

ICU MEDICAL INC/DE
Form 10-Q
October 22, 2009
Table of Contents

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

FORM 10-Q

x

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

For the quarterly period ended: September 30, 2009

or

o

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

For the transition period from: to

Commission File No.: 0-19974

ICU MEDICAL, INC.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

951 Calle Amanecer, San Clemente, California
(Address of principal executive offices)

33-0022692
(I.R.S. Employer
Identification No.)

92673
(Zip Code)

(949) 366-2183

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

(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 October 11, 2009 |
|--------|---------------------------------|
| Common | 14,809,239 |

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 September 30, 2009 and December 31, 2008</u> | 3 |
| <u>Condensed Consolidated Statements of Income for the three and nine months ended September 30, 2009 and 2008</u> | 4 |
| <u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2009 and 2008</u> | 5 |
| <u>Condensed Consolidated Statements of Comprehensive Income for the three and nine months ended September 30, 2009 and 2008</u> | 6 |
| <u>Notes to Condensed Consolidated Financial Statements</u> | 7 |
| Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations | 12 |
| Item 3. Quantitative and Qualitative Disclosures About Market Risk | 21 |
| Item 4. Controls and Procedures | 21 |
| Part II - Other Information | |
| <u>Item 1. Legal Proceedings</u> | 22 |
| <u>Item 1A. Risk Factors</u> | 22 |
| <u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u> | 26 |
| <u>Item 3. Default Upon Senior Securities</u> | 26 |
| <u>Item 4. Submission of Matters to a Vote of Security Holders</u> | 26 |
| <u>Item 5. Other Information</u> | 26 |
| <u>Item 6. Exhibits</u> | 27 |
| <u>Signature</u> | 29 |

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

Condensed Consolidated Balance Sheets

(Amounts in thousands, except per share data)

| | September 30, 2009 (unaudited) | December 31, 2008 (1) |
|--|--------------------------------------|-----------------------------|
| ASSETS | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | \$ 53,259 | \$ 55,696 |
| Investment securities | 70,126 | 56,093 |
| Cash, cash equivalents and investment securities | 123,385 | 111,789 |
| Accounts receivable, net of allowance for doubtful accounts of \$304 at September 30, 2009 and \$320 at December 31, 2008 | 32,447 | 38,423 |
| Inventories | 44,942 | 17,930 |
| Prepaid income taxes | 838 | 4,544 |
| Prepaid expenses and other current assets | 6,196 | 3,471 |
| Deferred income taxes - current portion | 2,877 | 3,231 |
| Total current assets | 210,685 | 179,388 |
| PROPERTY AND EQUIPMENT, net | 74,486 | 69,897 |
| PROPERTY HELD FOR SALE | 940 | 940 |
| RESTRICTED CASH | 532 | 6,014 |
| INVESTMENT SECURITIES - non-current portion | | 11,350 |
| GOODWILL | 1,478 | |
| INTANGIBLE ASSETS, net | 17,263 | 10,780 |
| DEFERRED INCOME TAXES - non-current portion | 3,855 | 3,855 |
| INCOME TAXES RECEIVABLE - non-current portion | 1,210 | 1,210 |
| | \$ 310,449 | \$ 283,434 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| CURRENT LIABILITIES: | | |
| Accounts payable | \$ 9,706 | \$ 7,879 |
| Accrued liabilities | 11,887 | 14,081 |
| Deferred revenue | 1,923 | |
| Total current liabilities | 23,516 | 21,960 |
| DEFERRED INCOME TAXES - non-current portion | 5,383 | 4,007 |
| INCOME TAXES PAYABLE - non-current portion | 4,663 | 4,436 |
| COMMITMENTS AND CONTINGENCIES | | |
| STOCKHOLDERS' EQUITY: | | |
| Convertible preferred stock, \$1.00 par value Authorized 500 shares; issued and outstanding none | | |
| Common stock, \$0.10 par value Authorized 80,000 shares; Issued 14,809 shares at September 30, 2009 and 14,784 shares at December 31, 2008, outstanding 14,809 shares at September 30, 2009 and 14,731 shares at December 31, 2008 | 1,481 | 1,478 |
| Additional paid-in capital | 53,495 | 50,970 |
| Treasury stock, at cost - 0 and 53 shares at September 30, 2009 and December 31, 2008 | | (1,623) |
| Retained earnings | 220,431 | 201,304 |
| Accumulated other comprehensive income | 1,480 | 902 |
| Total stockholders' equity | 276,887 | 253,031 |

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

\$ 310,449 \$ 283,434

(1) December 31, 2008 balances were derived from audited consolidated financial statements.

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 Income

(Amounts in thousands, except per share data)

(unaudited)

| | Three months ended September 30, | | Nine months ended September 30, | |
|--|----------------------------------|-----------------|---------------------------------|------------------|
| | 2009 | 2008 | 2009 | 2008 |
| REVENUES: | | | | |
| Net sales | \$ 53,830 | \$ 54,374 | \$ 161,307 | \$ 146,427 |
| Other | 135 | 361 | 392 | 1,554 |
| TOTAL REVENUE | 53,965 | 54,735 | 161,699 | 147,981 |
| COST OF GOODS SOLD | | | | |
| | 28,916 | 29,788 | 84,295 | 84,459 |
| Gross profit | 25,049 | 24,947 | 77,404 | 63,522 |
| OPERATING EXPENSES: | | | | |
| Selling, general and administrative | 16,751 | 13,571 | 48,366 | 40,364 |
| Research and development | 661 | 857 | 2,016 | 4,328 |
| Total operating expenses | 17,412 | 14,428 | 50,382 | 44,692 |
| Income from operations | 7,637 | 10,519 | 27,022 | 18,830 |
| OTHER INCOME | 419 | 994 | 1,042 | 3,689 |
| Income before income taxes | 8,056 | 11,513 | 28,064 | 22,519 |
| PROVISION FOR INCOME TAXES | (1,732) | (3,868) | (8,937) | (7,204) |
| NET INCOME | \$ 6,324 | \$ 7,645 | \$ 19,127 | \$ 15,315 |
| NET INCOME PER SHARE | | | | |
| Basic | \$ 0.43 | \$ 0.53 | \$ 1.29 | \$ 1.09 |
| Diluted | \$ 0.42 | \$ 0.52 | \$ 1.27 | \$ 1.06 |
| WEIGHTED AVERAGE NUMBER OF SHARES | | | | |
| Basic | 14,796 | 14,327 | 14,771 | 14,016 |
| Diluted | 15,146 | 14,685 | 15,033 | 14,481 |

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)

| | Nine months ended September 30, | |
|--|--|---------------|
| | 2009 | 2008 |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net income | 19,127 | \$ 15,315 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Depreciation and amortization | 11,280 | 10,714 |
| Provision for doubtful accounts | (25) | (297) |
| Stock compensation | 1,963 | 1,357 |
| Cash provided (used) by changes in operating assets and liabilities, net of assets and business acquired | | |
| Accounts receivable | 6,502 | (6,125) |
| Inventories | (1,754) | 301 |
| Prepaid expenses and other assets | (2,425) | (631) |
| Accounts payable | 1,655 | (836) |
| Accrued liabilities | (3,240) | 1,698 |
| Deferred revenue | 1,923 | |
| Prepaid and deferred income taxes | 3,517 | (162) |
| Net cash provided by operating activities | 38,523 | 21,334 |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Purchases of property and equipment | (10,164) | (9,685) |
| Asset purchase | (30,533) | |
| Business acquisition, net of cash acquired | (5,662) | |
| Change in restricted cash | 5,497 | |
| Proceeds from finance loan repayments | | 60 |
| Purchases of investment securities | (88,237) | (42,064) |
| Proceeds from sale of investment securities | 85,554 | 73,543 |
| Net cash provided (used) by investing activities | (43,545) | 21,854 |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Proceeds from exercise of stock options | 1,352 | 5,035 |
| Proceeds from employee stock purchase plan | 1,271 | 1,373 |
| Tax benefits from exercise of stock options | 88 | 4,293 |
| Purchase of treasury stock | (560) | |
| Net cash provided by financing activities | 2,151 | 10,701 |
| Effect of exchange rate changes on cash | 434 | (187) |
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS | (2,437) | 53,702 |
| CASH AND CASH EQUIVALENTS, beginning of period | 55,696 | 7,873 |
| CASH AND CASH EQUIVALENTS, end of period | \$ 53,259 | \$ 61,575 |

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 September 30, | | Nine months ended September 30, | |
|--|----------------------------------|----------|---------------------------------|-----------|
| | 2009 | 2008 | 2009 | 2008 |
| Net income | \$ 6,324 | \$ 7,645 | \$ 19,127 | \$ 15,315 |
| Other comprehensive income (loss), net of tax: | | | | |
| Unrealized loss on investments | | (32) | | (320) |
| Foreign currency translation adjustment | 584 | (962) | 578 | (440) |
| Comprehensive income | \$ 6,908 | \$ 6,651 | \$ 19,705 | \$ 14,555 |

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

September 30, 2009

(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 Company's Annual Report on Form 10-K filed with the SEC for the year ended December 31, 2008.

ICU Medical, Inc. (the Company), a Delaware corporation, operates principally in one business segment engaged in the development, manufacturing and marketing of disposable medical devices. The Company's devices are sold principally to distributors and medical product manufacturers throughout the United States and internationally. All subsidiaries are wholly or majority owned and included in the consolidated financial statements. All intercompany balances and transactions have been eliminated.

Note 2: New Accounting Pronouncements:

In April 2009, the Financial Accounting Standards Board (FASB) issued Accounting Codification Statement (ASC) 805-10, 805-20 and 805-30 (formerly FSP SFAS 141(R)-1), Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies , to amend the provisions related to the initial recognition and measurement, subsequent measurement and disclosure of assets and liabilities arising from contingencies in a business combination under ASC 805 (formerly SFAS 141(R)). . Under the new guidance, assets acquired and liabilities assumed in a business combination that arise from contingencies should be recognized at fair value on the acquisition date if fair value can be determined during the measurement period. If fair value cannot be determined, companies should typically account for the acquired contingencies using existing guidance. The Company adopted this pronouncement on January 1, 2009. The adoption did not have a material effect on the Company's financial position or results of operations.

In April 2009, the FASB issued ASC 820-10-65-4 (formerly FSP SFAS 157-4), Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly which provides additional guidance for estimating fair value in accordance with ASC 820 (formerly SFAS No. 157), Fair Value Measurements , when the volume and level

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

of activity for the asset or liability have significantly decreased. This pronouncement also includes guidance on identifying circumstances that indicate a transaction is not orderly. The Company adopted this pronouncement on April 1, 2009. The adoption did not have a material effect on the Company's financial position or results of operations.

In April 2009, the FASB issued ASC 320-10-65-4 (formerly FSP SFAS 115-2 and SFAS 124-2), *Recognition and Presentation of Other-Than-Temporary Impairments*, to amend the other-than-temporary impairment guidance in debt securities to be based on intent and not more likely than not that the Company would be required to sell the security before recovery and to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities in the financial statements. The Company adopted this pronouncement on April 1, 2009. The adoption did not have a material effect on the Company's financial position or results of operations.

In May 2009, the FASB issued ASC 855-10 (formerly SFAS 165), *Subsequent Events*, to establish general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. The Company adopted this pronouncement for the quarter ended June 30, 2009. The adoption did not have an effect on the Company's financial position or results of operations.

In June 2009, the FASB issued ASC 105-10 (formerly SFAS No. 168), *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles*, which authorized the Codification as the sole source for authoritative U.S. GAAP. The Company adopted ASC 105-10 for the quarter ended September 30, 2009. The adoption did not have an effect on the Company's financial position or results of operations.

Table of Contents**Note 3: Asset Purchase**

On August 31, 2009, the Company purchased the commercial rights and physical assets of Hospira Inc.'s (Hospira) critical care product line for \$30.5 million in cash. The purchase price was based on estimated inventory and fixed asset values at the time of purchase, and may be subsequently adjusted with amounts due to or from Hospira for up to 24 months after August 31, 2009 or for adjustments to asset classifications. The asset purchase agreement includes a repurchase right of up to \$6.0 million of finished goods inventory if the Company is not able to sell the purchased inventory by August 31, 2011. As of September 30, 2009, the purchase price was allocated to the acquired assets based on their relative fair values, as follows:

| | | |
|--|----|--------|
| Finished goods inventory | \$ | 22,898 |
| Intangible assets - customer contracts | | 1,522 |
| Intangible assets - patents | | 1,128 |
| Property, plant and equipment | | 3,899 |
| Total assets purchased | | 29,447 |
| Net due from Hospira for adjusted inventory post asset purchase close date of August 31, 2009 to September 30, 2009* | | 1,086 |
| Total adjusted purchase price on asset purchase date, August 31, 2009 | \$ | 30,533 |

*Reflected in Prepaid expenses and other current assets on the Condensed Consolidated Balance Sheet at September 30, 2009

The Company entered into the asset purchase agreement with Hospira on July 8, 2009. The Company analyzed the transaction and determined the transaction was an asset purchase as it did not include sufficient elements of a business combination. All critical care sales to Hospira from July 8, 2009 to August 31, 2009 were deferred and revenue was not recognized for these shipments. The deferred revenue of \$1.9 million on the Company's balance sheet as of September 30, 2009, represents the gross profit associated with the standard and custom critical care sales to Hospira from the time of signing the asset purchase agreement to the closing of the transaction. The Company will recognize the deferred revenue when the inventory is sold to the end customer, on a first-in, first-out, basis.

With the completion of the transaction, the Company is responsible for sales, marketing, customer contracting and distribution for the critical care line. In connection with the transaction, certain of the Company's obligations to fund certain critical care research and to provide sales specialist support under the Manufacturing Commercialization Development Agreement (MCDA) were released. On August 31, 2009, the Company entered into a transition services agreement with Hospira to facilitate the transition, under which Hospira will provide distribution services and light manufacturing for up to eighteen months from August 31, 2009, however, the Company's management currently expects these functions will be transitioned prior to the end of this eighteen-month period. The Company can provide no assurances that the transition will occur without delays or disruptions. Any delay or disruption in the transition may reduce or eliminate the expected benefits from the transaction.

Note 4: Restricted Cash and Intangible Assets

In February 2009, the Company acquired a small manufacturing and distribution company based in Germany for approximately \$5.7 million, which was reflected as restricted cash of \$6.0 million at December 31, 2008. The Company recorded \$5.7 million in intangible assets, which includes \$3.8 million for customer contracts, \$0.4 million for trademarks, \$1.5 million of goodwill and a deferred tax liability of \$1.4 million,

due to the non-tax deductibility of the intangible assets.

The \$0.5 million of restricted cash at September 30, 2009 is for cash in escrow related to the land purchase of the Company's future plant in Slovakia.

Note 5: Fair Value Measurement:

The Company's investment securities, which are considered available for sale and trading consist principally of corporate preferred stocks, certificates of deposit and federal-tax-exempt state and municipal government debt. The Company has \$8.4 million of its investment securities as Level 1 assets, which are certificates of deposit with quoted prices in active markets. The Company has \$60.9 million of its investment securities as Level 2 assets, which are pre-refunded municipal securities and have observable inputs. The Company has \$0.9 million invested in one auction rate security as a Level 3 asset due to the unobservable inputs caused by the lack of liquidity in the recent auctions. The valuation of this security was based on quotes received from our brokers which were derived from their internal models combined with internally developed discount factors. In determining a discount factor for the auction rate security, the model weights various factors, including assessments of credit quality, duration, insurance wraps, discount rates, overall capital market liquidity and comparable securities, if any. The security is carried at fair value.

Table of Contents

The following table provides the assets and liabilities carried at fair value measured on a recurring basis as of September 30, 2009:

| | Fair value measurements at September 30, 2009 using | | | |
|-------------------------------|---|--|---|---|
| | Total carrying value at September 30, 2009 | 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 | \$ 69,226 | \$ 8,360 | \$ 60,866 | \$ |
| Trading securities | 900 | | | 900 |
| | \$ 70,126 | \$ 8,360 | \$ 60,866 | \$ 900 |

The following tables summarize the change in the fair values for the Company's Level 3 asset for the quarter ended September 30, 2009:

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

| | Three months ended September 30, 2009 | Nine months ended September 30, 2009 |
|---|---------------------------------------|--------------------------------------|
| Beginning balance | \$ 2,425 | \$ 15,925 |
| Transfer into Level 3 | | |
| Sales | (1,525) | (15,025) |
| Unrealized holding gain, included in other comprehensive income | | |
| Ending balance | \$ 900 | \$ 900 |

The Company has an agreement with UBS AG ("UBS") that permits the Company to require UBS to purchase the Company's auction rate security at par value plus accrued interest. As of September 30, 2009, the Company has \$0.9 million in one auction rate security. There was less than \$0.1 million increase in the market values of the Company's auction rate security in the quarter ended September 30, 2009.

Note 6: Inventories:

Inventories consisted of the following:

| | September 30, 2009 | December 31, 2008 |
|-----------------|--------------------|-------------------|
| Raw material | \$ 16,558 | \$ 12,531 |
| Work in process | 2,497 | 2,577 |
| Finished goods | 25,887 | 2,822 |
| Total | \$ 44,942 | \$ 17,930 |

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

The Company's finished goods inventory at September 30, 2009, includes \$18.9 million from critical care inventory purchased from Hospira on August 31, 2009 in the asset purchase agreement discussed in Note 3.

Note 7: Property and Equipment:

Property and equipment consisted of the following:

| | September 30, 2009 | | December 31, 2008 |
|--|--------------------|----|-------------------|
| Machinery and equipment | \$ 56,195 | \$ | 50,337 |
| Land, building and building improvements | 49,640 | | 48,715 |
| Molds | 19,139 | | 16,791 |
| Computer equipment and software | 12,137 | | 9,890 |
| Furniture and fixtures | 1,898 | | 1,983 |
| Construction in progress | 5,517 | | 3,479 |
| Total property and equipment, cost | 144,526 | | 131,195 |
| Accumulated depreciation | (70,040) | | (61,298) |
| Net property and equipment | \$ 74,486 | \$ | 69,897 |

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 236,000 and 1,423,000 for the three months ended September 30, 2009 and 2008, respectively and 385,000 and 1,619,000 for the nine months ended September 30, 2009 and 2008, respectively.

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

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|-------------------------------------|----------|------------------------------------|-----------|
| | 2009 | 2008 | 2009 | 2008 |
| Net income | \$ 6,324 | \$ 7,645 | \$ 19,127 | \$ 15,315 |
| Weighted average number of common shares outstanding (for basic calculation) | 14,796 | 14,327 | 14,771 | 14,016 |
| Dilutive securities | 350 | 358 | 262 | 465 |
| Weighted average common and common equivalent shares outstanding (for diluted calculation) | 15,146 | 14,685 | 15,033 | 14,481 |
| EPS basic | \$ 0.43 | \$ 0.53 | \$ 1.29 | \$ 1.09 |
| EPS diluted | \$ 0.42 | \$ 0.52 | \$ 1.27 | \$ 1.06 |

Note 9: Income Taxes:

Income taxes were accrued at an estimated annual effective tax rate of 31.8% in the first nine months of 2009 compared to 32.0% in the first nine months of 2008. 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, tax exempt income and deductions for domestic production activities.

Note 10: Major Customer:

The Company had revenues equal to 10% or more of total revenues from one customer, Hospira, Inc. Such revenues were 45% and 71% of total revenue for the three months ended September 30, 2009 and 2008, respectively and 60% and 68% for the nine months ended September 30, 2009 and 2008, respectively. As of September 30, 2009 and December 31, 2008, the Company had accounts receivable from Hospira of 47% and 66%, of consolidated accounts receivable, respectively.

Note 11: Commitments and Contingencies:

In a previously reported action entitled Medegen MMS, Inc. v. ICU Medical, Inc., filed on July 6, 2006 in the United States District Court for the Central District of California, Medegen alleged that ICU Medical infringed one of its patents by offering for sale and selling the CLC2000 and TEGO. Medegen sought monetary damages and injunctive relief. In March 2007, Medegen withdrew its action as to the TEGO. On September 14, 2007, the Court issued an order granting our summary judgment motion of non-infringement and entered judgment of non-infringement, dismissing Medegen's case with prejudice. Medegen appealed the Court's claim construction and summary judgment orders. By decision issued in November 2008, the Federal Circuit reversed the order granting summary judgment and remanded the case to the District Court. This case was dismissed by agreement of the parties in the third quarter of 2009.

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. Although we can provide no assurances, the Company has never incurred, nor do we expect to incur, any liability for indemnification. Except for indemnification agreements, the Company does not have any off balance sheet arrangements.

Pursuant to the Asset Purchase Agreement, as described in Note 3, entered into on July 8, 2009 with Hospira, the Company has agreed to indemnify Hospira and its affiliates from certain liabilities arising out of (i) inaccuracies of the Company's representations and breaches of the Company's 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 will terminate eighteen months after the closing of the transaction, August 31, 2009, except for liabilities arising out of certain provisions of the asset purchase agreement and liabilities for which notice was previously provided.

Table of Contents

Notwithstanding the foregoing, the Company is not obligated to indemnify Hospira for any liabilities for which Hospira is obligated to indemnify the Company or the Company's affiliates under the MCDA. Although the Company can provide no assurances, the Company does not expect to incur material liability arising out of the indemnification provision of the asset purchase agreement.

Note 12: Subsequent Event:

Treasury Stock:

In July 2008, the Company's board of directors authorized a program to purchase up to \$40.0 million of the Company's common stock. Through September 2009, \$6.4 million was purchased from this program. In October 2009, the Company's board of directors authorized to increase the maximum to purchase under this plan by \$15.0 million, bringing the total authorized to purchase to \$55.0 million.

The Company has evaluated subsequent events through October 22, 2009, which is the date the financial statements were available to be issued.

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 proprietary, disposable medical connection systems for use in vascular therapy applications. Our devices are designed to protect patients from catheter related bloodstream infections and healthcare workers from exposure to diseases through accidental needlesticks or hazardous drugs. We are also a leader in the production of custom infusion sets and we incorporate our proprietary products into many of those custom infusion sets. In addition, we are a significant manufacturer of critical care medical devices, including catheters, angiography kits and cardiac monitoring systems.

Business Overview

Until the late 1990s, our primary emphasis in product development, sales and marketing was disposable medical connectors for use in I.V. therapy, and our principal product was the CLAVE. 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.

We believe the success of the CLAVE has motivated, and will continue to motivate others to develop one-piece, swabbable, needleless connectors that may incorporate many of the same functional and physical characteristics as the CLAVE. We are aware of a number of such products. We have patents covering the technology embodied in the CLAVE and intend to enforce those patents as appropriate. If we are not successful in enforcing our patents, competition from such products could adversely affect our market share and prices for our CLAVE products. Although overall pricing has been stable recently, the average price of our CLAVE products may decline in the future. There is no assurance that our current or future products will be able to successfully compete with products developed by others.

We are reducing our dependence on our current proprietary products by introducing new products and systems and acquiring product lines. Under one of our Hospira Agreements, we manufacture custom infusion sets for sale by Hospira and jointly promote the products under the name SetSource. In 2005, we acquired Hospira's Salt Lake City manufacturing facility and entered into an agreement with Hospira to produce their critical care products, including invasive monitoring, angiography products and certain other products they had manufactured at that facility. On August 31, 2009, we purchased the commercial rights and physical assets from Hospira's critical care product line which provide us control over all aspects of our critical care product line. We also contract with group purchasing organizations and independent dealer networks for inclusion of our non-critical care CLAVE and custom products in the product offerings of those entities. We are expanding our custom products business through increased sales to medical product manufacturers, independent distributors and direct sales to the end users of our product. These expansions include our 2008 agreement with Premier and an agreement extension with MedAssets. Both organizations are U.S. healthcare purchasing networks. Custom products, which include custom infusion, custom oncology and custom critical care products, accounted for approximately \$56.4 million or 35% of total revenue in the first nine months of 2009 and \$70.2 million or 34% of total revenue in 2008. We expect continued increases in sales of custom infusion sets and custom oncology products. As part of this effort, we have recently introduced a number of new products: the TEGO for use in dialyses, the Orbit 90 diabetes set, and a line of oncology products including the Spiros male luer connector device, the Genie vial access device, custom I.V. sets and ancillary products specifically designed for chemotherapy. There is no assurance that we will be successful in finding future acquisition opportunities or integrating these new product lines into our existing business.

Custom products and new products will be of increasing importance to us in future years. We expect continued growth in 2009 in our CLAVE products in the U.S., but at a modest growth rate. We also potentially face substantial increases in competition in our CLAVE business. Growth

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

for all of our products outside the U.S., to date, has been relatively modest. Therefore, we are directing 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.

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

Table of Contents

In 2005, we acquired Hospira's Salt Lake City manufacturing facility, related capital equipment and entered into the MCDA under which we produced for sale, exclusively to Hospira, substantially all the products, primarily critical care, that Hospira had manufactured at that facility. Under this agreement, prior to August 31, 2009, Hospira retained commercial responsibility for the products we produced, including sales, marketing, pricing, distribution, customer contracts, customer service and billing. The U.S. market for most of the critical care products that we sell to Hospira has been declining in recent years. Under the MCDA, we manufactured the products and Hospira was responsible for sales to end customers, and we had little ability to directly influence Hospira's sales and marketing efforts, and our sales under the MCDA were subject to fluctuations over which we had little control. On August 31, 2009, we completed an asset purchase with Hospira in which we acquired the commercial rights and physical assets of Hospira's critical care product line. This purchase provides us with complete control over worldwide commercial responsibility for the critical care products including sales, marketing, customer contracting and distribution. Under the MCDA, we were also committed to fund certain critical care research and to provide sales specialist support. Both obligations under the MCDA were released by Hospira upon the closing of this transaction. On August 31, 2009, we entered into a transition services agreement with Hospira to facilitate the transition of services that Hospira previously provided under the MCDA relating to the critical care products. Under the transition services agreement, Hospira will provide distribution services and light manufacturing for up to eighteen months from August 31, 2009, however, we currently expect these functions will be transitioned prior to the end of this eighteen-month period. We can provide no assurances that the transition will occur without delays or disruptions. Any delay or disruption in the transition may reduce or eliminate the expected benefits from the transaction.

Our largest customer is Hospira. Our relationship with Hospira has been and will continue to be of singular importance to our growth. In the first nine months of 2009 and years ended 2008, 2007 and 2006, our revenues from worldwide sales to Hospira were 60%, 69%, 73% and 77%, respectively, of total revenues. Although we can provide no assurances, we expect this percentage will decrease because of our purchase of Hospira's critical care product line that closed on August 31, 2009. Hospira has a significant share of the I.V. set market in the U.S., and provides us access to that market. We expect that Hospira will be important to our growth for CLAVE, custom infusion and oncology products, and our other products worldwide.

In February 2009, we acquired a small manufacturing and distribution company based in Germany for \$5.7 million. The products and distribution from this company are in the oncology and neonatal markets.

We believe that achievement of our growth objectives worldwide will require increased efforts by us in sales and marketing and product development in these markets.

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 products, there is no assurance that we will achieve profitable sales of such products. An adverse change in our relationship with Hospira, or a deterioration of Hospira's position in the market, could have an adverse effect on us. Increased expenditures for sales and marketing and product acquisition and development may not yield desired results when expected, or at all. While we have taken steps to control these risks, there are certain risks that may be outside of our control, and there is no assurance that steps we have taken will succeed.

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

| Three months ended September 30, | Nine months ended September 30, | Fiscal Year Ended |
|---|--|--------------------------|
|---|--|--------------------------|

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

| Product Line | 2009 | 2008 | 2009 | 2008 | 2008 | 2007 |
|------------------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| CLAVE | 38% | 37% | 39% | 39% | 39% | 38% |
| Custom products | 36% | 35% | 35% | 34% | 34% | 31% |
| Standard Critical care | 14% | 19% | 16% | 18% | 18% | 23% |
| Other products | 12% | 8% | 10% | 8% | 8% | 7% |
| License, royalty and revenue share | 0% | 1% | 0% | 1% | 1% | 1% |
| Total | 100% | 100% | 100% | 100% | 100% | 100% |

We sell our I.V. administration products to independent distributors, direct sales and through agreements with Hospira and certain other medical product manufacturers. Most independent distributors handle the full line of our I.V. administration products. We sell our invasive monitoring, angiography and I.V. administration products through three agreements with Hospira (the Hospira Agreements). Under a 1995 agreement, Hospira purchases CLAVE products,

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

Table of Contents

principally bulk, non-sterile connectors 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 program 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 2007, we began a significant initiative to improve production processes, called the ICU Production System or IPS, which we believe will enable us to further improve our manufacturing efficiency. We started IPS in our Mexico facility in 2007 and in our Salt Lake City facility in 2008. These efforts are ongoing in both facilities and will continue into 2010. In July 2009, we purchased land in Slovakia. In the third quarter of 2009, we started construction on an assembly plant in Slovakia that will serve our European product distribution. We expect this plant to be operational in the second half of 2010. We may establish additional production facilities outside the U.S. There is no assurance as to the benefits of IPS or our success in establishing manufacturing facilities outside the U.S.

We distribute products through three distribution channels. Product revenues for each distribution channel were as follows:

| Channel | Three months ended | | Nine months ended | | Fiscal Year Ended | |
|-----------------------------------|--------------------|--------------------|--------------------|--------------------|-------------------|------|
| | September 30, 2009 | September 30, 2008 | September 30, 2009 | September 30, 2008 | 2008 | 2007 |
| Medical product manufacturers | 42% | 67% | 56% | 67% | 67% | 71% |
| Domestic distributors/direct | 35% | 18% | 24% | 18% | 18% | 16% |
| International distributors/direct | 23% | 15% | 20% | 15% | 15% | 13% |
| Total | 100% | 100% | 100% | 100% | 100% | 100% |

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

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 to domestic distributors, through direct sales and to international customers instead of to Hospira in September 2009. 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.

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

Quarter-to-quarter and nine month-to-nine month comparisons: We present summarized income statement data in Item 1- Financial Statements. The following table shows, for the year ended December 31, 2008 and the three and nine months ended September 30, 2009 and 2008, the percentages of each income statement caption in relation to total revenues.

| | Fiscal Year 2008 | Three months ended September 30, 2009 | 2008 | Nine months ended September 30, 2009 | 2008 |
|--|---------------------|---|------|--|------|
| Revenue | | | | | |
| Net sales | 99% | 100% | 99% | 100% | 99% |
| Other | 1% | % | 1% | % | 1% |
| Total revenues | 100% | 100% | 100% | 100% | 100% |
| Gross profit | 44% | 46% | 46% | 48% | 43% |
| Selling, general and administrative expenses | 26% | 31% | 25% | 30% | 27% |
| Research and development expenses | 2% | 1% | 2% | 1% | 3% |
| Total operating expenses | 28% | 32% | 27% | 31% | 30% |
| Income from operations | 16% | 14% | 19% | 17% | 13% |
| Other income | 2% | 1% | 2% | 1% | 2% |
| Income before income taxes | 18% | 15% | 21% | 18% | 15% |
| Income taxes | 6% | 3% | 7% | 6% | 5% |
| Net income | 12% | 12% | 14% | 12% | 10% |

Table of Contents

Quarterly results: The healthcare business in the United States is subject to seasonal fluctuations, and activity tends to diminish somewhat in the summer months of June, July and August, when illness is less frequent than in winter months and patients tend to postpone elective procedures. This may cause seasonal fluctuations in our business. 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. The current challenging economic environment has not had a meaningful impact on our business in the operating results reported in this report, however, towards the end of the first quarter of 2009, some of our customers stated their intent to take a more conservative stance on inventory levels. Through the end of the third quarter of 2009, this has not caused a significant impact to our earnings. Our expenses often do not fluctuate consistently with net sales, which may cause fluctuations in operating income that are disproportionate to fluctuations in our revenue.

Quarter Ended September 30, 2009 Compared to the Quarter Ended September 30, 2008

Revenues were \$54.0 million in the third quarter of 2009, compared to \$54.7 million in the third quarter of 2008.

Distribution channels: Net U.S. sales to Hospira in the third quarter of 2009 were \$21.4 million, compared to net sales of \$35.7 million in the third quarter of 2008. The \$14.3 million decrease was primarily due to minimal standard and custom critical care sales to Hospira as a result of the critical care asset purchase from Hospira. We entered into the asset purchase agreement with Hospira on July 8, 2009 and closed the transaction on August 31, 2009. The sales for all standard and custom critical care shipments to Hospira between signing the agreement and closing the transaction were not recognized as revenue. The gross profit from these sales of \$1.9 million was deferred and will be recognized when the inventory is sold to the end customer. We had \$0.7 million of standard and custom critical care sales to Hospira in the third quarter of 2009 compared to \$13.7 million in the third quarter of 2008. Excluding standard and custom critical care, our sales to Hospira decreased \$1.3 million in the third quarter of 2009 compared to the third quarter of 2008. The decrease was primarily due to lower sales of custom oncology of \$1.0 million, CLAVE of \$0.4 million, CLC of \$0.3 million, partially offset by increased custom infusion set sales of \$0.9 million. The decrease in CLAVE sales was from lower unit sales as Hospira began to reduce their inventory levels due to their stated objective to reduce their overall inventory balances. The decrease in custom oncology products was primarily due to lower unit sales. We may look for alternative distribution if this trend continues. The increase in infusion set sales is from higher unit sales primarily attributable to the conversion by certain of our customers from a competitor's standard sets to our custom systems. Excluding critical care products, we expect minimal growth in sales to Hospira in 2009 as Hospira continues to take a more conservative stance in their inventory levels. There is no assurance that these expectations will be realized.

Net sales to domestic distributors and through direct sales in the third quarter of 2009 (including Canada) were \$18.8 million compared to \$9.5 million in the third quarter of 2008, an increase of 98%. The increased sales were primarily from new standard and custom critical care sales, increased oncology and TEGO sales, both newer product lines and increased custom infusion set sales. We began selling standard and custom critical care products directly to distributors and through direct sales in September 2009. New standard and custom critical care sales in the third quarter of 2009 were \$5.8 million and \$1.0 million, respectively. The increase in custom infusion set sales was primarily in increased unit volume sales. We expect increased sales in domestic distributor and direct sales in 2009 compared to 2008 from new standard and custom critical care sales, growth in custom infusion sets, custom oncology products and other new product sales, although there is no assurance that these expectations will be realized.

Net sales to international distributors and through direct sales (excluding Canada) were \$12.6 million in the third quarter of 2009, compared with \$8.2 million in the third quarter of 2008. The increased sales were primarily from new standard critical care sales of \$1.0 million, new custom critical care sales of \$0.4 million and increased custom infusion set sales of \$1.2 million. The majority of the increase was attributable to increased sales in Europe and the Pacific Rim. We expect increases in international sales in 2009, primarily from new standard and custom critical care sales and increased CLAVE, custom infusion and oncology products and standard oncology product sales and additional sales of

our new products from our recent acquisition in Germany, although there is no assurance that these expectations will be realized.

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

Table of Contents

Product and other revenue: Net sales of CLAVE products were \$20.5 million in the third quarters of 2009 and 2008. Increased international CLAVE sales were offset by lower sales to Hospira of \$0.4 million. We continue to expect increases in CLAVE product sales in 2009 compared to 2008, 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 \$19.4 million in the third quarter of 2009 compared to \$18.9 million in the third quarter of 2008. This increase was primarily comprised of increased sales of custom infusion sets of \$3.0 million, partially offset by lower custom critical care sales of \$1.8 million and lower custom oncology sales of \$0.8 million. 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. The lower custom critical care sales are due to lower unit volumes. We expect increases in custom infusion set sales and new custom oncology sales in 2009 compared to 2008. We expect comparable to slightly lower custom critical care sales in 2009 compared to 2008 because of higher unit volumes expected in the fourth quarter of 2009 that should offset the lower unit sales in the first nine months of 2009.

Standard critical care product sales were \$7.4 million in the third quarter of 2009 compared to \$10.4 million in the third quarter of 2008. This decrease was due to the deferral of revenue on critical care sales to Hospira from July 8, 2009 to August 31, 2009, the period between signing and closing the asset purchase transaction with Hospira. We expect comparable to slightly higher standard critical care sales in 2009 compared to 2008 because of higher volumes expected in the fourth quarter of 2009 that should offset the lower sales of the third quarter caused by the revenue deferral.

Our standard oncology product sales were \$1.6 million in the third quarter of 2009 compared to \$0.9 million in the third quarter of 2008.

Other revenue consists of license, royalty and revenue share income and was approximately \$0.1 million in the third quarter of 2009 and \$0.4 million in the third quarter of 2008. 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 third quarters of 2009 and 2008 were each 46%. Favorable exchange rates contributed two percent in our gross margin in the third quarter of 2009 compared to the third quarter of 2008. This was offset by expenses in our Salt Lake City manufacturing facility related to our investment in new manufacturing processes related to our IPS initiative.

We estimate our gross margin in 2009 will approximate 46-47%. There is no assurance that these expectations will be realized.

Selling, general and administrative expenses (SG&A) were \$16.8 million and 31% of revenues in the third quarter of 2009, compared with \$13.6 million and 25% of revenues in the third quarter of 2008. The increase was primarily from increased legal expenses of \$0.9 million, increased compensation and benefits of \$1.4 million and higher travel costs of \$0.3 million. The increase in legal expenses is primarily from higher patent litigation costs. The increase in compensation and benefits is primarily from 29 new hires in sales, which include the addition of personnel from our acquisition in Germany, the increase in our sales force in September to take over the sales function of our critical care product line and higher salary costs. We expect SG&A in 2009 to be approximately 29-30% of revenue with the increase principally from the addition of sales personnel, increased travel related expenses, increased compensation and stock compensation expense and higher legal expenses from ongoing litigation. There is no assurance that these expectations will be realized.

Research and development expenses (R&D) were \$0.7 million and one percent of revenue in the third quarter of 2009 compared to \$0.9 million and two percent of revenue in the third quarter of 2008. The decrease is primarily due to our increased focus on our core projects that started in the latter half of 2008. We expect R&D in 2009 to be one to two percent of revenue, although there is no assurance that these expectations will be realized.

Other income decreased \$0.6 million to \$0.4 million in the third quarter of 2009 compared to \$1.0 million in the third quarter of 2008. Other income in the third quarter of 2009 is primarily comprised of interest income. Other income in the third quarter of 2008 includes \$0.5 million of interest income and \$0.4 million from a payment under a settlement agreement. The decrease in interest income was due to lower interest rates.

Table of Contents

Income taxes were accrued at an estimated annual effective tax rate of 21.5% in the third quarter of 2009 compared to 33.6% in the third quarter of 2008. The 2008 rate differed from the statutory corporate rate of 35% principally because of the effect of foreign and state income taxes, tax credits, tax exempt income and deductions for domestic production activities. We expect our effective tax rate to be approximately 34% in 2009, before discrete items. The majority of the discrete tax benefits are attributable to tax credits for research and development.

Nine Months Ended September 30, 2009 Compared to Nine Months Ended September 30, 2008

Revenues were \$161.7 million in the first nine months of 2009, compared to \$148.0 million in the first nine months of 2008.

Distribution channels: Net U.S. sales to Hospira in the first nine months of 2009 were \$88.0 million, compared to net sales of \$95.4 million in the first nine months of 2008. The \$7.4 million decrease was primarily from \$8.3 million decrease in critical care sales, \$4.0 million decrease in custom critical care sales, \$1.3 million decrease in custom oncology sales, partially offset by \$4.7 million increase in CLAVE sales and \$2.5 million increase in custom infusion set sales. The decreases in standard and custom critical care sales were due to limited sales to Hospira as a result of the critical care asset purchase from Hospira. Sales to Hospira for critical care products were only recognized for the first seven days of the third quarter. The decrease in custom oncology sales was due to lower unit sales. The increase in CLAVE sales was primarily from higher unit sales due to increased market share through Hospira. The increase in custom infusion set sales was from higher unit sales from the conversion by certain of our customers from a competitor's standard sets to our custom systems.

Net sales to domestic distributors/direct in the first nine months of 2009 (including Canada) were \$37.7 million compared to \$26.5 million in the first nine months of 2008, an increase of 42%. The increased sales were primarily from new standard and custom critical care sales, increased standard oncology and TEGO sales, both newer product lines and increased custom infusion set sales. We began selling standard and custom critical care directly to distributors and through direct sales in September 2009. New standard and custom critical care sales in the September of 2009 were \$5.8 million and \$1.0 million, respectively. The increase in custom infusion set sales was primarily in increased unit volume sales.

Net sales to international distributors and through direct sales (excluding Canada) were \$32.7 million in the first nine months of 2009, compared with \$21.7 million in the first nine months of 2008. The increased sales were primarily from new standard critical care sales of \$1.0 million, new custom critical care sales of \$0.4 million, new custom oncology sales of \$3.2 million, other new product sales of \$1.4 million, increased unit sales in custom infusion sets adding \$1.7 million and increased unit sales in CLAVE adding \$1.0 million. Our international growth in other new product sales includes standard oncology products, TEGO used in dialysis and Orbit 90 diabetes sets. The majority of the increase was attributable to increased sales in Europe and the Pacific Rim.

Product and other revenue: Net sales of CLAVE products increased from \$57.1 million in the first nine months of 2008 to \$63.0 million in the first nine months of 2009, an increase of \$5.9 million or 10%. This increase was primarily from increased sales to Hospira from increased market share and demographic growth.

Net sales of custom products, which include custom infusion, custom oncology products and custom critical care products, were \$56.4 million in the first nine months of 2009 compared to \$50.9 million in the first nine months of 2008. This increase was primarily comprised of increased sales of custom infusion sets and custom oncology products of \$6.0 million and \$2.0 million, respectively, partially offset by lower custom critical care sales of \$2.5 million. The unit growth in custom infusion sets was primarily due to the conversion by certain of our customers from

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

a competitor's standard sets to our custom systems. The increase in custom oncology was because it is a new product line. The lower custom critical care sales were primarily due to lower unit volumes with Hospira.

Standard critical care product sales were \$25.3 million in the first nine months of 2009 compared to \$26.7 million in the first nine months of 2008. This decrease was due to the deferral of revenue on critical care sales to Hospira from July 8, 2009 to August 31, 2009, the period between entering into the asset purchase agreement and closing the transaction with Hospira.

Sales of our standard oncology products, a newer product line, were \$3.5 million in the first nine months of 2009 compared to \$1.9 million in the first nine months of 2008.

Other revenue consists of license, royalty and revenue share income and was approximately \$0.4 million in the first nine months of 2009 and \$1.6 million in the first nine months of 2008. The decrease from 2008 was due to an exclusivity payment we received in 2008 that did not recur in 2009. 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.

Table of Contents

Gross margins for the first nine months of 2009 and 2008 were 48% and 43%, respectively. Favorable exchange rates contributed two percentage points of the five percent increase in our gross margin. The balance of the margin change was from favorable product mix and improved manufacturing efficiencies at our Mexico facility.

Selling, general and administrative expenses (SG&A) were \$48.4 million and 30% of revenues in the first nine months of 2009, compared with \$40.4 million and 27% of revenues in the first nine months of 2008. The increase was primarily from increased legal expenses of \$3.8 million and increased compensation and benefits of \$2.6 million. The increase in legal expenses is primarily from higher patent litigation costs. The increase in compensation and benefits is primarily from 29 new hires in sales, which include the addition of personnel from our acquisition in Germany, the increase in our sales force in September to take over the commercial rights of our critical care product line, higher stock compensation and higher salary costs.

Research and development expenses (R&D) were \$2.0 million and one percent of revenue in the first nine months of 2009 compared to \$4.3 million and three percent of revenue in the first nine months of 2008. The decrease is primarily due to our increased focus on our core projects that started in the latter half of 2008 and MedScanSonic's ceasing operations in 2008.

Other income decreased \$2.7 million to \$1.0 million in the first nine months of 2009 compared to \$3.7 million in the first nine months of 2008. Other income in the first nine months of 2009 is primarily comprised of interest income. Other income in the first nine months of 2008 includes \$2.3 million of interest income and \$1.3 million from a payment under a settlement agreement. The decrease in interest income was due to lower interest rates.

Income taxes were accrued at an estimated annual effective tax rate of 31.8% in the first nine months of 2009 compared to 32.0% in the first nine months of 2008. The 2008 rate differed from the statutory corporate rate of 35% principally because of the effect of foreign and state income taxes, tax credits, tax exempt income and deductions for domestic production activities.

Liquidity and Capital Resources

During the first nine months of 2009, our cash, cash equivalents and investment securities increased by \$0.2 million.

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

During the first nine months of 2009, our cash provided by operations was \$38.5 million, which was mainly comprised of net income of \$19.1 million, depreciation and amortization of \$11.3 million, stock compensation expense of \$2.0 million, plus changes in our operating assets and liabilities. The \$6.5 million decrease in accounts receivable, \$3.2 million decrease in accrued liabilities and \$3.7 million decrease in prepaid income taxes for the first nine months of 2009 were the largest contributors to the change in our operating assets and liabilities. The decrease in

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

accounts receivable was primarily due to cash collection on sales from the fourth quarter of 2008. The decrease in accrued liabilities was primarily due to the payment of an accrual associated with the Alaris litigation. The decrease in prepaid income taxes was due to the timing of estimated tax payments.

Investing Activities: During the first nine months of 2009, cash used by investing activities was \$43.6 million. This was primarily comprised of our critical care asset purchase from Hospira of \$30.5 million, purchases of property, plant and equipment of \$10.2 million, which were primarily for equipment and mold additions and net investment purchases of \$2.7 million.

We estimate that our capital expenditures in 2009 will approximate \$19.0 million, including an estimated \$4.0 million to purchase land and begin construction of a manufacturing plant for our custom products in Slovakia and \$1.7 million in progress payments for a new sterilizer in our Slovakia plant. Amounts of spending are estimates and actual spending may substantially differ from those amounts.

Financing Activities: Our cash provided by financing activities was \$2.2 million in the first nine months of 2009. Cash provided by stock options and the employee stock purchase plan, including tax benefits, was \$2.7 million from the sale of 95,013 shares. The tax benefits from the exercise of stock options fluctuates based principally on when employees choose to exercise their vested stock options.

Table of Contents

In July 2008, we announced a program to purchase up to \$40.0 million of our common stock. We purchased \$5.9 million in 2008 and \$ 0.6 million in the first quarter of 2009. We did not make any purchases in the second or third quarters of 2009. Additional share repurchases may be made as we deem appropriate and based upon prevailing market and business conditions.

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 of this Quarterly Report on Form 10-Q.

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 liability for indemnification. Except for indemnification agreements, we do not have any off balance sheet arrangements .

Pursuant to the Asset Purchase Agreement with Hospira, we have agreed to indemnify Hospira and its affiliates from certain liabilities arising out of (i) inaccuracies of our representations and breaches of our warranties; (ii) defaults of our covenants or obligations; (iii) certain assumed obligations and (iv) use of the acquired assets after the date of closing. Most of Hospira's rights to indemnification will terminate eighteen months after the closing of the transaction on August 31, 2009, 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 MCDA. Although we can provide no assurances, we do not expect to incur material liability arising out of the indemnification provision of the asset purchase agreement.

Contractual Obligations

We have contractual obligations, at September 30, 2009, 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, these amounts are excluded from the table below. We have excluded from the table below, the FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement no. 109 (FIN 48) noncurrent liability of \$4.7 million due to the high degree of uncertainty regarding the timing of future cash outflows associated with the FIN 48 liabilities.

| | 2009 (in thousands) |
|------------------------|--------------------------------------|
| Property and equipment | 9,620 |

Critical Accounting Policies

In our Annual Report on Form 10-K for the year ended December 31, 2008, 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 that Annual Report.

New Accounting Pronouncements

See Note 2 in this Quarterly Report on Form 10-Q.

Table of Contents

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 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; deferred revenue; future license, royalty and revenue share income; production costs; gross margins; litigation expense; SG&A; R&D expense; future costs of expanding our business; income; losses; cash flow; 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; warranty claims; rebates; product returns; bad debt expense; inventory requirements; manufacturing efficiencies and cost savings; unit manufacturing costs; establishment of production facilities outside the U.S.; plans and timing of the establishment of a plant in Slovakia; adequacy of production capacity; results of R&D; initiatives to improve the ICU Production System; asset impairment losses; relocation of manufacturing facilities and personnel; planned increases in the number of personnel; effect of expansion of manufacturing facilities on production efficiencies and resolution of production inefficiencies; business seasonality and fluctuations in quarterly results; customer ordering patterns and the effects of new accounting pronouncements; and
- new or extended contracts with manufacturers and buying organizations; dependence on a small number of customers; effect of the acquisition of Hospira's Salt Lake City manufacturing facility and the effects of the purchase of Hospira's critical care product line; the transition services we expect to receive from Hospira during the eighteen-month period following the acquisition; the outcome of our strategic initiatives; regulatory approvals and compliance; outcome of litigation; competitive and market factors, including continuing development of competing products by other manufacturers; consolidation of the healthcare provider market and downward pressure on selling prices; future purchases of treasury stock; working capital requirements; liquidity and realizable value of our investment securities; outcome of future auctions of auction rate securities; future investment alternatives; foreign currency denominated financial instruments; capital expenditures; 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 Item 1A of our Annual Report on Form 10-K filed with the SEC for the year ended December 31, 2008, in Part II, Item 1A of this Quarterly Report on Form 10-Q for the

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

quarter ended September 30, 2009 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;
- outcome of litigation;
- fluctuations in foreign exchange rates;
- increases in labor costs or competition for skilled workers;
- unexpected delays or complications in the closing of the purchase of Hospira's critical care product line;

Table of Contents

- 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;
- 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;
- unanticipated production problems; and
- the availability of patent protection and the cost of enforcing and of defending patent claims.

The forward-looking statements contained in this Quarterly Report on Form 10-Q are made only as of the date hereof. We assume no obligation to update the statements or to announce publicly the result of any revision to any of the statements contained herein to reflect future events or developments.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We had a portfolio of corporate preferred stocks, federal-tax exempt state and municipal government debt securities and certificates of deposit of \$70.1 million as of September 30, 2009. The securities are all investment grade. As of September 30, 2009, \$60.9 million of our investment securities were invested in pre-refunded municipal securities, \$0.9 million were invested in auction rate securities and \$8.3 million were certificates of deposit. The pre-refunded municipal securities are fully escrowed by U.S. government Treasury bills with low market risk. For the quarter ended September 30, 2009, we had less than \$0.1 million in increases in the market values of the auction rate securities.

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, commercial paper and corporate preferred stocks in our portfolio and market conditions specific to the securities in which we invest. A two-thirds to three-quarters of a percentage point change in our earnings on investment securities would create a change of approximately \$0.5 million to investment income based on the investment securities balance at December 31, 2008.

Foreign currency exchange risk for financial instruments on our balance sheet, which consist of cash, accounts receivable and accounts payable, is not significant to our financial statements. Sales from the U.S. and Mexico to foreign distributors are all denominated in U.S. dollars. We have manufacturing, sales and distribution facilities in several countries and we conduct business transactions denominated in various foreign currencies, principally the Euro and Mexican Peso. A 10% change in the conversion of the Mexican Peso to the U.S. dollar from the average exchange rate we experienced in 2008 and our manufacturing spending from 2008 would impact our cost of goods sold by approximately \$1.8 million. Cash and receivables in those countries have been insignificant and are generally offset by accounts payable and accruals in the same foreign currency, except for our European operations, where our net Euro asset position at September 30, 2009 and 2008 were approximately 12.0 million and 6.2 million, respectively. 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. We are not dependent upon any single source for any of our principal raw materials and we believe all such materials and products are readily available. Based on our average price for resin in fiscal year 2008, a 10% increase to the price of resin would result in approximately a \$0.6 million change in material cost.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our principal executive officer and principal financial officer have concluded, based on their evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934), as of the end of the period covered by this Report, that our disclosure controls and procedures are effective to ensure that the information we are required to disclose in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure and that such information is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC.

Table of Contents

There was no change in our internal control over financial reporting during the quarter ended September 30, 2009 that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

PART II

OTHER INFORMATION

Item 1. Legal Proceedings

In an action filed July 27, 2007 entitled ICU Medical, Inc. v. RyMed Technologies, Inc. (RyMed), in the United States District Court for the District of Delaware, we alleged that RyMed infringes certain of ICU's patents through the manufacture and sale of certain products, including its InVision-Plus valves. Trial has been scheduled for January 19, 2010. We seek monetary damages and injunctive relief and intend to vigorously pursue this matter. In response to this action, RyMed denied our allegations and sued ICU in the United States District Court for the Central District of California seeking a declaratory judgment of non-infringement and invalidity of our patents and alleging that we have infringed RyMed's trademark and engaged in unfair competition and other improper conduct. The Central District Court transferred all patent claims to Delaware. The Central District Court granted summary judgment on RyMed's trademark and unfair competition claims, and entered Judgment in favor of ICU on October 8, 2009.

As previously reported, in an action filed June 16, 2004 entitled ICU Medical, Inc. v. Alaris Medical Systems, Inc. in the United States District Court for the Central District of California, we alleged that Alaris infringes on several of our patents through the manufacture and sale of its SmartSite and SmartSite Plus Needle-Free Valves and Systems. As previously reported, in a series of decisions, the District Court dismissed our claims, including our request for a preliminary injunction, and awarded Alaris \$5.0 million in fees and costs, plus post-judgment interest. On March 13, 2009, the Federal Circuit affirmed the District Court's decision. We paid the award of attorneys' fees, costs and interest in the total sum of \$5.5 million, in the second quarter of 2009.

In a previously reported action entitled Medegen MMS, Inc. v. ICU Medical, Inc. filed on July 6, 2006 in the United States District Court for the Central District of California, Medegen alleged that ICU Medical infringed one of its patents by offering for sale and selling the CLC2000 and TEGO. Medegen sought monetary damages and injunctive relief. In March 2007, Medegen withdrew its action as to the TEGO. On September 14, 2007, the Court issued an order granting our summary judgment motion of non-infringement and entered judgment of non-infringement, dismissing Medegen's case with prejudice. Medegen appealed the Court's claim construction and summary judgment orders. By decision issued in November 2008, the Federal Circuit reversed the order granting summary judgment and remanded the case to the District Court. This case was dismissed by agreement of the parties in the third quarter of 2009.

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.

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

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, 2008, as well as the information contained in this Quarterly Report and our other reports and registration statements filed with the SEC. Except for the risk factors set forth below, 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, 2008.

Unexpected changes in our arrangements with Hospira or unexpected difficulties in connection with the purchase of Hospira's critical care product line may cause a decline in our sales could result in a significant reduction in our sales and profits.

We depend on Hospira for a high percentage of our sales. The table below shows our total revenue and percentage of total revenue attributable to various types of customers for the first nine months of 2009 and years ended December 31, 2008 and 2007 (dollars in millions):

| | Nine months ended | | Years Ended December 31, | | | |
|---|--------------------|-----|--------------------------|-----|----------|-----|
| | September 30, 2009 | | 2008 | | 2007 | |
| Hospira (U.S.) | \$ 88.0 | 54% | \$ 132.6 | 65% | \$ 129.7 | 69% |
| Other manufacturers | 2.9 | 2% | 3.7 | 2% | 2.7 | 1% |
| Domestic distributors/direct sales | 37.7 | 23% | 35.9 | 17% | 29.5 | 16% |
| International distributors/direct sales | 32.7 | 20% | 30.8 | 15% | 23.7 | 13% |
| Other revenue | 0.4 | 0% | 1.7 | 1% | 2.5 | 1% |

Table of Contents

Our principal agreements with Hospira are the MCDA, a strategic supply and distribution agreement for most of our other medical devices in the domestic and international markets and an agreement to sell Hospira custom infusion systems. The MCDA is scheduled to expire in 2025 and the latter two agreements are scheduled to expire in 2014. Since closing our asset purchase of Hospira's critical care product line in August 2009, the commitments under the MCDA to fund certain research and development to improve critical care products and develop new products for sale to Hospira and to provide sales specialists focused on critical care were terminated.

The U.S. market for critical care products has been declining in recent years and our sales of critical care products to Hospira declined in 2008 compared to 2007. We expect further declines in 2009. If the market for critical care products continues to decline, our critical care product sales could continue to decline, resulting in a substantial reduction to our sales and profits.

Under the terms of our agreements with Hospira, we are dependent on the marketing and sales efforts of Hospira for a large percentage of our sales, and Hospira determines the prices at which the products that we sell to Hospira will be sold to its customers. Hospira has conditional exclusive rights to sell CLAVE and our other products as well as custom infusion systems under the SetSource program in many of its major accounts. If Hospira is unable to maintain its position in the marketplace, our sales and operations could be adversely affected.

In 2004, Hospira substantially reduced its purchases of CLAVE products because it was reducing its inventories of our products. This caused a significant reduction in our sales and led to a net loss in the third and fourth quarters of 2004. If the steps we have taken to monitor and control the amount of Hospira's inventory of CLAVE products to avoid future inventory reductions are not successful we could experience sharp fluctuations in sales of CLAVE products to Hospira in the future.

Our ability to maintain and increase our market penetration depends on the success of our arrangement with Hospira and Hospira's arrangements with major buying organizations and its ability to renew such arrangements, as to which there is no assurance. Our business could be materially adversely affected if Hospira terminates its arrangement with us, negotiates lower prices, sells more competing products, whether manufactured by themselves or others, or otherwise alters the nature of its relationship with us. Although we believe that Hospira views us as a source of innovative and profitable products, there is no assurance that our relationship with Hospira will continue in its current form.

In contrast to our dependence on Hospira, our principal competitors in the market for protective I.V. connection systems are much larger companies that dominate the market for I.V. products and have broad product lines and large internal distribution networks. In many cases, these competitors are able to establish exclusive relationships with large hospitals, hospital chains, major buying organizations and home healthcare providers to supply substantially all of their requirements for I.V. products. In addition, we believe that there is a trend among individual hospitals and alternate site healthcare providers to consolidate into or join large major buying organizations with a view to standardizing and obtaining price advantages on disposable medical products. These factors may limit our ability to gain market share through our independent dealer network, resulting in continued concentration of sales to and dependence on Hospira.

On August 31, 2009, we completed an asset purchase with Hospira, acquiring the commercial and physical assets of Hospira's critical care line. We are responsible for all aspects of the critical care line, including sales, marketing, customer contracting and distribution. In connection with the closing of this asset purchase, our obligations under the MCDA were released. We entered into a transition services agreement with Hospira to facilitate the transition, but we can provide no assurances that the transition will occur without delays or disruptions. Any delay or disruption in the transition may reduce or eliminate the expected benefits from the transaction.

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

We began distribution of critical care products directly to existing customers on September 1, 2009. We can provide no assurances, however, that we will be successful in maintaining relationships with major buying organizations fostered by Hospira. Even if we can maintain such relationships, we can provide no assurances that customers will purchase products from us, with the same or similar terms. Furthermore, we can provide no assurances that we will be as successful as Hospira in marketing the critical care product line. Any failure on our part to adequately market and sell the critical care line will have an adverse effect on our financial results.

Table of Contents

Although we expect the transaction will reduce the percentage of our revenues attributable to Hospira, we expect that Hospira will continue to be one of our most important customers, particularly with respect to our CLAVE products and custom infusion systems. With respect to these products, we remain dependent on our continued relationship with Hospira as well as Hospira's position in the marketplace. While we do not anticipate changes in our sales to Hospira of these products, we can provide no assurances that our relationship will not change, resulting in adverse effects on sales and operations.

We are increasingly dependent on manufacturing in Mexico and could be adversely affected by any economic, social or political disruptions

We continue to expand our production in Mexico. Any political or economic disruption in Mexico or a change in the local economy could have an adverse effect on our operations. In 2008, production costs in Mexico were approximately \$58.2 million. Most of the material we use in manufacturing is imported into Mexico, and substantially all the production in Mexico is exported. We depend on our ability to move goods across the border quickly. Any disruption in the free flow of goods across the border could have an adverse effect on our business.

As of September 30, 2009, we employed 1,117 people in our plant in Ensenada, Mexico and we expect this number to increase in the fourth quarter of 2009 and into 2010. Business activity in the Ensenada area has expanded significantly, providing increased employment opportunities. This could have an adverse effect on our ability to hire or retain necessary personnel and result in an increase in labor rates. We continue to take steps to compete for labor through attractive employment conditions and benefits, but there is no assurance that these steps will continue to be successful or that we will not face increasing labor costs in the future.

Additionally, recent political and social instability resulting from increased violence in certain areas of Mexico have raised concerns about the safety of our personnel. These concerns may hinder our ability to send domestic personnel abroad and to hire and retain local personnel. Such concerns may require us to increase security for personnel traveling to our Mexico facility or to conduct more operations from the United States rather than Mexico, which may negatively impact our operations and result in higher costs and inefficiencies.

Healthcare reform legislation could adversely affect our revenue and financial condition.

In recent years, there have been numerous initiatives on the federal and state levels for comprehensive reforms affecting the payment for, the availability of and reimbursement for healthcare services in the United States. These initiatives have ranged from proposals to fundamentally change federal and state healthcare reimbursement programs, including providing comprehensive healthcare coverage to the public under governmental funded programs, to minor modifications to existing programs. Recently, the current administration and members of Congress have proposed significant reforms to the U.S. healthcare system. Both the U.S. Senate and House of Representatives have conducted hearings about U.S. healthcare reform. The federal fiscal year 2010 budget included proposals to limit Medicare payments. In addition, members of Congress have proposed a single-payer healthcare system, a government health insurance option to compete with private plans and other expanded public healthcare measures as well as a tax on manufacturers of medical devices and diagnostic products. The ultimate content or timing of any future healthcare reform legislation, and its impact on us, is impossible to predict. If significant reforms are made to the healthcare system in the United States, or in other jurisdictions, those reforms may have an adverse effect on our financial condition and results of operations.

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

The expansion of our distribution facilities may face significant risks inherent in construction projects, including receipt of necessary government approvals.

In July 2009, we purchased land in Slovakia to construct a new assembly plant. We commenced construction on the Slovakian plant in the third quarter of 2009, and when completed, it will serve our European product distribution. We expect this plant to be operational in the second half of 2010.

This project, and any other development projects we may undertake, will be subject to the many risks inherent in the construction of a new enterprise, including unanticipated design, construction, regulatory, environmental and operating problems. Our current and future projects could also experience:

- delays and significant cost increases;
- shortages of materials;
- shortages of skilled labor or work stoppages;
- unforeseen construction scheduling, engineering, environmental, permitting, construction or geological problems; and
- weather interference, floods, fires or other casualty losses.

Table of Contents

The completion dates of any of our projects could differ significantly from expectations for construction-related or other reasons. Our initial project costs and construction periods are based upon budgets, conceptual design documents and construction schedule estimates prepared at inception of the project in consultation with architects and contractors. Many of these costs can increase over time as the project is built to completion. The cost of any project may vary significantly from initial budget expectations and we may have a limited amount of capital resources to fund cost overruns. If we cannot finance cost overruns on a timely basis, the completion of one or more projects may be delayed until adequate funding is available. We can provide no assurance that any project will be completed on time, if at all, or within established budgets, or that any project will result in increased earnings to us. Significant delays, cost overruns, or failures of our projects could have a material adverse effect on our business, financial condition and results of operations. Furthermore, our projects may not help us compete with new or increased competition in our markets.

Certain permits, licenses and approvals necessary for some of our current or anticipated projects have not yet been obtained. The scope of the approvals required for expansion, development, investment or renovation projects can be extensive and may require land-use permits and building and zoning permits. Unexpected changes or concessions required by regulatory authorities could involve significant additional costs and delay the scheduled openings of the facilities. We may not obtain the necessary permits, licenses and approvals within the anticipated time frames, or at all.

If we are unable to effectively manage our internal growth or growth through acquisitions of companies, assets or products, our financial performance may be adversely affected.

We intend to continue to expand our marketing and distribution capability internally, by expanding our sales and marketing staff and resources and may expand it externally, by acquisitions both in the United States and foreign markets. We may also consider expanding our product offerings through acquisitions of companies or product lines. For example, in August 2009, we completed our acquisition of the commercial rights and the physical assets of Hospira's critical care line. We can provide no assurance that we will be able to identify, acquire, develop or profitably manage additional companies or operations or successfully integrate such companies or operations into our existing operations without substantial costs, delays or other problems.

We intend to build additional production facilities or contract for manufacturing in markets outside the United States, to reduce labor costs and eliminate transportation and other costs of shipping finished products from the United States and Mexico to customers outside North America. In addition, we are currently constructing a new assembly plant in Slovakia that will serve our European product distribution. The expansion of our manufacturing, marketing, distribution and product offerings both internally and through acquisitions or by contract may place substantial burdens on our management resources and financial controls. Decentralization of assembly and manufacturing could place further burdens on management to manage those operations, and maintain efficiencies and quality control.

The increasing burdens on our management resources and financial controls resulting from internal growth and acquisitions could adversely affect our operating results. In addition, acquisitions may involve a number of special risks in addition to the difficulty of integrating cultures and operations and the diversion of management's attention, including adverse short-term effects on our reported operating results, dependence on retention, hiring and training of key personnel, risks associated with unanticipated problems or legal liabilities and amortization of acquired intangible assets, some or all of which could materially and adversely affect our operations and financial performance.

Our business could be materially and adversely affected if we fail to defend and enforce our patents, if our products are found to infringe patents owned by others or if the cost of patent litigation becomes excessive or as our key patents expire.

We have patents on certain products, software and business methods, and pending patent applications on other intellectual property and inventions. There is no assurance, however, that patents pending will issue or that the protection from patents which have issued or may issue in the future will be broad enough to prevent competitors from introducing similar devices, that such patents, if challenged, will be upheld by the courts or that we will be able to prove infringement and damages in litigation.

Table of Contents

We are substantially dependent upon the patents on our proprietary products, such as the CLAVE, to prevent others from manufacturing and selling products similar to ours. We have pending litigation against RyMed Technologies, Inc. for alleged infringement of our patents. We believe the alleged infringement had and continues to have an adverse effect on our sales. Failure to prevail in this or in other litigation we bring against third parties for violating our patents could adversely affect our sales.

We are substantially dependent upon the patents on our proprietary products to prevent others from manufacturing and selling products similar to ours. We generally have multiple patents covering various features of a product, and as each patent expires, the protection afforded by that patent is no longer available to us, even though protection of features that are covered by other unexpired patents may continue to be available to us. The loss of patent protection on certain features of our products may make it possible for others to manufacture and sell products with features similar to ours, which could adversely affect our business.

If others chose to manufacture and sell products similar to or substantially the same as our products, it could have a material adverse effect on our business through loss of unit volume or price erosion, or both, and could adversely affect our ability to secure new business.

In the past, we have faced patent infringement claims related to the CLAVE, the CLC2000 and TEGO. We believe these claims had no merit, and all have been settled or dismissed. We may also face claims in the future. Any adverse determination on these claims related to the CLAVE or other products, if any, could have a material adverse effect on our business.

From time to time we become aware of newly issued patents on medical devices which we review to evaluate any infringement risk. We are aware of a number of patents for I.V. connection systems that have been issued to others. While we believe these patents will not affect our ability to market our products, there is no assurance that these or other issued or pending patents might not interfere with our right or ability to manufacture and sell our products.

There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. Patent infringement litigation, which may be necessary to enforce patents issued to us or to defend ourselves against claimed infringement of the rights of others, can be expensive and may involve a substantial commitment of our resources which may divert resources from other uses. Adverse determinations in litigation or settlements could subject us to significant liabilities to third parties, could require us to seek licenses from third parties, could prevent us from manufacturing and selling our products or could fail to prevent competitors from manufacturing products similar to ours. Any of these results could materially and adversely affect our business.

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

Inapplicable

Item 3. Default Upon Senior Securities

Inapplicable

Item 4. Submission of Matters to a Vote of Security Holders

Inapplicable

Item 5. Other Information

The following is provided in lieu of disclosure under Item 5.03 of a Current Report on Form 8-K:

On October 16, 2009, the Company's board of directors approved an amendment and restatement of the Company's bylaws (the Bylaws), effective on the same date. Among other provisions, Section 2.6 of the Bylaws was amended to provide that the board of directors may designate any officer of the Company to serve as the chairman of a meeting of stockholders and that the chairman may appoint any person to act as the secretary of the meeting.

In addition, Sections 2.10 and 3.3 of the Bylaws were amended to change the deadlines by which stockholders must provide notice to the Company of stockholder proposals or director nominations to be considered at annual meetings of stockholders occurring after the 2010 annual meeting of stockholders. For a stockholder proposal or director nomination to be considered for inclusion in the Company's proxy statement, notice must be provided to the Company between 120 and 180 days prior to the first anniversary of the date on which the Company first mailed its proxy materials for the previous year's annual meeting. If a stockholder proposal or director nomination is not being submitted for consideration for inclusion in the proxy statement, notice must be delivered between 60 and 90 days prior to the anniversary of the previous year's annual meeting of stockholders.

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

Table of Contents

If the Company did not hold an annual meeting of stockholders or the date of the annual meeting is more than 30 days before or after the anniversary of the previous year's annual meeting of stockholders, then in each case, notice must be provided by the later of (i) the 90th day prior to the annual meeting of stockholders or (ii) the 15th day following public announcement of the annual meeting of stockholders.

The amendments did not alter the deadlines for stockholder proposals and director nominations to be considered at the 2010 annual meeting of stockholders. Notice must be provided between 50 and 75 days prior to the 2010 annual meeting of stockholders, or, if less than 60 days' notice of the meeting is provided, within 10 days of public disclosure of the meeting.

The amendments also add a requirement that any stockholder bringing a proposal or making a nomination must furnish to the Company certain information, including information regarding the proposal, the nominee and the stockholder (as well information regarding any arrangements entered into by the stockholder relating to hedging or other similar transactions, among other things), as applicable.

The amendments provide that only business specified in the notice of a special meeting may be considered at the special meeting.

The foregoing description of the amendment and restatement of the Company's Bylaws is qualified in its entirety by reference to the complete text of the amended and restated Bylaws, which is attached as Exhibit 3.1 to this Quarterly Report on Form 10-Q and incorporated herein by reference.

The following is provided in lieu of disclosure under Item 8.01 of a Current Report on Form 8-K:

On October 16, 2009, the Company announced that its board of directors has amended its previously announced stock repurchase program to permit share repurchases up to an aggregate of \$55.0 million. The Company's stock repurchase program was originally adopted on July 18, 2008 and permitted repurchases up to \$40.0 million. Under current board of directors authorizations and taking into account previous purchases of \$6.4 million of shares under the existing authorization, the Company has the ability, and currently intends to repurchase up to approximately \$43.5 million of its common stock in the open market. Such repurchases will be made in accordance with applicable securities laws and other requirements, and will depend on the stock price, prevailing market and business conditions and other considerations.

The foregoing contains 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. Such statements include statements regarding the Company's increased share repurchase program and whether shares will be repurchased. These forward-looking statements are based on Management's current expectations, estimates, forecasts and projections about the Company and assumptions Management believes are reasonable, all of which are subject to risks and uncertainties that could cause actual results and events to differ materially from those stated in the forward-looking statements. These risks and uncertainties include, but are not limited to other potential uses of the Company's capital and the prevailing prices for the Company's common stock. The Company is not obligated to purchase any shares under its stock repurchase program. Subject to applicable corporate securities laws, repurchases under its stock repurchase program may be made at such times and in such amounts as the Company deems appropriate. Purchases under its stock repurchase program can be discontinued at any time the Company feels additional purchases are not warranted. Future results are subject to risks and uncertainties, including the risk factors, and other risks and uncertainties, described in the Company's filings with the Securities and Exchange Commission, which include those in the Form 10-K for the year ended December 31, 2008 and this Form 10-Q. These forward-looking statements are made only as of the date hereof, and the Company undertakes no obligation to update

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

or revise the forward-looking statements, whether as a result of new information, future events or otherwise.

Item 6. Exhibits

| | |
|--------------|---|
| Exhibit 2.1* | Asset Purchase Agreement made and entered into as of July 8, 2009, by and between Registrant and Hospira, Inc. (incorporated by reference to Exhibit 2.1 of the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 4, 2009) |
| Exhibit 3.1 | Registrant's Bylaws, as amended |
| Exhibit 10.1 | Amendment No. 1 to 2001 Directors' Stock Option Plan |
| Exhibit 10.2 | Amendment No. 2 to 2001 Directors' Stock Option Plan |

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

Table of Contents

| | |
|-----------------|---|
| Exhibit 10.3 | Amendment No. 3 to 2001 Directors' Stock Option Plan |
| 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.LAB | XBRL Taxonomy Extension Label Linkbase Document |
| Exhibit 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document |

* Certain confidential portions of this exhibit have been omitted pursuant to a request for confidential treatment. Omitted portions have been filed separately with the Securities and Exchange Commission.

Denotes an executive compensation plan or other arrangement.

Table of Contents

Signature

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ICU Medical, Inc.

(Registrant)

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

Date: October 22, 2009

Table of Contents

Exhibit Index

| | |
|-----------------|---|
| Exhibit 3.1 | Registrant s Bylaws, as amended |
| Exhibit 10.1 | Amendment No. 1 to 2001 Directors Stock Option Plan |
| Exhibit 10.2 | Amendment No. 2 to 2001 Directors Stock Option Plan |
| Exhibit 10.3 | Amendment No. 3 to 2001 Directors Stock Option Plan |
| 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.LAB | XBRL Taxonomy Extension Label Linkbase Document |
| Exhibit 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document |