ICU MEDICAL INC/DE
Form 10-Q
October 21, 2011

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, 2011
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 October 10, 2011
Common	13,830.693

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

ICU Medical, Inc.

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PART I - FINANCIAL INFORMATION
Item1. Financial Statements (Unaudited)

ICU Medical, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(Amounts in thousands, except per share data)

	September 30, 2011 (unaudited)	December 31, 2010 (1)
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$66,939	$78,850
Investment securities	52,153	14,507
Cash, cash equivalents and investment securities	119,092	93,357
Accounts receivable, net of allowance for doubtful accounts of $1,242 at September 30, 2011 and $742 at December 31, 2010	53,081	55,106
Inventories	43,363	44,056
Prepaid income taxes	8,478	687
Prepaid expenses and other current assets	8,005	9,574
Deferred income taxes	5,251	5,053
Total current assets	237,270	207,833
PROPERTY AND EQUIPMENT, net	86,718	83,545
ASSETS HELD FOR SALE	1,743	—
GOODWILL	1,478	1,478
INTANGIBLE ASSETS, net	11,712	14,806
DEFERRED INCOME TAXES	4,586	4,564
	$343,507	$312,226
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$11,209	$10,879
Accrued liabilities	12,877	14,629
Deferred revenue	—	254
Total current liabilities	24,086	25,762
COMMITMENTS AND CONTINGENCIES	—	—
DEFERRED INCOME TAXES	8,008	8,023
INCOME TAX LIABILITY	4,471	4,155
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 14,855 shares at September 30, 2011 and December 31, 2010, outstanding 13,831 shares at September 30, 2011 and 13,659 shares at December 31, 2010	1,486	1,486
Additional paid-in capital	56,426	56,502
Treasury stock, at cost — 1,024 shares at September 30, 2011 and 1,196 shares at December 31, 2010	(36,734)	(41,428)
Retained earnings	285,617	258,790
Accumulated other comprehensive income (loss)	147	(1,064)
Total stockholders' equity	306,942	274,286
	$343,507	$312,226

(1) December 31, 2010 balances were derived from audited consolidated financial statements.
The accompanying notes are an integral part of these 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 September 30,		Nine months ended September 30,	
	2011	2010	2011	2010
REVENUES:				
Net sales	$76,317	$75,589	$225,316	$208,511
Other	141	148	409	451
TOTAL REVENUE	76,458	75,737	225,725	208,962
COST OF GOODS SOLD	40,884	41,705	119,324	115,876
Gross profit	35,574	34,032	106,401	93,086
OPERATING EXPENSES:				
Selling, general and administrative	20,411	18,341	63,004	57,368
Research and development	1,877	1,067	6,420	2,937
Legal settlement	—	—	(2,500)	—
Total operating expenses	22,288	19,408	66,924	60,305
Income from operations	13,286	14,624	39,477	32,781
OTHER INCOME (EXPENSE)	132	(215)	966	40
Income before income taxes	13,418	14,409	40,443	32,821
PROVISION FOR INCOME TAXES	(4,157)	(5,434)	(13,616)	(11,878)
NET INCOME	$9,261	$8,975	$26,827	$20,943
NET INCOME PER SHARE				
Basic	$0.66	$0.67	$1.94	$1.54
Diluted	$0.65	$0.65	$1.89	$1.51
WEIGHTED AVERAGE NUMBER OF SHARES				
Basic	13,932	13,489	13,826	13,605
Diluted	14,184	13,752	14,169	13,838

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)

	Nine months ended September 30,	
	2011	2010
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$26,827	$20,943
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	13,687	12,796
Provision for doubtful accounts	509	154
Stock compensation	2,998	2,568
Loss (gain) on disposal of property and equipment	(57)	449
Bond premium amortization	801	1,145
Cash provided (used) by changes in operating assets and liabilities		
Accounts receivable	1,575	(7,763)
Inventories	1,143	(2,670)
Prepaid expenses and other assets	(2,406)	(1,874)
Accounts payable	(272)	(6,365)
Accrued liabilities	(1,698)	1,381
Deferred revenue	(254)	(2,013)
Prepaid and deferred income taxes	(6,802)	69
Net cash provided by operating activities	36,051	18,820
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(13,761)	(17,751)
Proceeds from sale of asset	—	893
Proceeds from insurance	2,781	622
Purchases of investment securities	(66,330)	(20,853)
Proceeds from sale of investment securities	26,935	60,370
Net cash provided (used) by investing activities	(50,375)	23,281
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	7,021	903
Proceeds from employee stock purchase plan	909	1,576
Tax benefits from exercise of stock options	3,682	708
Purchase of treasury stock	(9,992)	(28,648)
Net cash provided (used) by financing activities	1,620	(25,461)
Effect of exchange rate changes on cash	793	(2,217)
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(11,911)	14,423
CASH AND CASH EQUIVALENTS, beginning of period	78,850	51,248
CASH AND CASH EQUIVALENTS, end of period	$66,939	$65,671
NON-CASH INVESTING ACTIVITIES		
Accrued liabilities for property and equipment	$557	$11

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,		Nine months ended September 30,	
	2011	2010	2011	2010
Net income	$9,261	$8,975	$26,827	$20,943
Other comprehensive income (loss), net of tax of $(283) and $(120) for the three months ended September 30, 2011 and 2010, respectively and $(154) and $836 for the nine months ended September 30, 2011 and 2010, respectively:				
Foreign currency translation adjustment	(3,865)	5,236	1,211	(778)
Comprehensive income	$5,396	$14,211	$28,038	$20,165

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, 2011 and 2010
(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, 2010.

The Company operates in one business segment engaged in the development, manufacturing and sale of innovative medical technologies used in I.V. therapy, oncology and critical care applications. 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 September 2011, the Financial Accounting Standards Board issued Accounting Standards Update No. 2011-08 for Intangibles - Goodwill and Other (Topic 350): "Testing Goodwill for Impairment". This Update is to simplify how entities test goodwill for impairment. The amendments in the Update permit an entity to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If the entity determines that it is more likely than not that the fair value of a reporting unit is more than the carrying amount in step one, performing step-two is not required. If the entity determines that the fair value of a reporting unit is less than the carrying value in step one, step two is required to determine the impairment loss. Under the amendments, an entity is no longer permitted to carry forward its detailed calculation of a reporting unit's fair value from a prior year as previously permitted. This Update is effective for fiscal years beginning after December 15, 2011 and is not expected to have a material effect on our results of operations.

In June 2011, the Financial Accounting Standards Board issued Accounting Standards Update No. 2011-05 for Comprehensive Income (Topic 220): "Presentation of Comprehensive Income". This Update improves the comparability, consistency and transparency of financial reporting and increases the prominence of items reported in other comprehensive income. This Update eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholder's equity, which is how the Company presented such components in its Annual Report on Form 10-K for the year ended December 31, 2010. This Update is effective for interim and annual periods beginning after December 15, 2011 and is not expected to have a material effect on our results of operations, but will change the presentation of our financial statements.

In May 2011, the Financial Accounting Standards Board issued Accounting Standards Update No. 2011-04 for Fair Value Measurement (Topic 820): "Amendments to Achieve Common Fair Value Measurement and Disclosure

Requirements in
U.S. GAAP and IFRSs". This Update addresses how to measure fair value and requires new disclosures about fair value measurements. The amendments in this Update are effective for interim and annual periods beginning after December 15, 2011.

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. The Company had no Level 3 investments in the fiscal year beginning after December 15, 2010, and was therefore not impacted by this new pronouncement in the three and nine months ended September 30, 2011.

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Note 3: Assets Held for Sale

In September 2011, the Company's management and Board of Directors made the decision to sell a small product line to focus the Company's operations on its core products in vascular therapy, oncology and critical care applications. In September 2011, $1.7 million in intangible assets and less than $0.1 million of fixed assets became classified as assets held for sale. The Company's management expects the sale of these assets to be completed in the fourth quarter of 2011.

Note 4: Legal Settlement:

In February 2011, the Company reached a settlement in its litigation against a law firm that formerly represented the Company in patent litigation matters, representing reimbursement of legal fees previously paid to the firm. Under the terms of the settlement, the Company received $2.5 million and this amount is included as a credit in operating expenses on the Condensed Consolidated Statement of Income for the nine months ended September 30, 2011.

Note 5: Exit Activity from Italy and Germany Facilities

The Company’s new plant in Slovakia will serve our European product distribution. Product assembly previously done in the Company’s Italy and Germany facilities is now done in its Slovakia plant. As a result of this, the Company had termination costs to certain manufacturing and operations employees from the Italy facility. The product assembly transition from the Company’s Italy plant to the Slovakia plant was completed in March 2011. The Italy facility continues to support sales in Europe. The product assembly transition from the Company's Germany plant to the Slovakia plant was completed in the third quarter of 2011. The Germany facility will continue to support a small amount of manufacturing that is not intended to transfer to the Slovakia plant at this time. In the nine months ended September 30, 2011, the Company recorded $0.8 million in one-time termination costs, $0.7 million in cost of goods sold and $0.1 million in sales, general and administrative expense. As of September 30, 2011, $0.4 million is accrued for these exit costs.

Note 6: 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, corporate bonds and tax-exempt state and municipal government debt. The Company has $5.1 million of its investment securities as Level 1 assets, which are certificates of deposit with quoted prices in active markets. The Company has $47.1 million of its investment securities as Level 2 assets, which are pre-refunded municipal securities, non-pre-refunded municipal securities and corporate bonds and have observable market based inputs such as quoted prices, interest rates and yield curves.

The following table provides the assets and liabilities carried at fair value measured on a recurring basis.

	Fair value measurements at September 30, 2011 using			
	Total carrying value at September 30, 2011	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	$52,153	$5,079	$47,074	$—
	$52,153	$5,079	$47,074	$—

	Fair value measurements at December 31, 2010 using			
	Total carrying value at December 31, 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	$14,507	$2,820	$11,687	$—
	$14,507	$2,820	$11,687	$—

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The Company had no Level 3 investments for the three and nine months ended September 30, 2011. The following table presents the change in the fair values for Level 3 items for the three and nine months 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	$—	$—

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Note 7: Investment Securities:

The Company's investment securities consist of certificates of deposit, corporate bonds and federal-tax-exempt state and municipal government debt. All investment securities are considered available-for-sale and are “investment grade”, carried at fair value and there have been no gains or losses on their disposal. Unrealized gains and losses on available-for-sale securities, net of tax, are included in accumulated other comprehensive income in the shareholders' equity section of the Company's balance sheets. The Company had no gross unrealized gains or losses on available-for-sale securities at September 30, 2011 or December 31, 2010. The scheduled maturities of the debt securities are between 2011 and 2037 and are all callable within one year. The investment securities consist of the following at September 30, 2011 and December 31, 2010:

	September 30, 2011	December 31, 2010
Federal tax-exempt debt securities	$31,051	$11,687
Corporate bonds	16,023	—
Certificates of deposit	5,079	2,820
	$52,153	$14,507

Note 8: Inventories:

Inventories consisted of the following:

	September 30, 2011	December 31, 2010
Raw material	$24,262	$22,805
Work in process	3,721	3,806
Finished goods	15,380	17,445
Total	$43,363	$44,056

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Note 9: Property and Equipment:

Property and equipment consisted of the following:

	September 30, 2011	December 31, 2010
Machinery and equipment	$73,217	$62,680
Land, building and building improvements	61,772	57,810
Molds	23,864	22,521
Computer equipment and software	16,749	14,613
Furniture and fixtures	2,285	2,107
Construction in progress	5,665	9,866
Total property and equipment, cost	183,552	169,597
Accumulated depreciation	(96,834)	(86,052)
Net property and equipment	$86,718	$83,545

Note 10: 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 295,000 and 559,000 for the three months ended September 30, 2011 and 2010, respectively and 189,000 and 742,000 for the nine months ended September 30, 2011 and 2010, respectively.

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,	
	2011	2010	2011	2010
Net income	$9,261	$8,975	$26,827	$20,943
Weighted average number of common shares outstanding (for basic calculation)	13,932	13,489	13,826	13,605
Dilutive securities	252	263	343	233
Weighted average common and common equivalent shares outstanding (for diluted calculation)	14,184	13,752	14,169	13,838
EPS — basic	$0.66	$0.67	$1.94	$1.54
EPS — diluted	$0.65	$0.65	$1.89	$1.51

Note 11: Major Customer:

The Company had revenues equal to 10% or more of total revenues from one customer, Hospira, Inc. Such revenues were 44% and 47% of total revenue for the three months ended September 30, 2011 and 2010, respectively and 42% and 43% of total revenue for the nine months ended September 30, 2011 and 2010, respectively. As of September 30, 2011 and December 31, 2010, the Company had accounts receivable from Hospira of 34% and 43% of consolidated accounts receivable, respectively.

Note 12: Income Taxes:

Income taxes were accrued at an estimated annual effective tax rate of 34% and 36% in the first nine months of 2011 and 2010. The effective tax rate differs from that computed at the federal statutory rate of 35% principally because of the effect tax credits, domestic production activities and discrete tax items.

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Note 13: 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 presently expect to incur, any liability for indemnification.

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 I.V. therapy, oncology and critical care applications. We believe our products help to reduce the cost of healthcare and improve patient outcomes by helping prevent bloodstream infections, 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

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, a one-piece, needleless I.V. connection device.

One of our strategies 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 this critical care product line, including production, sales, marketing, customer contracting and distribution. We had previously manufactured for sale, exclusively to Hospira, its 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. 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.

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. In the I.V. therapy market, we have introduced the clear microCLAVE and the neutron for improved catheter patency. We can provide no assurance that we will be able to successfully manufacture, market and sell these new products.

We are also expanding our 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, our recently awarded full-line critical care products agreement with Premier, our being named the single-source supplier of critical care products to Premier's ASCEND program, the extension of the term of our agreement with MedAssets, our recent entry into an agreement with Novation covering all of our critical care products and the growth of our internal sales and marketing group. Premier, MedAssets and Novation are U.S. healthcare purchasing networks. Custom products, which include custom infusion, custom oncology and custom critical care products, accounted for approximately $70.9 million or 31% of total revenue for the first nine months of 2011 and $100.6 million or 35% of total revenue for fiscal year 2010. CLAVE sales were $80.1 million or 35% of total revenue for the nine months of 2011 and $98.4 million or 35% of total revenue for fiscal year 2010. Standard critical care sales were $37.4 million or 17% of total revenue in the first nine months of 2011 and $50.4 million or 18% of total revenue for fiscal year 2010. We 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 important for 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. For the first nine months of 2011 and the years ended December 31, 2010 and 2009, our revenues from worldwide sales to Hospira were 42%, 44% and 53%, respectively, of total revenues. 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 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 September 30,		Nine months ended September 30,		Fiscal Year Ended	
Product Line	2011	2010	2011	2010	2010	2009
CLAVE	37.5 %	33.9 %	35.49 %	34.84 %	35 %	37 %
Custom products	29.9 %	37.4 %	31.39 %	34.44 %	35 %	34 %
Standard critical care	15.1 %	16 %	16.55 %	18.49 %	18 %	18 %
Standard oncology products	7.3 %	2.3 %	6.14 %	2.55 %	3 %	2 %
Other products/other revenue	10.2 %	10.4 %	10.43 %	9.68 %	9 %	9 %
Total	100 %	100 %	100 %	100 %	100 %	100 %

We sell our I.V. administration products to independent distributors, via 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 also sell our I.V. administration and oncology products to Hospira pursuant to two agreements. 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, stream-line our distribution, 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 January 2011, we completed an additional expansion of our production facility in Mexico. In late 2010, we completed construction of an assembly plant in Slovakia that

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serves our European product distribution. Product shipments from this plant commenced 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 or expanding new manufacturing facilities outside the U.S.

We distribute products through three distribution channels. Product revenues for each distribution channel as a percentage of total channel product revenue were as follows:

	Three months ended September 30,		Nine months ended September 30,		Fiscal Year Ended	
Channel	2011	2010	2011	2010	2010	2009
Medical product manufacturers	41 %	44 %	39 %	41 %	41 %	50 %
Domestic distributors/direct	36 %	34 %	35 %	36 %	36 %	29 %
International customers	23 %	22 %	26 %	23 %	23 %	21 %
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 comparisons: We present summarized income statement data in Part I, Item 1- Financial Statements. The following table shows, for the year ended December 31, 2010 and the three and nine months ended September 30, 2011 and 2010, the percentages of each income statement caption in relation to total revenues.

	Percentage of Revenues				
	Fiscal Year	Three months ended September 30,		Nine months ended September 30,	
	2010	2011	2010	2011	2010
Total revenues	100 %	100 %	100 %	100 %	100 %
Gross profit	46 %	47 %	45 %	47 %	45 %
Selling, general and administrative expenses	27 %	27 %	24 %	28 %	28 %
Research and development expenses	2 %	2 %	2 %	3 %	1 %
Legal settlement	— %	— %	— %	(1)%	— %
Total operating expenses	29 %	29 %	26 %	30 %	29 %
Income from operations	17 %	18 %	19 %	17 %	16 %
Other income	—	—	— %	1 %	—
Income before income taxes	17 %	18 %	19 %	18 %	16 %
Income taxes	6 %	6 %	7 %	6 %	6 %
Net income	11 %	12 %	12 %	12 %	10 %

Quarterly results: The healthcare business in the United States is subject to quarterly fluctuations due to illness, elective procedures, and over the last few years, the economy. 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.

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Quarter Ended September 30, 2011 Compared to the Quarter Ended September 30, 2010

Revenues were $76.5 million in the third quarter of 2011, compared to $75.7 million in the third quarter of 2010.

Distribution channels: Net U.S. sales to Hospira in the third quarter of 2011 were $30.3 million, compared to net sales of $32.6 million in the third quarter of 2010, a decrease of 7%. The decrease was primarily due to lower custom infusion set sales of $4.5 million, partially offset by $2.0 million in increased CLAVE sales and $1.3 million in increased standard oncology sales. In the third quarter of 2010, Hospira had $5.9 million in non-recurring custom infusion set and CLAVE orders when Hospira switched their I.V. tubing from DEHP to non-DEHP material. The increases in CLAVE and standard oncology are due to increased unit sales. Excluding the one-time orders in the latter part of 2010, we expect moderate growth in sales to Hospira in 2011 from 2010, although there is no assurance that these expectations will be realized.

Net sales to domestic distributors/direct in the third quarter of 2011 (including Canada) were $27.4 million compared to $25.9 million in the third quarter of 2010, an increase of 6%. The increased sales were primarily from $0.9 million in increased TEGO sales, our renal dialysis product, $0.6 million in increased CLAVE sales and $0.6 million in increased standard oncology sales, partially offset by lower standard and custom critical care revenue of $0.7 million. The increases in TEGO, CLAVE and standard oncology sales were due to higher unit volume sales. The decrease in critical care sales is primarily a result of increased competition in this market. Some of our competition aggressively prices their critical care products and this has resulted in us both lowering our prices to retain or win the customer and, in some cases, losing some customers. We expect increases in domestic distributor/direct sales in 2011 compared to 2010, principally from growth in renal, CLAVE and custom products, although there is no assurance that these expectations will be realized.

Net sales to international customers (excluding Canada) were $17.7 million in the third quarter of 2011, compared with $16.2 million in the third quarter of 2010, an increase of 9%. The increased sales were primarily from $2.0 million in increased standard oncology sales, partially offset by lower custom product sales. The increased standard oncology sales were from increased unit volume due to increased market share and demographic growth. We expect increases in international customer sales in 2011 compared to 2010, primarily from growth in CLAVE, custom infusion sets and oncology, although there is no assurance that these expectations will be realized.

Product and other revenue: Net sales of CLAVE products were $28.7 million in the third quarter of 2011 compared to $25.7 million in the third quarter of 2010, an increase of 12% from higher sales in all channels. We expect increases in CLAVE product sales in 2011 compared to 2010, 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 $22.8 million in the third quarter of 2011 compared to $28.3 million in the third quarter of 2010, a decrease of 19%. This decrease was primarily from $4.5 million of non-recurring custom infusion set sales to Hospira in the third quarter of 2010 when Hospira switched their I.V. tubing from DEHP to non-DEHP material. We expect only modest increases in custom product sales in 2011 compared to 2010 due to the additional sales to Hospira in 2010 for product line changes that do not occur in 2011 and because we expect oncology sales to grow in standard products instead of custom sets since this market does not demand as much customization, and we expect a decrease in custom critical care due to increased competition. There is no assurance that these expectations will be realized.

Standard critical care product sales were $11.6 million in the third quarter of 2011 compared to $12.1 million in the third quarter of 2010, a decrease of 5%. We expect standard critical care sales to be moderately lower for 2011 compared to 2010 because of the recent increased pricing competition discussed above. There is no assurance that these expectations will be realized.

Our standard oncology product sales were $5.6 million in the third quarter of 2011 compared to $1.7 million in the third quarter of 2010, an increase of 222%. The increase was from higher sales in all channels, with international sales contributing the largest sales growth. We expect higher standard oncology sales for 2011 compared to 2010 due to several trials in process that we expect to close in 2011, although there is no assurance that these expectations will be realized.

Sales of TEGO were $2.2 million in the third quarter of 2011 compared to $1.3 million in the third quarter of 2010, an increase of 80%. This increase was primarily due to an increase in unit sales in domestic distributors and direct sales. We expect TEGO sales to have significant increases in 2011 compared to 2010 due to a new agreement that we entered into in late 2010 with a major dialysis provider in the U. S., although there is no assurance that these expectations will be realized.

Other revenue consists of license, royalty and revenue share income and was approximately $0.1 million in the third quarter of 2011 and $0.1 million in the third quarter of 2010. We may receive other license fees or royalties in the future for the

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use of our technology. There is no assurance as to amounts or timing of any future payments, or whether such payments will be received.

Revenue by market segment: Our sales are primarily in three market segments: I.V. therapy, critical care and oncology. Revenues by segment for the three months ended September 30, 2011 and 2010 were as follows (dollars in millions):

	Three months ended September 30,		Percentage of total revenue			
Market segment	2011	2010	2011		2010	
I.V. therapy	$50.0	$52.3	66	%	69	%
Critical care	14.8	15.7	19	%	21	%
Oncology	6.8	4.1	9	%	5	%
Other	4.9	3.6	6	%	5	%
	$76.5	$75.7	100	%	100	%

Gross margins were 47% and 45% for the third quarters of 2011 and 2010, respectively. Our favorable product mix and lower freight costs added 3% to our margin and were partially offset by start up costs at our Slovakia plant and higher raw material costs.

We estimate our gross margin in 2011 will approximate 47% to 47.5%; however, there is no assurance that these expectations will be realized.

Selling, general and administrative expenses ("SG&A") were $20.4 million and 27% of revenues in the third quarter of 2011, compared with $18.3 million and 24% of revenues in the third quarter of 2010. Our sales and marketing workforce expansion resulted in $1.2 million of higher compensation and benefits and travel costs. Our sales and marketing promotion costs increased by $0.6 million, which was primarily due to higher dealer fees. We expect SG&A in 2011 to be approximately 28% of revenue. There is no assurance that these expectations will be realized.

Research and development expenses ("R&D") were $1.9 million and 2% of revenue in the third quarter of 2011 compared to $1.1 million and 2% of revenue in the third quarter of 2010. The increase was primarily from higher project related R&D expenses in all our market segments. We expect R&D in 2011 to be approximately 3% of revenue, although there is no assurance that these expectations will be realized.

Other income was $0.1 million in the third quarter of 2011 compared to other loss of $0.2 million in the third quarter of 2010.

Income taxes were accrued at an effective tax rate of 31% in the third quarter of 2011 compared to 38% in the third quarter of 2010. Our third quarter 2011 tax included $0.5 million in various discrete items, tax credits and domestic production activities deductions that reduced our effective rate from the statutory corporate rate of 35% to 31% in the third quarter of 2011. We expect our effective tax rate to be approximately 34% in 2011.

Nine months Ended September 30, 2011 Compared to the Nine months Ended September 30, 2010

Revenues were $225.7 million in the first nine months of 2011, compared to $209.0 million in the first nine months of 2010.

Distribution channels: Net U.S. sales to Hospira in the first nine months of 2011 were $85.6 million, compared to net sales of $82.8 million in the first nine months of 2010, an increase of 3%. The increase was primarily due to increased standard oncology sales of $2.4 million, increased CLAVE sales of $3.1 million and increased other I.V. product sales

of $1.1 million, partially offset by lower custom infusion set sales of $3.5 million. The increases were due to higher unit sales from increased market share through Hospira. CLAVE sales and custom infusion set sales in the nine months ended September 30, 2010 included $1.4 million and $4.5 million, respectively, of non-recurring revenue due to Hospira switching their I.V. tubing from DEHP to non-DEHP material. The increases were due to higher unit sales from increased market share through Hospira.

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Net sales to domestic distributors/direct in the first nine months of 2011 (including Canada) were $79.5 million compared to $74.5 million in the first nine months of 2010, an increase of 7%. The increased sales were primarily from $2.6 million in increased custom infusion set sales, $2.0 million of increased CLAVE sales and $2.6 million in increased TEGO sales partially offset by lower standard and custom critical care sales of $2.2 million. The increases in custom infusion sets, CLAVE and TEGO sales were due to higher unit volume sales. The decrease in critical care sales is primarily a result of increased competition in this market.

Net sales to international customers (excluding Canada) were $57.5 million in the first nine months of 2011, compared with $48.2 million in the first nine months of 2010, an increase of 19%. The increased sales were primarily from $5.2 million in increased standard oncology sales, $2.5 million in increased custom infusion set sales and $1.6 million in increased CLAVE sales. All increases were from higher unit volume due to increased market share and demographic growth.

Product and other revenue: Net sales of CLAVE products were $80.1 million in the first nine months of 2011 compared to $72.8 million in the first nine months of 2010, an increase of 10%. The increase was from higher sales in all channels from increased market share and demographic growth.

Net sales of custom products, which include custom infusion, custom oncology products and custom critical care products, were $70.9 million in the first nine months of 2011 compared to $72.0 million in the first nine months of 2010, a decrease of 2%. This decrease was from lower custom critical care and custom oncology sales, partially offset by a modest growth in custom infusion set sales. The decrease in custom critical care sales is primarily a result of increased competition in this market. The decrease in custom oncology is primarily due to increased orders of standard oncology over custom oncology, which we believe will be the trend going forward. Custom infusion set sales in the first nine months of 2010 included $4.5 million of non-recurring custom infusion set sales to Hospira when they switched their I.V. tubing from DEHP to non-DEHP material.

Standard critical care product sales were $37.4 million in the first nine months of 2011 compared to $38.6 million in the first nine months of 2010, a decrease of 3%. The decrease is primarily a result of increased competition in this market.

Our standard oncology product sales were $13.9 million in the first nine months of 2011 compared to $5.3 million in the first nine months of 2010, an increase of 160%. The increase was from higher unit sales in all channels from increased market share, with international sales contributing $5.2 million of the increase.

TEGO sales were $5.9 million in the first nine months of 2011 compared to $2.9 million in the first nine months of 2010, an increase of 101%. This increase was primarily due to higher domestic unit sales from adding new customers.

Other revenue consists of license, royalty and revenue share income and was approximately $0.4 million in the first nine months of 2011 and $0.5 million in the first nine months of 2010. 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.

Revenue by market segment: Our sales are primarily in three market segments: I.V. therapy, critical care and oncology. Revenues by segment for the nine months ended September 30, 2011 and 2010 were as follows (dollars in millions):

	Nine months ended September 30,		Percentage of total revenue			
Market segment	2011	2010	2011		2010	
I.V. therapy	$145.4	$137.2	64	%	65	%

Critical care	47.2	49.5	21	%	24	%
Oncology	19.0	12.1	9	%	6	%
Other	14.1	10.2	6	%	5	%
	$225.7	$209.0	100	%	100	%

Gross margins for the first nine months of 2011 and 2010 were 47% and 45%, respectively. Our favorable product mix and lower freight costs added 3% to our margin and were partially offset by start up costs at our Slovakia plant and higher raw material costs.

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Selling, general and administrative expenses ("SG&A") were $63.0 million and 28% of revenues in the first nine months of 2011, compared with $57.4 million and 28% of revenues in the first nine months of 2010. The increase in expense was primarily from a one-time expense for the Long Term Retention Plan ("LTRP") of $2.0 million, increased sales and marketing compensation and benefits and travel of $2.9 million, increases general and administrative compensation and benefits of $0.9 million, increased information technology ("IT") costs of $0.6 million, partially offset by $1.1 million in lower legal costs. In January 2011, our Compensation Committee determined to pay out the 2005 LTRP grants and to not make any future payments for the 2006 and 2007 awards, thus effectively cancelling the plan. As a result, we recognized $2.0 million of non-recurring expense to SG&A in the first nine months of 2011. The increase in sales and marketing compensation and benefits and travel is primarily a result of the expansion of our sales and marketing workforce by 14 employees and compensation increases. The increase in our general and administrative compensation and benefits is primarily a result of compensation increases. The increased IT costs were from increased software maintenance costs. The decrease in legal expenses is due to lower general legal expense.

Research and development expenses ("R&D") were $6.4 million and 3% of revenue in the first nine months of 2011 compared to $2.9 million and 1% of revenue in the first nine months of 2010. The increase was primarily from $2.6 million of higher project related R&D expenses in all our market segments, $0.3 million in one-time expense for the LTRP and $0.3 million in increased compensation and benefits from an increased workforce.

Legal settlement income of $2.5 million was received in the first nine months of 2011 and recorded in operating expenses. The payment to us was the result of a settlement of litigation against a law firm that formerly represented us in patent litigation.

Other income was $1.0 million in the first nine months of 2011 compared to less than $0.1 million in the first nine months of 2010. The increase was primarily due to higher interest income and favorable changes in gains/losses on disposal of assets.

Income taxes were accrued at an estimated annual effective tax rate of 34% in the first nine months of 2011 and 36% in the first nine months of 2010. Our tax expense in the first nine months of 2011 included $0.5 million in various discrete tax items, tax credits and domestic production activities deductions that reduced the statutory effective rate of 35% to 34% in the first nine months of 2011.

Liquidity and Capital Resources

During the first nine months of 2011, our cash, cash equivalents and investment securities increased by $25.7 million from $93.4 million at December 31, 2010 to $119.1 million at September 30, 2011.

Operating Activities: Our cash provided by operating activities tends to increase over time because of our positive operating results. However, it is subject to fluctuations, principally from the impact of integrating new locations, changes in net income, accounts receivable, inventories and the timing of tax payments.

During the first nine months of 2011, our cash provided by operations was $36.1 million, which was mainly comprised of net income of $26.8 million, depreciation and amortization of $13.7 million and stock compensation expense of $3.0 million, offset by changes in our operating assets and liabilities, including a $6.8 million increase in prepaid income taxes.

Investing Activities: During the first nine months of 2011, cash used in investing activities was $50.4 million. This was comprised of net investment purchases of $39.4 million and purchases of property and equipment of $13.8 million which were primarily for machinery, equipment and mold additions in our United States and Slovakia plants,

partially offset by insurance proceeds from the 2010 flood at our Slovakia plant of $2.8 million.

While we can provide no assurances, we estimate that our capital expenditures in 2011 will approximate $17.0 million to $19.0 million, which is primarily for investments in molds, machinery and equipment in our manufacturing operations in the United States and investments in information technology that benefit world-wide operations. We expect to use our cash and investments to fund our capital purchases. Estimates of capital expenditures may differ substantially from actual capital expenditures.

Financing Activities: During the first nine months of 2011, our cash provided by financing activities was $1.6 million. This was from stock option exercises and shares purchased from the employee stock purchase plan resulting in 426,469 shares issued to employees and directors. The tax benefits from the exercise of stock options was $3.7 million in the

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first nine months of 2011 which fluctuates based principally on when employees choose to exercise their vested stock options.

In July 2010, our Board of Directors approved a plan to purchase up to $40.0 million of our common stock. We purchased $10.0 million of our common stock in the third quarter of 2011. We may purchase additional shares in future quarters.

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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 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 not previously incurred, nor do we expect to incur, any material liabilities associated with this indemnification.

Pursuant to our 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 have terminated, 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 Manufacturing, Commercialization and Development Agreement with Hospira, Inc. dated May 1, 2005. Although we can provide no assurances, we do not expect to incur material liability arising out of the indemnification provision of the asset purchase agreement.

Contractual Obligations

We have contractual obligations, at September 30, 2011, of approximately the amount set forth in the table below. This amount excludes inventory related purchase orders for goods and services for current delivery. The majority of our inventory 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 inventory related 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 income tax liability of $4.5 million due to the high degree of uncertainty regarding the timing of future cash outflows associated with the liabilities.

	(in thousands)				
Contractual Obligations	Total	2011	2012	2013	2014
Operating leases	$164	$56	$60	$32	$16
Warehouse service agreements	1,298	219	875	204	—
Purchase obligations	5,320	5,320	—	—	—
	$6,782	$5,595	$935	$236	$16

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Critical Accounting Policies

In our Annual Report on Form 10-K for the year ended December 31, 2010, 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 1. 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," and by simil 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 growth; 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; future sales of assets; expected increases or decreases in sales; deferred revenue; future license, royalty and revenue share income; production costs; gross margins; litigation expense; SG&A and R&D expenses; future costs of expanding our business; income; losses; cash flow; capital expenditures; source and sufficiency of funds for capital purchases and operations; tax rates; changes in working capital items such as receivables and inventory; selling prices; and income taxes;
- factors affecting operating results, such as shipments to specific customers; 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 and sales of new products; planned increases in marketing; inventory requirements; manufacturing efficiencies and cost savings; unit manufacturing costs; establishment of production facilities outside the U.S.; planned new orders for automated assembly machines for new products; adequacy of production capacity; results of R&D; relocation of manufacturing facilities and personnel; planned growth of our sales and marketing group; 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 revenues from our custom infusion sets, custom critical care and custom oncology products and the importance of these products in the future; potential customer resistance to custom products; our focus on increasing product development, acquisition, sales and marketing efforts to custom products and similar products; new or extended contracts with manufacturers and buying organizations; dependence on a small number of customers; future sales to and revenues from Hospira and the importance of Hospira to our growth; effect of the acquisition of Hospira's critical care product line, including its effect on future revenues from Hospira and our positioning with respect to new product introductions and market share; growth of our CLAVE products in future years; the outcome of our strategic initiatives; outcome of litigation; competitive and market factors, including continuing development of competing products by other manufacturers; consolidation of the healthcare provider market; our dependence on securing long-term contracts with large healthcare providers and

major buying organizations; working capital requirements; liquidity and realizable value of our investment securities; future investment alternatives; our expectations regarding liquidity and capital resources over the next twelve months; acquisitions of other businesses or product lines, indemnification liabilities and contractual liabilities.

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

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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, 2010 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;
- unexpected changes in our arrangements with Hospira or our other large customers;
- 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;
- 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;
- 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, corporate bonds and certificates of deposit of $52.2 million as of September 30, 2011. The securities are all “investment grade”, comprised

of $28.2 million of pre-refunded municipal securities, $2.9 million of non-pre-refunded municipal securities, $16.0 million in corporate bonds and $5.1 million of 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 $0.2 million to investment income based on the investment securities balance at September 30, 2011.

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Foreign currency exchange risk for financial instruments on our balance sheet, which consist of cash, accounts receivable, insurance 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 2010 and our manufacturing spending from 2010 would have impacted our cost of goods sold by approximately $2.0 million. Cash and receivables in those countries have been insignificant and are generally offset by accounts payable in the same foreign currency, except for our European operations, where our net Euro asset position at September 30, 2011 and 2010 were approximately €16.2 million and €12.0 million, respectively. A 10% change in the conversion of the Euro to the U.S. dollar for our cash and investments, accounts receivable, accounts payable and accrued liabilities from the September 30, 2011 spot rate would impact our consolidated amounts on these balance sheet items by approximately $2.2 million or less than 2% of these net assets. We expect that in the future, with the growth of our European distribution operation, that net Euro denominated instruments will continue to increase. We currently do not hedge our foreign currency exposures.

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. Based on our average price for resin in fiscal year 2010 and 2009, a 10% increase to the price of resin would have resulted in approximately a $0.7 million change and $0.6 million change in material cost, respectively.

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, 2011 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. in the United States District Court for the District of Delaware (the "District Court"), ICU Medical, Inc. (“ICU”) alleged that RyMed Technologies, Inc. (“RyMed”) infringes certain ICU patents through the manufacture and sale of its original and current InVision-Plus valves. ICU seeks monetary damages and injunctive relief and intends to vigorously pursue this matter.
A jury trial commenced on December 13, 2010. On December 17, 2010, the jury returned a verdict that: (1) RyMed's original device literally infringed ICU's Patent No. 5,685,866 ('866) and ICU's Patent No. 5,873,862 ('862); (2)

RyMed's current device infringes the '862 Patent both literally and under the doctrine of equivalents; (3) RyMed's current device infringes the '866 Patent under the doctrine of equivalents; (4) RyMed has engaged in contributory infringement and induced infringement of ICU's '862 Patent; and (5) ICU's '866 and '862 Patents are valid. Following the verdict, ICU filed a Motion for a New Trial on whether RyMed's current device literally infringes ICU's '866 Patent and RyMed filed a Motion for Judgment as a Matter of Law seeking a ruling that its current device does not literally infringe ICU's '866 Patent, as well as a Motion for New Trial on the literal infringement of ICU's '862 Patent by RyMed's current device. Following a hearing on September 16, 2011, the District Court granted ICU's Motion for a New Trial and denied RyMed's Motions.

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The new jury trial on whether RyMed's current device literally infringes ICU's '866 Patent is scheduled to commence on May 7, 2012, at 9:30 a.m., and will be followed by a one-day bench trial addressing any remaining issues.
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, 2010, 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, 2010.

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, 2011, all of the $55.0 million authorized had been used.

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. We are not obligated to make any purchases under our stock purchase program. Subject to applicable state and federal corporate and securities laws, purchases under a stock purchase program may be made at such times and in such amounts as we deem appropriate. Purchases made under our stock purchase program can be discontinued at any time we feel additional purchases are not warranted

The following is a summary of our stock purchasing activity during the third quarter of 2011:

Period	Shares purchased	Average price paid per share	Shares purchased as part of a publicly announced program	Approximate dollar value that may yet be purchased under the program
07/01/2011 — 07/31/2011	—	$—	—	$ 40,054,000
08/01/2011 — 08/31/2011	231,205	39.21	231,205	30,988,000
09/01/2011 — 09/30/2011	24,052	38.85	24,052	30,054,000
Third quarter of 2011 total	255,257	$39.18	255,257	$ 30,054,000

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Item 6. Exhibits

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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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 Date: October 21, 2011
Scott E. Lamb
Chief Financial Officer
(Principal Financial Officer)

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