

ICU MEDICAL INC/DE
Form 10-Q
November 05, 2015

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q
 QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT
OF 1934

For the quarterly period ended: September 30, 2015

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 October 21, 2015
Common	15,976,438

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act):

Yes No

ICU Medical, Inc.

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

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

	September 30, 2015 (unaudited)	December 31, 2014 (1)
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$355,368	\$275,812
Investment securities	38,695	70,952
Cash, cash equivalents and investment securities	394,063	346,764
Accounts receivable, net of allowance for doubtful accounts of \$1,123 at September 30, 2015 and \$1,127 at December 31, 2014	49,242	39,051
Inventories	40,681	36,933
Prepaid income taxes	8,798	3,963
Prepaid expenses and other current assets	14,379	5,818
Deferred income taxes	6,534	4,683
Total current assets	513,697	437,212
PROPERTY AND EQUIPMENT, net	78,768	86,091
GOODWILL	1,478	1,478
INTANGIBLE ASSETS, net	6,365	7,063
DEFERRED INCOME TAXES	9,920	9,258
	\$610,228	\$541,102
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$14,732	\$11,378
Accrued liabilities	22,471	17,350
Total current liabilities	37,203	28,728
LONG-TERM LIABILITIES	1,566	—
DEFERRED INCOME TAXES	3,069	1,376
INCOME TAX LIABILITY	1,222	2,746
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 and outstanding, 15,951 shares at September 30, 2015 and 15,595 shares at December 31, 2014	1,595	1,559
Additional paid-in capital	134,413	107,336
Retained earnings	448,433	408,911
Accumulated other comprehensive loss	(17,273)	(9,554)
Total stockholders' equity	567,168	508,252
	\$610,228	\$541,102

(1) December 31, 2014 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,	
	2015	2014	2015	2014
REVENUES:				
Net sales	\$85,891	\$77,329	\$250,876	\$228,997
Other	125	128	405	367
TOTAL REVENUE	86,016	77,457	251,281	229,364
COST OF GOODS SOLD	39,751	39,310	118,741	117,648
Gross profit	46,265	38,147	132,540	111,716
OPERATING EXPENSES:				
Selling, general and administrative	20,206	21,843	60,698	68,640
Research and development	4,227	5,055	11,657	13,252
Restructuring and strategic transaction	3,411	2,840	3,411	2,840
Gain on sale of building	(1,086)) —	(1,086)) —
Legal settlements	(5,261)) —	1,798	—
Total operating expenses	21,497	29,738	76,478	84,732
Income from operations	24,768	8,409	56,062	26,984
OTHER INCOME	230	155	996	572
Income before income taxes	24,998	8,564	57,058	27,556
PROVISION FOR INCOME TAXES	(8,732)) (2,136)) (17,536)) (8,593)
NET INCOME	\$16,266	\$6,428	\$39,522	\$18,963
NET INCOME PER SHARE				
Basic	\$1.02	\$0.42	\$2.50	\$1.25
Diluted	\$0.98	\$0.42	\$2.41	\$1.22
WEIGHTED AVERAGE NUMBER OF SHARES				
Basic	15,894	15,319	15,790	15,220
Diluted	16,575	15,488	16,409	15,497

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 (Loss)
 (Amounts in thousands)
 (unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Net income	\$16,266	\$6,428	\$39,522	\$18,963
Other comprehensive income (loss), net of tax of \$345 and \$(1,833) for the three months ended September 30, 2015 and 2014, respectively and \$(1,867) and \$(2,060) for the nine months ended September 30, 2015 and 2014, respectively.				
Foreign currency translation adjustment	504	(6,936)	(7,719)	(7,739)
Comprehensive income (loss)	\$16,770	\$(508)	\$31,803	\$11,224

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,	
	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	\$39,522	\$18,963
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	13,266	14,642
Provision for doubtful accounts	53	3
Provision for warranty and returns	38	(488)
Stock compensation	9,305	6,990
Loss (gain) on disposal of property and equipment	(1,102)	8
Bond premium amortization	1,451	1,599
Cash provided (used) by changes in operating assets and liabilities		
Accounts receivable	(11,390)	9,433
Inventories	(4,867)	(4,655)
Prepaid expenses and other assets	(8,824)	2,146
Accounts payable	3,246	681
Accrued liabilities	6,915	2,123
Income taxes, including excess tax benefits and deferred income taxes	(5,177)	(3,098)
Net cash provided by operating activities	42,436	48,347
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(7,729)	(14,924)
Proceeds from sale of asset	3,592	5
Intangible asset additions	(778)	(709)
Purchases of investment securities	(40,217)	(78,993)
Proceeds from sale of investment securities	70,293	69,470
Net cash provided (used) by investing activities	25,161	(25,151)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	10,974	9,105
Proceeds from employee stock purchase plan	2,162	2,485
Tax benefits from exercise of stock options	6,194	2,734
Purchase of treasury stock	(1,523)	(5,836)
Net cash provided by financing activities	17,807	8,488
Effect of exchange rate changes on cash	(5,848)	(5,465)
NET INCREASE IN CASH AND CASH EQUIVALENTS	79,556	26,219
CASH AND CASH EQUIVALENTS, beginning of period	275,812	226,022
CASH AND CASH EQUIVALENTS, end of period	\$355,368	\$252,241
NON-CASH INVESTING ACTIVITIES		
Accrued liabilities for property and equipment	\$1,106	\$100

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
September 30, 2015 and 2014
(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 (U.S.) 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, 2014.

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 U. S. 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: Legal Settlements

On April 2, 2015, an arbitrator ruled on a breach of contract claim between us and a customer, Hospira, Inc., awarding Hospira \$8.2 million Canadian dollars (\$6.5 million U.S. dollars). The arbitrator also ruled that we pay 75% of Hospira's legal fees and expenses, which were \$0.7 million U.S. dollars. We made a \$7.5 million U.S. dollars settlement payment in the second quarter of 2015, which includes a foreign exchange transaction adjustment to Canadian dollars at the time of payment.

On September 23, 2015, an arbitrator ruled on a breach of contract claim between us and a service provider, awarding us \$8.8 million. Our legal counsel for this matter represented us under a contingency fee agreement. We recorded a settlement award, net of legal fees and costs, of \$5.3 million.

Note 3: Restructuring Charges

In the third quarter of 2015, we entered into an agreement with George A. Lopez, M.D, a member of our Board of Directors and a former employee in our research and development department, pursuant to which we bought out Dr. Lopez's right to employment under his then-existing employment agreement. The \$1.8 million buy-out will be paid in equal monthly installments until December 2020. Also in the third quarter of 2015, we reorganized our corporate infrastructure, resulting in one-time employee termination benefits and other associated costs. These restructuring actions resulted in a charge of \$2.3 million in the third quarter of 2015 which is presented as a separate line item combined with strategic transaction expenses on our condensed consolidated statements of income. The \$2.3 million restructuring charge was accrued as of September 30, 2015 and will be paid out monthly until December 2020. Payments that will exceed one year have been accrued under long-term liabilities in our condensed consolidated balance sheet.

In the third quarter of 2014, we reorganized our selling and corporate infrastructure, resulting in a reduction in workforce. We recognized a \$2.8 million restructuring charge for one-time employee termination benefits and other associated costs. The restructuring charge is presented on a separate line item in our condensed consolidated statements of income.

Note 4: Strategic Transaction Expenses

In the third quarter of 2015, we incurred \$1.1 million in charges associated with a strategic transaction that closed in October 2015. See Note 16, Subsequent Events for additional information.

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Note 5: Gain on Sale of Building

On September 30, 2015, we sold an office building in our San Clemente location to Dr. Lopez. The building was sold for \$3.6 million, its fair market value as determined by a third party. The net book value of the land and building was \$2.5 million, resulting in a gain on the sale of the land and building of \$1.1 million.

Note 6: New Accounting Pronouncements

In September 2015, the Financial Accounting Standards Board ("FASB") issued ASU No. 2015-16, Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments. ASU 2015-16 requires that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined, including the cumulative effect of the change in provisional amount as if the accounting had been completed at the acquisition date. The adjustments related to previous reporting periods since the acquisition date must be disclosed by income statement line item either on the face of the income statement or in the notes. The amendments are effective prospectively for the fiscal years, and interim reporting periods within those years, beginning on or after December 15, 2015 (early adoption is permitted only for financial statements that have not been issued). We do not anticipate a material impact on our consolidated financial statements from adoption of this ASU.

In July 2015, the FASB issued ASU No. 2015-11 Inventory (Topic 330): Simplifying the Measurement of Inventory. ASU 2015-11 changes the measurement of inventory from lower of cost or market to lower of cost and net realizable value. The amendments are effective prospectively for the fiscal years, and interim reporting periods within those years, beginning on or after December 15, 2016. We do not anticipate a material impact on our consolidated financial statements from adoption of this ASU.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). ASU 2014-09 removes inconsistencies and weaknesses in revenue requirements, provides a more robust framework for addressing revenue issues, improves comparability of revenue recognition practices across entities, industries, jurisdictions and capital markets, provides more useful information to users of financial statements through improved disclosure requirements and simplifies the preparation of financial statements by reducing the number of requirements to which an entity must refer. This guidance requires that an entity depict the consideration by applying a five-step analysis in determining when and how revenue is recognized. The new model will require revenue recognition to depict the transfer of promised goods or services to customers in an amount that reflects the consideration a company expects to receive in exchange for those goods or services. On April 1, 2015, the FASB voted for a one-year deferral of the effective date of the new revenue recognition standard, ASU No. 2014-09. On July 15, 2015, the FASB affirmed these changes, which requires public entities to apply the amendments in ASU 2014-09 for annual reporting beginning after December 15, 2017. Early adoption is permitted beginning after December 31, 2016, the original effective date in ASU 2014-09. We are currently evaluating the impact of this ASU on the consolidated financial statements and related disclosures.

In June 2014, the FASB issued ASU No. 2014-12, Compensation - Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide that a Performance Target Could be Achieved after the Requisite Service Period. ASU 2014-12 requires that a performance target that affects vesting, and that could be achieved after the requisite service period, be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant date fair value of the award. This update further clarifies that compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. The amendments in ASU 2014-12 are effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Early adoption is permitted. Entities may apply the amendments in ASU 2014-12 either: (a) prospectively to all awards granted or modified after the effective date; or (b) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual

period presented in the financial statements and to all new or modified awards thereafter. This guidance will become effective for us at the beginning of the first quarter of 2016. We do not anticipate a material impact on our consolidated financial statements from adoption of this ASU.

Note 7: Fair Value Measurement

Our investment securities consist of certificates of deposit, corporate bonds, U.S. Treasury securities, commercial paper 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, 2015, we had \$6.3 million of our investment securities as Level 1 assets, which are certificates of deposit and U.S. Treasury securities with quoted prices in active markets, and \$32.4 million of our investment securities as Level 2 assets, which are pre-

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refunded municipal securities, non-pre-refunded municipal securities, corporate bonds and commercial paper and have observable market based inputs such as quoted prices, interest rates and yield curves. The following table provides the assets and liabilities carried at fair value measured on a recurring basis.

	Fair value measurements at September 30, 2015 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	\$38,695	\$6,292	\$32,403	\$—
	\$38,695	\$6,292	\$32,403	\$—

	Fair value measurements at December 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	\$70,952	\$5,884	\$65,068	\$—
	\$70,952	\$5,884	\$65,068	\$—

Note 8: Investment Securities

Our investment securities consist of certificates of deposit, corporate bonds, U.S. Treasury securities, commercial paper 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 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, 2015 or December 31, 2014. The scheduled maturities of the debt securities are between 2015 and 2036 and are all callable within one year. The investment securities consist of the following at September 30, 2015 and December 31, 2014:

	September 30, 2015	December 31, 2014
Federal tax-exempt debt securities	\$3,463	\$15,013
Corporate bonds	25,253	46,209
U.S. Treasury securities	4,039	—
Commercial paper	3,687	3,846
Certificates of deposit	2,253	5,884
	\$38,695	\$70,952

Note 9: Inventories

Inventories consisted of the following:

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	September 30, 2015	December 31, 2014
Raw material	\$23,559	\$23,006
Work in process	5,233	3,546
Finished goods	11,889	10,381
Total	\$40,681	\$36,933

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Note 10: Property and Equipment

Property and equipment consisted of the following:

	September 30, 2015	December 31, 2014
Machinery and equipment	\$92,664	\$90,744
Land, building and building improvements	66,519	71,415
Molds	33,862	33,166
Computer equipment and software	23,050	23,228
Furniture and fixtures	3,587	3,571
Construction in progress	5,400	2,590
Total property and equipment, cost	225,082	224,714
Accumulated depreciation	(146,314) (138,623
Net property and equipment	\$78,768	\$86,091

Note 11: 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 211,000 for the three months ended September 30, 2014. There were no anti-dilutive options for the three months ended September 30, 2015. Options that are anti-dilutive because their exercise price exceeded the average market price of the common stock for the period approximated 44,000 for the nine months ended September 30, 2015 and 235,000 for the nine months ended September 30, 2014.

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,	
	2015	2014	2015	2014
Net income	\$16,266	\$6,428	\$39,522	\$18,963
Weighted average number of common shares outstanding (for basic calculation)	15,894	15,319	15,790	15,220
Dilutive securities	681	169	619	277
Weighted average common and common equivalent shares outstanding (for diluted calculation)	16,575	15,488	16,409	15,497
EPS — basic	\$1.02	\$0.42	\$2.50	\$1.25
EPS — diluted	\$0.98	\$0.42	\$2.41	\$1.22

Note 12: Major Customer

We had revenues equal to 10% or more of total revenues from one customer, Hospira. Such revenues were 36% and 37% of total revenue for the three months ended September 30, 2015 and 2014, respectively and 36% and 36% of total revenue for the nine months ended September 30, 2015 and 2014, respectively. As of September 30, 2015 and

December 31, 2014, we had accounts receivable from Hospira of 32% and 27% of consolidated accounts receivable, respectively.

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Note 13: Income Taxes

Income taxes were accrued at an estimated effective tax rate of 31% in the first nine months of 2015 and 2014, 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 material discrete tax benefits related to the impact of changes in estimates of tax reserves related to uncertainties in income taxes as a result of the favorable conclusion of recent federal and state examinations.

Note 14: Treasury Stock

In July 2010, our Board of Directors approved a common stock purchase plan to purchase up to \$40.0 million of our common stock. This plan has no expiration date and we have \$22.5 million remaining on this purchase plan. We expect to use the treasury stock to issue shares for stock option exercises, restricted stock grants and employee stock purchase plan stock purchases.

In the first nine months of 2015, we withheld 17,299 shares of our common stock from employee vested restricted stock units in consideration for \$1.5 million in payments for the employee's share award income tax withholding obligations.

Note 15: 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 unsettled 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.

Note 16: Subsequent Events

On October 5, 2015, we signed a definitive agreement to acquire all outstanding shares of EXC Holding Corp ("EXC"), a manufacturer of healthcare devices used to disinfect and protect access into a patient's bloodstream, for \$59.5 million in cash. Also on October 5, 2015, we signed a definitive agreement to sell the operating assets of certain products acquired in our acquisition of EXC to Excelsior Medical, LLC, an affiliate of Medline Industries, Inc. for \$27.0 million in cash. Both transactions closed on October 6, 2015.

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

Business Overview

We are a leader in the development, manufacture and sale of innovative medical devices used in infusion therapy, oncology and critical care applications. Our product line includes needlefree connection devices, custom infusion sets, closed system transfer devices ("CSTD") for the handling of hazardous drugs, advanced sensor catheters, closed blood sampling systems and hemodynamic monitoring systems.

Our products are used in acute care hospitals and ambulatory clinics in more than 60 countries throughout the world. We categorize our products into three main market segments: Infusion Therapy, Oncology and Critical Care. Reclassifications were done on certain items in the market segments. Prior period revenue amounts have been adjusted to reflect the current market segment classification. Our primary products include:

Infusion Therapy

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

Oncology

- ChemoLock CSTD and components
- ChemoClave CSTD and components
- Diana hazardous drug compounding system

Critical Care

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

Our largest customer is Hospira. Hospira accounted for 36%, 36% and 39% of our worldwide revenues in the first nine months of 2015 and each of the years ended 2014 and 2013, respectively. Our relationship with Hospira has been and will continue to be important for our growth. Hospira has a significant share of the I.V. set market in the U.S. and provides us access to that market. We expect revenues from infusion therapy products and new product sales to Hospira to remain a significant percentage of our revenues. 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. We believe that our recent arbitration with Hospira, that concluded in their favor in April 2015, will not have a significant impact on our earnings

going forward.

Revenues for the first nine months of 2015 and the years ended 2014 and 2013 were \$251.3 million, \$309.3 million and \$313.7 million, respectively. We currently sell our products to medical product manufacturers and independent distributors as well as direct sales to the end user. Most of our independent distributors handle the full line of our products. We sell our infusion administration and oncology products under two agreements with Hospira. Under a 1995 agreement, as amended, Hospira purchases Clave products, principally bulk, non-sterile connectors and oncology products. Under a 2001 agreement, as amended, we sell custom infusion sets to Hospira under a program referred to as SetSource. These 1995 and 2001 agreements with Hospira provide Hospira with conditional exclusive and nonexclusive rights to distribute these ICU Medical products worldwide with terms that extend through most of 2018.

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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 manufacturing customers' 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 acquisition and development; however, there is no assurance that we will be successful in implementing our growth strategy. 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. Expenditures for sales and marketing and product acquisition and development may not yield desired results when expected, or at all. While we have taken steps to control these risks, there are certain risks that may be outside of our control, and there is no assurance that steps we have taken will succeed.

The following table sets forth, for the periods indicated, total revenues by product line as a percentage of total revenues.

Product line	Three months ended September 30,		Nine months ended September 30,		Fiscal year ended			
	2015	2014	2015	2014	2014	2013		
Infusion therapy	72	% 71	% 71	% 70	% 70	% 71	%	
Oncology	13	% 12	% 12	% 12	% 12	% 12	%	
Critical care	15	% 17	% 17	% 18	% 18	% 17	%	
	100	% 100	% 100	% 100	% 100	% 100	%	

Seasonality/Quarterly Results

The healthcare business in the U.S. 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. In addition, we can experience fluctuations in net sales as a result of variations in the ordering patterns of our largest customers, which may be driven more by production scheduling and their inventory levels, and less by seasonality. Our expenses often do not fluctuate in the same manner as net sales, which may cause fluctuations in operating income that are disproportionate to fluctuations in our revenue.

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Quarter-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, 2015 and 2014, respectively, and the year ended December 31, 2014, the percentages of each income statement caption in relation to total revenues.

	Percentage of revenues					
	Three months ended September 30, 2015		Nine months ended September 30, 2015		Fiscal year 2014	
	2015	2014	2015	2014	2014	
Total revenues	100	% 100	% 100	% 100	% 100	%
Gross margin	54	% 49	% 53	% 49	% 49	%
Selling, general and administrative expenses	23	% 28	% 24	% 30	% 29	%
Research and development expenses	5	% 7	% 5	% 6	% 6	%
Restructuring and strategic transaction expenses	4	% 3	% 1	% 1	% 1	%
Gain on sale of building	1	% —	% 1	% —	% —	%
Legal settlements	6	% —	% 1	% —	% —	%
Total operating expenses	25	% 38	% 30	% 37	% 36	%
Income from operations	29	% 11	% 23	% 12	% 13	%
Other income	—	% —	% —	% —	% —	%
Income before income taxes	29	% 11	% 23	% 12	% 13	%
Income taxes	10	% 3	% 7	% 4	% 4	%
Net income	19	% 8	% 16	% 8	% 9	%

A portion of our sales is conducted in currencies other than the U.S. dollar, particularly the Euro. In the third quarter of 2015 and the first nine months of 2015, approximately 13% and 14%, respectively, of our total revenue was denominated in the Euro and translated to the U.S. dollar. Significant fluctuations in foreign currency exchange rates, particularly the Euro, impact the comparability of our total revenues. In addition to comparing changes in revenue on a U.S. GAAP basis, we also compare the changes in revenue from one period to another using constant currency. We provide constant currency information to enhance the visibility of underlying business trends, excluding the effects of changes in foreign currency translation rates. To calculate our constant currency results, we apply the average exchange rate for revenues from the prior year to the current year results. These results should be considered in addition to, not as a substitute for, results reported in accordance with GAAP. Results on a constant currency basis, as we present them, may not be comparable to similarly titled measures used by other companies and are not measures of performance presented in accordance with GAAP.

Quarter Ended September 30, 2015 Compared to the Quarter Ended September 30, 2014

Revenues were \$86.0 million in the third quarter of 2015 and \$77.5 million in the third quarter of 2014. On a constant currency basis, revenues would have been \$88.1 million in the third quarter of 2015, an increase of \$10.7 million, or 14%, from the third quarter of 2014.

Infusion Therapy: Net infusion therapy sales were \$62.1 million in the third quarter of 2015, an increase of \$7.1 million, or 13%, from the third quarter of 2014. On a constant currency basis, net infusion therapy sales would have been \$63.3 million in the third quarter of 2015, an increase of \$8.3 million, or 15%, from the third quarter of 2014. The increase in infusion therapy sales is primarily due to new customers and higher volume to existing customers. Domestic infusion therapy sales were \$45.3 million in the third quarter of 2015, an increase of \$4.3 million, or 10%, from the third quarter of 2014. The increase in domestic infusion therapy was from \$2.8 million in higher direct

domestic sales and \$1.4 million in higher sales to U.S. Hospira. International infusion therapy sales were \$16.8 million in the third quarter of 2015, an increase of \$2.8 million, or 20%, from the third quarter of 2014. The increase in international infusion therapy sales was due to higher sales outside of Europe. On a constant currency basis, international infusion therapy sales would have increased \$4.0 million in the third quarter of 2015, compared to the third quarter of 2014.

Oncology: Net oncology sales were \$11.2 million in the third quarter of 2015, an increase of \$1.8 million, or 20%, from the third quarter of 2014. On a constant currency basis, net oncology sales would have been \$11.9 million in the third

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quarter of 2015, an increase of \$2.5 million, or 27%, from the third quarter of 2014. The increase in oncology sales is primarily due to new customers and higher volume to existing customers. Domestic oncology sales were \$5.5 million in the third quarter of 2015, an increase of \$1.1 million, or 27%, from the third quarter of 2014. The increase in domestic oncology sales is primarily from \$1.1 million in increased direct domestic oncology sales due to increased unit sales. International oncology sales were \$5.7 million in the third quarter of 2015, an increase of \$0.7 million, or 14%, from the third quarter of 2014. On a constant currency basis, international infusion therapy sales would have increased \$1.4 million in the third quarter of 2015, compared to the third quarter of 2014.

Critical Care: Net critical care sales were \$12.5 million in the third quarter of 2015, a decrease of \$0.3 million, or 2%, from the third quarter of 2014. On a constant currency basis, net critical care sales would have been \$12.7 million in the third quarter of 2015, a decrease of \$0.1 million, or 1%, from the third quarter of 2014. The decrease in critical care sales is primarily due to decreased volume to existing customers. Domestic critical care sales were \$9.5 million in the third quarter of 2015, an increase of \$0.4 million, or 4%, from the third quarter of 2014. International critical care sales were \$3.0 million in the third quarter of 2015, a decrease of \$0.7 million, or 19%, from the third quarter of 2014. The decrease in international critical care sales was primarily due to decreased sales outside of Europe. On a constant currency basis, international critical care sales would have decreased \$0.5 million in the third quarter of 2015, compared to the third quarter of 2014.

Gross margins for the third quarter of 2015 and 2014 were 54% and 49%, respectively. The increase in gross margin was primarily due to favorable customer and product mix, operational efficiencies and favorable foreign exchange rates on our operations expenses due to the decline in the average exchange rate of the Mexican Peso to the U.S. dollar.

Selling, general and administrative (“SG&A”) expenses were \$20.2 million, or 23% of revenues, in the third quarter of 2015, compared with \$21.8 million, or 28%, of revenues in the third quarter of 2014. The decrease in SG&A expenses is primarily due to \$1.2 million in lower sales and marketing compensation and benefits, promotion expenses and travel expenses and \$0.9 million in lower outside services and legal expenses, partially offset by \$0.7 million in higher stock compensation expenses. The lower sales and marketing expenses are primarily due to the restructuring of the U.S. sales organization in the third quarter of 2014 and the decline in the average exchange rate of the Euro to the U.S. dollar.

Research and development (“R&D”) expenses were \$4.2 million, or 5% of revenue, in the third quarter of 2015 compared to \$5.1 million, or 7%, of revenue in the third quarter of 2014. The decrease in R&D expenses was primarily due to lower R&D project expenses.

Restructuring and strategic transaction expenses were \$3.4 million, or 4% of revenues, in the third quarter of 2015, compared with \$2.8 million, or 3%, of revenues in the third quarter of 2014. In the third quarter of 2015, we incurred \$1.1 million in charges associated with a strategic transaction that closed in October 2015. Also, in the third quarter of 2015, we entered into an agreement with George A. Lopez, M.D, a member of our Board of Directors and a former employee in our research and development department, pursuant to which we bought out Dr. Lopez's right to employment under his then-existing employment agreement. We also reorganized our corporate infrastructure, resulting in one-time employee termination benefits and other associated costs. These restructuring actions resulted in a charge of \$2.3 million in the third quarter of 2015.

In the third quarter of 2014, we reorganized our selling and corporate infrastructure, resulting in a reduction in workforce. We recognized a \$2.8 million restructuring charge for one-time employee termination benefits and other associated costs.

Gain on sale of building was \$1.1 million, or 1% of revenues, in the third quarter of 2015 from the sale of one of our buildings in San Clemente to Dr. Lopez.

Legal settlement awards were \$5.3 million, or 6% of revenues, in the third quarter of 2015. On September 23, 2015, an arbitrator ruled on a breach of contract claim between us and a service provider, awarding us \$8.8 million. Our legal counsel for this matter represented us under a contingency fee agreement. We recorded a settlement award, net of legal fees and costs, of \$5.3 million.

Other income was \$0.2 million in both the third quarter of 2015 and 2014.

Income taxes were accrued at an estimated effective tax rate of 35% in the third quarter of 2015 and 25% in the third quarter of 2014. The 2014 rate differed from the statutory corporate rate of 35% principally because of the effect of foreign and state income taxes, tax credits and deductions for domestic production activities.

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Nine Months Ended September 30, 2015 Compared to the Nine Months Ended September 30, 2014

Revenues were \$251.3 million in the first nine months of 2015 and \$229.4 million in the first nine months of 2014. On a constant currency basis, revenues would have been \$258.7 million in the first nine months of 2015, an increase of \$29.3 million, or 13%, from the first nine months of 2014.

Infusion Therapy: Net infusion therapy sales were \$178.6 million in the first nine months of 2015, an increase of \$19.0 million, or 12%, from the first nine months of 2014. On a constant currency basis, net infusion therapy sales would have been \$182.9 million in the first nine months of 2015, an increase of \$23.2 million, or 15%, from the first nine months of 2014. The increase in infusion therapy sales is primarily due to new customers and higher volume to existing customers. Domestic infusion therapy sales were \$130.7 million in the first nine months of 2015, an increase of \$15.5 million, or 13%, from the first nine months of 2014. The increase in domestic infusion therapy was from \$7.8 million in higher sales to Hospira and \$7.7 million in higher direct domestic sales, both due to higher unit sales. International infusion therapy sales were \$48.0 million in the first nine months of 2015, an increase of \$3.5 million, or 8%, from the first nine months of 2014. International infusion therapy sales outside of Europe increased \$4.6 million and were offset by \$1.1 million in lower European sales due to the decline in the exchange rate of the Euro to the U.S. dollar. On a constant currency basis, international infusion therapy sales would have increased \$7.7 million in the first nine months of 2015, compared to the first nine months of 2014.

Oncology: Net oncology sales were \$30.4 million in the first nine months of 2015, an increase of \$3.0 million, or 11%, from the first nine months of 2014. On a constant currency basis, net oncology sales would have been \$32.7 million in the first nine months of 2015, an increase of \$5.3 million, or 19%, from the first nine months of 2014. The increase in oncology sales is primarily due to new customers and higher volume to existing customers. Domestic oncology sales were \$14.5 million in the first nine months of 2015, an increase of \$2.3 million, or 19%, from the first nine months of 2014. The increase in domestic oncology sales was from \$0.4 million in higher sales to Hospira and \$1.9 million in higher direct domestic sales, both due to increased unit sales. International oncology sales were \$16.0 million in both the first nine months of 2015, an increase of \$0.7 million, or 5%, from the first nine months of 2014. On a constant currency basis, international oncology sales would have increased \$3.0 million in the first nine months of 2015, compared to the first nine months of 2014.

Critical Care: Net critical care sales were \$41.2 million in the first nine months of 2015, a decrease of \$0.1 million from the first nine months of 2014. On a constant currency basis, net critical care sales would have been \$41.9 million in the first nine months of 2015, an increase of \$0.7 million, or 2%, from the first nine months of 2014. The decrease in critical care sales is primarily due the decline in the exchange rate of the Euro to the U.S. dollar. Domestic critical care sales were \$29.9 million in the first nine months of 2015, an increase of \$0.1 million from the first nine months of 2014. International critical care sales were \$11.4 million in the first nine months of 2015, a decrease of \$0.2 million, or 1%, from the first nine months of 2014. International critical care sales in Europe decreased \$1.0 million and were partially offset by \$0.8 million in increased sales outside of Europe. The decrease in international critical care sales was due to the decline in the exchange rate of the Euro to the U.S. dollar. On a constant currency basis, international critical care sales would have increased \$0.6 million in the first nine months of 2015, compared to the first nine months of 2014.

Gross margins for the first nine months of 2015 and 2014 were 53% and 49%, respectively. The increase in gross margin was primarily due to favorable customer and product mix, operational efficiencies and favorable foreign exchange rates on our operations expenses due to the decline in the average exchange rate of the Mexican Peso to the U.S. dollar.

SG&A expenses were \$60.7 million, or 24% of revenues, in the first nine months of 2015, compared with \$68.6 million, or 30%, of revenues in first nine months of 2014. The decrease in SG&A expenses is primarily due to \$8.3

million in lower sales and marketing compensation and benefits, promotion and travel expenses and \$2.1 million in lower outside services and legal expenses, partially offset by \$3.3 million in higher stock compensation expense and higher incentive compensation expense. The lower sales and marketing expenses are primarily due to the restructuring of the U.S. sales organization in the third quarter of 2014 and the decline in the average exchange rate of the Euro to the U.S. dollar.

R&D expenses were \$11.7 million, or 5% of revenue, in the first nine months of 2015 compared to \$13.3 million, or 6%, of revenue in the first nine months of 2014. The decrease in R&D expenses was primarily due to lower R&D project expenses.

Restructuring and strategic transaction expenses were \$3.4 million, or 1% of revenues, in the first nine months of 2015, compared with \$2.8 million, or 1%, of revenues in the first nine months of 2014. In the third quarter of 2015, we incurred \$1.1 million in charges associated with a strategic transaction that closed in October 2015. Also, in the third quarter of 2015, we entered into an agreement with Dr. Lopez, pursuant to which we bought out Dr. Lopez's right to employment under his then-

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existing employment agreement. We also reorganized our corporate infrastructure, resulting in one-time employee termination benefits and other associated costs. These restructuring actions resulted in a charge of \$2.3 million in the third quarter of 2015.

In the third quarter of 2014, we reorganized our selling and corporate infrastructure, resulting in a reduction in workforce. We recognized a \$2.8 million restructuring charge for one-time employee termination benefits and other associated costs.

Gain on sale of building was \$1.1 million, or 1% of revenues, in the first nine months of 2015 from the sale of one of our buildings in San Clemente to Dr. Lopez.

Legal settlement charges were \$1.8 million, or 1% of revenues, in the first nine months of 2015. On April 2, 2015, an arbitrator ruled on a breach of contract claim between us and a customer, Hospira, awarding Hospira a settlement and that we pay 75% of Hospira's legal fees and expenses, resulting in a \$7.1 million legal settlement charge.

On September 23, 2015, an arbitrator ruled on a breach of contract claim between us and a service provider, awarding us \$8.8 million. Our legal counsel for this matter represented us under a contingency fee agreement. We recorded a settlement award, net of legal fees and costs, of \$5.3 million.

Other income was \$1.0 million in the first nine months of 2015 and \$0.6 million in the first nine months of 2014.

Income taxes were accrued at an estimated effective tax rate of 31% in both the first nine months of 2015 and the first nine months of 2014. 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, discrete tax items related to the conclusion of federal tax examinations and changes in estimates of tax reserves.

Liquidity and Capital Resources

During the first nine months of 2015, our cash, cash equivalents and investment securities increased by \$47.3 million from \$346.8 million at December 31, 2014 to \$394.1 million at September 30, 2015.

Operating Activities: Our cash provided by operations was \$42.4 million in the first nine months of 2015. Net income plus adjustments for non-cash net expenses contributed \$62.5 million to cash provided by operations, which was partially offset by a \$20.1 million decrease in cash provided by operating assets and liabilities. The \$11.4 million increase in accounts receivable and \$8.8 million increase in prepaid expenses and other were the largest changes in operating assets and liabilities. The increase in accounts receivable is primarily due to higher revenue in the third quarter of 2015 compared to the fourth quarter of 2014 and a slight increase in days sales outstanding. The increase in prepaid expenses and other is primarily due to the \$8.8 million receivable for the September 2015 legal settlement.

Investing Activities: Our cash provided by investing activities was \$25.2 million in the first nine months of 2015, which was primarily comprised of net investment sales of \$30.1 million and proceeds from the sale of our building of \$3.6 million, partially offset by \$7.7 million in capital purchases.

While we can provide no assurances, we estimate that our capital expenditures in 2015 will approximate \$10.0 million to \$13.0 million. We anticipate making additional investments in molds, machinery and equipment in our manufacturing operations in the U.S. and Mexico to support new and existing products and in IT to 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 \$17.8 million in the first nine months of 2015. Cash and tax benefits provided by the exercise of stock options and shares purchased by our employees under the employee stock purchase plan was \$19.3 million in the first nine months of 2015. In the first nine months of 2015, we withheld 17,299 shares of our common stock from vested restricted stock units as consideration for \$1.5 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. To date, we have purchased \$17.5 million of our common 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.

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On October 5, 2015, we signed a definitive agreement to acquire all outstanding shares of EXC Holding Corp ("EXC"), a manufacturer of healthcare devices used to disinfect and protect access into a patient's bloodstream, for \$59.5 million in cash. Also on October 5, 2015, we signed a definitive agreement to sell the operating assets of certain products acquired in our acquisition of EXC to Excelsior Medical, LLC, an affiliate of Medline Industries, Inc. for \$27.0 million in cash. Both transactions closed on October 6, 2015.

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 of September 30, 2015, we have \$31.9 million of cash and cash equivalents held by our foreign subsidiaries. If these funds were needed for our operations in the U.S., we would be required to accrue and pay U.S. taxes to repatriate these funds. However, we expect to permanently reinvest these funds outside of the U.S. and, based on our current plans, we do not presently anticipate a need to repatriate them to fund our U.S. operations.

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

As of September 30, 2015, we had contractual obligations of approximately the amounts set forth in the table below. These amounts exclude 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 \$1.2 million due to the high degree of uncertainty regarding the timing of future cash outflows associated with the liabilities.

	(in thousands)						
Contractual Obligations	Total	2015	2016	2017	2018	2019	2020
Operating leases	\$1,100	\$184	\$379	\$211	\$131	\$123	\$72
Service agreements	971	153	613	205	—	—	—
Purchase obligations	3,556	3,556	—	—	—	—	—

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Other contractual obligations	19	3	13	3	—	—	—
	\$5,646	\$3,896	\$1,005	\$419	131	\$123	\$72

Critical Accounting Policies

In our Annual Report on Form 10-K for the year ended December 31, 2014, 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 3 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 and effects with respect to sales and marketing and product development and acquisition efforts; future sales and unit volumes of products; expected increases and decreases in sales; deferred revenue; accruals for restructuring charges, future license, royalty and revenue share income; production costs; gross margins; litigation expense; future SG&A and R&D expenses; manufacturing expenses; future costs of expanding our business; income; losses; cash flow; amortization; source of funds for capital purchases and operations; future tax rates; alternative sources of capital or financing; 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; loss of a strategic relationship; change in demand; domestic and international sales; expansion in international markets, selling prices; future increases or decreases in sales of certain products and in certain markets and distribution channels; maintaining strategic relationships and securing long-term and multi-product contracts with large healthcare providers and major buying organizations; increases in systems capabilities; introduction, development and sales of new products; benefits of our products over competing systems; qualification of our new products for the expedited Section 510(k) clearance procedure; possibility of lengthier clearance process for new products; planned increases in marketing; warranty claims; rebates; product returns; bad debt expense; amortization expense; inventory requirements; lives of property and equipment; manufacturing efficiencies and cost savings; unit manufacturing costs; establishment or expansion of production facilities inside or outside of the U. S.; planned new orders for machinery and equipment; adequacy of production capacity; results of R&D; our plans to repurchase shares of our common stock; asset impairment losses; effect of expansion of manufacturing facilities on production efficiencies and resolution of production inefficiencies; the effect of costs to customers and delivery times; business seasonality and fluctuations in quarterly results; customer ordering patterns and the effects of new accounting pronouncements; and

new or extended contracts with manufacturers and buying organizations; dependence on a small number of customers; loss of larger distributors and the ability to locate other distributors; future sales to and revenues from Hospira and the

importance of Hospira to our growth; effect of the current relationship with Hospira and the settlement with Hospira, including its effect on future revenues and our positioning with respect to new product introductions and market share; growth of our products in future years; design features of products; the outcome of our strategic initiatives; regulatory approvals and compliance; outcome and impact of litigation; patent protection and intellectual property landscape; patent infringement claims and the impact of newly issued patents on other medical devices; competitive and market factors, including continuing development of competing products by other manufacturers; improved production processes and higher volume production; innovation requirements; consolidation of the healthcare provider market and downward pressure on selling prices; distribution or financial capabilities of competitors; healthcare reform legislation; use of treasury stock; working capital requirements; liquidity and realizable value of our investment securities; future investment alternatives; foreign currency denominated financial instruments; foreign exchange risk; commodity price risk; our expectations regarding liquidity and capital resources over the next twelve months; capital expenditures; our planned reinvestment of cash and cash equivalents held by our foreign subsidiaries; 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.

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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, 2014 and our other reports and registration statements filed with the SEC. Also, actual future operating results are subject to other important factors and risks that we cannot predict or control, including without limitation, the following:

- general economic and business conditions, both in the U.S. and internationally;
- unexpected changes in our arrangements with Hospira or our other large customers;
- outcome of litigation;
- fluctuations in foreign exchange rates and other risks of doing business internationally;
- increases in labor costs or competition for skilled workers;
- increases in costs or availability of the raw materials need to manufacture our products;
- the effect of price and safety considerations on the healthcare industry;
- competitive factors, such as product innovation, new technologies, marketing and distribution strength and price erosion;
- the successful development and marketing of new products;
- unanticipated market shifts and trends;
- the impact of legislation affecting government reimbursement of healthcare costs;
- changes by our major customers and independent distributors in their strategies that might affect their efforts to market our products;
- the effects of additional governmental regulations;
- unanticipated production problems; and
- the availability of patent protection and the cost of enforcing and of defending patent claims.

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Financial Market Risk

We had a portfolio of federal tax-exempt state and municipal government bonds, corporate bonds, U.S. Treasury securities, commercial paper and certificates of deposit of \$38.7 million as of September 30, 2015. The securities are

all “investment grade”, comprised of \$3.1 million of pre-refunded municipal securities, \$0.4 million of non-pre-refunded municipal securities, \$25.3 million of corporate bonds, \$4.0 million of U.S. Treasury securities, \$3.7 million of commercial paper and \$2.3 million of certificates of deposit. The pre-refunded municipal securities are fully escrowed by U.S. government Treasury bills with low market risk.

Our future earnings are subject to potential increase or decrease because of changes in short-term interest rates. Generally, each one-percentage point change in the discount rate will cause our overall yield to change by two-thirds to three-quarters of a percentage point, depending upon the relative mix of federal-tax-exempt securities in our portfolio and market conditions specific to the securities in which we invest. Two-thirds to three-quarters of a percentage point change in our earnings on investment securities would create a change of approximately \$0.3 million to investment income based on the investment securities balance at September 30, 2015.

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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, 2015 was approximately €21.9 million. We also have approximately €63.1 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, 2015 spot rate would impact our consolidated amounts on these balance sheet items by approximately \$9.6 million, or 2.4% of these consolidated 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 Mexican Peso and the Euro. A 10% change in the conversion of the Mexican Peso to the U.S. dollar from the average exchange rate we experienced in 2014 and our manufacturing spending from 2014 would have impacted 2014 cost of goods sold by approximately \$2.4 million. To date, the change in the conversion of the Euro to the U.S. dollar has not had a material impact to our operating earnings.

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, 2015 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 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, 2014, 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, 2014.

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 2015:

Period	Shares purchased	Average price paid per share	Shares purchased as part of a publicly announced program	Approximate dollar value that may yet be purchased under the program
07/01/2015 — 07/31/2015	—	\$—	—	\$ 22,522,000
08/01/2015 — 08/31/2015	—	—	—	22,522,000
09/01/2015 — 09/30/2015	—	—	—	22,522,000
Third quarter of 2015 total	—	\$—	—	\$ 22,522,000

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Item 6. Exhibits

Exhibit 10.1	Buy-Out Agreement, dated September 30, 2015, between the Company and George A. Lopez, M.D. (1)*
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

*Executive or director compensation plan or other arrangement.

(1) Filed as an Exhibit to Registrant's Current Report on Form 8-K filed October 1, 2015, 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: November 5, 2015

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