

ICU MEDICAL INC/DE
Form 10-Q
May 07, 2014

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: March 31, 2014

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)	33-0022692 (I.R.S. Employer Identification No.)
951 Calle Amanecer, San Clemente, California (Address of principal executive offices)	92673 (Zip Code)
(949) 366-2183 (Registrant's telephone number including area code)	

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

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

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

Large accelerated filer <input checked="" type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input type="checkbox"/>

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	Outstanding at April 21, 2014
Common	15,209,943

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)

	March 31, 2014 (unaudited)	December 31, 2013 (1)
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$227,623	\$226,022
Investment securities	76,224	70,869
Cash, cash equivalents and investment securities	303,847	296,891
Accounts receivable, net of allowance for doubtful accounts of \$1,207 at March 31, 2014 and \$1,208 at December 31, 2013	43,323	45,318
Inventories	36,687	34,451
Prepaid income taxes	4,440	5,966
Prepaid expenses and other current assets	8,065	7,319
Deferred income taxes	4,371	4,351
Total current assets	400,733	394,296
PROPERTY AND EQUIPMENT, net	90,379	87,861
GOODWILL	1,478	1,478
INTANGIBLE ASSETS, net	8,013	8,490
DEFERRED INCOME TAXES	5,829	7,518
	\$506,432	\$499,643
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$11,714	\$11,335
Accrued liabilities	13,787	15,551
Total current liabilities	25,501	26,886
DEFERRED INCOME TAXES	4,011	3,630
INCOME TAX LIABILITY	2,713	4,402
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 15,202 shares at March 31, 2014 and 15,103 at December 31, 2013, outstanding 15,175 shares March 31, 2014 and 15,102 shares at December 31, 2013	1,520	1,510
Additional paid-in capital	83,043	78,495
Treasury stock, at cost — 27 shares at March 31, 2014 and 1 shares at December 31, 2013	(1,706) (49
Retained earnings	389,233	382,576
Accumulated other comprehensive income	2,117	2,193
Total stockholders' equity	474,207	464,725
	\$506,432	\$499,643

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(1) December 31, 2013 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 March 31,	
	2014	2013
REVENUES:		
Net sales	\$73,113	\$74,173
Other	117	126
TOTAL REVENUE	73,230	74,299
COST OF GOODS SOLD	37,203	37,505
Gross profit	36,027	36,794
OPERATING EXPENSES:		
Selling, general and administrative	22,519	22,866
Research and development	3,631	1,903
Total operating expenses	26,150	24,769
Income from operations	9,877	12,025
OTHER INCOME	210	168
Income before income taxes	10,087	12,193
PROVISION FOR INCOME TAXES	(3,430)	(3,508)
NET INCOME	\$6,657	\$8,685
NET INCOME PER SHARE		
Basic	\$0.44	\$0.60
Diluted	\$0.43	\$0.58
WEIGHTED AVERAGE NUMBER OF SHARES		
Basic	15,097	14,507
Diluted	15,395	15,053

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 March 31,	
	2014	2013
Net income	\$6,657	\$8,685
Other comprehensive income, net of tax of (\$21) and (\$493) for the three months ended March 31, 2014 and 2013, respectively:		
Foreign currency translation adjustment	(76) (2,370
Comprehensive income	\$6,581	\$6,315

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)

	Three months ended March 31,	
	2014	2013
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	\$6,657	\$8,685
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	4,765	4,712
Provision for doubtful accounts	3	(191)
Provision for warranty and returns	(410)	(6)
Stock compensation	1,973	1,390
Gain on disposal of property and equipment	(5)	—
Bond premium amortization	601	675
Cash provided (used) by changes in operating assets and liabilities		
Accounts receivable	2,416	(3,981)
Inventories	(2,267)	(578)
Prepaid expenses and other assets	(800)	1,234
Accounts payable	382	(244)
Accrued liabilities	(2,557)	(2,949)
Income taxes, including excess tax benefits and deferred income taxes	1,956	2,017
Net cash provided by operating activities	12,714	10,764
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(5,908)	(5,831)
Proceeds from sale of assets	5	—
Intangible asset additions	(120)	(355)
Purchases of investment securities	(36,908)	(19,131)
Proceeds from sale of investment securities	30,936	18,317
Net cash used by investing activities	(11,995)	(7,000)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	4,202	2,904
Proceeds from employee stock purchase plan	1,384	1,267
Tax benefits from exercise of stock options	1,178	1,034
Purchase of treasury stock	(5,835)	—
Net cash provided by financing activities	929	5,205
Effect of exchange rate changes on cash	(47)	(1,238)
NET INCREASE IN CASH AND CASH EQUIVALENTS	1,601	7,731
CASH AND CASH EQUIVALENTS, beginning of period	226,022	146,900
CASH AND CASH EQUIVALENTS, end of period	\$227,623	\$154,631
NON-CASH INVESTING ACTIVITIES		
Accrued liabilities for property and equipment	\$1,008	\$196

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 Months Ended March 31, 2014 and 2013

(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, 2013.

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 April 2014, the Financial Accounting Standards Board issued Accounting Standards Update ("ASU") number 2014-08, Presentation of Financial Statements (Topic 205) and Property, Plant, and Equipment (Topic 360): Reporting Discontinued Operations and Disclosure of Disposals of Components of an Entity. This ASU changes the criteria for reporting discontinued operations and adds additional disclosures on discontinued operations. ASU 2014-08 improves the definition of discontinued operations by limiting discontinued operations reporting to disposals of components of an entity that represent strategic shifts that have or will have a major effect on an entities operations and financial results. Under current U.S. GAAP, disposals of small groups of assets that are recurring in nature and do not change an entity's strategy currently qualify for discontinued operations. ASU 2014-08 is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2014. We do not anticipate a material impact on our consolidated financial statements from adoption of this ASU.

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 March 31, 2014, we had \$5.5 million of our investment securities as Level 1 assets, which are certificates of deposit with quoted prices in active markets, and \$70.7 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. 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 March 31, 2014 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	\$76,224	\$5,540	\$70,684	\$—
	\$76,224	\$5,540	\$70,684	\$—

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	Fair value measurements at December 31, 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	\$70,869	\$3,205	\$67,664	\$—
	\$70,869	\$3,205	\$67,664	\$—

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 in the stockholders' equity section of our consolidated balance sheets. We had no gross unrealized gains or losses on available-for-sale securities at March 31, 2014 or December 31, 2013. The scheduled maturities of the debt securities are between 2014 and 2040 and are all callable within one year. The investment securities consist of the following at March 31, 2014 and December 31, 2013:

	March 31, 2014	December 31, 2013
Federal tax-exempt debt securities	\$22,375	\$21,968
Corporate bonds	48,309	45,696
Certificates of deposit	5,540	3,205
	\$76,224	\$70,869

Note 5: Inventories:

Inventories consisted of the following:

	March 31, 2014	December 31, 2013
Raw material	\$20,722	\$21,867
Work in process	4,849	2,749
Finished goods	11,116	9,835
Total	\$36,687	\$34,451

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Note 6: Property and Equipment:

Property and equipment consisted of the following:

	March 31, 2014	December 31, 2013
Machinery and equipment	\$87,318	\$84,317
Land, building and building improvements	64,310	64,238
Molds	31,894	30,813
Computer equipment and software	21,777	21,625
Furniture and fixtures	3,655	3,552
Construction in progress	10,642	8,456
Total property and equipment, cost	219,596	213,001
Accumulated depreciation	(129,217) (125,140
Net property and equipment	\$90,379	\$87,861

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 237,000 for the three months ended March 31, 2014 and 142,000 for the three months ended March 31, 2013, respectively.

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

	Three months ended March 31,	
	2014	2013
Net income	\$6,657	\$8,685
Weighted average number of common shares outstanding (for basic calculation)	15,097	14,507
Dilutive securities	298	546
Weighted average common and common equivalent shares outstanding (for diluted calculation)	15,395	15,053
EPS — basic	\$0.44	\$0.60
EPS — diluted	\$0.43	\$0.58

Note 8: Major Customer:

We had revenues equal to 10% or more of total revenues from one customer, Hospira, Inc. Such revenues were 35% and 38% of total revenue for the three months ended March 31, 2014 and 2013, respectively. As of March 31, 2014 and December 31, 2013, we had accounts receivable from Hospira of 46% and 32% of consolidated accounts receivable, respectively.

Note 9: Income Taxes:

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Income taxes were accrued at an estimated effective tax rate of 34% and 29% in the first quarter of 2014 and 2013, 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.

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Note 10: 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.

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 infectious diseases or hazardous drugs. Our complete product line includes needlefree infusion connectors, custom infusion systems, hemodynamic monitoring systems and Closed System Transfer Devices ("CSTD") and systems for handling hazardous drugs.

Business Overview

In the early 1990's, we launched the Clave, an innovative one-piece, needlefree infusion connection device. The Clave is a leader in worldwide connector sales. 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 35% of our revenues in 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 growth strategies is through acquisitions of companies, assets or product lines. We are continuously exploring acquisition opportunities, however 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 2013, we introduced the ChemoLock CSTD. ChemoLock prevents the escape of hazardous drug or vapor concentrations, blocks the transfer of environmental contaminants into the system, and eliminates needlestick injuries. In 2011 and 2012, we introduced the Neutron, a catheter patency device using Clave technology, the NanoClave, a smaller Clave product designed for neonatal and pediatric 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, but are not limited to, our 2014 agreement with Premier, the extension of the term of our agreement with MedAssets and our 2011

agreement with Novation covering all our critical care products. 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.

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Our products are used in hospitals and alternate medical sites in more than 55 countries throughout the world. We categorize our products into three main market segments: Infusion Therapy, Critical Care and Oncology. In prior periods, we included Tego needlefree hemodialysis connector and Lopez enteral valve under "Other". These are now included under Infusion Therapy. Our primary products include:

Infusion Therapy

- Needlefree connector products
 - MicroClave and MicroClave Clear
 - Anti-Microbial MicroClave
 - Neutron
 - NanoClave
 - Clave
 - Y-Clave
 - Anti-Microbial Clave
- Custom infusion sets
- Tego needlefree hemodialysis connector
- Lopez enteral valve

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

- ChemoLock closed system transfer device and components
- ChemoClave closed system transfer device and components including:
 - Genie closed vial access device
 - Spiros closed male luer
- Custom preparation and administration sets and accessories
- Diana hazardous drug compounding system

Our largest customer is Hospira. Hospira accounted for 35%, 39% and 42% of our worldwide revenues in the first quarter of 2014 and the years ended 2013 and 2012, respectively. Our relationship with Hospira has been and will continue to be important. 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. 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 quarter of 2014 and the years ended 2013 and 2012 were \$73.2 million, \$313.7 million and \$316.9 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 and oncology products. Under a 2001 agreement, we sell custom infusion sets to Hospira under a program referred to as SetSource. Our 1995 and 2001 agreements with Hospira provide Hospira with conditional exclusive and nonexclusive rights to distribute all existing ICU Medical products worldwide with terms that extend to 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.

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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	Quarter ended March 31,		Fiscal year ended		
	2014	2013	2013	2012	
Clave products	31	% 35	% 35	% 37	%
Custom infusion therapy	30	% 29	% 29	% 27	%
Other infusion therapy	8	% 8	% 7	% 8	%
Infusion therapy	69	% 72	% 71	% 72	%
Critical care	18	% 17	% 17	% 17	%
Oncology	12	% 11	% 12	% 10	%
Other	1	% —	% —	% 1	%
	100	% 100	% 100	% 100	%

We have an ongoing effort to increase systems capabilities, improve manufacturing efficiency, reduce labor costs, reduce time needed to produce an order, and minimize investment in inventory. This effort includes 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 in our Salt Lake City plant, which we expect to be completed by the second half of 2014. We may establish additional production facilities outside the U.S. There is no assurance that we will achieve success in establishing manufacturing facilities outside the U.S.

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

Channel	Quarter ended March 31,		Fiscal year ended		
	2014	2013	2013	2012	
Medical product manufacturers	36	% 39	% 40	% 43	%
Domestic distributors/direct sales	37	% 35	% 36	% 35	%
International customers	27	% 26	% 24	% 22	%
Total	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 and sales to Hospira for destinations outside of the U.S. are included in sales to medical product manufacturers.

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 months ended March 31, 2014 and 2013 and the year ended December 31, 2013, the percentages of each income statement caption in relation to total revenues.

	Percentage of revenues		Fiscal year	
	Quarter ended March 31, 2014	2013		
Total revenues	100	% 100	% 100	%
Gross margin	49	% 50	% 49	%
Selling, general and administrative expenses	31	% 31	% 28	%
Research and development expenses	5	% 2	% 4	%
Total operating expenses	36	% 33	% 32	%
Income from operations	13	% 17	% 17	%
Other income	—	% —	% —	%
Income before income taxes	13	% 17	% 17	%
Income taxes	4	% 5	% 4	%
Net income	9	% 12	% 13	%

Quarter Ended March 31, 2014 Compared to the Quarter Ended March 31, 2013

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Revenues were \$73.2 million in the first quarter of 2014, compared to \$74.3 million in the first quarter of 2013.

Worldwide Hospira sales: Net sales to Hospira were \$25.5 million in the first quarter of 2014, compared to \$28.3 million in the first quarter of 2013, a decrease of \$2.8 million, or 10%. Infusion therapy sales decreased \$3.2 million in the first quarter of 2014 from the first quarter of 2013. Oncology sales increased \$0.4 million in the first quarter of 2014 from the first

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quarter of 2013. The decrease in infusion therapy was primarily from a decrease in Clave product unit sales. The increase in oncology sales was from higher unit sales. Domestic sales to Hospira were \$21.1 million in the first quarter of 2014, compared to \$25.0 million in the first quarter of 2013. International sales to Hospira were \$4.4 million in the first quarter of 2014, compared to \$3.3 million in the first quarter of 2013.

Non-Hospira sales: Net non-Hospira sales were \$47.7 million in the first quarter of 2014, compared to \$46.0 million in the first quarter of 2013, an increase of \$1.7 million, or 4%.

Net domestic sales were \$27.6 million in the first quarter of 2014, compared to \$27.0 million in the first quarter of 2013. Infusion therapy sales increased \$0.4 million, or 3%, from the first quarter of 2013, which was primarily from an increase in other infusion therapy product sales. Oncology sales were \$1.8 million, an increase of 6%, from the first quarter of 2013. The increased oncology sales were due to increased unit sales from increased market share and demographic growth. Critical care sales were comparable in both quarters.

Non-Hospira net international sales were \$20.1 million in the first quarter of 2014, an increase of \$1.1 million, or 6%, from the first quarter of 2013. Non-Hospira European sales were \$10.1 million in the first quarter of 2014, an increase of \$0.6 million, or 7%, from the first quarter of 2013. Non-Hospira international sales outside of Europe were \$10.0 million in the first quarter of 2014, an increase of \$0.4 million, or 5%, from the first quarter of 2013. Infusion therapy sales increased \$0.3 million, or 3%, from the first quarter of 2013. Oncology sales increased \$0.3 million, or 10% from the first quarter of 2013. Critical care sales increased \$0.3 million, or 9%, from the first quarter of 2013. The increase in infusion therapy sales was primarily from increased international unit sales outside of Europe. The increase in oncology sales was primarily from increased unit sales in Europe. The increase in critical care sales was from increased unit sales inside and outside of Europe.

Sales by market segment and other revenue: Net infusion therapy sales were \$50.8 million in the first quarter of 2014, a decrease of \$2.4 million, or 5%, from the first quarter of 2013. The decrease in infusion therapy was primarily from \$3.4 million in lower Clave product sales, partially offset by \$1.1 million in increased other infusion product sales. The decrease in Clave product sales was from lower sales to Hospira. The increase in other infusion product sales was primarily from higher Tego and Neutron unit sales.

Net critical care sales were \$13.1 million in the first quarter of 2014, an increase of \$0.5 million, or 4%, from the first quarter of 2013. The increase was primarily from higher international unit sales.

Net oncology sales were \$9.0 million in the first quarter of 2014, an increase of \$0.8 million, or 10%, from the first quarter of 2013. The increase was from higher sales in all channels.

Non-product revenue, including freight, service, license, royalty and revenue share income, was approximately \$0.3 million in the first quarter of 2014 and \$0.2 million in the first quarter of 2013.

Gross margins for the first quarters of 2014 and 2013 were 49.2% and 49.5%, respectively. The decline in gross margin is primarily from higher freight expense.

Selling, general and administrative expenses ("SG&A") were \$22.5 million, or 31% of revenues, in the first quarter of 2014, compared with \$22.9 million, or 31% of revenues in the first quarter of 2013. Compensation and benefits and travel expenses decreased by \$1.0 million in first quarter of 2014 compared to the first quarter of 2013. Outside services, including legal expenses, increased by \$0.8 million in first quarter of 2014 compared to the first quarter of 2013.

Research and development expenses (“R&D”) were \$3.6 million, or 5% of revenue, in the first quarter of 2014 compared to \$1.9 million, or 2% of revenue in the first quarter of 2013. The increase in R&D expenses was primarily from increased compensation and benefits expenses from an increase of five R&D employees and increased R&D project expenses.

Other income was \$0.2 million in the first quarters of 2014 and 2013.

Income taxes were accrued at an estimated effective tax rate of 34% in the first quarter of 2014 and 29% in the first quarter of 2013. 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.

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Liquidity and Capital Resources

During the first quarter of 2014, our cash, cash equivalents and investment securities increased by \$6.9 million from \$296.9 million at December 31, 2013 to \$303.8 million at March 31, 2014.

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 \$12.7 million in the first quarter of 2014. Net income plus adjustments for non-cash net expenses contributed \$13.6 million to cash provided by operations. This was partially offset by the net decrease in changes in operating assets and liabilities of \$0.9 million to cash provided by operations.

Investing Activities: Our cash used by investing activities was \$12.0 million in the first quarter of 2014, which was primarily comprised of net investment purchases of \$6.0 million and \$5.9 million in capital purchases. Our property, plant and equipment purchases were primarily for the plant expansion, machinery, equipment and mold additions in our Salt Lake City Plant and investments in IT that benefit world-wide operations.

While we can provide no assurances, we estimate that our capital expenditures in 2014 will approximate \$18.0 million to \$24.0 million. We are currently converting existing warehouse space into manufacturing space and a new clean room at our Salt Lake City plant and estimate 2014 capital expenditures for this expansion to approximately \$7.0 million. We also anticipate 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. Amounts of spending are estimates and actual spending may substantially differ from those amounts.

Financing Activities: Our cash provided by financing activities was \$0.9 million in the first quarter of 2014. Cash and tax benefits provided by the exercise of stock options and shares purchased by our employees under the employee stock purchase plan was \$6.7 million in the first quarter of 2014. In the first quarter of 2014, we withheld 6,031 shares of our common stock from employee option exercises and vested restricted stock units as consideration for making \$0.2 million in payments for the employee's share award 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 purchased \$5.6 million in our common stock in the first quarter of 2014. As of March 31, 2014, we purchased \$17.5 million of our stock pursuant to this plan, leaving a balance of \$22.5 million available for future purchases. 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 March 31, 2014, we have \$26.9 million of cash and cash equivalents held outside of the United States, 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.

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Contractual Obligations

We have contractual obligations, at March 31, 2014, 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 \$2.7 million due to the high degree of uncertainty regarding the timing of future cash outflows associated with the liabilities.

	(in thousands)			
	Total	2014	2015	2016
Contractual Obligations				
Operating leases	\$338	\$124	\$151	\$63
Warehouse service agreements	317	317	—	—
Purchase obligations	7,254	7,254	—	—
	\$7,909	\$7,695	\$151	\$63

Critical Accounting Policies

In our Annual Report on Form 10-K for the year ended December 31, 2013, 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 of Financial Condition and Results of Operations, 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," "intend," "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:

- 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.; 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

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and marketing group; business seasonality and fluctuations in quarterly results; customer ordering patterns, production scheduling and inventory levels 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; expectations regarding days' sales outstanding in Hospira accounts receivable; 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, 2013 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;
- 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.

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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

Financial Market Risk

We had a portfolio of federal tax-exempt state and municipal government bonds, corporate bonds and certificates of deposit of \$76.2 million as of March 31, 2014. The securities are all “investment grade”, comprised of \$21.2 million of pre-refunded municipal securities, \$1.2 million of non-pre-refunded municipal securities, \$48.3 million in corporate bonds and \$5.5 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 annual investment income based on the investment securities balance at March 31, 2014.

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 March 31, 2014 was approximately €23.0 million. We also have approximately €39.3 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 March 31, 2014 spot rate would impact our consolidated amounts on these balance sheet items by approximately \$8.6 million, or 2.7% 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 2013 and our manufacturing spending from 2013 would have impacted our cost of goods sold by approximately \$2.4 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 2013, a 10% increase to the price of resin would have resulted in approximately a \$1.2 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 March 31, 2014 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 continues to vigorously pursue this matter.

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 have overcome this defense based on the doctrine of equivalents. We are currently considering options to appeal and 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, 2013, 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, 2013.

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 first quarter of 2014:

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
01/01/2014 — 01/31/2014	26,748	\$62.98	26,748	\$ 26,404,000
02/01/2014 — 02/28/2014	62,044	62.57	62,044	22,522,000
03/01/2014 — 03/31/2014	—	—	—	22,522,000
First quarter of 2014 total	88,792	\$62.69	88,792	\$ 22,522,000

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Item 6. Exhibits

Exhibit 10.1	2014 Inducement Stock Incentive Plan (1)
Exhibit 10.2	Executive Employment Agreement, dated as of February 7, 2014, by and between ICU Medical, Inc. and Vivek Jain (2)
Exhibit 10.3	Amendment to Executive Employment Agreement, dated as of February 12, 2014, by and between ICU Medical, Inc. and Vivek Jain (2)
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

(1) Filed as an Exhibit to Registrant's Current Report on Form 8-K filed February 26, 2014, and incorporated herein by reference.

(2) Filed as an Exhibit to Registrant's Current Report on Form 8-K filed February 12, 2014, and incorporated herein by reference.

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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: May 7, 2014

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