

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

ICU MEDICAL INC/DE
Form 10-Q
October 19, 2012

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q

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

For the quarterly period ended: September 30, 2012

Or

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

For the transition period from: to

Commission File No.: 0-19974

ICU MEDICAL, INC.

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

951 Calle Amanecer, San Clemente, California

(Address of principal executive offices)

(949) 366-2183

(Registrant's telephone number including area code)

33-0022692

(I.R.S. Employer
Identification No.)

92673

(Zip Code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act (check one):

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

Smaller reporting company ☐

(Do not check if a smaller reporting company)

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

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Class
Common

Outstanding at October 10, 2012
14,586,369

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

ICU Medical, Inc.

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

ICU Medical, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

(Amounts in thousands, except per share data)

	September 30, 2012 (unaudited)	December 31, 2011 (1)
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 127,524	\$ 99,590
Investment securities	76,768	60,395
Cash, cash equivalents and investment securities	204,292	159,985
Accounts receivable, net of allowance for doubtful accounts of \$1,146 at September 30, 2012 and \$1,293 at December 31, 2011	53,010	43,571
Inventories	37,587	40,423
Prepaid income taxes	7,568	5,589
Prepaid expenses and other current assets	5,931	6,759
Deferred income taxes	4,220	4,081
Total current assets	312,608	260,408
 PROPERTY AND EQUIPMENT, net	 83,641	 83,048
GOODWILL	1,478	1,478
INTANGIBLE ASSETS, net	10,423	11,419
DEFERRED INCOME TAXES	4,757	4,759
	\$ 412,907	\$ 361,112
 LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 12,165	\$ 13,251
Accrued liabilities	16,745	16,059
Total current liabilities	28,910	29,310
 DEFERRED INCOME TAXES	 7,148	 7,144
INCOME TAX LIABILITY	3,816	4,081
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Convertible preferred stock, \$1.00 par value Authorized—500 shares; Issued and outstanding— none	—	—
Common stock, \$0.10 par value — Authorized—80,000 shares; Issued 14,855 shares at September 30, 2012 and December 31, 2011, outstanding 14,404 shares September 30, 2012 and 13,871 shares at December 31, 2011	1,486	1,486
Additional paid-in capital	62,255	56,796
Treasury stock, at cost — 451 shares at September 30, 2012 and 984 shares at December 31, 2011	(17,009)	(35,348)
Retained earnings	329,815	300,877
Accumulated other comprehensive loss	(3,514)	(3,234)
Total stockholders' equity	373,033	320,577
	\$ 412,907	\$ 361,112

(1) December 31, 2011 balances were derived from audited consolidated financial statements.

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

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,	
	2012	2011	2012	2011
REVENUES:				
Net sales	\$81,266	\$76,317	\$233,788	\$225,316
Other	139	141	409	409
TOTAL REVENUE	81,405	76,458	234,197	225,725
COST OF GOODS SOLD	40,710	40,884	119,455	119,324
Gross profit	40,695	35,574	114,742	106,401
OPERATING EXPENSES:			—	—
Selling, general and administrative	20,177	20,411	63,873	63,004
Research and development	2,988	1,877	8,410	6,420
Legal settlement	—	—	—	(2,500)
Total operating expenses	23,165	22,288	72,283	66,924
Income from operations	17,530	13,286	42,459	39,477
OTHER INCOME	158	132	438	966
Income before income taxes	17,688	13,418	42,897	40,443
PROVISION FOR INCOME TAXES	(5,500)	(4,157)	(13,959)	(13,616)
NET INCOME	\$12,188	\$9,261	\$28,938	\$26,827
NET INCOME PER SHARE				
Basic	\$0.85	\$0.66	\$2.04	\$1.94
Diluted	\$0.82	\$0.65	\$1.98	\$1.89
WEIGHTED AVERAGE NUMBER OF SHARES				
Basic	14,321	13,932	14,153	13,826
Diluted	14,826	14,184	14,613	14,169

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,	
	2012	2011	2012	2011
Net income	\$12,188	\$9,261	\$28,938	\$26,827
Other comprehensive income, net of tax of \$255 and \$(283) for the three months ended September 30, 2012 and 2011, respectively and \$(132) and \$(154) for the nine months ended September 30, 2012 and 2011, respectively:				
Foreign currency translation adjustment	1,737	(3,865)	) (280	) 1,211
Comprehensive income	\$13,925	\$5,396	\$28,658	\$28,038

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,		
	2012	2011	
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income	\$28,938	\$26,827	
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	14,262	13,687	
Provision for doubtful accounts	(143	) 509	
Provision for warranty and returns	291	—	
Stock compensation	4,361	2,998	
Loss (gain) on disposal of property and equipment	41	(57	)
Bond premium amortization	1,660	801	
Cash provided (used) by changes in operating assets and liabilities			
Accounts receivable	(9,790	) 1,575	
Inventories	2,974	1,143	
Prepaid expenses and other assets	792	(2,406	)
Accounts payable	(943	) (272	)
Accrued liabilities	682	(1,698	)
Deferred revenue	—	(254	)
Prepaid and deferred income taxes	(2,194	) (6,802	)
Net cash provided by operating activities	40,931	36,051	
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property and equipment	(13,208	) (13,761	)
Proceeds from sale of asset	10	—	
Intangible asset additions	(951	) —	
Proceeds from insurance	—	2,781	
Purchases of investment securities	(78,534	) (66,330	)
Proceeds from sale of investment securities	60,452	26,935	
Net cash used by investing activities	(32,231	) (50,375	)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from exercise of stock options	13,214	7,021	
Proceeds from employee stock purchase plan	2,220	909	
Tax benefits from exercise of stock options	4,002	3,682	
Purchase of treasury stock	—	(9,992	)
Net cash provided by financing activities	19,436	1,620	
Effect of exchange rate changes on cash	(202	) 793	
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	27,934	(11,911	)
CASH AND CASH EQUIVALENTS, beginning of period	99,590	78,850	
CASH AND CASH EQUIVALENTS, end of period	\$127,524	\$66,939	
NON-CASH INVESTING ACTIVITIES			
Accrued liabilities for property and equipment	\$288	\$557	

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, 2012 and 2011

(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, 2011.

The Company operates in one business segment engaged in the development, manufacturing and sale of innovative medical devices used in infusion 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 are included in the consolidated financial statements. All intercompany balances and transactions have been eliminated.

Note 2: New Accounting Pronouncements:

In June 2011, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update number 2011-05, Comprehensive Income (Topic 220) — Presentation of Comprehensive Income ("ASU 2011-05"), to require an entity to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. ASU 2011-05 eliminates the option to present the components of other comprehensive income as part of the statement of equity. In December 2011, the FASB issued ASU No. 2011-12, Comprehensive Income (Topic 220) – Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in ASU 2011-05 ("ASU 2011-12"), which defers the effective date of those changes in ASU 2011-05 that relate to the presentation of reclassification adjustments. The adoption of ASU 2011-05 and ASU 2011-12 results in a change in how the Company presents the components of comprehensive income.

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, corporate bonds, federal tax-exempt state and municipal government debt and sovereign bonds. As of September 30, 2012, the Company has \$7.3 million of its investment securities as Level 1 assets, which are certificates of deposit with quoted prices in active markets, and \$69.5 million of its investment securities as Level 2 assets, which are pre-refunded municipal securities, non-pre-refunded municipal securities, corporate bonds and sovereign bonds and have observable market based inputs such as quoted prices, interest rates and yield curves. The Company had no Level 3 investments for the three and nine months ended September 30, 2012 and September 30, 2011. The following table provides the assets and liabilities carried at fair value measured on a

recurring basis.

Fair value measurements at September 30, 2012 using

	Total carrying value	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	\$76,768	\$7,290	\$69,478	\$—
	\$76,768	\$7,290	\$69,478	\$—

Fair value measurements at December 31, 2011 using

	Total carrying value	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	\$60,395	\$5,459	\$54,936	\$—
	\$60,395	\$5,459	\$54,936	\$—

Note 4: Investment Securities:

The Company's investment securities consist of certificates of deposit, corporate bonds, federal tax-exempt state and municipal government bonds and sovereign bonds. 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, 2012 or December 31, 2011. The scheduled maturities of the debt securities are between 2012 and 2043 and are all callable within one year. The investment securities consist of the following at September 30, 2012 and December 31, 2011:

	September 30, 2012	December 31, 2011
Federal tax-exempt debt securities	\$29,564	\$39,745
Corporate bonds	39,267	13,263
Sovereign bonds	647	1,928
Certificates of deposit	7,290	5,459
	\$76,768	\$60,395

Note 5: Inventories:

Inventories consisted of the following:

	September 30, 2012	December 31, 2011
Raw material	\$20,855	\$25,227
Work in process	3,095	2,901
Finished goods	13,637	12,295
Total	\$37,587	\$40,423

Note 6: Property and Equipment:

Property and equipment consisted of the following:

	September 30, 2012	December 31, 2011
Machinery and equipment	\$77,840	\$73,390
Land, building and building improvements	60,955	60,334
Molds	26,456	24,133
Computer equipment and software	18,648	17,518
Furniture and fixtures	2,612	2,298
Construction in progress	6,826	5,277
Total property and equipment, cost	193,337	182,950
Accumulated depreciation	(109,696)	(99,902)
Net property and equipment	\$83,641	\$83,048

Note 7: 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 and restricted stock units(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 for the three months ended September 30, 2011 and 5,000 and 189,000 for the nine months ended September 30, 2012 and 2011, 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,	
	2012	2011	2012	2011
Net income	\$12,188	\$9,261	\$28,938	\$26,827
Weighted average number of common shares outstanding (for basic calculation)	14,321	13,932	14,153	13,826
Dilutive securities	505	252	460	343
Weighted average common and common equivalent shares outstanding (for diluted calculation)	14,826	14,184	14,613	14,169
EPS — basic	\$0.85	\$0.66	\$2.04	\$1.94
EPS — diluted	\$0.82	\$0.65	\$1.98	\$1.89

Note 8: Major Customer:

The Company had revenues equal to 10% or more of total revenues from one customer, Hospira, Inc. Such revenues were 44% of total revenue for the three months ended September 30, 2012 and 2011, and 41% and 42% of total revenue for the nine months ended September 30, 2012 and 2011, respectively. As of September 30, 2012 and December 31, 2011, the Company had accounts receivable from Hospira of 37% and 36% of consolidated accounts receivable, respectively.

Note 9: Income Taxes:

Income taxes were accrued at an estimated effective tax rate of 33% and 34% in the first nine months of 2012 and 2011, respectively. 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, deductions for domestic production activities and discrete tax items.

Note 10: 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. 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 11: 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 devices used in infusion therapy, oncology and critical care applications. Our products improve patient outcomes by helping to prevent bloodstream infections and protect healthcare workers from exposure to needlestick injuries and hazardous drugs. Our critical care devices are used for monitoring continuous cardiac output, oxygen saturation and other key parameters used to diagnose and treat critical care patients. Our product lines include custom infusion and monitoring systems, closed systems for the preparation and delivery of hazardous drugs, needlefree infusion connectors, catheters and cardiac monitoring systems.

Business Overview

In the early 1990's, we launched the CLAVE, an innovative one-piece, needlefree infusion connection device. The CLAVE is a worldwide leader in connector products. The CLAVE's unique design ensures compliance with needlefree policies because of its passive technology which cannot accept a needle. Our CLAVE products accounted for 36% of our revenues in 2011.

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 infusion 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 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 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 new product lines into our existing business.

Another strategy for reducing our dependence on our current proprietary products has been to introduce new products. In 2007 and 2008, we introduced a line of oncology products including the Spiros male lure connector device, the Genie vial access device and ancillary products specifically designed for chemotherapy. In 2011, we introduced Neutron, a needlefree catheter patency device and Diana, a hazardous drug compounding system. 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

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Premier, the extension of the term of our agreement with MedAssets, our 2011 agreement with Novation covering all of our critical care products and the growth of our internal sales and marketing group. Each of these organizations is a U.S. healthcare purchasing network. 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 infusion systems, oncology products, critical care products and other products that lend themselves to customization and new products in the U.S. and international markets.

Our products are used in hospitals and alternate medical sites in more than 50 countries throughout the world. We categorize our products into three main product lines: Infusion Therapy, Critical Care and Oncology. Products outside of our main product lines are grouped under the heading titled "Other" below. Our primary products include:

Infusion Therapy

- Needlefree connector products
 - CLAVE
 - MicroCLAVE/ MicroCLAVE Clear
 - Y-CLAVE
 - Anti-Microbial CLAVE
 - Anti-Microbial MicroCLAVE
 - Neutron
- Custom infusion sets

Critical Care

- Hemodynamic monitoring systems
 - Transpac disposable pressure transducers
 - SAFESET closed needlefree blood conservation systems
 - Custom monitoring systems
- Catheters
 - Advanced sensor catheters
 - Pulmonary artery thermodilution catheters
 - Multi-lumen central venous catheters
- Custom angiography and interventional radiology kits

Oncology

- Vial and bag access devices
- Genie closed vial access device
- Spiros closed male luer
- Custom preparation and administration sets and accessories
- Diana - hazardous drug compounding system

Other

- TEGO needlefree hemodialysis connector
- Lopez enteral valve

Our largest customer is Hospira. Hospira accounted for 41%, 42% and 44% of our worldwide revenues in the first nine months of 2012 and the years ended 2011 and 2010, respectively. Our relationship with Hospira has been and will continue to be important for our growth. We currently manufacture custom I.V. 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. 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 continue to be important to our growth for CLAVE, custom infusion sets and our other

products worldwide.

Revenues for the first nine months of 2012 and the years ended 2011 and 2010 were \$234.2 million, \$302.2 million and \$283.0 million, respectively. We currently sell substantially all of our products to medical product manufacturers, independent distributors and through direct sales to the end user. Most of our independent distributors handle the full line of our infusion 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. Pursuant to 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 through 2018. We sell invasive monitoring

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and angiography products 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 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 market segment and its major product groups as a percentage of total revenues:

Product line	Three months ended September 30,		Nine months ended September 30,		Fiscal year ended		
	2012	2011	2012	2011	2011	2010	
CLAVE products	37	% 37	% 37	% 35	% 36	% 35	%
Custom infusion therapy	28	% 24	% 27	% 25	% 25	% 27	%
Other infusion therapy	5	% 5	% 4	% 5	% 5	% 4	%
Infusion therapy	70	% 66	% 68	% 65	% 66	% 66	%
Critical care	16	% 19	% 18	% 21	% 20	% 23	%
Oncology	9	% 9	% 9	% 8	% 8	% 6	%
TEGO	3	% 3	% 3	% 3	% 3	% 2	%
Other products/other revenue	2	% 3	% 2	% 3	% 3	% 3	%
Other	5	% 6	% 5	% 6	% 6	% 5	%
	100	% 100	% 100	% 100	% 100	% 100	%

We have ongoing efforts to increase systems capabilities, improve manufacturing efficiency, reduce labor costs, reduce time needed to produce an order, and minimize investment in inventory. These efforts 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 2010 and early 2011, we expanded our production facility in Mexico. In late 2010, we completed construction of an assembly plant in Slovakia that serves our European product distribution. We may establish additional production facilities outside the U.S.; however, 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 as a percentage of total channel product revenue were as follows:

Channel	Three months ended September 30,		Nine months ended September 30,		Fiscal year ended		
	2012	2011	2012	2011	2011	2010	
Medical product manufacturers	41	% 41	% 39	% 39	% 40	% 42	%
Domestic distributors/direct sales	36	% 35	% 35	% 34	% 36	% 35	%
International customers	23	% 24	% 26	% 27	% 24	% 23	%
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 used in I.V. products manufactured by Hospira and exported. 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.

Seasonality/Quarterly Results

The healthcare business in the United States is subject to quarterly fluctuations due to frequency of illness during the seasons, 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.

Quarter-to-Quarter Comparisons

We present income statement data in Part I, Item 1 - Financial Statements. The following table shows, for the three and nine months ended September 30, 2012 and 2011 and the year ended December 31, 2011, the percentages of each income statement caption in relation to total revenues.

	Percentage of revenues Three months ended September 30,		Nine months ended September 30,		Fiscal year		
	2012	2011	2012	2011	2011		
Total revenues	100	% 100	% 100	% 100	% 100	%	
Gross margin	50	% 47	% 49	% 47	% 47	%	
Selling, general and administrative expenses	25	% 27	% 27	% 28	% 28	%	
Research and development expenses	3	% 2	% 4	% 3	% 3	%	
Legal settlement	—	% —	% —	% (1	)% (1	)%	
Gain on sale of assets	—	% —	% —	% —	% (5	)%	
Total operating expenses	28	% 29	% 31	% 30	% 25	%	
Income from operations	22	% 18	% 18	% 17	% 22	%	
Other income	—	% —	% —	% 1	% —	%	
Income before income taxes	22	% 18	% 18	% 18	% 22	%	
Income taxes	7	% 6	% 6	% 6	% 7	%	
Net income	15	% 12	% 12	% 12	% 15	%	

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Quarter Ended September 30, 2012 Compared to the Quarter Ended September 30, 2011

Revenues were \$81.4 million in the third quarter of 2012, compared to \$76.5 million in the third quarter of 2011.

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Domestic sales: Net domestic sales in the third quarter of 2012 were \$62.5 million, compared to net domestic sales of \$57.9 million in third quarter of 2011, an increase of 8%. Net domestic sales to Hospira accounted for 53% and 52% of our domestic sales in the third quarters of 2012 and 2011, respectively. Domestic sales to distributors, through direct sales, through other OEM and other revenue account for the balance of domestic sales, making up 47% and 48% in the third quarters of 2012 and 2011, respectively.

Net domestic sales to Hospira were \$33.1 million in the third quarter of 2012, compared to \$30.0 million in the third quarter of 2011, an increase of 10%. Infusion therapy sales increased \$2.7 million in the third quarter of 2012 from the third quarter of 2011. Oncology sales increased \$0.3 million in the third quarter of 2012 from the third quarter of 2011. The increase in infusion therapy was from \$0.9 million in higher CLAVE product unit sales, \$1.0 million in higher custom infusion set sales and \$0.8 million in higher other infusion therapy unit sales. The increases in sales to Hospira were from higher unit sales from increased market share through Hospira. We expect modest increases in U.S. sales to Hospira in 2012 compared to 2011, primarily from higher infusion therapy and oncology sales, although there is no assurance that these expectations will be realized.

Net other domestic sales (excluding Hospira) in the third quarter of 2012 were \$29.4 million, an increase of \$1.6 million, or 6%, from the third quarter of 2011. Infusion therapy sales increased \$2.8 million, or 23%, from the third quarter of 2011, which was primarily from a \$0.8 million increase in CLAVE product sales and a \$2.0 million increase in custom infusion set sales. The increased CLAVE and custom infusion set sales were primarily due to increased unit sales. Oncology sales increased \$0.3 million, or 26%, from the third quarter of 2011. The increased oncology sales were due to increased unit sales from increased market share and demographic growth. Critical care sales decreased \$1.3 million, or 11%, from the third quarter of 2011. The critical care decrease was due to lower unit sales, primarily from increased competition in this market. We expect modest increases in other domestic sales (excluding Hospira) in 2012 compared to 2011, primarily from higher infusion therapy and oncology sales, although there is no assurance that these expectations will be realized.

International sales: Net sales to international customers were \$18.9 million in the third quarter of 2012, an increase of \$0.3 million, or 2%, from the third quarter of 2011. Infusion therapy sales increased \$1.3 million, or 13%, from the third quarter of 2011. Oncology sales in the third quarter of 2012 remained the same compared to oncology sales in the third quarter of 2011. Critical care sales in the third quarter of 2012 decreased \$0.4 million from the third quarter of 2011. Other product sales decreased \$0.6 million from the third quarter of 2011. The increase in infusion therapy sales was from increased international sales outside of Europe. The decrease in critical care sales was primarily from Europe's soft economy and the weakened Euro to the U.S. dollar. The decrease in other product sales is primarily due to our sale of our former diabetes product line, Orbit, which was sold in November 2011, and consequently there were no sales of this product line in the third quarter of 2012.

Geographically, our international sales were primarily in Europe and the Pacific Rim. The decrease in international sales was primarily attributable to decreased sales in Europe. Our third quarter of 2012 international sales were negatively impacted by an estimated \$1.3 million due to the decrease in the exchange rate of the Euro to the U.S. dollar compared to the third quarter of 2011. We expect moderate increases in international sales from higher infusion therapy and oncology sales, partially offset by lower critical care sales, although there is no assurance that these expectations will be realized.

Sales by market segment and other revenue: Net infusion therapy sales were \$57.2 million in the third quarter of 2012, an increase of \$6.8 million, or 14%, from the third quarter of 2011. The increases in infusion therapy were primarily from \$1.8 million in higher CLAVE product sales and \$4.8 million in increased custom infusion set sales. The increase in CLAVE product sales was from higher domestic sales to distributors and through direct sales. The increase in custom infusion set sales was from higher sales in all channels. We expect modest increases in infusion therapy sales in 2012 compared to 2011, primarily from higher sales in CLAVE products and custom infusion set

sales. There is no assurance that these expectations will be realized.

Net critical care sales were \$13.0 million in the third quarter of 2012, a decrease of \$1.7 million, or 12%, from the third quarter of 2011. The decrease was from lower domestic and international sales from increased competition. We experienced lower unit sales in certain products and decreased our domestic critical care prices in the middle of 2011 to retain existing customers and attract new customers. We expect critical care sales to decrease in 2012 compared to 2011 because of our price decreases, increased competition and unfavorable exchange rates on the Euro to the U.S. dollar, although there is no assurance that these expectations will be realized.

Net oncology sales were \$7.5 million in the third quarter of 2012, an increase of \$0.7 million, or 10%, from the third quarter of 2011. The increase was primarily from higher domestic sales. We expect growth in oncology sales in 2012 compared to 2011, although there is no assurance that these expectations will be realized.

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Net other product sales were \$3.6 million in the third quarter of 2012, a decrease of \$0.9 million, or 19%, from the third quarter of 2011. The decrease is primarily from the sale of our former diabetes product line, Orbit, which was sold in November 2011, and consequently there were no sales of this product line in the third quarter of 2012. Orbit sales in the third quarter of 2011 were \$0.7 million. Excluding Orbit, we expect a modest decrease in our other product sales in 2012 compared to 2011, 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 quarters of 2012 and 2011.

Gross margins for the third quarters of 2012 and 2011 were 50% and 47%, respectively. Product mix contributed to two percentage points of the gross margin increase. Favorable exchange rates on the Mexican Peso contributed to one percentage point of the gross margin increase.

Selling, general and administrative expenses ("SG&A") were \$20.2 million, or 25% of revenues, in the third quarter of 2012, compared with \$20.4 million, or 27%, of revenues in third quarter of 2011. The decrease in SG&A was primarily due to a decrease of \$0.5 million in promotion expenses, partially offset by \$0.3 million in higher stock compensation expense. We expect SG&A expenses in 2012 to be approximately 26.5% of revenue, although there is no assurance that these expectations will be realized.

Research and development expenses ("R&D") were \$3.0 million, or 3% of revenue, in the third quarter of 2012 compared to \$1.9 million, or 2%, of revenue in the third quarter of 2011. The increase in R&D expenses was primarily from higher project related R&D expenses supporting all our infusion therapy, critical care and oncology market segments. Our R&D projects focus on filling in product line gaps and product enhancements for our product line target markets and creating additional market opportunities. We expect R&D expenses in 2012 to be approximately 3.6% of revenue, although there is no assurance that these expectations will be realized.

Other income was \$0.2 million in the third quarter of 2012 and \$0.1 million in the third quarter of 2011.

Income taxes were accrued at an estimated effective tax rate of 31% in the third quarter of 2012 and 31% in the third quarter of 2011. The rate differed from the statutory corporate rate of 35% principally because of the effect of foreign and state income taxes, tax credits, deductions for domestic production activities and discrete tax items. While we can provide no assurances, we expect our effective tax rate to be approximately 33% in 2012.

Nine Months Ended September 30, 2012 Compared to the Nine Months Ended September 30, 2011

Revenues were \$234.2 million in the first nine months of 2012, compared to \$225.7 million in the first nine months of 2011.

Domestic sales: Net domestic sales in the first nine months of 2012 were \$174.7 million, compared to net domestic sales of \$165.6 million in the first nine months of 2011, an increase of 6%. Net domestic sales to Hospira accounted for 51% of our domestic sales in the first nine months of 2012 and 2011. Domestic sales to distributors, through direct sales, through other OEM and other revenue account for the balance of domestic sales, making up 49% in the first nine months of 2012 and 2011.

Net domestic sales to Hospira in the first nine months of 2012 were \$89.1 million, an increase of \$4.1 million, or 5%, from the first nine months of 2011. The increase was primarily from higher infusion therapy unit sales which increased \$3.7 million from the first nine months of 2011. The increase in infusion therapy was primarily from \$1.8 million in higher CLAVE product unit sales and \$1.9 million in higher custom infusion set unit sales, partially offset

by lower other infusion therapy unit sales. The increase in CLAVE and custom infusion set sales product sales was from higher unit sales due to conversion of products sold for needlefree connectors and increased market share through Hospira.

Net other domestic sales (excluding Hospira) in the first nine months of 2012 were \$85.6 million, an increase of \$5.0 million, or 6%, from the first nine months of 2011. Infusion therapy sales increased \$6.8 million, or 20%, from the first nine months of 2011, which was primarily from a \$3.3 million increase in CLAVE product sales and a \$3.4 million increase in custom infusion set sales. The increased CLAVE and custom infusion set sales were primarily due to increased unit sales. Critical care sales decreased \$2.9 million, or 8%, from the first nine months of 2011. The critical care decrease was primarily from increased competition in this market that resulted in lower average sales prices and lower unit sales on certain items. Oncology sales increased \$1.2 million, or 37%, from the first nine months of 2011 due to higher unit sales.

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International sales: Net sales to international customers were \$59.5 million in the first nine months of 2012, a decrease of \$0.6 million, or 1%, from the first nine months of 2011. Infusion therapy sales increased \$2.8 million, or 9%, from the first nine months of 2011, which was primarily from a \$0.8 million increase in CLAVE product sales and a \$2.2 million increase in custom infusion set sales. Oncology sales increased \$0.3 million from the first nine months of 2011. Critical care sales decreased \$1.9 million from the first nine months of 2011. Other product sales decreased \$1.9 million. The increases in infusion therapy and oncology sales were from increased unit sales due to increased market share and demographic growth. The decrease in critical care sales was primarily from increased competition in this market and the decline of the Euro to U.S. dollar. The decrease in other product sales is primarily from the sale of the Orbit diabetes product line.

Geographically, our international sales were primarily in Europe and the Pacific Rim. The decrease in international sales was primarily from lower sales in Europe which were impacted by the weak Euro. This decrease was partially offset by increased sales in the Pacific Rim, Canada and Africa. Our first nine months of 2012 international sales were negatively impacted by an estimated \$3.1 million due to the decrease in the exchange rate of the Euro to the U.S. dollar compared to the first nine months of 2011.

Sales by market segment and other revenue: Net infusion therapy sales were \$159.6 million in the first nine months of 2012, an increase of \$13.2 million, or 9%, from the first nine months of 2011. The increases in infusion therapy were primarily from \$5.9 million in higher CLAVE product sales and \$7.5 million in increased custom infusion set sales. The increase in CLAVE product sales and custom infusion set sales was from higher sales in all channels.

Net critical care sales were \$42.4 million in the first nine months of 2012, a decrease of \$4.8 million, or 10%, from the first nine months of 2011. The decrease was from lower domestic and international sales from increased competition. We experienced lower unit sales in certain products and decreased our domestic critical care prices in the middle of 2011 to retain existing customers and attract new customers.

Net oncology sales were \$21.0 million in the first nine months of 2012, an increase of \$2.0 million, or 10%, from the first nine months of 2011. The increase was primarily from higher domestic sales to distributors and through direct sales.

Net other product sales were \$10.8 million in the first nine months of 2012, a decrease of \$1.9 million, or 15%, from the first nine months of 2011. The decrease is primarily from the sale of our former diabetes product line, Orbit, which was sold in November 2011 and consequently there were no Orbit sales after the first quarter of 2012.

Other revenue consists of license, royalty and revenue share income and was approximately \$0.4 million in the first nine months of 2012 and 2011.

Gross margins for the first nine months of 2012 and 2011 were 49% and 47%, respectively. Product mix and favorable exchange rates on the Mexican Peso each contributed to one percentage point of the gross margin increase.

Selling, general and administrative expenses ("SG&A") were \$63.9 million, or 27% of revenues, in the first nine months of 2012, compared with \$63.0 million, or 28% of revenues, in the first nine months of 2011. The 2011 expense includes a one-time expense for the Long-Term Retention Plan ("LTRP") of \$2.0 million. Our sales and marketing compensation and benefits increased by \$0.6 million, promotion costs increased by \$0.5 million, IT consulting and outside services costs increased by \$0.5 million and our stock compensation expense increased by \$1.2 million. The increase in sales and marketing compensation and benefits is primarily the result of the expansion of our sales and marketing workforce by 11 employees. These increases were partially offset by \$0.6 million in lower bad debt expenses.

Research and development expenses (“R&D”) were \$8.4 million, or 4% of revenue, in the first nine months of 2012 compared to \$6.4 million, or 3% of revenue, in the first nine months of 2011. The increase in R&D expenses was primarily from higher project related R&D expenses supporting all our infusion therapy, critical care and oncology market segments. Our R&D projects focus on filling in product line gaps and product enhancements for our product line target markets and creating additional market opportunities.

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

Other income was \$0.4 million in the first nine months of 2012 and \$1.0 million in the first nine months of 2011.

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Income taxes were accrued at an estimated effective tax rate of 33% in the first nine months of 2012 compared to 34% in the first nine months of 2011. The rate differed from the statutory corporate rate of 35% principally because of the effect of foreign and state income taxes, tax credits, deductions for domestic production activities and discrete tax items.

Liquidity and Capital Resources

During the first nine months of 2012, our cash, cash equivalents and investment securities increased by \$44.3 million from \$160.0 million at December 31, 2011 to \$204.3 million at September 30, 2012.

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 changes in net income, accounts receivable, inventories and the timing of tax payments.

Our cash provided by operations was \$40.9 million in the first nine months of 2012. Net income plus adjustments for non-cash net expenses contributed \$49.4 million to cash provided by operations. This was partially offset by the net decrease in changes in operating assets and liabilities of \$8.5 million to cash provided by operations. The \$9.8 million increase in accounts receivable was the largest contributor to the change in operating assets and liabilities. The increase in accounts receivable is primarily due to higher quarterly sales in the third quarter of 2012 compared to the fourth quarter of 2011 and increased days sales outstanding on international receivables which tend to have longer collection periods than domestic receivables.

Investing Activities: Our cash used by investing activities was \$32.2 million in the first nine months of 2012, which was primarily comprised of net investment purchases of \$18.1 million and \$13.2 million in capital purchases. Our property, plant and equipment purchases were primarily comprised of machinery, equipment and mold additions in our United States plant.

While we can provide no assurances, we estimate that our capital expenditures in 2012 will approximate \$16.0 million to \$21.0 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. Amounts of spending are estimates and actual spending may substantially differ from those amounts.

Financing Activities: Our cash provided by financing activities was \$19.4 million in the first nine months of 2012. This was from cash provided by the exercise of stock options and shares purchased by our employees under the employee stock purchase plan, resulting in 532,823 shares issued to our employees and directors. The tax benefits from the exercise of stock options was \$4.0 million in the first nine months of 2012, which fluctuates based principally on when employees choose to exercise their vested stock options.

In July 2010, our Board of Directors approved a share purchase plan to purchase up to \$40.0 million of our common stock. We have purchased \$11.9 million of our stock pursuant to this plan, leaving a balance of \$28.1 million available for future purchases. There were no purchases under this plan in the first nine months of 2012. This plan has no expiration date. We may purchase additional shares in future quarters and expect we would use our cash and investments to fund the share purchases.

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 capital preservation, as further described in Part 1, Item 3. Quantitative and Qualitative Disclosures about Market Risk.

As of September 30, 2012, we have \$15.5 million of cash and cash equivalents held by our foreign subsidiaries, the majority of which is available to fund foreign operations and obligations.

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

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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 liability for 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 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, 2012, 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 non-current income tax liability of \$3.8 million due to the high degree of uncertainty regarding the timing of future cash outflows associated with the liabilities.

	(in thousands)					
Contractual Obligations	Total	2012	2013	2014	2015	2016
Operating leases	\$796	\$79	\$317	\$186	\$151	\$63
Warehouse service agreements	1,130	303	544	283	—	—
Purchase obligations	13,995	13,995	—	—	—	—
	\$15,921	\$14,377	\$861	\$469	\$151	\$63

Critical Accounting Policies

In our Annual Report on Form 10-K for the year ended December 31, 2011, 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 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:

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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; expected increases or decreases in sales; deferred revenue; 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 and use of foreign currency, selling prices; foreign exchange rate fluctuations, economic conditions in European and other international markets; 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 efforts; inventory requirements; manufacturing efficiencies and cost savings; unit manufacturing costs; establishment of production facilities outside the U.S.; planned capital purchases for manufacturing operations and investments in information technology; adequacy of production capacity; results of R&D; planned growth of our sales and marketing group; effect of expansion of manufacturing facilities on production efficiencies and resolution of production inefficiencies; business seasonality and fluctuations in quarterly results; customer ordering patterns and the effects of new accounting pronouncements; and

expansion of our custom products business; expectations regarding 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 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; future share repurchases; 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 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, 2011 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, in the U.S., Europe and other international locations;
- 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;

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- 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 bonds, corporate bonds, sovereign bonds and certificates of deposit of \$76.8 million as of September 30, 2012. The securities are all “investment grade”, comprised of \$28.0 million of pre-refunded municipal securities, \$1.6 million of non-pre-refunded municipal securities, \$39.3 million in corporate bonds, \$0.6 million in sovereign bonds and \$7.3 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 \$0.4 million to investment income based on the investment securities balance at September 30, 2012.

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 2011 and our manufacturing spending from 2011 would have impacted our cost of goods sold by approximately \$2.1 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, 2012 and 2011 were approximately €14.5 million and €16.2 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, 2012 spot rate would impact our consolidated amounts on these balance sheet items by approximately \$1.9 million or less than 1% of these net assets. We expect

that in the future, with the growth of our European distribution operation, 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 2011 and 2010, a 10% increase to the price of resin would have resulted in approximately a \$0.9 million change and \$0.7 million change in material cost, respectively.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

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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, 2012 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 continues 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 U.S. Patent No. 5,685,866 ('866 Patent) and ICU's U.S. Patent No. 5,873,862 ('862 Patent); (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.

On May 11, 2012, a bench trial was held on RyMed's prosecution history estoppel defense. The parties have completed a post-trial briefing. Once the Court rules on this defense, a further trial will be scheduled to determine the damages, if any, owing by RyMed to ICU Medical.

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, 2011, 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, 2011.

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Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

In July 2010, our Board of Directors approved a 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 repurchasing activity during the third quarter of 2012:

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
07/01/2012 — 07/31/2012	—	\$—	—	\$ 28,089,000
08/01/2012 — 08/31/2012	—	—	—	28,089,000
09/01/2012 — 09/30/2012	—	—	—	28,089,000
Third quarter of 2012 total	—	\$—	—	\$ 28,089,000

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

Date: October 19, 2012

Exhibit Index

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