

ICU MEDICAL INC/DE
Form 10-Q
April 22, 2011
[Table of Contents](#)

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, 2011

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)

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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 Accelerated filer
Non-accelerated filer Smaller reporting company
(Do not check if a smaller reporting company)

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

| Class | Outstanding at April 10, 2011 |
|--------|-------------------------------|
| Common | 13,774,276 |

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

Table of Contents

ICU Medical, Inc.

Index

| | Page Number |
|---|--------------------|
| Part I - Financial Information | |
| Item 1. Financial Statements (Unaudited) | |
| <u>Condensed Consolidated Balance Sheets, at March 31, 2011 and December 31, 2010</u> | 3 |
| <u>Condensed Consolidated Statements of Income for the three months ended March 31, 2011 and 2010</u> | 4 |
| <u>Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2011 and 2010</u> | 5 |
| <u>Condensed Consolidated Statements of Comprehensive Income for the three months ended March 31, 2011 and 2010</u> | 6 |
| <u>Notes to Condensed Consolidated Financial Statements</u> | 7 |
| Item 2. | |
| <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> | 10 |
| Item 3. | |
| <u>Quantitative and Qualitative Disclosures About Market Risk</u> | 17 |
| Item 4. | |
| <u>Controls and Procedures</u> | 17 |
| Part II - Other Information | |
| <u>Item 1. Legal Proceedings</u> | 18 |
| <u>Item 1A. Risk Factors</u> | 18 |
| <u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u> | 18 |
| <u>Item 6. Exhibits</u> | 19 |
| <u>Signature</u> | 19 |

Table of Contents**ICU Medical, Inc. and Subsidiaries**

Condensed Consolidated Balance Sheets

(Amounts in thousands, except per share data)

| | March 31, 2011 (unaudited) | December 31, 2010 (1) |
|---|----------------------------------|-----------------------------|
| ASSETS | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | \$ 71,114 | \$ 78,850 |
| Investment securities | 35,713 | 14,507 |
| Cash, cash equivalents and investment securities | 106,827 | 93,357 |
| Accounts receivable, net of allowance for doubtful accounts of \$991 at March 31, 2011 and \$742 at December 31, 2010 | 50,587 | 55,106 |
| Inventories | 51,198 | 44,056 |
| Prepaid income taxes | | 687 |
| Prepaid expenses and other current assets | 9,401 | 9,574 |
| Deferred income taxes | 4,939 | 5,053 |
| Total current assets | 222,952 | 207,833 |
| PROPERTY AND EQUIPMENT, net | 85,863 | 83,545 |
| GOODWILL | 1,478 | 1,478 |
| INTANGIBLE ASSETS, net | 14,285 | 14,806 |
| DEFERRED INCOME TAXES | 4,617 | 4,564 |
| | \$ 329,195 | \$ 312,226 |
| LIABILITIES AND STOCKHOLDERS EQUITY | | |
| CURRENT LIABILITIES: | | |
| Accounts payable | \$ 13,753 | \$ 10,879 |
| Accrued liabilities | 12,704 | 14,629 |
| Deferred revenue | 77 | 254 |
| Income taxes payable | 1,097 | |
| Total current liabilities | 27,631 | 25,762 |
| COMMITMENTS AND CONTINGENCIES | | |
| DEFERRED INCOME TAXES | 7,987 | 8,023 |
| INCOME TAX LIABILITY | 4,155 | 4,155 |
| STOCKHOLDERS EQUITY: | | |
| Convertible preferred stock, \$1.00 par value Authorized 500 shares; Issued and outstanding none | | |
| Common stock, \$0.10 par value Authorized 80,000 shares; Issued 14,855 shares at March 31, 2011 and December 31, 2010, outstanding 13,732 shares at March 31, 2011 and 13,659 shares at December 31, 2010 | 1,486 | 1,486 |
| Additional paid-in capital | 57,222 | 56,502 |
| Treasury stock, at cost 1,123 shares at March 31, 2011 and 1,196 shares at December 31, 2010 | (38,954) | (41,428) |
| Retained earnings | 266,863 | 258,790 |
| Accumulated other comprehensive income (loss) income | 2,805 | (1,064) |
| Total stockholders equity | 289,422 | 274,286 |
| | \$ 329,195 | \$ 312,226 |

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(1) December 31, 2010 balances were derived from audited consolidated financial statements.

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

Table of Contents**ICU Medical, Inc. and Subsidiaries**

Condensed Consolidated Statements of Income

(Amounts in thousands, except per share data)

(unaudited)

| | Three months ended March 31, | |
|--|-------------------------------------|-----------------|
| | 2011 | 2010 |
| REVENUES: | | |
| Net sales | \$ 71,338 | \$ 64,212 |
| Other | 133 | 151 |
| TOTAL REVENUE | 71,471 | 64,363 |
| COST OF GOODS SOLD | | |
| | 36,845 | 37,436 |
| Gross profit | 34,626 | 26,927 |
| OPERATING EXPENSES: | | |
| Selling, general and administrative | 22,863 | 19,655 |
| Research and development | 2,052 | 918 |
| Legal settlement | (2,500) | |
| Total operating expenses | 22,415 | 20,573 |
| Income from operations | 12,211 | 6,354 |
| OTHER INCOME | | |
| Income before income taxes | 12,614 | 6,546 |
| PROVISION FOR INCOME TAXES | (4,541) | (2,291) |
| NET INCOME | \$ 8,073 | \$ 4,255 |
| NET INCOME PER SHARE | | |
| Basic | \$ 0.59 | \$ 0.31 |
| Diluted | \$ 0.57 | \$ 0.30 |
| WEIGHTED AVERAGE NUMBER OF SHARES | | |
| Basic | 13,692 | 13,863 |
| Diluted | 14,056 | 14,111 |

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

Table of Contents**ICU Medical, Inc. and Subsidiaries**

Condensed Consolidated Statements of Cash Flows

(Amounts in thousands)

(unaudited)

| | Three months ended March 31, | |
|---|-------------------------------------|----------------|
| | 2011 | 2010 |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net income | \$ 8,073 | \$ 4,255 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Depreciation and amortization | 4,500 | 4,551 |
| Provision for doubtful accounts | 208 | 52 |
| Stock compensation | 978 | 823 |
| Loss on disposal of property and equipment | | 50 |
| Bond premium amortization | 19 | 587 |
| Cash provided (used) by changes in operating assets and liabilities, net of assets acquired | | |
| Accounts receivable | 5,085 | (1,793) |
| Inventories | (6,186) | 2,997 |
| Prepaid expenses and other assets | (252) | (1,158) |
| Accounts payable | 2,764 | (224) |
| Accrued liabilities | (2,091) | (1,042) |
| Deferred revenue | (278) | (1,203) |
| Prepaid and deferred income taxes | 2,347 | 2,305 |
| Net cash provided by operating activities | 15,167 | 10,200 |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Purchases of property and equipment | (4,942) | (10,375) |
| Proceeds from sale of asset | | 893 |
| Purchases of investment securities | (24,530) | (6,386) |
| Proceeds from sale of investment securities | 3,304 | 20,672 |
| Net cash provided (used) by investing activities | (26,168) | 4,804 |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Proceeds from exercise of stock options | 1,027 | 46 |
| Proceeds from employee stock purchase plan | 909 | 747 |
| Tax benefits from exercise of stock options | 280 | 29 |
| Purchase of treasury stock | | (23,976) |
| Net cash provided (used) by financing activities | 2,216 | (23,154) |
| Effect of exchange rate changes on cash | 1,049 | (198) |
| NET DECREASE IN CASH AND CASH EQUIVALENTS | (7,736) | (8,348) |
| CASH AND CASH EQUIVALENTS, beginning of period | 78,850 | 51,248 |
| CASH AND CASH EQUIVALENTS, end of period | \$ 71,114 | \$ 42,900 |

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

Table of Contents

ICU Medical, Inc. and Subsidiaries

Condensed Consolidated Statements of Comprehensive Income

(Amounts in thousands)

(unaudited)

| | Three months ended March 31, | |
|--|-------------------------------------|-------------|
| | 2011 | 2010 |
| Net income | \$ 8,073 | \$ 4,255 |
| Other comprehensive income (loss), net of tax of \$176 and \$1,110 for the three months ended March 31, 2011 and 2010, respectively: | | |
| Foreign currency translation adjustment | 3,869 | (1,507) |
| Comprehensive income | \$ 11,942 | \$ 2,748 |

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

Table of Contents

ICU Medical, Inc.

Notes to Condensed Consolidated Financial Statements

Three Months Ended March 31, 2011 and 2010

(Amounts in tables in thousands, except per share data)

(unaudited)

Note 1: Basis of Presentation:

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America and pursuant to the rules and regulations of the Securities and Exchange Commission (SEC) and reflect all adjustments, consisting of only normal recurring adjustments, which are, in the opinion of management, necessary for a fair statement of the consolidated results for the interim periods presented. Results for the interim period are not necessarily indicative of results for the full year. Certain information and footnote disclosures normally included in annual consolidated financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. The condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Annual Report on Form 10-K of ICU Medical, Inc., a Delaware corporation (the Company), filed with the SEC for the year ended December 31, 2010.

Subsequent to the issuance of the Company s first quarter 2010 10-Q, the Company reclassified \$0.6 million in bond premium amortization, a noncash item, from investing activities in the consolidated statement of cash flows for the three months ended March 31, 2010 to a noncash item in cash flows from operating activities as an adjustment to reconcile net income to net cash provided by operating activities. The Company considers this an immaterial reclassification and has changed the first quarter of 2010 condensed consolidated statement of cash flows.

The Company operates in one business segment engaged in the development, manufacturing and sale of innovative medical technologies used in vascular therapy, oncology and critical care applications. The Company s devices are sold directly or to distributors and medical product manufacturers throughout the United States and internationally. All subsidiaries are wholly owned and included in the consolidated financial statements. All intercompany balances and transactions have been eliminated.

Note 2: New Accounting Pronouncements:

In January 2010, the Financial Accounting Standards Board issued Accounting Standards Update No. 2010-06 for Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements . This Update requires new disclosures for transfers in and out of Level 1 and 2 and activity in Level 3. This Update also clarifies existing disclosures for level of disaggregation and about inputs and valuation techniques. The new disclosures are effective for interim and annual periods beginning after December 15, 2009, except for the Level 3 disclosures, which are effective for fiscal years beginning after December 15, 2010 and for interim periods within those years. The Company had no Level 3 investments in the fiscal year beginning after December 15, 2010, and was therefore not impacted by this new pronouncement in the quarter ended March 31, 2011.

Note 3: Legal Settlement:

In February 2011, the Company reached a settlement in its litigation against a law firm that formerly represented the Company in patent litigation matters, representing reimbursement of legal fees previously paid to the firm. Under the terms of the settlement, the Company received \$2.5 million and this amount is included as a credit in operating expenses on the Condensed Consolidated Statement of Income for the quarter ended March 31, 2011.

Note 4: Exit Activity from Italy Facility:

The Company's new plant in Slovakia will serve our European product distribution. Product assembly previously done in the Company's Italy facility will now be done in our Slovakia plant. As a result of this, the Company had termination costs to certain manufacturing and operations employees from the Italy facility. The product assembly transition from the Company's Italy plant to the Slovakia plant was completed in March 2011. The Italy facility will continue to support sales in Europe. In the quarter ended March 31, 2011, the Company recorded \$0.6 million in one-time termination costs, \$0.5 million in cost of goods sold and \$0.1 million in sales, general and administrative expense. As of March 31, 2011, \$0.5 million is accrued for these exit costs.

Note 5: Fair Value Measurement:

The Company's investment securities, which are carried at fair value and are considered available-for-sale, consist principally of certificates of deposit and tax-exempt state and municipal government debt. The Company has \$2.8 million of its investment securities as Level 1 assets, which are certificates of deposit with quoted prices in active markets. The Company has \$32.9 million of its investment securities as Level 2 assets, which are pre-refunded and non-pre-refunded municipal securities and have observable inputs.

Table of Contents

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

| | Fair value measurements at March 31, 2011 using | | | |
|-------------------------------|---|--|---|---|
| | Total carrying value at March 31, 2011 | Quoted prices in active markets for identical assets (level 1) | Significant other observable inputs (level 2) | Significant unobservable inputs (level 3) |
| Available for sale securities | \$ 35,713 | \$ 2,820 | \$ 32,893 | \$ |
| | \$ 35,713 | \$ 2,820 | \$ 32,893 | \$ |

The Company had no Level 3 investments for the quarter ended March 31, 2011.

| | Fair value measurements at March 31, 2010 using | | | |
|-------------------------------|---|--|---|---|
| | Total carrying value at March 31, 2010 | Quoted prices in active markets for identical assets (level 1) | Significant other observable inputs (level 2) | Significant unobservable inputs (level 3) |
| Available for sale securities | \$ 41,114 | \$ 8,855 | \$ 32,259 | \$ |
| Trading securities | 900 | | | 900 |
| | \$ 42,014 | \$ 8,855 | \$ 32,259 | \$ 900 |

The following tables summarize the change in the fair values for Level 3 items for the quarter ended March 31, 2010:

Level 3 changes in fair value (pre-tax):

| | Quarter ended March 31, 2010 |
|---|------------------------------|
| Beginning balance | \$ 900 |
| Transfer into Level 3 | |
| Sales | |
| Unrealized holding loss, included in other comprehensive income | |
| Ending balance | \$ 900 |

Note 6: Inventories:

Inventories consisted of the following:

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| | March 31, 2011 | | December 31, 2010 | |
|-----------------|----------------|--------|-------------------|--------|
| Raw material | \$ | 25,377 | \$ | 22,805 |
| Work in process | | 3,733 | | 3,806 |
| Finished goods | | 22,088 | | 17,445 |
| Total | \$ | 51,198 | \$ | 44,056 |

Note 7: Property and Equipment:

Property and equipment consisted of the following:

| | March 31, 2011 | | December 31, 2010 | |
|--|----------------|----------|-------------------|----------|
| Machinery and equipment | \$ | 63,978 | \$ | 62,680 |
| Land, building and building improvements | | 61,156 | | 57,810 |
| Molds | | 22,802 | | 22,521 |
| Computer equipment and software | | 15,585 | | 14,613 |
| Furniture and fixtures | | 2,215 | | 2,107 |
| Construction in progress | | 10,008 | | 9,866 |
| Total property and equipment, cost | | 175,744 | | 169,597 |
| Accumulated depreciation | | (89,881) | | (86,052) |
| Net property and equipment | \$ | 85,863 | \$ | 83,545 |

Table of Contents**Note 8: Net Income Per Share:**

Net income per share is computed by dividing net income by the weighted average number of common shares outstanding. Diluted net income per share is computed by dividing net income by the weighted average number of common shares outstanding plus dilutive securities. Dilutive securities are outstanding common stock options (excluding stock options with an exercise price in excess of the average market value for the period), less the number of shares that could have been purchased with the proceeds from the exercise of the options, using the treasury stock method. Options that are anti-dilutive because their exercise price exceeded the average market price of the common stock for the period approximated 135,000 and 472,000 for the three months ended March 31, 2011 and 2010, respectively.

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

| | Three months ended March 31, | |
|---|---------------------------------|----------|
| | 2011 | 2010 |
| Net income | \$ 8,073 | \$ 4,255 |
| Weighted average number of common shares outstanding (for basic calculation) | 13,692 | 13,863 |
| Dilutive securities | 364 | 248 |
| Weighted average common and common equivalent shares outstanding (for diluted calculation) | 14,056 | 14,111 |
| EPS basic | \$ 0.59 | \$ 0.31 |
| EPS diluted | \$ 0.57 | \$ 0.30 |

Note 9: Major Customer:

The Company had revenues equal to 10% or more of total revenues from one customer, Hospira, Inc. Such revenues were 41% of total revenue for both of the three months ended March 31, 2011 and 2010. As of March 31, 2011 and December 31, 2010, the Company had accounts receivable from Hospira of 37% and 43%, of consolidated accounts receivable, respectively.

Note 10: Income Taxes:

Income taxes were accrued at an estimated annual effective tax rate of 36% in the three months ended March 31, 2011 compared to 35% in the three months ended March 31, 2010. 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 and deductions for domestic production activities.

Note 11: Commitments and Contingencies:

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The Company is from time to time involved in various legal proceedings, most of which are routine litigation, in the normal course of business. In the opinion of management, the resolution of the legal proceedings in which the Company is involved will not likely have a material adverse impact on the Company's financial position or results of operations.

In the normal course of business, the Company has agreed to indemnify officers and directors of the Company to the maximum extent permitted under Delaware law and to indemnify customers as to certain intellectual property matters related to sales of the Company's products. There is no maximum limit on the indemnification that may be required under these agreements. The Company has never incurred, nor does it presently expect to incur, any liability for indemnification.

Table of Contents

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

We are a leader in the development, manufacture and sale of innovative medical technologies used in vascular therapy, oncology and critical care applications. Our products improve patient outcomes by helping prevent bloodstream infections, protect healthcare workers and patients from exposure to infectious diseases or hazardous drugs and monitor the hemodynamic status of critical care patients. Our complete product line includes custom I.V. systems, closed delivery systems for hazardous drugs, needleless I.V. connectors, catheters and cardiac monitoring systems.

Business Overview

In the late 1990s, we commenced a transition from a product-centered company to an innovative, fast, efficient, low-cost manufacturer of custom infusion sets, using processes that we believe can be readily applied to a variety of disposable medical devices. This strategy has enabled us to capture revenue on the entire I.V. delivery system, and not just a component of the system. We have furthered this effort to include all of our proprietary devices beyond the CLAVE, a one-piece, needleless I.V. connection device.

One of our strategies has been to acquire new product lines. For example, in August 2009, we purchased the commercial rights and physical assets of Hospira's critical care product line, which resulted in our control over all aspects of this critical care product line, including production, sales, marketing, customer contracting and distribution. We had previously manufactured for sale, exclusively to Hospira, its critical care products. Pursuant to the prior arrangements, Hospira retained commercial responsibility for the products that we manufactured, including sales to end customers, marketing, pricing, distribution, customer contracts, customer service and billing and we had little ability to directly influence Hospira's sales and marketing efforts, and our sales under this arrangement were subject to fluctuations over which we had little control. The purchase of Hospira's critical care line has resulted in an increase in direct sales and sales to independent distributors but a decrease in sales to Hospira. There is no assurance that we will be successful in finding future acquisition opportunities.

Another strategy for reducing our dependence on our current proprietary products has been to introduce new products. We have introduced a new line of oncology products including the Spiros male lure connector device, the Genie vial access device and ancillary products specifically designed for chemotherapy. We can provide no assurance that we will be able to successfully manufacture, market and sell these new products.

We are also expanding our business through increased sales to medical product manufacturers, independent distributors and through direct sales to the end users of our product. These expansions include our 2008 agreement with Premier, our recently awarded full-line critical care products agreement with Premier, our being named the single-source supplier of critical care products to Premier's ASCEND program, the extension of the term of our agreement with MedAssets, our recent entry into an agreement with Novation covering all of our critical care products and the growth of our internal sales and marketing group. Each of Premier, Med Assets and Novation is a U.S. healthcare purchasing network. Custom products, which include custom infusion, custom oncology and custom critical care products, accounted for approximately \$24.1 million or 34% of total revenue for the first quarter of 2011 and \$100.6 million or 35% of total revenue in 2010. CLAVE sales were \$25.0 million or 35% of total revenue for the first quarter of 2011 and \$98.4 million or 35% of revenue in 2010. Standard critical care sales were \$12.7 million or 18% of total revenue in the first quarter of 2011 and \$50.4 million or 18% of sales in 2010. We potentially face substantial increases in competition in our CLAVE business. Therefore, we are focusing on increasing product development, acquisition, sales and marketing efforts to custom products and other products that lend themselves to customization and new products in the U.S. and international markets.

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Our largest customer is Hospira. Our relationship with Hospira has been and will continue to be important for our growth. We currently manufacture custom infusion sets for sale by Hospira and jointly promote the products under the name SetSource. Additionally, as discussed above, prior to our acquisition of its critical care line, we previously manufactured Hospira's critical care products. For the first quarter of 2011 and the years ended December 31, 2010 and 2009, our revenues from worldwide sales to Hospira were 41%, 44% and 53%, respectively, of total revenues. We expect revenues from sales of CLAVE products, custom infusion sets and new products to Hospira to remain a significant percentage of our revenues. Hospira has a significant share of the I.V. set market in the U.S. and provides us access to that market, and we expect that Hospira will be important to our growth for CLAVE, custom infusion sets, and our other products worldwide.

We believe that achievement of our growth objectives worldwide will require increased efforts by us in sales and marketing and product development; however, there is no assurance that we will be successful in implementing our growth strategy. The custom products market is small, when compared to the larger market of standard products, and we could encounter customer resistance to custom products. Further, we could encounter increased competition as other companies see opportunity in this market. Product development or acquisition efforts may not succeed, and even if we do develop or acquire additional products, there is no assurance that we will achieve profitable sales of such products. An adverse change in our relationship with Hospira, or a deterioration of Hospira's position in the market, could have an adverse effect on us. Increased expenditures for sales and marketing and product acquisition and development may not yield desired results when expected, or at all. While we have taken steps to control these risks, there are certain risks that may be outside of our control, and there is no assurance that steps we have taken will succeed.

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Table of Contents

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

| Product Line | Quarter ended March 31, | | Fiscal Year Ended | |
|------------------------------|-------------------------|-------------|-------------------|-------------|
| | 2011 | 2010 | 2010 | 2009 |
| CLAVE | 35% | 36% | 35% | 37% |
| Custom products | 34% | 32% | 35% | 34% |
| Standard critical care | 18% | 19% | 18% | 18% |
| Standard oncology products | 3% | 2% | 3% | 2% |
| Other products/other revenue | 10% | 11% | 9% | 9% |
| Total | 100% | 100% | 100% | 100% |

We sell our I.V. administration products to independent distributors, via direct sales and through agreements with Hospira and certain other medical product manufacturers. Most of our independent distributors handle the full line of our I.V. administration products. We also sell our I.V. administration and oncology products to Hospira pursuant to two agreements. Under a 1995 agreement, Hospira purchases CLAVE products, principally bulk, non-sterile connectors, oncology products and the CLC2000. Under a 2001 agreement, we sell custom infusion sets to Hospira under a program referred to as SetSource. Our 1995 and 2001 agreements with Hospira provide Hospira with conditional exclusive and nonexclusive rights to distribute all existing ICU Medical products worldwide with terms that extend to 2014. We sell invasive monitoring and angiography to independent distributors and through direct sales. We also sell certain other products to a number of other medical product manufacturers.

We believe that as healthcare providers continue to either consolidate or join major buying organizations, the success of our products will depend, in part, on our ability, either independently or through strategic relationships such as our Hospira relationship, to secure long-term contracts with large healthcare providers and major buying organizations. As a result of this marketing and distribution strategy we derive most of our revenues from a relatively small number of distributors and manufacturers. The loss of a strategic relationship with a customer or a decline in demand for a manufacturing customer's products could have a material adverse effect on our operating results.

We have an ongoing effort to increase systems capabilities, improve manufacturing efficiency, reduce labor costs, reduce time needed to produce an order, and minimize investment in inventory. These include the use of automated assembly equipment for new and existing products and use of larger molds and molding machines. In 2006, we centralized our proprietary molding in Salt Lake City and expanded our production facility in Mexico, which took over the majority of our manual assembly previously done in Salt Lake City. In January 2011, we completed an additional expansion of our production facility in Mexico. In late 2010, we completed construction of an assembly plant in Slovakia that will serve our European product distribution. Product shipments from this plant commenced in the fourth quarter of 2010. We may establish additional production facilities outside the U.S. There is no assurance that we will achieve success in establishing or expanding new manufacturing facilities outside the U.S.

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

| Channel | Quarter ended March 31, | | Fiscal Year Ended | |
|-------------------------------|-------------------------|------|-------------------|------|
| | 2011 | 2010 | 2010 | 2009 |
| Medical product manufacturers | 40% | 39% | 41% | 50% |
| Domestic distributors/direct | 36% | 37% | 36% | 29% |

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| | | | | |
|-------------------------|-------------|-------------|-------------|-------------|
| International customers | 24% | 24% | 23% | 21% |
| Total | 100% | 100% | 100% | 100% |

Sales to international customers do not include bulk CLAVE products sold to Hospira in the U.S. but subsequently used in products exported by Hospira. Those sales are included in sales to medical product manufacturers. Other sales to Hospira for destinations outside the U.S. are included in sales to international customers.

With the completion of our purchase of the commercial rights and the physical assets of Hospira's critical care line in August 2009, we began selling critical care products in September 2009 to domestic and international distributors and through direct domestic and international sales instead of to Hospira. As a result, we expect to continue to see a shift in sales from medical product manufacturers to domestic and international distributors and direct sales.

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Net sales to domestic distributors/direct in the first quarter of 2011 (including Canada) were \$25.9 million compared to \$23.5 million in the first quarter of 2010, an increase of 10%. The increased sales were primarily from \$1.3 million in increased custom infusion set sales, \$0.7 million of increase CLAVE sales and \$1.1 million in increased TEGO sales, our renal dialysis product, partially offset by lower other product revenue. The increases in custom infusion set, CLAVE and TEGO sales were due to higher unit volume sales. We expect increases in domestic distributor sales in 2011 compared to 2010, principally from growth in custom products, CLAVE, renal and oncology, although there is no assurance that these expectations will be realized.

Net sales to international customers (excluding Canada) were \$16.7 million in the first quarter of 2011, compared with \$15.7 million in the first quarter of 2010, an increase of 7%. The increased sales were primarily from \$1.2 million in increased custom infusion set sales from increased unit volume due to increased market share and demographic growth. We expect modest increases in international customer sales in 2011 compared to 2010, primarily from growth in CLAVE, critical care product sales and custom set sales, although there is no assurance that these expectations will be realized.

Table of Contents

Product and other revenue: Net sales of CLAVE products were \$25.0 million in the first quarter of 2011 compared to \$23.4 million in the first quarter of 2010, an increase of 7%. The increase was primarily from higher U.S. Hospira sales and from higher domestic distributor/direct sales from increased market share and demographic growth. We expect modest increases in CLAVE product sales in 2011 compared to 2010, although there is no assurance that these expectations will be realized.

Net sales of custom products, which include custom infusion, custom oncology products and custom critical care products, were \$24.1 million in the first quarter of 2011 compared to \$20.4 million in the first quarter of 2010, an increase of 18%. This increase was primarily comprised of increased sales of custom infusion sets from unit growth. The unit growth in custom infusion sets was primarily due to the conversion by certain of our customers from a competitor's standard sets to our custom systems. We expect modest increases in custom product sales in 2011 compared to 2010 because of the additional sales to Hospira in 2010 for product line changes that are not expected to occur in 2011, although there is no assurance that these expectations will be realized.

Standard critical care product sales were \$12.7 million in the first quarter of 2011 compared to \$12.4 million in the first quarter of 2010, a small increase of 3%. We expect moderate increases in 2011 compared to 2010 in standard critical care sales, although there is no assurance that these expectations will be realized.

Our standard oncology product sales were \$2.2 million in the first quarter of 2011 compared to \$1.4 million in the first quarter of 2010, an increase of 60%. The increase was from higher sales to Hospira and higher international sales. We expect higher standard oncology sales in 2011 compared to 2010, although there is no assurance that these expectations will be realized.

TEGO sales, our renal dialysis product, were \$2.0 million in the first quarter of 2011 compared to \$0.8 million in the first quarter of 2010, an increase of 152%. This increase was primarily due to an increase in unit sales in domestic and international distributors and direct sales. We expect TEGO sales to have significant increases in 2011 compared to 2010 due to a new agreement with a major dialysis provider in the U. S., although there is no assurance that these expectations will be realized.

Other revenue consists of license, royalty and revenue share income and was approximately \$0.1 million in the first quarter of 2011 and \$0.2 million in the first quarter of 2010. We may receive other license fees or royalties in the future for the use of our technology. There is no assurance as to amounts or timing of any future payments, or whether such payments will be received.

Gross margins for the first quarters of 2011 and 2010 were 48% and 42%, respectively. The increase was primarily from favorable product mix and manufacturing efficiencies.

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

Selling, general and administrative expenses (SG&A) were \$22.9 million and 32% of revenues in the first quarter of 2011, compared with \$19.7 million and 31% of revenues in the first quarter of 2010. The increase was primarily from a one-time expense for the Long Term Retention Plan (LTRP) of \$2.0 million and increased sales and marketing compensation and benefits of \$0.7 million. In January 2011, our

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Compensation Committee determined to pay out the 2005 LTRP grants and to not make any future payments for the 2006 and 2007 awards, thus effectively cancelling the plan. As a result, we recognized \$2.0 million of non-recurring expense to SG&A in the first quarter of 2011. The increase in sales and marketing compensation and benefits is primarily a result of the expansion of our sales and marketing workforce and salary increases. We expect SG&A in 2011 to be approximately 28.0-28.5% of revenue. There is no assurance that these expectations will be realized.

Research and development expenses (R&D) were \$2.1 million and 3% of revenue in the first quarter of 2011 compared to \$0.9 million and 1% of revenue in the first quarter of 2010. The increase was primarily from \$0.3 million of LTRP payout expense and \$0.6 million of higher project related R&D expenses. We expect R&D in 2011 to be approximately 2.0% of revenue, although there is no assurance that these expectations will be realized.

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

Other income was \$0.4 million in the first quarter of 2011 compared to \$0.2 million in the first quarter of 2010.

Income taxes were accrued at an estimated annual effective tax rate of 36% in the first quarter of 2011 compared to 35% in the first quarter of 2010. The 2011 tax 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. We expect our effective tax rate to be approximately 36% in 2011.

Table of Contents

Liquidity and Capital Resources

During the first quarter of 2011, our cash, cash equivalents and investment securities increased by \$13.5 million from \$93.3 million at December 31, 2010 to \$106.8 million at March 31, 2011.

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

During the first quarter of 2011, our cash provided by operations was \$15.2 million, which was mainly comprised of net income of \$8.1 million, depreciation and amortization of \$4.5 million and stock compensation expense of \$1.0 million, offset by changes in our operating assets and liabilities.

Investing Activities: During the first quarter of 2011, cash used in investing activities was \$26.2 million. This was comprised of net investment purchases of \$21.3 million and purchases of property and equipment of \$4.9 million which were primarily for machinery, equipment and mold additions in our United States and Slovakia plants.

While we can provide no assurances, we estimate that our capital expenditures in 2011 will approximate \$16.0 million to \$19.0 million, which is primarily for investments in molds, machinery and equipment in our manufacturing operations in the United States and investments in information technology that benefit world-wide operations. We expect to use our cash and investments to fund our capital purchases. Estimates of capital expenditures may differ substantially from actual capital expenditures.

Financing Activities: During the first quarter of 2011, our cash provided by financing activities was \$2.2 million. This was from stock option exercises and shares purchased from the employee stock purchase plan resulting in 72,904 shares issued to employees and directors. The tax benefits from the exercise of stock options was \$0.3 million in the first quarter of 2011 which fluctuates based principally on when employees choose to exercise their vested stock options.

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 principal preservation, as further described below in Part I, Item 3. Quantitative and Qualitative Disclosures about Market Risk.

We believe that our existing cash, cash equivalents and investment securities along with funds expected to be generated from future operations will provide us with sufficient funds to finance our current operations for the next twelve months. In the event that we experience illiquidity in our investment securities, downturns or cyclical fluctuations in our business that are more severe or longer than anticipated or if we fail to achieve anticipated revenue and expense levels, we may need to obtain or seek alternative sources of capital or financing, and we can provide no assurances that the terms of such capital or financing will be available to us on favorable terms, if at all.

Off Balance Sheet Arrangements

In the normal course of business, we have agreed to indemnify our officers and directors to the maximum extent permitted under Delaware law and to indemnify customers as to certain intellectual property matters related to sales of our products. There is no maximum limit on the indemnification that may be required under these agreements. Although we can provide no assurances, we have not previously incurred, nor do we expect to incur, any material liabilities associated with this indemnification.

Pursuant to our asset purchase agreement with Hospira, we have agreed to indemnify Hospira and its affiliates from certain liabilities arising out of (i) inaccuracies of our representations and breaches of our warranties; (ii) defaults of our covenants or obligations; (iii) certain assumed obligations and (iv) use of the acquired assets after the date of closing. Most of Hospira's rights to indemnification have terminated, except for liabilities arising out of certain provisions of the asset purchase agreement and liabilities for which notice was previously provided. Notwithstanding the foregoing, we are not obligated to indemnify Hospira for any liabilities for which Hospira is obligated to indemnify us or our affiliates under the Manufacturing, Commercialization and Development Agreement with Hospira, Inc. dated May 1, 2005. Although we can provide no assurances, we do not expect to incur material liability arising out of the indemnification provision of the asset purchase agreement.

Table of Contents**Contractual Obligations**

We have contractual obligations, at March 31, 2011, of approximately the amount set forth in the table below. This amount excludes purchase orders for goods and services for current delivery. The majority of our 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 goods and services for current delivery, amounts related to such purchase orders are excluded from the table below. We have excluded from the table below pursuant to ASC 740-10-25 (formerly FIN 48), an interpretation of ASC 740-10 (formerly SFAS 109), a noncurrent income tax liability of \$4.2 million due to the high degree of uncertainty regarding the timing of future cash outflows associated with the liabilities.

| Contractual Obligations | Total | (in thousands) | | |
|------------------------------|----------|----------------|--------|--------|
| | | 2011 | 2012 | 2013 |
| Operating leases | \$ 127 | \$ 127 | \$ | \$ |
| Warehouse service agreements | 1,739 | 658 | 877 | 204 |
| Capital purchase obligations | 3,625 | 3,625 | | |
| | \$ 5,491 | \$ 4,410 | \$ 877 | \$ 204 |

Critical Accounting Policies

In our Annual Report on Form 10-K for the year ended December 31, 2010, we identified the critical accounting policies which affect our more significant estimates and assumptions used in preparing our consolidated financial statements. We have not changed these policies from those previously disclosed in our Annual Report.

New Accounting Pronouncements

See Note 2 to Part I, Item 1. Financial Statements.

Forward Looking Statements

Various portions of this Quarterly Report on Form 10-Q, including this Management's Discussion and Analysis, describe trends in our business and finances that we perceive and state some of our expectations and beliefs about our future. These statements about the future are forward looking statements, within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and we identify them by using words such as believe, expect, estimate, plan, will, continue, could, may, 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 in sales; deferred revenue; future license, royalty and revenue share income; production costs; gross margins; litigation expense; SG&A and R&D expenses; future costs of expanding our business; income; losses; cash flow; capital expenditures; source and sufficiency of funds for capital purchases and operations; tax rates; changes in working capital items such as receivables and inventory; selling prices; and income taxes;
- factors affecting operating results, such as shipments to specific customers; reduced dependence on current proprietary products; expansion in international markets, selling prices; future increases or decreases in sales of certain products and in certain markets and distribution channels; increases in systems capabilities; introduction and sales of new products; planned increases in marketing; inventory requirements; manufacturing efficiencies and cost savings; unit manufacturing costs; establishment of production facilities outside the U.S.; planned new orders for automated assembly machines for new products; adequacy of production capacity; results of R&D; relocation of manufacturing facilities and personnel; planned growth of our sales and marketing group; our expectation that sales will shift from medical product manufacturers to domestic and international distributors and direct sales; effect of expansion of manufacturing facilities on production efficiencies and resolution of production inefficiencies; the effect of costs to customers and delivery times; business seasonality and fluctuations in quarterly results; customer ordering patterns and the effects of new accounting pronouncements; and

Table of Contents

- expansion of our custom products business; expected increases in revenues from our custom infusion sets, custom critical care and custom oncology products and the importance of these products in the future; potential customer resistance to custom products; our focus on increasing product development, acquisition, sales and marketing efforts to custom products and similar products; new or extended contracts with manufacturers and buying organizations; dependence on a small number of customers; future sales to and revenues from Hospira and the importance of Hospira to our growth; effect of the acquisition of Hospira's critical care product line, including its effect on future revenues from Hospira and our positioning with respect to new product introductions and market share; growth of our CLAVE products in future years; the outcome of our strategic initiatives; outcome of litigation; competitive and market factors, including continuing development of competing products by other manufacturers; consolidation of the healthcare provider market; our dependence on securing long-term contracts with large healthcare providers and major buying organizations; working capital requirements; liquidity and realizable value of our investment securities; future investment alternatives; our expectations regarding liquidity and capital resources over the next twelve months; acquisitions of other businesses or product lines, indemnification liabilities and contractual liabilities.

Forward-looking statements involve certain risks and uncertainties, which may cause actual results to differ materially from those discussed in each such statement. First, one should consider the factors and risks described in the statements themselves or otherwise discussed herein. Those factors are uncertain, and if one or more of them turn out differently than we currently expect, our operating results may differ materially from our current expectations.

Second, investors should read the forward looking statements in conjunction with the Risk Factors discussed in Part I, Item 1A of our Annual Report on Form 10-K with the SEC for the year ended December 31, 2010 and our other reports and registration statements filed with the SEC. Also, actual future operating results are subject to other important factors and risks that we cannot predict or control, including without limitation, the following:

- general economic and business conditions, both in the U.S. and internationally;
- unexpected changes in our arrangements with Hospira or our other large customers;
- outcome of litigation;
- fluctuations in foreign exchange rates and other risks of doing business internationally;
- increases in labor costs or competition for skilled workers;
- increases in costs or availability of the raw materials need to manufacture our products;

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- 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.

Table of Contents

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We had a portfolio of federal-tax exempt state and municipal government debt securities and certificates of deposit of \$35.7 million as of March 31, 2011. The securities are all investment grade, comprised of \$31.7 million of pre-refunded municipal securities, \$1.2 million of non-pre-refunded municipal securities and \$2.8 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 March 31, 2011.

Foreign currency exchange risk for financial instruments on our balance sheet, which consist of cash, accounts receivable, insurance receivable and accounts payable, is not significant to our financial statements. Sales from the U.S. and Mexico to foreign distributors are all denominated in U.S. dollars. We have manufacturing, sales and distribution facilities in several countries and we conduct business transactions denominated in various foreign currencies, principally the Euro and Mexican Peso. A 10% change in the conversion of the Mexican Peso to the U.S. dollar from the average exchange rate we experienced in 2010 and our manufacturing spending from 2010 would impact our cost of goods sold by approximately \$2.0 million. Cash and receivables in those countries have been insignificant and are generally offset by accounts payable in the same foreign currency, except for our European operations, where our net Euro asset position at March 31, 2011 and 2010 were approximately 13.3 million and 8.5 million, respectively. A 10% change in the conversion of the Euro to the U.S. dollar for our cash, accounts receivable, insurance receivable and accounts payable from the March 31, 2011 spot rate would impact our consolidated amounts on these balance sheet items by approximately \$1.9 million or less than 2% of these net assets. We expect that in the future, with the growth of our European distribution operation, that net Euro denominated instruments will continue to increase. We currently do not hedge our foreign currency exposures.

Our exposure to commodity price changes relates primarily to certain manufacturing operations that use resin. We manage our exposure to changes in those prices through our procurement and supply chain management practices and the effect of price changes has not been material to date. Based on our average price for resin in fiscal year 2010 and 2009, a 10% increase to the price of resin would result in approximately a \$0.7 million change and \$0.6 million change in material cost, respectively.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our principal executive officer and principal financial officer have concluded, based on their evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934), as of the end of the period covered by this Report, that our disclosure controls and procedures are effective to ensure that the information we are required to disclose in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and

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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, 2011 that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

Table of Contents

**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, we alleged that RyMed Technologies, Inc. (RyMed) infringes certain of ICU s patents through the manufacture and sale of certain products, including its InVision-Plus valves. We sought monetary damages and injunctive relief. As noted in Part I, Item 3 of our Annual Report on Form 10-K for the year ended December 31, 2010, trial commenced on December 13, 2010, and on December 17, 2010, the jury returned a verdict in our favor on two patents. The parties are engaged in post-trial briefings and motion practice, and have requested a re-trial on certain matters. We intend to continue to vigorously pursue these matters.

We are from time to time involved in various other legal proceedings, either as a defendant or plaintiff, most of which are routine litigation in the normal course of business. We believe that the resolution of the legal proceedings in which we are involved will not have a material adverse effect on our financial position or results of operations.

Item 1A. Risk Factors

In evaluating an investment in our common stock, investors should consider carefully, among other things, the risk factors previously disclosed in Part I, Item 1A of our Annual Report on Form 10-K filed with the SEC for the year ended December 31, 2010, as well as the information contained in this Quarterly Report and our other reports and registration statements filed with the SEC. There have been no material changes in the risk factors as previously disclosed under Risk Factors in Part I, Item 1A of our Annual Report on Form 10-K with the SEC for the year ended December 31, 2010.

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

In July 2008, our Board of Directors authorized a program to purchase \$40.0 million of our common stock. In October 2009, our Board of Directors increased the amount that may be purchased under this plan by \$15.0 million, bringing the total authorized amount that may be purchased under the plan to \$55.0 million. As of March 31, 2011, all but \$54,000 of the \$55.0 million authorized had been used. This plan has no expiration date.

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In July 2010, our Board of Directors approved a new common stock purchase plan to purchase \$40.0 million of our common stock. This plan has no expiration date.

The following is a summary of our stock repurchasing activity during the first quarter of 2011:

| Period | Shares purchased | Average price paid per share | Shares purchased as part of a publicly announced program | Approximate dollar value that may yet be purchased under the program |
|-----------------------------|-------------------------|-------------------------------------|---|---|
| 01/01/2011 01/31/2011 | | \$ | | \$ 40,054,000 |
| 02/01/2011 02/28/2011 | | | | 40,054,000 |
| 03/01/2011 03/31/2011 | | | | 40,054,000 |
| First quarter of 2011 total | | \$ | | 40,054,000 |

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Table of Contents

Item 6. Exhibits

| | |
|-----------------|---|
| Exhibit 10.1* | 2008 Performance-Based Incentive Plan, as amended. |
| Exhibit 10.2* | Employment agreement between Registrant and George A. Lopez, M.D., effective January 1, 2011, dated March 30, 2011.. |
| 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 |

* Management contract or compensatory plan or other arrangement.

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

Date: April 22, 2011

(Principal Financial Officer)

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Table of Contents

Exhibit Index

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