ICU MEDICAL INC/DE
Form 10-Q
October 22, 2013

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, 2013
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 (State or other jurisdiction of incorporation or organization)	33-0022692 (I.R.S. Employer Identification No.)
951 Calle Amanecer, San Clemente, California (Address of principal executive offices)	92673 (Zip Code)

(949) 366-2183
(Registrant's telephone number including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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, 2013
Common	14,734,581

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, 2013 (unaudited)	December 31, 2012 (1)
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$188,030	$146,900
Investment securities	72,815	79,259
Cash, cash equivalents and investment securities	260,845	226,159
Accounts receivable, net of allowance for doubtful accounts of $1,093 at September 30, 2013 and $998 at December 31, 2012	51,791	49,127
Inventories	34,153	36,333
Prepaid income taxes	7,680	2,320
Prepaid expenses and other current assets	5,531	7,271
Deferred income taxes	3,818	4,293
Total current assets	363,818	325,503
PROPERTY AND EQUIPMENT, net	88,897	85,937
GOODWILL	1,478	1,478
INTANGIBLE ASSETS, net	8,843	9,952
DEFERRED INCOME TAXES	5,645	5,642
	$468,681	$428,512
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$10,827	$11,308
Accrued liabilities	16,244	17,810
Total current liabilities	27,071	29,118
DEFERRED INCOME TAXES	5,760	5,247
INCOME TAX LIABILITY	3,290	3,290
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, 2013 and December 31, 2012, outstanding 14,727 shares September 30, 2013 and 14,458 shares at December 31, 2012	1,486	1,486
Additional paid-in capital	70,205	63,770
Treasury stock, at cost —128 shares at September 30, 2013 and 397 shares at December 31, 2012	(8,948)	(15,128)
Retained earnings	369,244	342,158
Accumulated other comprehensive income (loss)	573	(1,429)
Total stockholders' equity	432,560	390,857
	$468,681	$428,512

(1) December 31, 2012 balances were derived from audited consolidated financial statements.
The accompanying notes are an integral part of these condensed consolidated financial statements.

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ICU Medical, Inc. and Subsidiaries
Condensed Consolidated Statements of Income
(Amounts in thousands, except per share data)
(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2013	2012	2013	2012
REVENUES:				
Net sales	$82,709	$81,266	$235,419	$233,788
Other	106	139	356	409
TOTAL REVENUE	82,815	81,405	235,775	234,197
COST OF GOODS SOLD	41,860	40,710	119,988	119,455
Gross profit	40,955	40,695	115,787	114,742
OPERATING EXPENSES:			—	—
Selling, general and administrative	22,399	20,177	68,447	63,873
Research and development	3,140	2,988	8,949	8,410
Total operating expenses	25,539	23,165	77,396	72,283
Income from operations	15,416	17,530	38,391	42,459
OTHER INCOME	190	158	570	438
Income before income taxes	15,606	17,688	38,961	42,897
PROVISION FOR INCOME TAXES	(4,572)	(5,500)	(11,875)	(13,959)
NET INCOME	$11,034	$12,188	$27,086	$28,938
NET INCOME PER SHARE				
Basic	$0.75	$0.85	$1.85	$2.04
Diluted	$0.72	$0.82	$1.79	$1.98
WEIGHTED AVERAGE NUMBER OF SHARES				
Basic	14,684	14,321	14,603	14,153
Diluted	15,324	14,826	15,139	14,613

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,	
	2013	2012	2013	2012
Net income	$11,034	$12,188	$27,086	$28,938
Other comprehensive income (loss), net of tax of $713 and $255 for the three months ended September 30, 2013 and 2012, respectively and $450 and $(132) for the nine months ended September 30, 2013 and 2012, respectively:				
Foreign currency translation adjustment	3,223	1,737	2,002	(280)
Comprehensive income	$14,257	$13,925	$29,088	$28,658

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,	
	2013	2012
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$27,086	$28,938
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	14,451	14,262
Provision for doubtful accounts	40	(143)
Provision for warranty and returns	124	291
Stock compensation	4,133	4,361
Loss (gain) on disposal of property and equipment	(20)	41
Bond premium amortization	2,045	1,660
Cash provided (used) by changes in operating assets and liabilities		
Accounts receivable	(2,538)	(9,790)
Inventories	2,471	2,974
Prepaid expenses and other assets	1,572	792
Accounts payable	(790)	(943)
Accrued liabilities	(1,236)	682
Prepaid and deferred income taxes	(5,094)	(2,194)
Net cash provided by operating activities	42,244	40,931
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(15,223)	(13,208)
Proceeds from sale of assets	21	10
Intangible asset additions	(839)	(951)
Purchases of investment securities	(71,919)	(78,534)
Proceeds from sale of investment securities	76,681	60,452
Net cash used by investing activities	(11,279)	(32,231)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	5,016	13,214
Proceeds from employee stock purchase plan	2,457	2,220
Tax benefits from exercise of stock options	4,567	4,002
Treasury stock acquired - share awards swap	(3,033)	—
Net cash provided by financing activities	9,007	19,436
Effect of exchange rate changes on cash	1,158	(202)
NET INCREASE IN CASH AND CASH EQUIVALENTS	41,130	27,934
CASH AND CASH EQUIVALENTS, beginning of period	146,900	99,590
CASH AND CASH EQUIVALENTS, end of period	$188,030	$127,524
NON-CASH INVESTING ACTIVITIES		
Accrued liabilities for property and equipment	$273	$288

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

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ICU Medical, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements
Three and nine months ended September 30, 2013 and 2012
(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, filed with the SEC for the year ended December 31, 2012.

We operate in one business segment engaged in the development, manufacturing and sale of innovative medical devices used in infusion therapy, oncology and critical care applications. Our 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 July 2013, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") number 2013-11, Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists — a consensus of the FASB Emerging Issues Task Force. ASU 2013-11 generally requires, with some exceptions, an entity to present its unrecognized tax benefits as it relates to its net operating loss carryforwards, similar tax losses, or tax credit carryforwards, as a reduction of deferred tax assets when settlement in this regard is available under the tax law of the applicable taxing jurisdiction as of the balance sheet reporting date. It is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013. Retrospective application is permitted. We do not anticipate a material impact on our financial position, results of operations or cash flows as a result of this change.

In February 2013, the FASB issued ASU number 2013-02, Other Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income to improve the reporting of reclassifications out of accumulated other comprehensive income. ASU 2013-02 requires reporting the effect of significant reclassifications out of accumulated other comprehensive income on the respective line items in net income. It is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2012. The adoption of this ASU does not affect our consolidated financial statements, but could require additional disclosure if applicable in future periods.

Note 3: Fair Value Measurement:

Our 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. As of September 30, 2013, we had $3.6 million of our investment securities as Level 1 assets, which are certificates of deposit with quoted prices in active markets, and $69.2 million of our 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. We had no Level 3 investments for the three and nine months ended September 30, 2013 and September 30, 2012. The following table provides the assets and liabilities carried at fair value measured on a recurring basis.

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	Fair value measurements at September 30, 2013 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	$72,815	$3,580	$69,235	$—
	$72,815	$3,580	$69,235	$—

	Fair value measurements at December 31, 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	$79,259	$8,490	$70,769	$—
	$79,259	$8,490	$70,769	$—

Note 4: Investment Securities:

Our 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 (loss) in the stockholders' equity section of our consolidated balance sheets. We had no gross unrealized gains or losses on available-for-sale securities at September 30, 2013 or December 31, 2012. The scheduled maturities of the debt securities are between 2013 and 2040 and are all callable within one year. The investment securities consist of the following at September 30, 2013 and December 31, 2012:

	September 30, 2013	December 31, 2012
Federal tax-exempt debt securities	$21,653	$23,732
Corporate bonds	47,582	47,037
Certificates of deposit	3,580	8,490
	$72,815	$79,259

Note 5: Inventories:

Inventories consisted of the following:

	September 30, 2013	December 31, 2012
Raw material	$18,704	$20,808
Work in process	4,134	3,013
Finished goods	11,315	12,512
Total	$34,153	$36,333

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Note 6: Property and Equipment:

Property and equipment consisted of the following:

	September 30, 2013	December 31, 2012
Machinery and equipment	$82,121	$78,332
Land, building and building improvements	64,220	61,521
Molds	30,159	27,704
Computer equipment and software	21,296	19,611
Furniture and fixtures	3,496	3,339
Construction in progress	8,854	8,266
Total property and equipment, cost	210,146	198,773
Accumulated depreciation	(121,249)	(112,836)
Net property and equipment	$88,897	$85,937

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. There were no anti-dilutive options for the three months ended September 30, 2013 and September 30, 2012, respectively. Options that are anti-dilutive because their exercise price exceeded the average market price of the common stock for the period approximated 8,000 and 5,000 for the nine months ended September 30, 2013 and September 30, 2012, 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,	
	2013	2012	2013	2012
Net income	$11,034	$12,188	$27,086	$28,938
Weighted average number of common shares outstanding (for basic calculation)	14,684	14,321	14,603	14,153
Dilutive securities	640	505	536	460
Weighted average common and common equivalent shares outstanding (for diluted calculation)	15,324	14,826	15,139	14,613
EPS — basic	$0.75	$0.85	$1.85	$2.04
EPS — diluted	$0.72	$0.82	$1.79	$1.98

Note 8: Major Customer:

We had revenues equal to 10% or more of total revenues from one customer, Hospira, Inc. Such revenues were 40% and 44% of total revenue for the three months ended September 30, 2013 and 2012, respectively and 40% and 41% of total revenue for the nine months ended September 30, 2013 and 2012, respectively. As of September 30, 2013 and December 31, 2012, we had accounts receivable from Hospira of 39% and 35% of consolidated accounts receivable, respectively.

Note 9: Income Taxes:

Income taxes were accrued at an estimated effective tax rate of 30% and 33% in the first nine months of 2013 and 2012, 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, including the extension of the federal research and development credit for the 2012 tax year.

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Note 10: Treasury Stock:

In the first nine months of 2013, we acquired 43,188 shares of our common stock from employee option exercises and vested restricted stock by remitting $3.0 million in payments for the employee's share award income tax withholding obligations. In the first nine months of 2013, we also acquired 94,535 shares of our common stock from option exercises with shares remitted back to us in lieu of a cash payment for the option exercise.

Note 11: Commitments and Contingencies:

From time to time, we are involved in various legal proceedings, most of which are routine litigation, in the normal course of business. Our management does not believe that the resolution of the other legal proceedings that we are involved with will have a material adverse impact on our financial position or results of operations.

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.

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

We are a leader in the development, manufacture and sale of innovative medical 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 and patients from exposure to infectious diseases or hazardous drugs and monitoring continuous cardiac output of critical care patients. Our complete product line includes custom infusion systems, closed delivery systems for 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 37% of our revenues in 2012 and 36% of our revenues in the first nine months of 2013.

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. We recently introduced the Neutron, a catheter patency device using Clave technology, the NanoClave, a smaller Clave product designed for neonatal and pediatric patients, CardioFlo Hemodynamic Monitoring Sensor System, a minimally invasive monitoring sensor for use on critical care patients and the Diana Hazardous Drug Compounding System, an automated sterile compounding system for preparing hazardous drugs. 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 the extension of the term of our 2008 agreement with 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
  MicroClave/ MicroClave Clear
  Anti-Microbial MicroClave
  Neutron
  Clave
  NanoClave
  Y-Clave

Anti-Microbial Clave
•Custom infusion sets

Critical Care
•Hemodynamic monitoring systems
Transpac disposable pressure transducers
SAFESET closed needlefree blood conservation systems
CardioFlo hemodynamic monitoring sensor system
Custom monitoring systems
•Catheters
Advanced sensor catheters
Pulmonary artery thermodilution catheters
Central venous oximetry catheters
Multi-lumen central venous catheters
•Custom angiography and interventional radiology kits
Oncology
•ChemoClave closed system transfer device including:
Genie closed vial access device
Spiros closed male luer
Vial and bag access devices
•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 40% and 42% of our worldwide revenues in the first nine months of 2013 and each of the years ended 2012 and 2011, 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. 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 2013 and the years ended 2012 and 2011 were $235.8 million, $316.9 million and $302.2 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 sterile, bulk, non-sterile connectors and oncology products. 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 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

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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:

	Three months ended September 30,		Nine months ended September 30,		Fiscal year ended	
Product line	2013	2012	2013	2012	2012	2011
Clave products	36 %	37 %	36 %	37 %	37 %	36 %
Custom infusion therapy	28 %	28 %	28 %	27 %	27 %	25 %
Other infusion therapy	4 %	5 %	4 %	4 %	4 %	5 %
Infusion therapy	68 %	70 %	68 %	68 %	68 %	66 %
Critical care	16 %	16 %	16 %	18 %	17 %	20 %
Oncology	12 %	9 %	12 %	9 %	10 %	8 %
TEGO	3 %	3 %	3 %	3 %	3 %	3 %
Other products/other revenue	1 %	2 %	1 %	2 %	2 %	3 %
Other	4 %	5 %	4 %	5 %	5 %	6 %
	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 are also converting existing warehouse space into manufacturing space and a new clean room at our Salt Lake City plant, which we expect to be completed in early 2014. 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.

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	2013	2012	2013	2012	2012	2011
Medical product manufacturers	37 %	41 %	36 %	39 %	40 %	39 %
Domestic distributors/direct sales	36 %	36 %	36 %	35 %	35 %	35 %
International customers	27 %	23 %	28 %	26 %	25 %	26 %
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

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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, 2013 and 2012 and the year ended December 31, 2012, 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	
	2013		2012		2013		2012		2012	
Total revenues	100	%	100	%	100	%	100	%	100	%
Gross margin	49	%	50	%	49	%	49	%	49	%
Selling, general and administrative expenses	27	%	25	%	29	%	27	%	27	%
Research and development expenses	3	%	3	%	4	%	4	%	3	%
Total operating expenses	30	%	28	%	33	%	31	%	30	%
Income from operations	19	%	22	%	16	%	18	%	19	%
Other income	—	%	—	%	—	%	—	%	—	%
Income before income taxes	19	%	22	%	16	%	18	%	19	%
Income taxes	6	%	7	%	5	%	6	%	6	%
Net income	13	%	15	%	11	%	12	%	13	%

Quarter Ended September 30, 2013 Compared to the Quarter Ended September 30, 2012

Revenues were $82.8 million in the third quarter of 2013, compared to $81.4 million in the third quarter of 2012.

Domestic sales: Net domestic sales in the third quarter of 2013 were $60.3 million, compared to net domestic sales of $62.5 million in third quarter of 2012, a decrease of 4%.

Net domestic sales to Hospira were $29.8 million in the third quarter of 2013, compared to $33.1 million in the third quarter of 2012, a decrease of 10%. Infusion therapy sales decreased $3.7 million in the third quarter of 2013 from the third quarter of 2012. Oncology sales increased $0.4 million in the third quarter of 2013 from the third quarter of 2012. The decrease in infusion therapy was due to continued improvements in Hospira's inventory management, resulting in $1.8 million in lower Clave product unit sales and $1.0 million in lower custom infusion product unit sales.

Net other domestic sales (excluding Hospira) in the third quarter of 2013 were $30.5 million, an increase of $1.1 million, or 4%, from the third quarter of 2012. Infusion therapy sales increased $1.3 million, or 9%, from the third quarter of 2012, which was primarily from an increase in custom infusion set sales and Clave product sales, both due to increased unit sales. Oncology sales increased $0.4 million, or 28%, from the third quarter of 2012. The increased oncology sales were due to increased unit sales from increased market share and demographic growth. Critical care sales decreased $0.3 million, or 3%, from the third quarter of 2012. The critical care decrease was due to lower unit sales, primarily from competition in this market. We expect modest increases in other domestic sales (excluding Hospira) in 2013 compared to 2012, 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 $22.5 million in the third quarter of 2013, an increase of $3.6 million, or 19%, from the third quarter of 2012. Infusion therapy sales increased $1.5 million, or 13%, from the third quarter of 2012. Oncology sales increased $1.5 million, or 40% from the third quarter of 2012. Critical care sales increased $0.9 million, or 31% from the third quarter of 2012. Other product sales decreased $0.3 million, or 34% from the third quarter of 2012. The increase in oncology sales was from increased unit sales inside and outside of Europe. The increase in critical care was from higher unit sales inside and outside of Europe. The decrease in other product sales was primarily from decreased Tego sales inside and outside of Europe.

Geographically, our third quarter of 2013 international sales were primarily in Europe, the Pacific Rim, Latin America and Canada. The $3.6 million increase in international sales was primarily attributable to $1.4 million, $0.9 million and $0.8 million increased sales in Pacific Rim, Europe and Latin America, respectively. We expect moderate increases in international sales from higher infusion therapy and oncology sales, although there is no assurance that these expectations will be realized.

Sales by market segment and other revenue: Net infusion therapy sales were $56.3 million in the third quarter of 2013, a decrease of $0.9 million, or 2%, from the third quarter of 2012. The decrease in infusion therapy was from $0.4 million in lower Clave product sales and $0.8 million in lower other infusion product sales, partially offset by $0.4 million in higher custom infusion product sales. We expect modest increases in infusion therapy sales in 2013 compared to 2012, primarily from higher custom infusion set sales. There is no assurance, however, that these expectations will be realized.

Net critical care sales were $13.5 million in the third quarter of 2013, an increase of $0.5 million, or 4%, from the third quarter of 2012. The increase was from higher international sales. We expect critical care sales to decrease in 2013 compared to 2012 from competition, although there is no assurance that these expectations will be realized.

Net oncology sales were $9.9 million in the third quarter of 2013, an increase of $2.4 million, or 32%, from the third quarter of 2012. The increase was from higher sales in all channels. We expect growth in oncology sales in 2013 compared to 2012, although there is no assurance that these expectations will be realized.

Net other product sales were $3.0 million in the third quarter of 2013, a decrease of $0.6 million, or 17%, from the third quarter of 2012. The decrease is primarily from lower Tego unit sales

Other revenue consists of license, royalty and revenue share income and was approximately $0.1 million in the third quarters of 2013 and 2012.

Gross margins for the third quarters of 2013 and 2012 were 49% and 50%, respectively. The decrease is primarily from the mix of products sold during the third quarter of 2013 compared to the third quarter of 2012, and was partially offset by lower freight expenses.

Selling, general and administrative expenses ("SG&A") were $22.4 million, or 27% of revenues, in the third quarter of 2013, compared with $20.2 million, or 25%, of revenues in third quarter of 2012. The new medical device excise tax, which became effective in 2013, contributed $0.5 million to our 2013 SG&A expenses. Sales and marketing promotion costs increased by $0.5 million in the third quarter of 2013 compared to the third quarter of 2012. In the third quarter of 2013, we also incurred one-time charges of $0.8 million associated with a strategic transaction that did not go forward. We expect SG&A expenses in 2013 to be approximately 28% of revenue, although there is no assurance that these expectations will be realized.

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Research and development expenses ("R&D") were $3.1 million, or 3% of revenue, in the third quarter of 2013 compared to $3.0 million, or 3%, of revenue in the third quarter of 2012. We expect R&D expenses in 2013 to be approximately 3% of revenue, although there is no assurance that these expectations will be realized.

Other income was $0.2 million in the third quarter of 2013 and $0.2 million in the third quarter of 2012.

Income taxes were accrued at an estimated effective tax rate of 29% in the third quarter of 2013 and 31% in the third quarter of 2012. 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 31% in 2013, including discrete tax items.

Nine Months Ended September 30, 2013 Compared to the Nine Months Ended September 30, 2012

Revenues were $235.8 million in the first nine months of 2013, compared to $234.2 million in the first nine months of 2012.

Domestic sales: Net domestic sales in the first nine months of 2013 were $169.3 million, compared to net domestic sales of $174.7 million in the first nine months of 2012, a decrease of 3%.

Net domestic sales to Hospira in the first nine months of 2013 were $83.1 million, a decrease of $5.9 million, or 7%, from the first nine months of 2012. The decrease was primarily from infusion therapy unit sales which decreased $6.8 million from the first nine months of 2012. The decrease in infusion therapy was primarily from $3.7 million in lower Clave product unit sales, $1.5 million in lower custom infusion set unit sales and $1.6 million in lower other infusion therapy sales. The decrease in infusion therapy was primarily from Hospira's planned reduction in Clave shipments in the first quarter of 2013. Hospira's planned reduction in the first quarter of 2013 and continued improvements in inventory management to achieve carrying lower levels of inventory. Oncology sales increased $0.9 million. The increase in oncology sales was from higher unit sales.

Net other domestic sales (excluding Hospira) in the first nine months of 2013 were $86.2 million, an increase of $0.5 million, or 1%, from the first nine months of 2012. Infusion therapy sales increased $3.6 million, or 9%, from the first nine months of 2012, which was primarily from a $2.7 million increase in custom infusion set sales and a $0.7 million increase in Clave product sales, both increases are due to increased unit sales. Critical care sales decreased $3.3 million, or 11%, from the first nine months of 2012. The critical care decrease was primarily from competition in this market. Oncology sales increased $1.3 million, or 30%, from the first nine months of 2012 due to higher unit sales. Other product sales decreased $1.1 million from the first nine months of 2012. The decrease is primarily due to $0.5 million in lower TEGO sales from lower unit sales and $0.3 million of sales in 2012 from our former diabetes product line, Orbit. The Orbit product line was sold in November 2011 and Orbit sales concluded in the first quarter of 2012.

International sales: Net sales to international customers were $66.5 million in the first nine months of 2013, an increase of $7.0 million, or 12%, from the first nine months of 2012. Infusion therapy sales increased $3.5 million, or 10%, from the first nine months of 2012, which was primarily from a $2.0 million increase in Clave product sales and a $2.5 million increase in custom infusion set sales, partially offset by $1.0 million in lower other infusion product sales. Oncology sales increased $4.1 million from the first nine months of 2012. Critical care sales decreased $0.1 million from the first nine months of 2012. Other product sales decreased $0.5 million. The increases in infusion therapy and oncology sales were from increased unit sales due to increased market share and demographic growth. In other product sales, renal product sales increased $0.3 million from the first nine months of 2012. Sales from our former diabetes product line, Orbit, were $0.6 million lower from the first nine months of 2012.

Geographically, our first nine months of 2013 international sales were primarily in Europe, the Pacific Rim, Latin America and Canada. The $7.0 million increase in international sales was primarily attributable to $3.4 million, $1.6 million, $0.9 million and $0.7 million increased sales in Europe, Pacific Rim, Canada and Latin America, respectively.

Sales by market segment and other revenue: Net infusion therapy sales were $159.8 million in the first nine months of 2013, an increase of $0.2 million, from the first nine months of 2012. The $3.7 million increase in custom infusion set sales, was partially offset by $1.1 million in lower Clave sales and $2.4 million in lower other infusion product sales. The increase in custom infusion set sales was from higher domestic sales to distributors and through direct sales and higher international sales, partially offset by lower sales to Hospira. The decrease in Clave product sales was from lower sales to Hospira, partially offset by higher sales to domestic distributors and direct customers and to international customers. The decrease in other infusion therapy sales was due to lower unit sales to Hospira in the U.S. and international sales.

Net critical care sales were $38.9 million in the first nine months of 2013, a decrease of $3.4 million, or 8%, from the first nine months of 2012. The decrease was primarily from lower domestic sales from competition.

Net oncology sales were $27.4 million in the first nine months of 2013, an increase of $6.4 million, or 31%, from the first nine months of 2012. The increase was from higher sales in all channels.

Net other product sales were $9.3 million in the first nine months of 2013, a decrease of $1.6 million, or 15%, from the first nine months of 2012. The decrease is primarily due to sales of $0.9 million in the first quarter of 2012 from our former diabetes product line, Orbit.

Other revenue consists of license, royalty and revenue share income and was approximately $0.4 million in the first nine months of 2013 and 2012.

Gross margins for the first nine months of 2013 and 2012 were 49% in both periods. Lower freight expenses added 0.5% to our gross margin and were offset by manufacturing inefficiencies.

Selling, general and administrative expenses ("SG&A") were $68.4 million, or 29% of revenues, in the first nine months of 2013, compared with $63.9 million, or 27% of revenues, in the first nine months of 2012. The new medical device excise tax, which became effective in 2013, contributed $1.3 million of the increase from the first nine months of 2012. Information technology costs increased $1.0 million and sales and marketing travel increased $0.5 million from the first nine months of 2012. In the first nine months of 2013, we also incurred one-time charges of $1.3 million associated with a strategic transaction that did not go forward.

Research and development expenses ("R&D") were $8.9 million, or 4% of revenue, in the first nine months of 2013 compared to $8.4 million, or 4% of revenue, in the first nine months of 2012. The increase in R&D expenses was primarily from increased compensation and benefit expenses from an increase of six R&D employees. Our R&D team focuses on filling in product line gaps and product enhancements for our target markets and creating additional market opportunities.

Other income was $0.6 million in the first nine months of 2013 and $0.4 million in the first nine months of 2012.

Income taxes were accrued at an estimated effective tax rate of 30% in the first nine months of 2013 compared to 33% in the first nine months of 2012. 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, including the extension of the federal research and development credit for the 2012 tax year.

Liquidity and Capital Resources

During the first nine months of 2013, our cash, cash equivalents and investment securities increased by $34.7 million from December 31, 2012 to $260.8 million at September 30, 2013.

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 $42.2 million in the first nine months of 2013. Net income plus adjustments for non-cash net expenses contributed $47.8 million to cash provided by operations. This was partially offset by the net decrease in changes in operating assets and liabilities of $5.6 million to cash provided by operations. The $5.1 million increase in prepaid and deferred income taxes was the largest contributor to the change in operating assets and liabilities. The increase in prepaid and deferred income taxes is primarily due to the timing of income tax payments.

Investing Activities: Our cash used by investing activities was $11.3 million in the first nine months of 2013, which was primarily comprised of $15.2 million in capital purchases, partially offset by net investment sales of $4.8 million. Our property, plant and equipment purchases were primarily comprised of machinery, equipment and mold additions in our United States plant and machinery and equipment in our Mexico plant.

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While we can provide no assurances, we estimate that our capital expenditures in 2013 will approximate $20.0 million to $24.0 million. Our capital expenditures include planned building improvements to prepare for anticipated capacity requirements beyond 2013. At our Salt Lake City, Utah plant, we are converting existing warehouse space into manufacturing space and a new clean room. We are also making investments in molds, machinery and equipment in our manufacturing operations in the United States and Mexico to support new and existing products and investments in information technology that benefit world-wide operations. We expect to use our cash and investments to fund our capital purchases. These planned amounts of spending are estimates and actual spending may substantially differ from these amounts.

Financing Activities: Our cash provided by financing activities was $9.0 million in the first nine months of 2013. Cash provided by the exercise of stock options and shares purchased by our employees under the employee stock purchase plan was $7.5 million, resulting in 389,824 shares issued to our employees and directors. The tax benefits from share awards was $4.5 million in the first nine months of 2013, which fluctuates based principally on when employees choose to exercise their vested stock options. In the first nine months of 2013, we acquired 43,188 shares of our common stock from employee option exercises and vested restricted stock by remitting $3.0 million in payments for the employee's share award income tax withholding obligations.

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 2013. 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, 2013, we have $15.1 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 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.

Contractual Obligations

We have contractual obligations, at September 30, 2013, 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 $3.3 million due to the high degree of uncertainty regarding the timing of future cash outflows associated with the liabilities.

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	(in thousands)				
Contractual Obligations	Total	2013	2014	2015	2016
Operating leases	$465	$81	$170	$151	$63
Warehouse service agreements	387	89	298	—	—
Purchase obligations	8,686	8,686	—	—	—
	$9,538	$8,856	$468	$151	$63

Critical Accounting Policies

In our Annual Report on Form 10-K for the year ended December 31, 2012, 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 “anticipate,” “believe,” “expect,” “estimate,” “plan,” “will,” “continue,” “could,” “may,’ similar expressions and statements about aims, goals and plans. The forward looking statements are based on the best information currently available to us and assumptions that we believe are reasonable, but we do not intend the statements to be representations as to future results. They include, without limitation, statements about:

- future operating results including income, losses, cash flow, anticipated expenditures on sales and marketing and product development, expected increases or decreases in sales, gross margins, capital expenditures;
- our expectations relating to various elements of operating results, including unit volumes of products, selling prices, production costs, unit manufacturing costs, litigation expense, SG&A and R&D expenses, source and sufficiency of funds for capital purchases and operations, tax rates, and changes in working capital items such as receivables and inventory;
- factors affecting operating results, such as shipments to specific customers, reduced dependence on current proprietary products, expansion in international markets, 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, plans to convert existing warehouse space into manufacturing space and a new clean room, planned capital purchases for molds, machinery and equipment in our manufacturing operations and investments in information technology, adequacy of production capacity, results of R&D, planned building improvements to prepare for anticipated capacity requirements, planned growth of our sales and marketing group, business seasonality, customer ordering patterns, production scheduling and inventory levels and the effects of new accounting pronouncements;
- 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, including the effects of the planned reduction in Clave shipments in 2013, and the importance of Hospira to our growth and our positioning with respect to new product introductions and market share, expectations regarding days' sales outstanding in Hospira accounts receivable;

- the development of our strategic relationships, including securing long-term contracts with large healthcare providers and major buying organizations;

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- competitive and market factors, including continuing development of competing products by other manufacturers and consolidation of the healthcare provider market; and

- anticipated 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, investors 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, 2012 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;

- the impact of litigation, including our ongoing ligation with RyMed Technologies, Inc.;

- 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

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Financial Market Risk

We had a portfolio of federal tax-exempt state and municipal government bonds, corporate bonds and certificates of deposit of $72.8 million as of September 30, 2013. The securities are all "investment grade", comprised of $21.2 million of pre-refunded municipal securities, $0.4 million of non-pre-refunded municipal securities, $47.6 million in corporate bonds and $3.6 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 $0.5 million to investment income based on the investment securities balance at September 30, 2013.

Foreign Exchange Risk

We have foreign currency exchange risk related to foreign-denominated cash, short-term investments, accounts receivable and accounts payable. In our European operations, our net Euro asset position at September 30, 2013 was approximately €15.5 million. We also have approximately €39.6 million in Euro denominated cash and investment accounts
held by our corporate entity. 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, 2013 spot rate would impact our consolidated amounts on these balance sheet items by approximately $7.4 million, or 2.6% 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.

Sales from the U.S. to foreign distributors are 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, although 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 2012 and our manufacturing spending from 2012 would have impacted 2012 cost of goods sold by approximately $2.2 million.

Commodity Risk

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 2012, a 10% increase to the price of resin would have resulted in approximately a $1.0 million change in material cost.

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, 2013 that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

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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. On September 30, 2013, the Court ruled that ICU could not overcome this defense as to the verdicts based on the doctrine of equivalents. We are currently considering options to appeal or to proceed to the damages phase of the case.

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, 2012, 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, 2012.

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 2013:

Period	Shares purchased	Average price paid	Shares purchased as	Approximate dollar value that

		per share	part of a publicly announced program	may yet be purchased under the program
07/01/2013 — 07/31/2013	—	$—	—	$ 28,089,000
08/01/2013 — 08/31/2013	—	—	—	28,089,000
09/01/2013 — 09/30/2013	—	—	—	28,089,000
Third quarter of 2013 total	—	$—	—	$ 28,089,000

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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+

+ These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.

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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 22, 2013
Scott E. Lamb		
Chief Financial Officer		
(Principal Financial Officer)		

Exhibit Index

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+

+ These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.

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