449
PROPERTY HELD FOR SALE		940
GOODWILL	1,478	1,478
INTANGIBLE ASSETS, net	15,256	16,782
DEFERRED INCOME TAXES	3,690	3,710
INCOME TAXES RECEIVABLE	856	856
	\$ 300,423	\$ 309,153
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 12,056	\$ 18,423
Accrued liabilities	14,191	12,884
Deferred revenue	376	2,389
Total current liabilities	26,623	33,696
DEFERRED INCOME TAXES	7,157	5,698
INCOME TAX LIABILITY	4,366	4,754
COMMITMENTS AND CONTINGENCIES		
<b>STOCKHOLDERS' EQUITY:</b>		
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 14,855 shares at September 30, 2010 and 14,811 shares at December 31, 2009, outstanding 13,547 shares at September 30, 2010 and 14,239 shares at December 31, 2009	1,485	1,481
Additional paid-in capital	57,112	54,357
Treasury stock, at cost 1,308 and 572 shares at September 30, 2010 and December 31, 2009	(45,533)	(19,881)
Retained earnings	248,804	227,861
Accumulated other comprehensive income	409	1,187
Total stockholders' equity	262,277	265,005
	\$ 300,423	\$ 309,153

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(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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## Condensed Consolidated Statements of Income

(Amounts in thousands, except per share data)

(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2010	2009	2010	2009
<b>REVENUES:</b>				
Net sales	\$ 75,589	\$ 53,830	\$ 208,511	\$ 161,307
Other	148	135	451	392
<b>TOTAL REVENUE</b>	<b>75,737</b>	<b>53,965</b>	<b>208,962</b>	<b>161,699</b>
<b>COST OF GOODS SOLD</b>	<b>41,705</b>	<b>28,916</b>	<b>115,876</b>	<b>84,295</b>
Gross profit	34,032	25,049	93,086	77,404
<b>OPERATING EXPENSES:</b>				
Selling, general and administrative	18,341	16,751	57,368	48,366
Research and development	1,067	661	2,937	2,016
<b>Total operating expenses</b>	<b>19,408</b>	<b>17,412</b>	<b>60,305</b>	<b>50,382</b>
Income from operations	14,624	7,637	32,781	27,022
<b>OTHER INCOME (EXPENSE)</b>	<b>(215)</b>	<b>419</b>	<b>40</b>	<b>1,042</b>
Income before income taxes	14,409	8,056	32,821	28,064
<b>PROVISION FOR INCOME TAXES</b>	<b>(5,434)</b>	<b>(1,732)</b>	<b>(11,878)</b>	<b>(8,937)</b>
<b>NET INCOME</b>	<b>\$ 8,975</b>	<b>\$ 6,324</b>	<b>\$ 20,943</b>	<b>\$ 19,127</b>
<b>NET INCOME PER SHARE</b>				
Basic	\$ 0.67	\$ 0.43	\$ 1.54	\$ 1.29
Diluted	\$ 0.65	\$ 0.42	\$ 1.51	\$ 1.27
<b>WEIGHTED AVERAGE NUMBER OF SHARES</b>				
Basic	13,489	14,796	13,605	14,771
Diluted	13,752	15,146	13,838	15,033

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

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## Condensed Consolidated Statements of Cash Flows

(Amounts in thousands)

(unaudited)

	<b>Nine months ended September 30,</b>	
	<b>2010</b>	<b>2009</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net income	\$ 20,943	\$ 19,127
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	12,796	11,280
Provision for doubtful accounts	154	(25)
Stock compensation	2,568	1,963
Bond premium amortization	1,145	1,703
Loss on disposal/impairments of property and equipment	449	
Cash provided (used) by changes in operating assets and liabilities, net of assets acquired		
Accounts receivable	(7,763)	6,502
Inventories	(2,670)	(1,754)
Prepaid expenses and other assets	(1,874)	(2,425)
Accounts payable	(6,365)	1,655
Accrued liabilities	1,381	(3,240)
Deferred revenue	(2,013)	1,923
Prepaid and deferred income taxes	69	3,517
Net cash provided by operating activities	18,820	40,226
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	(17,751)	(10,164)
Proceeds from insurance for damaged assets	622	
Assets purchased		(30,533)
Proceeds from sale of asset	893	
Business acquisition, net of cash acquired		(5,662)
Change in restricted cash		5,497
Purchases of investment securities	(20,853)	(89,940)
Proceeds from sale of investment securities	60,370	85,554
Net cash provided (used) by investing activities	23,281	(45,248)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from exercise of stock options	903	1,352
Proceeds from employee stock purchase plan	1,576	1,271
Tax benefits from exercise of stock options	708	88
Purchase of treasury stock	(28,648)	(560)
Net cash provided (used) by financing activities	(25,461)	2,151
Effect of exchange rate changes on cash	(2,217)	434
<b>NET INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>14,423</b>	<b>(2,437)</b>
<b>CASH AND CASH EQUIVALENTS, beginning of period</b>	<b>51,248</b>	<b>55,696</b>
<b>CASH AND CASH EQUIVALENTS, end of period</b>	<b>\$ 65,671</b>	<b>\$ 53,259</b>

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### NON-CASH INVESTING ACTIVITIES

Accrued liabilities for property and equipment	\$	11	\$
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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 September 30, 2010		2009		Nine months ended September 30, 2010		2009	
Net income	\$	8,975	\$	6,324	\$	20,943	\$	19,127
Other comprehensive income (loss), net of tax:								
Foreign currency translation adjustment		5,236		584		(778)		578
Comprehensive income	\$	14,211	\$	6,908	\$	20,165	\$	19,705

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 Nine Months Ended September 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 Annual Report on Form 10-K of ICU Medical, Inc., a Delaware corporation (the Company ), 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 \$1.7 million of bond premium amortization, a noncash item, from investing activities in the consolidated statement of cash flows for the nine months ended September 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.

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 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 carried at fair value and are considered available-for-sale, consist principally of certificates of deposit and federal-tax-exempt state and municipal government debt. The Company has \$3.5 million of its investment securities as Level 1 assets, which are certificates of deposit with quoted prices in active markets. The Company has \$12.7 million of its investment securities as Level 2 assets, which are pre-refunded and non-pre-refunded municipal securities and have observable inputs.

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

	Fair value measurements at September 30, 2010 using			
	Total carrying value at September 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	\$ 16,225	\$ 3,520	\$ 12,705	\$
Trading securities	\$ 16,225	\$ 3,520	\$ 12,705	\$

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

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

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

### Note 4: Inventories:

Inventories consisted of the following:

	September 30, 2010		December 31, 2009	
Raw material	\$	19,029	\$	16,268
Work in process		2,639		2,711
Finished goods		21,957		22,348
Total	\$	43,625	\$	41,327

### Note 5: Property and Equipment:

Property and equipment consisted of the following:

	September 30, 2010		December 31, 2009	
Machinery and equipment	\$	59,490	\$	57,966
Land, building and building improvements		51,006		50,200
Molds		21,518		18,939
Computer equipment and software		14,041		12,196
Furniture and fixtures		1,971		1,928
Construction in progress		18,178		9,565
Total property and equipment, cost		166,204		150,794
Accumulated depreciation		(82,427)		(73,345)
Net property and equipment	\$	83,777	\$	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 559,000 and 236,000 for the three months ended September 30, 2010 and 2009, respectively, and 742,000 and 385,000 for the nine months ended September 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 September 30,		Nine months ended September 30,	
	2010	2009	2010	2009
Net income	\$ 8,975	\$ 6,324	\$ 20,943	\$ 19,127
Weighted average number of common shares outstanding (for basic calculation)	13,489	14,796	13,605	14,771
Dilutive securities	263	350	233	262
Weighted average common and common equivalent shares outstanding (for diluted calculation)	13,752	15,146	13,838	15,033
EPS basic	\$ 0.67	\$ 0.43	\$ 1.54	\$ 1.29
EPS diluted	\$ 0.65	\$ 0.42	\$ 1.51	\$ 1.27

### **Note 7: Income Taxes:**

Income taxes were accrued at an estimated annual effective tax rate of 36% in the nine months of 2010 compared to 32% in the first nine months 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 47% and 45% of total revenue for the three months ended September 30, 2010 and 2009, respectively, and 43% and 60% for the nine months ended September 30, 2010 and 2009, respectively. As of September 30, 2010 and December 31, 2009, the Company had accounts receivable from Hospira of 46% 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. As of September 30, 2010, the Company has completed all but less than \$0.1 million of its \$55.0 million share repurchase program. The Company purchased \$28.6 million of its common stock in the nine months ended September 30, 2010. The Company did not repurchase any shares of its Common Stock during the three months ended September 30, 2010.

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. This plan has no expiration date.

**Note 10: Commitments and Contingencies:**

The Company is from time to time involved in various legal proceedings, most of which are routine litigation, in the normal course of business. In the opinion of management, the resolution of the 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 does it 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 the Company or its affiliates under its 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 innovative medical technologies used in vascular therapy, oncology and critical care applications. Our products improve patient outcomes by helping prevent bloodstream infections and protect healthcare workers and patients from exposure to infectious diseases or hazardous drugs and monitor the hemodynamic status of critical care patients. Our complete product line includes custom I.V. systems, closed delivery systems for hazardous drugs, needleless I.V. connectors, catheters 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. Pursuant to the prior arrangements, Hospira retained commercial responsibility for the products that we manufactured, including sales to end customers, marketing, pricing, distribution, customer contracts, customer service and billing and 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 \$72.0 million or 34% of total revenue in the first nine months 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 compared to 2009 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.

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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 nine months of 2010 and the years ended December 31, 2009 and 2008, our revenues from worldwide sales to Hospira were 43%, 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.

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

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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:

Product Line	Three months ended September 30,		Nine months ended September 30,		Fiscal Year Ended	
	2010	2009	2010	2009	2009	2008
CLAVE	34%	38%	35%	39%	37%	39%
Custom products	37%	36%	34%	35%	34%	34%
Standard critical care	16%	14%	18%	15%	18%	17%
Standard oncology products	2%	3%	3%	2%	2%	1%
Other product/other revenue	11%	9%	10%	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 of our 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 we expect will be completed in early 2011. 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 launched operations at the new plant in Slovakia during the third quarter of 2010, and we expect that we will start shipments of products in the fourth quarter of 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:

Channel	Three months ended September 30,		Nine months ended September 30,		Fiscal Year Ended	
	2010	2009	2010	2009	2009	2008
Medical product manufacturers	44%	42%	41%	56%	50%	67%
Independent domestic distributors / direct sales	34%	35%	36%	24%	29%	18%
International distributors /direct sales	22%	23%	23%	20%	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.

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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 nine month-to-nine 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 nine months ended September 30, 2010 and 2009, the percentages of each income statement caption in relation to total revenues.

	Fiscal Year 2009	Three months ended September 30, 2010	Three months ended September 30, 2009	Nine months ended September 30, 2010	Nine months ended September 30, 2009
Total revenues	100%	100%	100%	100%	100%
Gross margin	47%	45%	46%	45%	48%
Selling, general and administrative expenses	30%	24%	31%	28%	30%
Research and development expenses	1%	2%	1%	1%	1%
Total operating expenses	31%	26%	32%	29%	31%
Income from operations	16%	19%	14%	16%	17%
Other income	1%	0%	1%	0%	1%
Income before income taxes	17%	19%	15%	16%	18%
Income taxes	5%	7%	3%	6%	6%
Net income	12%	12%	12%	10%	12%

**Quarterly results:** The healthcare business in the United States is subject to seasonal fluctuations, and activity tends to diminish somewhat in the summer months of June, July and August, when illness is less frequent than in winter months and patients tend to postpone elective procedures. This typically causes seasonal fluctuations in our business. In Europe, the healthcare business generally slows down in the summer months due to vacations resulting in fewer elective surgeries. Also in Europe, hospitals' budgets tend to finish at the end of the year which may cause fewer purchases in the last three months of the year as hospitals await their new budgets in January. In addition, we can experience fluctuations in net sales as a result of variations in the ordering patterns of our largest customers, which may be driven more by production scheduling and their inventory levels, and less by seasonality. Our expenses often do not fluctuate in the same manner as net sales, which may cause fluctuations in operating income that are disproportionate to fluctuations in our revenue.

## Quarter Ended September 30, 2010 Compared to the Quarter Ended September 30, 2009

Revenues were \$75.7 million in the third quarter of 2010, compared to \$54.0 million in the third quarter of 2009, a \$21.8 million or 40% increase.

**Distribution channels:** Net U.S. sales to Hospira in the third quarter of 2010 were \$32.6 million, compared to net sales of \$21.4 million in the third quarter of 2009, an increase of 53%. The \$11.2 million increase was primarily from \$4.5 million of increased CLAVE sales and \$5.6

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million of increased custom infusion set sales. The increase in CLAVE and custom infusion set sales was from higher unit sales due to increased market share through Hospira and from additional Hospira orders as they prepare for potential business due to market conditions and switch their IV tubing from DEHP to non-DEHP material which are expected to conclude in the fourth quarter of 2010. Although we can provide no assurances, we expect to ship extra CLAVE products to help Hospira in preparation for potential additional business due to market conditions in the fourth quarter of 2010. Excluding critical care products and the additional CLAVE and custom infusion set orders in 2010, we continue to expect moderate growth in sales to Hospira for 2010 from 2009, although there is no assurance that these expectations will be realized.

Net sales to domestic distributors/direct in the third quarter of 2010 (including Canada) were \$25.9 million compared to \$18.8 million in the third quarter of 2009, an increase of 38%. The \$7.1 million increase was primarily from \$3.9 million in higher standard critical care sales, \$1.3 million in higher custom critical care sales and \$1.3 million in increased custom infusion set sales. As a result of our purchase of Hospira's critical care line, we ceased selling critical care products to Hospira and began selling the critical care products directly to distributors and through direct sales in September 2009. The increase in standard and custom critical care sales is primarily due to only one month of sales in the third quarter of 2009 compared to a full quarter of sales in the third quarter of 2010. The increase in custom infusion set sales was due to higher unit volume sales. We expect increases in domestic distributor/direct sales for 2010 compared to 2009, principally from growth in custom products and new critical care product sales, although there is no assurance that these expectations will be realized.

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Net sales to international customers (excluding Canada) were \$16.2 million in the third quarter of 2010, compared with \$12.6 million in the third quarter of 2009, an increase of 29%. The \$3.6 million increase was primarily from \$1.3 million in higher standard critical care sales, \$0.5 million in higher custom critical care sales and \$0.4 million in increased CLAVE sales. The increase in standard and custom critical care sales is primarily due to only one month of sales in the third quarter of 2009 compared to a full quarter of sales in the third quarter of 2010. The CLAVE increase is from increased unit volume due to increased market share and demographic growth. We expect increases in international customer sales for 2010, primarily from growth in CLAVE, custom infusion sets and critical care product sales, although there is no assurance that these expectations will be realized.

**Product and other revenue:** Net sales of CLAVE products were \$25.7 million in the third quarter of 2010 compared to \$20.5 million in the third quarter of 2009, an increase of 26%. The \$5.2 million increase was primarily from higher U.S. Hospira sales from increased market share, demographic growth and additional Hospira orders as they prepare for potential additional business due to market conditions and product line changes. We expect to ship extra CLAVE product to help Hospira in preparation for potential additional business due to market conditions in the fourth quarter of 2010. Excluding these additional CLAVE orders in 2010, we expect increases in CLAVE product sales for 2010 compared to 2009, although there is no assurance that these expectations will be realized.

Net sales of custom products, which include custom infusion, custom oncology products and custom critical care products, were \$28.3 million in the third quarter of 2010 compared to \$19.4 million in the third quarter of 2009, an increase of 46%. The \$8.9 million increase was primarily comprised of increased sales of custom infusion sets of \$7.3 million and increased custom critical care product sales of \$1.7 million. The unit growth in custom infusion sets was primarily due to the conversion by certain of our customers from a competitor's standard sets to our custom systems and product line changes for Hospira. The increase in custom critical care sales is primarily due to only one month of distributor/direct sales in the third quarter of 2009 compared to a full quarter of sales in the third quarter of 2010. We had minimal custom critical care sales to Hospira in the third quarter of 2009 because we did not recognize sales for shipments after July 8, 2009, when we signed the asset purchase agreement with Hospira to purchase their commercial rights and physical assets of Hospira's critical care line. We expect increases in custom infusion set sales from increased unit volume in 2010 compared to 2009 and from the additional orders from Hospira's product line changes. We expect increases in custom critical care sales from increased unit sales at a higher average selling price for 2010 compared to 2009. In each case, however, there can be no assurance that the expectations will be realized.

Standard critical care product sales were \$12.1 million in the third quarter of 2010 compared to \$7.3 million in the third quarter of 2009, an increase of 66%. The \$4.8 million increase was due to only one month of distributor/direct sales in the third quarter of 2009 compared to a full quarter of sales in the third quarter of 2010 and minimal sales to Hospira because of signing the asset purchase agreement on July 8, 2009. We expect increased sales for 2010 compared to 2009 because of higher sales through distributors and through direct sales than to Hospira, although there is no assurance that these expectations will be realized.

Our standard oncology product sales were \$1.7 million in the third quarter of 2010 compared to \$1.6 million in the third quarter of 2009.

Other revenue consists of license, royalty and revenue share income and was \$0.1 million in the third quarter of 2010 and 2009. We may receive other license fees or royalties in the future for the use of our technology. There is no assurance as to amounts or timing of any future payments, or whether such payments will be received.

**Gross margins** for the third quarters of 2010 and 2009 were 45% and 46%, respectively. The decrease was primarily from critical care integration costs and higher freight costs, which were partially offset by manufacturing efficiencies at our factories.

We estimate our gross margin for 2010 will approximate 45%; however, there is no assurance that this expectation will be realized.

***Selling, general and administrative expenses ( SG&A )*** were \$18.3 million and 24% of revenues in the third quarter of 2010, compared with \$16.8 million and 31% of revenues in the third quarter of 2009. The \$1.5 million increase was primarily from increased sales compensation and benefits of \$1.6 million, higher dealer fees and group purchasing organization fees of \$0.6 million which were primarily from critical care sales and our agreement with Premier, and pre-start-up costs for our Slovakia plant of \$0.6 million, partially offset by \$0.7 million in lower legal expenses and \$0.4 million in lower outside services. The increase in compensation and benefits is primarily a result of the expansion of our sales workforce by 32 employees from the third quarter of 2009 to the third quarter of 2010 for our critical care product line as well as growth in other product lines. The decrease in legal expenses is primarily from lower patent litigation costs. We expect SG&A for 2010 to be approximately 27.5% of revenue, although there is no assurance that this expectation will be realized.

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**Research and development expenses ( R&D )** were \$1.1 million and 2% of revenue in the third quarter of 2010 compared to \$0.7 million and 1% of revenue in the third quarter of 2009. We expect R&D for 2010 to be approximately 1.5% to 2.0% of revenue, although there is no assurance that this expectation will be realized.

**Other expense** was \$0.2 million in the third quarter of 2010 compared to other income of \$0.4 million in the third quarter of 2009.

**Income taxes** were accrued at an estimated effective tax rate of 38% in the third quarter of 2010 compared to 21% in the third quarter of 2009. The rate differed from the statutory corporate 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. We expect our effective tax rate to be approximately 36% for 2010.

**Nine Months Ended September 30, 2010 Compared to the Nine Months Ended September 30, 2009**

Revenues were \$209.0 million in the first nine months of 2010, compared to \$161.7 million in the first nine months of 2009.

**Distribution channels:** Net U.S. sales to Hospira in the first nine months of 2010 were \$82.8 million, compared to net sales of \$88.0 million in the first nine months of 2009, a decrease of 6%. The \$5.2 million decrease was primarily due to \$21.7 million in decreased standard and custom critical care sales, partially offset by \$7.1 million in increased CLAVE sales and \$6.9 million in increased custom infusion set sales. The decreased standard and custom critical care sales to Hospira were primarily related to our acquisition of the critical care assets from Hospira. As a result of this acquisition, which closed on August 31, 2009, we no longer sell critical care products to Hospira. The increase in CLAVE and custom infusion set sales was from higher unit sales due to increased market share through Hospira and from additional orders as they prepare for potential business due to market conditions and switch their IV tubing from DEHP to non-DEHP material which will conclude in the fourth quarter of 2010.

Net sales to domestic distributors/direct in the first nine months of 2010 (including Canada) were \$74.5 million compared to \$37.7 million in the first nine months of 2009, an increase of 97%. The \$36.8 million increase was primarily from \$23.9 million in higher standard critical care sales, \$5.9 million in higher custom critical care sales and \$4.1 million in increased custom infusion set sales. As a result of our purchase of Hospira's critical care line, we ceased selling critical care products to Hospira and began selling the critical care products directly to distributors and through direct sales in September 2009. The increase in standard and custom critical care sales is primarily due to only one month of sales in the first nine months of 2009 compared to nine months of sales in the first nine months of 2010. The increase in custom infusion set sales was due to higher unit volume sales. The increase in custom infusion set sales was due to higher unit volume sales.

Net sales to international customers (excluding Canada) were \$48.2 million in the first nine months of 2010, compared with \$32.7 million in the first nine months of 2009, an increase of 47%. The \$15.5 million increase was primarily from \$7.7 million in higher standard critical care sales, \$2.5 million in higher custom critical care sales, \$2.0 million in increased CLAVE sales and \$1.6 million of increased custom infusion set sales, partially offset by \$1.4 million in lower custom oncology sales. The increase in standard and custom critical care sales is primarily due to only one month of sales in the first nine months of 2009 compared to nine months of sales in the first nine months of 2010. The CLAVE and custom infusion set increases are from increased unit volume due to increased market share and demographic growth. The decrease in custom oncology sales was due to lower unit volume sales.

**Product and other revenue:** Net sales of CLAVE products were \$72.8 million in the first nine months of 2010 compared to \$63.0 million in the first nine months of 2009, an increase of 16%. The \$9.8 million increase was primarily from higher U.S. Hospira sales and higher international sales from increased market share and demographic growth and additional Hospira orders as they prepare for potential additional business due to market conditions and product line changes.

Net sales of custom products, were \$72.0 million in the first nine months of 2010 compared to \$56.4 million in the first nine months of 2009, an increase of 28%. The \$15.6 million increase was primarily comprised of increased sales of custom infusion sets of \$12.5 million and increased custom critical care product sales of \$4.1 million, partially offset by \$1.0 million in lower custom oncology set sales. The unit growth in custom infusion sets was primarily due to the conversion by certain of our customers from a competitor's standard sets to our custom systems and product line changes for Hospira. The increase in custom critical care sales is due to higher average selling prices and more months of revenue recognized. Our 2010 sales are to distributors and through direct sales which are at higher average selling prices than we previously charged to Hospira, which is an OEM. Also, in 2009, we only recognized custom critical care sales to Hospira for slightly more than six months, to July 8, 2009, when the asset purchase agreement with Hospira was signed. September 2009 was the only month that we had distributor and direct sales in the nine months ended September 2009. The decrease in custom oncology is due to lower unit sales.

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Standard critical care product sales were \$38.6 million in the first nine months of 2010 compared to \$24.5 million in the first nine months of 2009, an increase of 57%. The \$14.1 million increase is due to higher average selling prices and more months of revenue recognized. Our 2010 sales are to distributors and through direct sales which are at higher average selling prices than we previously charged to Hospira, which is an OEM. Also, in 2009, we only recognized critical care sales to Hospira for slightly more than six months, to July 8, 2009, when the asset purchase agreement with Hospira was signed. September 2009 is the only month we had distributor and direct sales in the nine months ended September 30, 2009.

Our standard oncology product sales were \$5.3 million in the first nine months of 2010 compared to \$3.5 million in the first nine months of 2009. The \$1.8 million increase was from higher sales in all our distribution channels.

Other revenue consists of license, royalty and revenue share income and was approximately \$0.5 million in the first nine months of 2010 compared to \$0.4 million in the first nine months of 2009.

**Gross margins** for the first nine months of 2010 and 2009 were 45% and 48%, respectively. The decrease was primarily from critical care integration costs and higher freight costs, which were partially offset by manufacturing efficiencies at our factories.

**Selling, general and administrative expenses ( SG&A )** were \$57.4 million and 28% of revenues in the first nine months of 2010, compared with \$48.4 million and 30% of revenues in the first nine months of 2009. The \$9.0 million increase was primarily from increased sales compensation and benefits of \$5.3 million, higher sales travel expenses of \$1.1 million, higher sales and marketing promotional costs of \$3.1 million, including \$2.6 million in higher dealer fees and group purchasing organization fees which were primarily from critical care sales and our agreement with Premier, pre-start-up costs associated with our Slovakia plant of \$1.7 million, increased depreciation and amortization expenses of \$0.8 million, and higher stock compensation expense of \$0.5 million, partially offset by \$2.5 million in lower legal expenses and \$0.6 million in lower outside services. The increase in sales compensation and benefits and travel expenses is primarily a result of the expansion of our sales workforce by 33 employees from the first nine months of 2009 compared to the first nine months of 2010 for our critical care products and growth in other products. The increase in depreciation and amortization was primarily from the amortization of critical care intangible assets from the 2009 critical care purchase. The decrease in legal expenses is primarily from lower patent litigation costs.

**Research and development expenses ( R&D )** were \$2.9 million and 1% of revenue in the first nine months of 2010 compared to \$2.0 million and 1% of revenue in the first nine months of 2009.

**Other income** was less than \$0.1 million in the first nine months of 2010 compared to \$1.0 million in the first nine months of 2009. The decrease is primarily due to lower interest income earned because of lower invested balances.

**Income taxes** were accrued at an estimated annual effective tax rate of 36% in the first nine months of 2010 compared to 32% in the first nine months of 2009. The rate differed from the statutory corporate 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.

**Liquidity and Capital Resources**

During the first nine months of 2010, our cash, cash equivalents and investment securities decreased by \$26.2 million.

***Operating Activities:*** Our cash provided by operating activities tends to correlate to our operating results; however, it is subject to fluctuations, principally from the impact of integrating new locations from acquisitions, changes in net income, accounts receivable, inventories and the timing of tax payments.

During the first nine months of 2010, our cash provided by operations was \$18.8 million, which was mainly comprised of net income of \$20.9 million, depreciation and amortization of \$12.8 million, stock compensation expense of \$2.6 million and bond premium amortization of \$1.1 million, partially offset by changes in our operating assets and liabilities. The increase in accounts receivable and decrease in accounts payable were the primary contributors to the decrease in cash provided by operating asset and liabilities.

***Investing Activities:*** During the first nine months of 2010, our cash provided by investing activities was \$23.3 million. This was primarily comprised of net investment sales of \$39.5 million and cash received from the sale of a building of \$0.9 million, partially offset by cash paid for purchases of property and equipment of \$17.8 million which were primarily for building construction and equipment purchases for our Slovakia plant, expansion of our manufacturing facility in Mexico and additional molding and machinery in our U.S. and Mexico operations.

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We estimate that our capital expenditures in 2010 will approximate \$21.0 million to \$23.0 million. This includes approximately \$11.0 to \$13.0 million for our Mexico plant expansion, various molds and machinery for our manufacturing operations in the U.S. and \$10.0 million for our manufacturing plant in Slovakia. We anticipate using our existing cash position to fund these capital expenditures. Amounts of spending are estimates and actual spending may substantially differ from those amounts.

**Financing Activities:** Our cash used by financing activities in the first nine months of 2010 was \$25.5 million. Stock repurchases in the first nine months of 2010 were \$28.6 million. Cash provided by stock options and the employee stock purchase plan, including tax benefits, was \$3.2 million from the sale of 129,747 shares. The tax benefits from the exercise of stock options fluctuates based principally on when employees choose to exercise their vested stock options.

In 2010, we completed all but less than \$0.1 million of our \$55.0 million share repurchase program originally announced in July 2008 and amended in October 2009, by our Board of Directors. In July 2010, our Board of Directors approved a new share repurchase plan to purchase up to \$40.0 million of our common stock. This plan has no expiration date.

We have a substantial cash and investment security position generated from profitable operations and stock sales, principally from the exercise of employee stock options. We maintain this position to fund our growth, meet increasing working capital requirements, fund capital expenditures, and to take advantage of acquisition opportunities that may arise. Our primary investment goal is principal preservation, as further described below in Part I, Item 3. Quantitative and Qualitative Disclosures about Market Risk.

We believe that our existing cash, cash equivalents and investment securities along with funds expected to be generated from future operations will provide us with sufficient funds to finance our current operations for the next twelve months. In the event that we experience illiquidity in our investment securities, downturns or cyclical fluctuations in our business that are more severe or longer than anticipated or if we fail to achieve anticipated revenue and expense levels, we may need to obtain or seek alternative sources of capital or financing, and we can provide no assurances that the terms of such capital or financing will be available to us on favorable terms, if at all.

**Off Balance Sheet Arrangements**

In the normal course of business, we have agreed to indemnify our officers and directors to the maximum extent permitted under Delaware law and to indemnify customers as to certain intellectual property matters related to sales of our products. There is no maximum limit on the indemnification that may be required under these agreements. Although we can provide no assurances, we have never incurred, nor do we expect to incur, any material liabilities associated with this indemnification.

Pursuant to the Asset Purchase Agreement with Hospira, we have agreed to indemnify Hospira and its affiliates from certain liabilities arising out of (i) inaccuracies of our representations and breaches of our warranties; (ii) defaults of our 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, we are not obligated to indemnify Hospira for any liabilities for which Hospira is obligated to indemnify us or our affiliates under the MCDA. Although we can provide no assurances, we do not expect to incur material liabilities arising out of the indemnification provision of the Asset Purchase Agreement.

**Contractual Obligations**

We have contractual obligations, at September 30, 2010, of approximately the amount set forth in the table below. This amount excludes purchase orders for goods and services for current delivery. The majority of our purchase orders are blanket purchase orders that represent an estimated forecast of goods and services. We do not have a commitment liability on the blanket purchase orders. Since we do not have the ability to separate out blanket purchase orders from non-blanket purchase orders for goods and services for current delivery, amounts related to such purchase orders are excluded from the table below. We have excluded from the table below pursuant to ASC 740-10-25 (formerly FIN 48), an interpretation of ASC 740-10 (formerly SFAS 109), a noncurrent liability of \$4.4 million due to the high degree of uncertainty regarding the timing of future cash outflows associated with the liabilities.

Contractual Obligations	(in thousands)				
	Total	2010	2011	2012	
Operating leases	\$ 1,850	\$ 226	\$ 908	\$ 716	
Capital purchase obligations	5,366	5,366			
	\$ 7,216	\$ 5,592	\$ 908	\$ 716	

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**Critical Accounting Policies**

In our Annual Report on Form 10-K for the year ended December 31, 2009, we identified the critical accounting policies which affect our more significant estimates and assumptions used in preparing our consolidated financial statements. We have not changed these policies from those previously disclosed in our Annual Report.

**New Accounting Pronouncements**

See Note 2 to Part I, Item I. Financial Statements.

**Forward Looking Statements**

Various portions of this Quarterly Report on Form 10-Q, including this Management's Discussion and Analysis, describe trends in our business and finances that we perceive and state some of our expectations and beliefs about our future. These statements about the future are 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, and we identify them by using words such as believe, expect, estimate, plan, will, continue, could, may, similar expressions and statements about aims, goals and plans. The forward looking statements are based on the best information currently available to us and assumptions that we believe are reasonable, but we do not intend the statements to be representations as to future results. They include, without limitation, statements about:

- future operating results and various elements of operating results, including future expenditures on sales and marketing and product development; future sales and unit volumes of products; deferred revenue; future license, royalty and revenue share income; production costs; gross margins; litigation expense; SG&A; R&D expense; future costs of expanding our business; income; losses; cash flow; tax rates; capital expenditures; changes in working capital items such as receivables and inventory; selling prices; and income taxes;
- factors affecting operating results, such as reduced dependence on current proprietary products; expansion in international markets, selling prices; future increases or decreases in sales of certain products and in certain markets and distribution channels; increases in systems capabilities; introduction, timing and sales of new products; planned increases in marketing; unit manufacturing costs; establishment of production facilities outside the U.S.; planned new orders for automated assembly machines for new products; the timing of planned shipments from our plant in Slovakia; costs and timing of the expansion of our manufacturing facility in Mexico; adequacy of production capacity; results of R&D; our plans to repurchase shares of our common stock; relocation of manufacturing facilities and personnel; planned increases in the number of personnel; our expectation that sales will shift from medical product manufacturers to domestic and international distributors and direct sales; effect of expansion of manufacturing facilities on production efficiencies and resolution of production inefficiencies; the effect of costs to customers and delivery times; business seasonality and fluctuations in quarterly results; customer ordering patterns and the effects of new accounting pronouncements; and

- expansion of our custom products business; expected increases in our custom infusion sets, custom critical care and custom oncology products and importance of these products in the future; our focus on increasing product development, acquisition, sales and marketing efforts to custom products and similar products; our relationship with Hospira; new or extended contracts with manufacturers and buying organizations; dependence on a small number of customers; effect of the acquisition of Hospira's Salt Lake City manufacturing facility and its critical care product line, including its effect on future revenues from Hospira; the timing of the completion of changes to Hospira's products, as well as its affect on our sales; the timing of the transition; growth of our CLAVE products in future years; the outcome of our strategic initiatives; regulatory approvals and compliance; outcome of litigation; competitive and market factors, including continuing development of competing products by other manufacturers; consolidation of the healthcare provider market and our dependence on securing long-term contracts with large healthcare providers and major buying organizations; future repurchases of our common stock; working capital requirements; liquidity and realizable value of our investment securities; future investment alternatives; expected capital expenditures; availability of raw materials; foreign currency denominated financial instruments; foreign exchange risk; commodity price risk; our expectations regarding liquidity and the sufficiency of our capital resources over the next twelve months; capital expenditures; acquisitions of new product lines, indemnification liabilities and contractual liabilities.

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Forward-looking statements involve certain risks and uncertainties, which may cause actual results to differ materially from those discussed in each such statement. First, one should consider the factors and risks described in the statements themselves or otherwise discussed herein. Those factors are uncertain, and if one or more of them turn out differently than we currently expect, our operating results may differ materially from our current expectations.

Second, investors should read the forward looking statements in conjunction with the Risk Factors discussed in Part I, Item 1A of our Annual Report on Form 10-K with the SEC for the year ended December 31, 2009 and our other reports and registration statements filed with the SEC. Also, actual future operating results are subject to other important factors and risks that we cannot predict or control, including without limitation, the following:

- general economic and business conditions, both in the U.S. and internationally;
- outcome of litigation;
- fluctuations in foreign exchange rates and other risks of doing business internationally;
- increases in labor costs or competition for skilled workers;
- increases in costs or availability of the raw materials need to manufacture our products;
- complications arising from the purchase of Hospira's critical care product line;
- the effect of price and safety considerations on the healthcare industry;
- competitive factors, such as product innovation, new technologies, marketing and distribution strength and price erosion;
- the successful development and marketing of new products;

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- unanticipated market shifts and trends;
- the impact of legislation affecting government reimbursement of healthcare costs;
- changes by our major customers and independent distributors in their strategies that might affect their efforts to market our products;
- the effects of additional governmental regulations;
- unanticipated production problems; and
- the availability of patent protection and the cost of enforcing and of defending patent claims.

The forward-looking statements in this report are subject to additional risks and uncertainties, including those detailed from time to time in our other filings with the Securities and Exchange Commission. These forward-looking statements are made only as of the date hereof and, except as required by law, we undertake no obligation to update or revise any of them, whether as a result of new information, future events or otherwise.

### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

We had a portfolio of federal-tax exempt state and municipal government debt securities and certificates of deposit of \$16.2 million as of September 30, 2010. The securities are all investment grade. As of September 30, 2010, \$12.7 million of our investment securities were invested in pre-refunded and non-pre-refunded municipal securities and \$3.5 million were invested in certificates of deposit. The pre-refunded municipal securities are fully escrowed by U.S. government Treasury bills with low market risk.

Our future earnings are subject to potential increase or decrease because of changes in short-term interest rates. Generally, each one-percentage point change in the discount rate will cause our overall yield to change by two-thirds to three-quarters of a percentage point, depending upon the relative mix of federal-tax-exempt securities in our portfolio and market conditions specific to the securities in which we invest. Two-thirds to three-quarters of a percentage point change in our earnings on investment securities would create a change of approximately \$0.4 million to investment income based on the investment securities balance at December 31, 2009.

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Foreign currency exchange risk for financial instruments on our balance sheet, which consist of cash, accounts receivable and accounts payable, is not significant to our financial statements. Sales from the U.S. and Mexico to foreign distributors are all denominated in U.S. dollars. We have manufacturing, sales and distribution facilities in several countries and we conduct business transactions denominated in various foreign currencies, principally the Euro and Mexican Peso. A 10% change in the conversion of the Mexican Peso to the U.S. dollar from the average exchange rate we experienced in 2009 and our manufacturing spending from 2009 would impact our cost of goods sold in 2009 by approximately \$1.6 million. Cash and receivables in those countries have been insignificant and are generally offset by accounts payable and accruals in the same foreign currency, except for our European operations, where our net Euro asset position at September 30, 2010 and 2009 were approximately 12.0 million at the end of both periods. We expect that in the future, with the growth of our European distribution operation, that net Euro denominated instruments will continue to increase.

Our exposure to commodity price changes relates primarily to certain manufacturing operations that use resin. We manage our exposure to changes in those prices through our procurement and supply chain management practices and the effect of price changes has not been material to date. We are dependent upon single source for some of our principal raw materials, including resin and silicone, although we believe all such materials and products are readily available from other suppliers. Based on our average price for resin in fiscal year 2009, a 10% increase to the price of resin would result in approximately a \$0.6 million change in material cost in 2009.

**Item 4. Controls and Procedures**

Disclosure Controls and Procedures

Our principal executive officer and principal financial officer have concluded, based on their evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934), as of the end of the period covered by this Report, that our disclosure controls and procedures are effective to ensure that the information we are required to disclose in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure and that such information is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC.

There was no change in our internal control over financial reporting during the quarter ended September 30, 2010 that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

**PART II**  
**OTHER INFORMATION**

**Item 1. Legal Proceedings**

We have not been required to pay any penalty to the IRS for failing to make disclosures required with respect to certain transactions that have been identified by the IRS as abusive or that have a significant tax avoidance purpose.

In an action filed July 27, 2007 entitled ICU Medical, Inc. v. RyMed Technologies, Inc. ( RyMed ), in the United States District Court for the District of Delaware, we alleged that RyMed infringes certain of ICU s patents through the manufacture and sale of certain products, including its InVision-Plus valves. We seek monetary damages and injunctive relief and intend to vigorously pursue this matter. Trial has been scheduled for December 13, 2010.

We are from time to time involved in various other legal proceedings, either as a defendant or plaintiff, most of which are routine litigation in the normal course of business. We believe that the resolution of the legal proceedings in which we are involved will not have a material adverse effect on our financial position or results of operations.

#### **Item 1A. Risk Factors**

In evaluating an investment in our common stock, investors should consider carefully, among other things, the risk factors previously disclosed in Part I, Item 1A of our Annual Report on Form 10-K filed with the SEC for the year ended December 31, 2009, as well as the information contained in this Quarterly Report and our other reports and registration statements filed with the SEC. There have been no material changes in the risk factors as previously disclosed under Risk Factors in Part I, Item 1A of our Annual Report on Form 10-K with the SEC for the year ended December 31, 2009.

Table of Contents**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

In July 2008, our Board of Directors authorized a program to purchase \$40.0 million of our common stock. In October 2009, our Board of Directors increased the amount that may be purchased under this plan by \$15.0 million, bringing the total authorized amount that may be purchased under the plan to \$55.0 million. As of September 30, 2010, all but \$54,000 of the \$55.0 million authorized had been used. This plan has no expiration date.

In July 2010, our Board of Directors approved a new common stock purchase plan to purchase \$40.0 million of our common stock. This plan has no expiration date.

The following is a summary of our stock repurchasing activity during the third quarter of 2010:

Period	Shares purchased as part of a publicly announced program	Average price paid per share	Approximate dollar value that may yet be purchased under the program
07/01/2010 07/31/2010		\$	\$ 40,054,000
08/01/2010 08/31/2010			40,054,000
09/01/2010 09/30/2010			40,054,000
Third quarter 2010 total		\$	40,054,000

**Item 5. Other Information**

On October 15, 2010, we entered into a new form of indemnification agreement (the "Indemnification Agreements") with our directors and executive officers that provide for the indemnification of our directors and executive officers, to the fullest extent permitted by the General Corporation Law of the State of Delaware, against expenses reasonably incurred by such persons in any threatened, pending or completed action, suit, investigation or proceeding in connection with their service as (i) our director or officer or (ii) as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust or other enterprise, including service with respect to employee benefit plans, at our request. In addition, the Indemnification Agreements provide for our obligation to advance expenses, under certain circumstances, and provide for procedural protections, including a determination by a reviewing party whether the indemnitee is permitted to be indemnified under applicable law. In the Indemnification Agreements, we acknowledge that we will be the indemnitor of first resort should the indemnitee have rights to indemnification provided by other persons.

The foregoing summary of the Indemnification Agreements is a general description only, does not purport to be complete and is qualified in its entirety by the full text of the form of Indemnification Agreement attached as Exhibit 10.1 hereto, which is incorporated herein by reference.



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**Item 6. Exhibits**

Exhibit 10.1*	Form of Indemnification Agreement.
Exhibit 31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
Exhibit 31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
Exhibit 32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
Exhibit 101.INS	XBRL Instance Document
Exhibit 101.SCH	XBRL Taxonomy Extension Schema Document
Exhibit 101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
Exhibit 101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
Exhibit 101.LAB	XBRL Taxonomy Extension Label Linkbase Document
Exhibit 101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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\* Management contract or compensatory plan or other arrangement.

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**Signature**

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.

ICU Medical, Inc.

(Registrant)

/s/ Scott E. Lamb  
Scott E. Lamb  
Chief Financial Officer  
(Principal Financial Officer)

Date: October 22, 2010

## Edgar Filing: ICU MEDICAL INC/DE - Form 10-Q

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### Exhibit Index

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