

ICU MEDICAL INC/DE  
Form 10-Q  
April 23, 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: March 31, 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 is a shell company (as defined in Rule 12b-2 of the Exchange Act):

Yes  No

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

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

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

| Class  | Outstanding at April 10, 2009 |
|--------|-------------------------------|
| Common | 14,777,612                    |

Table of Contents

*ICU Medical, Inc.*

**Index**

|   | <b>Page Number</b> |
|---|--------------------|
| <b>Part I - Financial Information</b>   |                    |
| <b>Item 1. Financial Statements (Unaudited)</b>   |                    |
| <u>Condensed Consolidated Balance Sheets, at March 31, 2009 and December 31, 2008</u>                               | 3                  |
| <u>Condensed Consolidated Statements of Income for the three months ended March 31, 2009 and 2008</u>               | 4                  |
| <u>Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2009 and 2008</u>           | 5                  |
| <u>Condensed Consolidated Statements of Comprehensive Income for the three months ended March 31, 2009 and 2008</u> | 6                  |
| <u>Notes to Condensed Consolidated Financial Statements</u>   | 7                  |
| <b>Item 2.</b>  |                    |
| <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>                        | 11                 |
| <b>Item 3.</b>  |                    |
| <u>Quantitative and Qualitative Disclosures About Market Risk</u>   | 18                 |
| <b>Item 4.</b>  |                    |
| <u>Controls and Procedures</u>  | 19                 |
| <b>Part II - Other Information</b>  |                    |
| <u>Item 1. Legal Proceedings</u>  | 19                 |
| <u>Item 1A. Risk Factors</u>  | 20                 |
| <u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>  | 21                 |
| <u>Item 3. Default Upon Senior Securities</u>   | 21                 |
| <u>Item 4. Submission of Matters to a Vote of Security Holders</u>  | 21                 |
| <u>Item 5. Other Information</u>  | 21                 |
| <u>Signature</u>  | 22                 |
| <u>Item 6. Exhibits</u>   | 23                 |

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

## Condensed Consolidated Balance Sheets

(Amounts in thousands, except per share data)

|   | March 31,<br>2009<br>(unaudited) | December 31,<br>2008<br>(1) |
|---|----------------------------------|-----------------------------|
| <b>ASSETS</b>   |                                  |                             |
| <b>CURRENT ASSETS:</b>  |                                  |                             |
| Cash and cash equivalents   | \$ 68,029                        | \$ 55,696                   |
| Investment securities   | 64,788                           | 56,093                      |
| Cash, cash equivalents and investment securities  | 132,817                          | 111,789                     |
| Accounts receivable, net of allowance for doubtful accounts of \$321 at March 31, 2009 and \$320 at December 31, 2008   | 30,297                           | 38,423                      |
| Inventories   | 21,696                           | 17,930                      |
| Prepaid income taxes  | 271                              | 4,544                       |
| Prepaid expenses and other current assets   | 4,334                            | 3,471                       |
| Deferred income taxes - current portion   | 3,771                            | 3,231                       |
| Total current assets  | 193,186                          | 179,388                     |
| PROPERTY AND EQUIPMENT, net   | 68,787                           | 69,897                      |
| PROPERTY HELD FOR SALE  | 940                              | 940                         |
| RESTRICTED CASH   |                                  | 6,014                       |
| INVESTMENT SECURITIES - non-current portion   | 9,050                            | 11,350                      |
| INTANGIBLE ASSETS, net  | 16,987                           | 10,780                      |
| DEFERRED INCOME TAXES - non-current portion   | 3,855                            | 3,855                       |
| INCOME TAXES RECEIVABLE - non-current portion   | 1,210                            | 1,210                       |
|   | \$ 294,015                       | \$ 283,434                  |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>   |                                  |                             |
| <b>CURRENT LIABILITIES:</b>   |                                  |                             |
| Accounts payable  | \$ 8,717                         | \$ 7,879                    |
| Accrued liabilities   | 14,385                           | 14,081                      |
| Total current liabilities   | 23,102                           | 21,960                      |
| <b>COMMITMENTS AND CONTINGENCIES</b>  |                                  |                             |
| DEFERRED INCOME TAXES - non-current portion   | 5,383                            | 4,007                       |
| INCOME TAXES PAYABLE - non-current portion  | 4,436                            | 4,436                       |
| <b>STOCKHOLDERS' EQUITY:</b>  |                                  |                             |
| 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 14,784 shares at March 31, 2009 and December 31, 2008, outstanding 14,778 shares at March 31, 2009 and 14,731 shares at December 31, 2008 | 1,478                            | 1,478                       |
| Additional paid-in capital  | 51,440                           | 50,970                      |
| Treasury stock, at cost - 6 and 53 shares at March 31, 2009 and December 31, 2008   | (205)                            | (1,623)                     |
| Retained earnings   | 208,366                          | 201,304                     |
| Accumulated other comprehensive income  | 15                               | 902                         |
| Total stockholders' equity  | 261,094                          | 253,031                     |
|   | \$ 294,015                       | \$ 283,434                  |

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

---

(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)

|  | <b>Three months ended March 31,</b> |                 |
|--|-------------------------------------|-----------------|
|  | <b>2009</b>                         | <b>2008</b>     |
| <b>REVENUES:</b>                         |                                     |                 |
| Net sales                                | \$ 54,195                           | \$ 43,671       |
| Other                                    | 140                                 | 983             |
| <b>TOTAL REVENUE</b>                     | <b>54,335</b>                       | <b>44,654</b>   |
| <b>COST OF GOODS SOLD</b>                |                                     |                 |
|  | 27,769                              | 26,883          |
| Gross profit                             | 26,566                              | 17,771          |
| <b>OPERATING EXPENSES:</b>               |                                     |                 |
| Selling, general and administrative      | 15,112                              | 13,108          |
| Research and development                 | 738                                 | 2,019           |
| Total operating expenses, net            | 15,850                              | 15,127          |
| Income from operations                   | 10,716                              | 2,644           |
| <b>OTHER INCOME</b>                      |                                     |                 |
| Income before income taxes               | 11,034                              | 4,200           |
| <b>PROVISION FOR INCOME TAXES</b>        | <b>(3,972)</b>                      | <b>(1,302)</b>  |
| <b>NET INCOME</b>                        | <b>\$ 7,062</b>                     | <b>\$ 2,898</b> |
| <b>NET INCOME PER SHARE</b>              |                                     |                 |
| Basic                                    | \$ 0.48                             | \$ 0.21         |
| Diluted                                  | \$ 0.47                             | \$ 0.20         |
| <b>WEIGHTED AVERAGE NUMBER OF SHARES</b> |                                     |                 |
| Basic                                    | 14,735                              | 13,752          |
| Diluted                                  | 14,869                              | 14,376          |

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)

|   | <b>Three months ended March 31,</b> |               |
|---|-------------------------------------|---------------|
|   | <b>2009</b>                         | <b>2008</b>   |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>  |                                     |               |
| Net income  | \$ 7,062                            | \$ 2,898      |
| Adjustments to reconcile net income to net cash provided by operating activities:           |                                     |               |
| Depreciation and amortization   | 3,564                               | 3,410         |
| Provision for doubtful accounts   | 16                                  | (38)          |
| Stock compensation  | 599                                 | 416           |
| Loss on disposal of property and equipment  | 20                                  |               |
| Cash provided (used) by changes in operating assets and liabilities, net of assets acquired |                                     |               |
| Accounts receivable   | 7,777                               | 172           |
| Inventories   | (2,273)                             | (1,646)       |
| Prepaid expenses and other assets   | (1,340)                             | 566           |
| Accounts payable  | 748                                 | (699)         |
| Accrued liabilities   | (276)                               | (568)         |
| Prepaid and deferred income taxes   | 3,872                               | 152           |
| Net cash provided by operating activities   | 19,769                              | 4,663         |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>  |                                     |               |
| Purchases of property and equipment   | (2,144)                             | (3,592)       |
| Business acquisition, net of cash acquired  | (5,663)                             |               |
| Change in restricted cash   | 6,014                               |               |
| Proceeds from finance loan repayments   |                                     | 24            |
| Purchases of investment securities  | (20,936)                            | (9,027)       |
| Proceeds from sale of investment securities   | 14,541                              | 34,622        |
| Net cash provided (used) by investing activities  | (8,188)                             | 22,027        |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>  |                                     |               |
| Proceeds from exercise of stock options   | 1,207                               | 1,071         |
| Proceeds from employee stock purchase plan  | 623                                 | 744           |
| Tax benefits from exercise of stock options   | 19                                  | 954           |
| Purchase of treasury stock  | (560)                               |               |
| Net cash provided by financing activities   | 1,289                               | 2,769         |
| Effect of exchange rate changes on cash   | (537)                               | 263           |
| <b>NET INCREASE IN CASH AND CASH EQUIVALENTS</b>  | <b>12,333</b>                       | <b>29,722</b> |
| CASH AND CASH EQUIVALENTS, beginning of period  | 55,696                              | 7,873         |
| CASH AND CASH EQUIVALENTS, end of period  | \$ 68,029                           | \$ 37,595     |

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)

|  | <b>Three months ended March 31,</b> |             |
|--|-------------------------------------|-------------|
|  | <b>2009</b>                         | <b>2008</b> |
| Net income                                     | \$ 7,062                            | \$ 2,898    |
| Other comprehensive income (loss), net of tax: |                                     |             |
| Foreign currency translation adjustment        | (887)                               | 736         |
| Comprehensive income                           | \$ 6,175                            | \$ 3,634    |

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**

**March 31, 2009**

(Amounts in tables in thousands)

(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 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 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 FAS 141(R) and FSP SFAS 141(R)-1 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 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 FASB Statement No. 157, Fair Value Measurements , when the volume and level of activity for the asset or liability have significantly decreased. This FSP also includes guidance on identifying circumstances that indicate a transaction is not orderly. This

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

pronouncement is effective for periods ending after June 15, 2009. The Company's management does not expect this pronouncement to have a material effect on the Company's financial position and results of operations.

In April 2009, the FASB issued 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 to sell instead of ability to hold the security and to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities in the financial statements. This pronouncement is effective for periods ending after June 15, 2009. The Company's management does not expect this pronouncement to have a material effect on the Company's financial position and results of operations.

### **Note 3: Restricted Cash / 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 \$6.1 million in intangible assets, which includes \$3.8 million for customer contracts, \$0.4 million for trademarks and \$1.9 million of goodwill. Of the total amount of goodwill, \$1.4 million is expected to be deductible for tax purposes. The Company also recorded a deferred tax liability of \$1.4 million as a result of this transaction.

Table of Contents**Note 4: Fair Value Measurement:**

The Company's investment securities, which are considered available for sale and trading consist principally of corporate preferred stocks and federal-tax-exempt state and municipal government debt. The Company has \$61.7 million of its investment securities as Level 2 assets, which are pre-refunded municipal securities and have observable inputs. The Company has \$11.7 million invested in auction rate securities and \$0.4 million in put option assets related to the auction rate securities as Level 3 assets due to the unobservable inputs caused by the lack of liquidity in the recent auctions. The valuation of these securities 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 each 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. They are carried at fair value.

The following table provides the assets and liabilities carried at fair value measured on a recurring basis as of March 31, 2009:

|                               | Total carrying<br>value at<br>March 31, 2009 | Fair value measurements at March 31, 2009 using                            |  |   |
|-------------------------------|--|--|--|---|
|                               |  | Quoted prices<br>in active<br>markets for<br>identical<br>assets (level 1) | Significant<br>other<br>observable<br>inputs (level 2) | Significant<br>unobservable<br>inputs (level 3) |
| Available for sale securities | \$ 61,738                                    | \$   | \$ 61,738  | \$  |
| Trading securities            | 12,100                                       |  |  | 12,100  |
|                               | \$ 73,838                                    | \$   | \$ 61,738  | \$ 12,100                                       |

The following tables summarize the change in the fair values for Level 3 items for the quarter ended March 31, 2009:

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

|   | Quarter ended<br>March 31, 2009 |
|---|---------------------------------|
| Beginning balance   | \$ 15,925                       |
| Transfer into Level 3   |                                 |
| Sales   | (3,825)                         |
| Unrealized holding loss, included in other comprehensive income |                                 |
| Ending balance  | \$ 12,100                       |

The Company has agreements in place with Morgan Stanley & Co. ( Morgan ) and UBS AG ( UBS ) that permit the Company to require Morgan and UBS to purchase the Company's auction rate securities at par value plus accrued interest. As of March 31, 2009, the Company has \$11.7 million in auction rate securities. There was less than \$0.1 million in declines in the market values of the Company's auction rate securities in the quarter ended March 31, 2009.

**Note 5: Inventories:**

Inventories consisted of the following:

|                 | <b>March 31, 2009</b> |        | <b>December 31, 2008</b> |        |
|-----------------|-----------------------|--------|--------------------------|--------|
| Raw material    | \$                    | 14,696 | \$                       | 12,531 |
| Work in process |                       | 2,449  |                          | 2,577  |
| Finished goods  |                       | 4,551  |                          | 2,822  |
| Total           | \$                    | 21,696 | \$                       | 17,930 |

Table of Contents**Note 6: Property and Equipment:**

Property and equipment consisted of the following:

|  | March 31, 2009 | December 31, 2008 |
|--|----------------|-------------------|
| Machinery and equipment                  | \$ 51,147      | \$ 50,337         |
| Land, building and building improvements | 48,547         | 48,715            |
| Molds                                    | 18,300         | 16,791            |
| Computer equipment and software          | 9,973          | 9,890             |
| Furniture and fixtures                   | 1,972          | 1,983             |
| Construction in progress                 | 2,917          | 3,479             |
| Total property and equipment, cost       | 132,856        | 131,195           |
| Accumulated depreciation                 | (64,069)       | (61,298)          |
| Net property and equipment               | \$ 68,787      | \$ 69,897         |

**Note 7: Net Income Per Share:**

Net income per share is computed by dividing net income by the weighted average number of common shares outstanding. Diluted net income per share is computed by dividing net income by the weighted average number of common shares outstanding plus dilutive securities. Dilutive securities are outstanding common stock options (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, and were 133,463 and 624,129 for the quarters ended March 31, 2009 and 2008, respectively. Options that are anti-dilutive because their exercise price exceeded the average market price of the common stock for the period approximated 1,135,000 and 1,397,000 for the quarters ended March 31, 2009 and 2008, respectively.

**Note 8: Income Taxes:**

Income taxes were accrued at an estimated annual effective tax rate of 36% in the first quarter of 2009 compared to 34% in the first quarter 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 9: Major Customer:**

The Company had revenues equal to 10% or more of total revenues from one customer, Hospira, Inc. Such revenues were 71% and 66% of total revenue for the quarters ended March 31, 2009 and 2008, respectively. As of March 31, 2009 and December 31, 2008, the Company had accounts receivable from Hospira of 62% and 66%, of consolidated accounts receivable, respectively.

**Note 10: Commitments and Contingencies:**

In an action filed July 6, 2006 entitled Medegen MMS, Inc. v. ICU Medical, Inc. filed 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 June 21, 2007, the Court issued an order interpreting certain terms and phrases of Medegen's patent in a manner that we believe supported our position. On September 14, 2007, the Court issued an order granting our summary judgment motion of non-infringement and On October 19, 2007, entered judgment of non-infringement, dismissing Medegen's case with prejudice. On October 19, 2007, the Court also dismissed, without prejudice, our counterclaims that the asserted patent is invalid and unenforceable due to inequitable conduct by Medegen before the United States Patent and Trademark Office. Medegen has 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. The Company intends to defend itself against Medegen's claims in this action. The outcome of this action is uncertain, therefore no accrual has been recorded.

Table of Contents

The Company is from time to time involved in various other legal proceedings, most of which are routine litigation, in the normal course of business. In the opinion of management, the resolution of the other 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 .



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.

**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 our Annual Report.

**New Accounting Pronouncements**

In April 2009, the FASB issued 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 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. We adopted FAS 141(R) and FSP SFAS 141(R)-1 on January 1, 2009. The adoption did not have a material effect on our financial position or results of operations.

In April 2009, the FASB issued 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 FASB Statement No. 157, *Fair Value Measurements*, when the volume and level of activity for the asset or liability have significantly decreased. This FSP also includes guidance on identifying circumstances that indicate a transaction is not orderly. This pronouncement is effective for periods ending after June 15, 2009. We do not expect this pronouncement to have a material effect on our financial position and results of operations.

In April 2009, the FASB issued 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 to sell instead of ability to hold the security and to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities in the financial statements. This pronouncement is effective for periods ending after June 15, 2009. We do not expect this pronouncement to have a material effect on our financial position and results of operations.

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

We have implemented all new accounting pronouncements that are in effect and that may impact our consolidated financial statements and do not believe that there are any other new accounting pronouncements that have been issued that might have a material impact on our consolidated financial statements.

Table of Contents

**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.

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 quarter of 2009 and years ended 2008, 2007 and 2006, our revenues from worldwide sales to Hospira were 71%, 69%, 73% and 77%, respectively, of total revenues. Although we can provide no assurances, we expect this percentage will be maintained in the future as a result of sales of CLAVE products, custom infusion sets, new products and critical care products to Hospira. 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 products, and our other products worldwide.

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 the Manufacturing Commercialization and Development Agreement ( MCDA ) with Hospira to produce their invasive monitoring, angiography products and certain other products they had manufactured at that facility. 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 \$19.0 million or 35% of total revenue in the first quarter 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 and custom I.V sets and ancillary products specifically designed for chemotherapy. There is no assurance that we will be successful in finding acquisition opportunities acquiring companies or products or integrating them into our existing business.

Custom products and new products will be of increasing importance to us in future years. We expect continued growth 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 for all of our products outside the U.S. could be substantial, although to date it 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.

In 2005, we acquired Hospira's Salt Lake City manufacturing facility, related capital equipment and entered into a 20-year MCDA with Hospira, under which we produce for sale, exclusively to Hospira, substantially all the products, primarily critical care, that Hospira had manufactured at that facility. Hospira retains commercial responsibility for the products we are producing, 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 manufacture the products and Hospira is responsible for sales to end customers, and we have little ability to directly influence Hospira's sales and marketing efforts, and our sales under the MCDA are subject to fluctuations over which we have little control.

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

### Table of Contents

We have also committed to fund certain research and development to improve critical care products and develop new products for sale to Hospira and to provide sales specialist support. Our prices and our gross margins on the products we sell to Hospira under the MCDA are based on cost savings that we are able to achieve in producing those products over Hospira's cost to manufacture those same products at the purchase date. We record revenue net of any such reductions. There is no assurance as to the amounts of future sales or profits under the MCDA.

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, 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 those risks, there are certain of those risks which 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:

| Product Line                       | Quarter ended March 31,, |             | Fiscal Year Ended |             |
|------------------------------------|--------------------------|-------------|-------------------|-------------|
|                                    | 2009                     | 2008        | 2008              | 2007        |
| CLAVE                              | 39%                      | 41%         | 39%               | 38%         |
| Custom products                    | 35%                      | 33%         | 34%               | 31%         |
| Critical care                      | 18%                      | 17%         | 18%               | 23%         |
| Other products                     | 8%                       | 7%          | 8%                | 7%          |
| License, royalty and revenue share | %                        | 2%          | 1%                | 1%          |
| <b>Total</b>                       | <b>100%</b>              | <b>100%</b> | <b>100%</b>       | <b>100%</b> |

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, 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. Under the MCDA, we sell Hospira invasive monitoring, angiography and other products which they formerly manufactured at the Salt Lake City facility. The terms of the MCDA extend to 2025. 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

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

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 in 2009. 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.

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

### Table of Contents

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

| Channel                       | Quarter ended March 31, |      | Fiscal Year Ended |      |
|-------------------------------|-------------------------|------|-------------------|------|
|                               | 2009                    | 2008 | 2008              | 2007 |
| Medical product manufacturers | 66%                     | 68%  | 67%               | 71%  |
| Domestic distributors/direct  | 15%                     | 18%  | 18%               | 16%  |
| International customers       | 19%                     | 14%  | 15%               | 13%  |
| Total                         | 100%                    | 100% | 100%              | 100% |

Sales to international customers do not include bulk CLAVE products sold to Hospira in the U.S., but used in I.V. products manufactured by Hospira and exported. Those sales 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.

**Quarter-to-quarter 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 first quarters of 2009 and 2008, the percentages of each income statement caption in relation to total revenues.

|  | Fiscal Year | Quarter ended March 31, |      |
|--|-------------|-------------------------|------|
|  | 2008        | 2009                    | 2008 |
| Revenue                                      |             |                         |      |
| Net sales                                    | 99%         | 100%                    | 98%  |
| Other  | 1%          | %                       | 2%   |
| Total revenues                               | 100%        | 100%                    | 100% |
| Gross profit                                 | 44%         | 49%                     | 40%  |
| Selling, general and administrative expenses | 26%         | 28%                     | 29%  |
| Research and development expenses            | 2%          | 1%                      | 5%   |
| Total operating expenses                     | 28%         | 29%                     | 34%  |
| Income from operations                       | 16%         | 20%                     | 6%   |
| Other income                                 | 2%          | %                       | 3%   |
| Income before income taxes                   | 18%         | 20%                     | 9%   |
| Income taxes                                 | 6%          | 7%                      | 3%   |
| Net income                                   | 12%         | 13%                     | 6%   |

**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, starting towards the end of the first quarter of 2009, a few of our customers began to take a more conservative stance on inventory levels. Our expenses often do not fluctuate in the same manner as net sales, which may cause fluctuations in operating income that are disproportionate to fluctuations in our revenue.

**Quarter Ended March 31, 2009 Compared to the Quarter Ended March 31, 2008**

Revenues were \$54.3 million in the first quarter of 2009, compared to \$44.7 million in the first quarter of 2008.

***Distribution channels:*** Net U.S. sales to Hospira in the first quarter of 2009 were \$34.8 million, compared to net sales of \$28.8 million in the first quarter of 2008. The \$6.0 million increase was primarily from a \$2.6 million increase in CLAVE sales, a \$2.1 million increase in critical care product sales and a \$1.1 million increase custom product sales. The increase in CLAVE sales was from higher unit sales due to increased market share through Hospira. The increase in critical care product sales was due to higher unit sales charged for certain critical care products. The increase in custom products was primarily due to higher unit sales in custom infusion sets from the conversion by certain of our customers from a



Table of Contents

competitor's standard sets to our custom systems. We expect the growth in sales to Hospira in 2009 from 2008 in CLAVE and custom infusion sets to be offset by declines in critical care and custom critical care product sales, although there is no assurance that these expectations will be realized.

Net sales to domestic distributors/direct in the first quarter of 2009 (including Canada) were \$8.3 million compared to \$7.7 million in the first quarter of 2008, an increase of seven percent. The increase was primarily from increased oncology and TEGO sales, both newer product lines. We expect increases in domestic distributor sales in 2009 compared to 2008, principally from growth in custom products and new product sales, although there is no assurance that these expectations will be realized.

Net sales to international customers (excluding Canada) were \$10.2 million in the first quarter of 2009, compared with \$6.2 million in the first quarter of 2008. The increased sales were primarily from \$2.9 million of increased custom product sales and \$0.4 million of increased CLAVE sales. We acquired a small company in Germany that closed in the middle of the first quarter of 2009. Sales from this acquisition were approximately \$0.7 million in the first quarter of 2009. The custom sales increase was primarily from unit growth in custom oncology due to a product launch of this line in the first quarter of 2008. The CLAVE increase is from increased unit volume due to increased market share and demographic growth. The majority of the increase was attributable to increased sales in Europe. We expect increases in international customer sales in 2009, primarily from increased custom product sales and oncology product sales and additional sales of our new products from our recent acquisition, although there is no assurance that these expectations will be realized.

**Product and other revenue:** Net sales of CLAVE products increased from \$18.3 million in the first quarter of 2008 to \$21.2 million in the first quarter of 2009, an increase of \$2.9 million or 16%. This increase was primarily from increased sales to Hospira from increased market share and demographic growth. We 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 \$19.0 million in the first quarter of 2009 compared to \$14.9 million in the first quarter of 2008. This increase was primarily comprised of increased sales of custom oncology products of \$2.7 million and custom infusion sets of \$1.4 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 unit growth in custom oncology is due to a product launch of this line in the first quarter of 2008. We expect increases in custom infusion set sales and new custom oncology sales. We expect decreases in custom critical care sales from unit volume decreases in 2009 compared to 2008.

Critical care product sales were \$9.6 million in the first quarter of 2009 compared to \$7.4 million in the first quarter of 2008. This increase was due to higher unit sales of certain critical care products. We expect unit volume decreases in 2009 compared to 2008.

Our new oncology product sales, including custom oncology, were \$4.3 million in the first quarter of 2009 compared to \$1.3 million in the first quarter of 2008.

Other revenue consists of license, royalty and revenue share income and was approximately \$0.1 million in the first quarter of 2009 and \$1.0 million in the first quarter 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.

**Gross margins** for the first quarters of 2009 and 2008 were 49% and 40%, respectively. The margin improvement is attributed to a favorable product mix, improved efficiencies at our Mexico manufacturing facility, favorable exchange rate fluctuations on costs incurred at our Mexico manufacturing facility and lower transportation costs on our products.

We estimate our gross margin in 2009 will approximate 44-45%. There is no assurance that these expectations will be realized.

**Selling, general and administrative expenses ( SG&A )** were \$15.1 million and 28% of revenues in the first quarter of 2009, compared with \$13.1 million and 29% of revenues in the first quarter of 2008. The increase was primarily from increased legal expenses of \$1.4 million, increased compensation and benefits of \$0.5 million and higher sales and marketing promotional costs of \$0.2 million. The increase in legal expenses is primarily from higher patent litigation costs. The increase in compensation and benefits is primarily from greater stock compensation and higher salary costs, which includes 13 new hires in sales. We expect SG&A in 2009 to be approximately 27-28% of revenue with the increase

Table of Contents

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 first quarter of 2009 compared to \$2.0 million and five percent of revenue in the first quarter of 2008. The decrease is primarily due to our increased focus on our core projects in the latter half of 2008 and MedScanSonic's ceasing operations in 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 \$1.2 million to \$0.3 million in the first quarter of 2009 compared to \$1.5 million in the first quarter of 2008. Other income in the first quarter of 2009 is primarily comprised of interest income. Other income in the first quarter of 2008 includes \$1.1 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.

**Income taxes** were accrued at an estimated annual effective tax rate of 36% in the first quarter of 2009 compared to 34% in the first 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 36% in 2009.

Liquidity and Capital Resources

During the first quarter of 2009, our cash, cash equivalents and current and long-term investment securities increased by \$18.7 million.

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

During the first quarter of 2009, our cash provided by operations was \$19.8 million, which was mainly comprised of net income of \$7.1 million, depreciation and amortization of \$3.6 million, stock compensation expense of \$0.6 million, offset by changes in our operating assets and liabilities. The \$7.8 million decrease in accounts receivable was the largest contributor to the change in our operating assets and liabilities. The decrease was primarily due to cash collection on sales in the fourth quarter of 2008.

**Investing Activities:** During the first quarter of 2009, cash used by investing activities was \$8.2 million. This was primarily comprised of net investment purchases of \$6.4 million and cash paid for purchases of property and equipment of \$2.1 million which were primarily for equipment and mold additions.

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

We estimate that our capital expenditures in 2009 will approximate \$15.0 million, including an estimated \$4.0 million to purchase land and begin construction of a manufacturing plant for our custom products in Slovakia. Amounts of spending are estimates and actual spending may substantially differ from those amounts.

**Financing Activities:** Our cash provided by financing activities was \$1.3 million in the first quarter of 2009. Cash provided by stock options and the employee stock purchase plan, including tax benefits, was \$1.8 million from the sale of 63,386 shares. The tax benefits from the exercise of stock options fluctuates based principally on when employees choose to exercise their vested stock options.

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. 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 Item 3. Quantitative and Qualitative Disclosures about Market Risk.

We believe that our existing cash, cash equivalents and investment securities along with funds expected to be generated from future operations will provide us with sufficient funds to finance our current operations for the next twelve

Table of Contents

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 .

**Contractual Obligations**

We have contractual obligations of approximately the amounts set forth in the table below. These amounts exclude 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. The commitments under the MCDA are those 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. We believe that our existing cash and investment securities along with funds expected to be generated from future operations will provide us with sufficient funds to meet commitments under all of our contractual obligations. 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 \$4.4 million due to the high degree of uncertainty regarding the timing of future cash outflows associated with the FIN 48 liabilities.

|                        | <b>2009</b>           |               |
|------------------------|-----------------------|---------------|
|                        | <b>(in thousands)</b> |               |
| MCDA                   | \$                    | 8,131         |
| Property and equipment |                       | 4,156         |
| <b>Total</b>           | <b>\$</b>             | <b>12,287</b> |

**Forward Looking Statements**



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

Various portions of this Report, 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, and we identify them by using words such as believe, expect, estimate, plan, will, continue, could, may, and by similar expressions and 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, among other things, 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, 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, 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., adequacy of production capacity, results of R&D, asset impairment losses, relocation of manufacturing facilities and 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

Table of Contents

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 manufacture of products for Hospira under the MCDA, cost savings and use of our systems and procedures under the MCDA, and 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; contractual liabilities.

The kinds of statements described above and similar forward looking statements about our future performance are subject to a number of risks and uncertainties which one should consider in evaluating the statements. 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, one should read the forward looking statements in conjunction with the Risk Factors in Item 1A of our Annual Report on Form 10-K filed with the SEC for the year ended December 31, 2008. Also, our actual future operating results are subject to other important factors that we cannot predict or control, including among others the following:

- general economic and business conditions, both in the U.S. and internationally;
- 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.

We disclaim any 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, commercial paper and put options of \$73.8 million as of March 31, 2009. The securities are all investment grade. As of March 31, 2009, \$61.7 million of our investment securities were invested in pre-refunded municipal securities, \$11.7 million were invested in auction rate securities and \$0.4 million were in put option assets related to auction rate securities. The pre-refunded municipal securities are fully escrowed by U.S. government Treasury bills with low market risk. For most of the auction rate securities, dividend and interest rates reset at auction at fourteen to thirty-five day intervals. For the quarter ended March 31, 2009, we had less than \$0.1 million in declines in the market values of the auction rate securities.

Up until early February 2008, the market for our auction rate securities was highly liquid. However, as a result of liquidity issues in the global credit and capital markets, auctions for all of our auction rate securities failed beginning in February 2008 when sell orders exceeded buy orders. The failures of these auctions do not affect the value of the collateral underlying the auction rate securities, and we continue to earn and receive interest on our auction rate securities at pre-determined formula with spreads tied to particular interest rate indexes. Liquidity has been substantially impaired since February 2008 and accordingly we have substantially reduced our position in these types of investments since that time. We have further mitigated liquidity concerns by acquiring put options on our auction rate securities from Morgan Stanley & Co. and UBS AG. The put options are enforceable, non-transferrable rights and agreement to purchase our existing auction rate

Table of Contents

securities at par value plus accrued interest. We intend to continue our investment objectives of avoiding credit and market risk in the future.

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 March 31, 2009 and 2008 were approximately 11.1 million and 5.1 million. 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.

There was no change in our internal control over financial reporting during the quarter ended March 31, 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**

We have not been required to pay any penalty to the IRS for failing to make disclosures required with respect to certain transactions that have been identified by the IRS as abusive or that have a significant tax avoidance purpose.

In an action filed 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 ICU's patent through the manufacture and sale of the SmartSite and SmartSite Plus Needle-Free Valves and Systems. On August 2, 2004, the Court denied our request for a preliminary injunction. On December 27, 2004, we amended our complaint to allege that Alaris infringes three additional patents. On July 17, 2006, the Court issued an order interpreting certain claims in the asserted patents in a manner that, if upheld, could significantly impair our ability to enforce those patents against Alaris and potentially others. The Court also issued partial summary judgment in favor of Alaris based on one of those interpretations. On January 22, 2007, the Court granted Alaris' summary judgment motion of invalidity as to the remaining claims asserted against Alaris and on

Table of Contents

February 22, 2007, the Court entered judgment dismissing those remaining claims. The Court's order adjudicated only the asserted claims of the patents in suit, not other claims in the patents. Following entry of the judgment dismissing our case, the Court heard Alaris' motion to recover its fees, costs and expenses, and on April 16, 2007, the Court granted in part Alaris' motion. On June 28, 2007, the Court awarded Alaris \$4.8 million in fees and costs, which were later increased to \$5.0 million, plus post-judgment interest. We appealed the Court's decisions. The Federal Circuit has affirmed the District Court's decision, and we have filed a Petition for Rehearing En Banc relating to a portion of the fee award. Because the award of fees and costs is a judgment against us and the outcome of the appeal is uncertain, we recorded a charge of \$5.0 million in our financial statements for the year ended December 31, 2007. We have not paid the judgment, pending outcome of the appeal.

In an action filed July 6, 2006 entitled Medegen MMS, Inc. v. ICU Medical, Inc., filed 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 June 21, 2007, the Court issued an order interpreting certain terms and phrases of Medegen's patent in a manner that we believe supported our position. 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, on October 19, 2007. On October 19, 2007, the Court also dismissed, without prejudice, our counterclaims that the asserted patent is invalid and unenforceable due to inequitable conduct by Medegen before the United States Patent and Trademark Office. Medegen has 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. We intend to defend ourselves against Medegen's claims in this action.

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. We seek monetary damages and injunctive relief and intend to vigorously pursue this matter. RyMed has 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. RyMed seeks monetary damages and injunctive relief. The Central District Court has transferred the patent claims to Delaware. RyMed's trademark and unfair competition claims remain pending in the Central District of California. ICU will continue to defend itself in the California action, and vigorously pursue its patent infringement claims against RyMed in the Delaware action.

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

**Item 1A. Risk Factors.**

In evaluating an investment in our common stock, investors should consider carefully, among other things, the risk factors previously disclosed in Part I, Item 1A of our Annual Report on Form 10-K filed with the SEC for the year ended December 31, 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 factor 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.

*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 December 31, 2008, we employed 1,165 people in our plant in Ensenada, Mexico and we expect this number to increase during 2009. 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.

Table of Contents**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

In July 2008, our Board of Directors authorized a program to purchase \$40.0 million of our common stock. In 2008, we purchased \$5.8 million of our common stock from this program. Future purchases will depend on the stock price, prevailing market and business conditions and other considerations.

The following is a summary of our stock repurchasing activity during the first quarter of 2009:

| Period                   | Shares purchased | Average price paid per share | Shares purchased as part of a publicly announced program | Approximate dollar value that may yet be purchased under the program |
|--------------------------|------------------|------------------------------|--|--|
| 01/01/2009 01/31/2009    |                  | \$                           |  | \$ 34,142,000  |
| 02/01/2009 02/28/2009    | 16,499           |                              | 16,499   | 33,582,000   |
| 03/01/2009 03/31/2009    |                  |                              |  | 33,582,000   |
| First quarter 2009 total | 16,499           | \$                           | 16,499   | 33,582,000   |

**Item 3. Default Upon Senior Securities**

Inapplicable

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

Inapplicable

**Item 5. Other Information**

None

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: April 23, 2009

Table of Contents

**Item 6. Exhibits**

|                 |   |
|-----------------|---|
| Exhibit 10.1    | Employment Agreement between the Registrant and George A. Lopez, M.D. effective January 1, 2009, dated March 10, 2009   |
| Exhibit 14.1    | Code of Business Conduct and Ethics for Directors and Officers, filed as Exhibit 14.1 to Form 8-K with the SEC on February 2, 2009, and incorporated herein by reference. |
| 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  |