

# ICU MEDICAL INC/DE

## FORM 10-Q (Quarterly Report)

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 10-Q**

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

For the quarterly period ended: **September 30, 2007**

Or

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

For the transition period from: \_\_\_\_\_ to \_\_\_\_\_

Commission File No.: **0-19974**

**ICU MEDICAL, INC.**

(Exact name of Registrant as provided in charter)

**Delaware**

(State or Other Jurisdiction of  
Incorporation or Organization)

**33-0022692**

(I.R.S. Employer  
Identification No.)

**951 Calle Amanecer, San Clemente, California**

(Address of Principal Executive Offices)

**92673**

(Zip Code)

**(949) 366-2183**

(Registrant's Telephone No. 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 large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act:

Large accelerated filer

Accelerated filer

Non-accelerated filer

Indicate by check mark whether or not the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes   
No

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

Class	Outstanding at October 15, 2007
Common	13,883,162

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

	9/30/07 (unaudited)	12/31/06 (1)
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 6,806	\$ 13,153
Liquid investments	95,790	103,765
Cash, cash equivalents and liquid investments	<u>102,596</u>	<u>116,918</u>
Accounts receivable, net of allowance for doubtful accounts of \$699 and \$310 as of September 30, 2007 and December 31, 2006, respectively	27,893	26,533
Inventories	17,700	16,315
Prepaid income taxes	2,533	4,541
Prepaid expenses and other current assets	5,131	4,255
Deferred income taxes - current portion	2,494	2,876
Total current assets	<u>158,347</u>	<u>171,438</u>
PROPERTY AND EQUIPMENT, net	71,325	59,037
INTANGIBLE ASSETS, net	12,115	9,781
DEFERRED INCOME TAXES, non-current	3,016	2,878
INCOME TAXES RECEIVABLE, non-current	1,848	—
OTHER ASSETS	465	1,114
	<u>\$ 247,116</u>	<u>\$ 244,248</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 6,823	\$ 8,130
Accrued liabilities	13,180	7,789
Total current liabilities	<u>20,003</u>	<u>15,919</u>
DEFERRED INCOME TAXES	3,084	3,084
INCOME TAXES PAYABLE - non-current	2,890	—
MINORITY INTEREST	—	358
COMMITMENTS AND CONTINGENCIES	—	—
<b>STOCKHOLDERS' EQUITY:</b>		
Convertible preferred stock, \$1.00 par value- Authorized - 500,000 shares, issued and outstanding - none	—	—
Common stock, \$0.10 par value- Authorized — 80,000,000 shares, issued 14,746,951 shares at September 30, 2007 and December 31, 2006	1,475	1,475
Additional paid-in capital	73,938	74,489
Treasury stock, at cost - 683,183 and 126,530 shares at September 30, 2007 and December 31, 2006, respectively	(26,356)	(5,383)
Retained earnings	170,991	153,925
Accumulated other comprehensive income	1,091	381
Total stockholders' equity	<u>221,139</u>	<u>224,887</u>
	<u>\$ 247,116</u>	<u>\$ 244,248</u>

(1) December 31, 2006 balances were derived from audited consolidated financial statements.

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

**ICU Medical, Inc. and Subsidiaries**  
Condensed Consolidated Statements of Income  
(Amounts in thousands, except share and per share data)  
(unaudited)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2007</u>	<u>2006</u>	<u>2007</u>	<u>2006</u>
<b>REVENUES:</b>				
Net sales	\$ 44,379	\$ 48,097	\$ 140,412	\$ 146,445
Other	489	503	2,179	2,361
<b>TOTAL REVENUE</b>	<b>44,868</b>	<b>48,600</b>	<b>142,591</b>	<b>148,806</b>
<b>COST OF GOODS SOLD</b>				
	25,502	29,750	83,371	85,532
Gross profit	19,366	18,850	59,220	63,274
<b>OPERATING EXPENSES:</b>				
Selling, general and administrative	11,485	11,090	34,988	33,917
Research and development	2,234	1,611	6,240	5,515
Gain on sale of building	—	(2,093)	—	(2,093)
Total operating expenses, net	13,719	10,608	41,228	37,339
Income from operations	5,647	8,242	17,992	25,935
<b>OTHER INCOME</b>	<b>1,379</b>	<b>1,267</b>	<b>7,376</b>	<b>3,225</b>
Income before income taxes and minority interest	7,026	9,509	25,368	29,160
<b>PROVISION FOR INCOME TAXES</b>	<b>(2,319)</b>	<b>(3,518)</b>	<b>(8,372)</b>	<b>(10,789)</b>
<b>MINORITY INTEREST</b>	<b>—</b>	<b>151</b>	<b>70</b>	<b>429</b>
<b>NET INCOME</b>	<b>\$ 4,707</b>	<b>\$ 6,142</b>	<b>\$ 17,066</b>	<b>\$ 18,800</b>
<b>NET INCOME PER SHARE</b>				
Basic	\$ 0.33	\$ 0.42	\$ 1.18	\$ 1.31
Diluted	\$ 0.31	\$ 0.39	\$ 1.10	\$ 1.21
<b>WEIGHTED AVERAGE NUMBER OF SHARES</b>				
Basic	14,346,766	14,466,882	14,460,760	14,339,844
Diluted	15,290,208	15,700,042	15,457,815	15,557,664

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

**ICU Medical, Inc. and Subsidiaries**  
Condensed Consolidated Statements of Cash Flows  
(Amounts in thousands)  
(unaudited)

	<b>Nine Months Ended September 30,</b>	
	<b>2007</b>	<b>2006</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net income	\$ 17,066	\$ 18,800
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	8,428	7,878
Gain on sale of building	—	(2,093)
Provision for doubtful accounts	386	(160)
Minority interest	(70)	(429)
Stock compensation	583	349
Cash provided (used by changes in operating assets and liabilities)		
Accounts receivable	(1,346)	(8,257)
Inventories	(1,297)	(3,882)
Prepaid expenses and other assets	(581)	(1,170)
Accounts payable	(1,335)	3,293
Accrued liabilities	5,313	370
Prepaid and deferred income taxes	2,815	2,554
Net cash provided by operating activities	<u>29,962</u>	<u>17,253</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	(19,128)	(14,940)
Cash paid for acquired assets	(3,224)	—
Proceeds from sale of building	—	6,062
Proceeds from finance loan repayments	68	895
Purchases of liquid investments	(19,210)	(36,334)
Proceeds from sale of liquid investments	27,185	15,497
Net cash used in investing activities	<u>(14,309)</u>	<u>(28,820)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from exercise of stock options	1,599	7,738
Proceeds from employee stock purchase plan	1,402	1,251
Tax benefits from exercise of stock options	434	4,455
Purchase of treasury stock	(25,734)	(3,987)
Net cash provided (used by financing activities)	<u>(22,299)</u>	<u>9,457</u>
Effect of exchange rate changes on cash	299	32
<b>NET DECREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(6,347)</b>	<b>(2,078)</b>
CASH AND CASH EQUIVALENTS, beginning of period	13,153	6,854
CASH AND CASH EQUIVALENTS, end of period	<u>\$ 6,806</u>	<u>\$ 4,776</u>

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

**ICU Medical, Inc. and Subsidiaries**  
Condensed Consolidated Statements of Comprehensive Income  
(Amounts in thousands)  
(unaudited)

	<b>Three Months ended September 30,</b>		<b>Nine Months ended September 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
Net income	\$ 4,707	\$ 6,142	\$ 17,066	\$ 18,800
Other comprehensive income, net of tax:				
Foreign currency translation adjustment	<u>552</u>	<u>53</u>	<u>710</u>	<u>161</u>
Comprehensive income	<u>\$ 5,259</u>	<u>\$ 6,195</u>	<u>\$ 17,776</u>	<u>\$ 18,961</u>

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

**ICU Medical, Inc.**  
**Notes to Condensed Consolidated Financial Statements**  
**September 30, 2007**

(Amounts in tables in thousands except share and 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 and reflect all adjustments, which consist 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 2006 Annual Report to Stockholders.

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 a portion 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:** Statement of Financial Accounting Standards No. 157, "Fair Value Measurements" ("SFAS 157"), defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles, and expands disclosures about fair value measurements. The Company will adopt the provisions of SFAS 157 effective January 1, 2008. The Company does not expect SFAS 157 to have a material impact on its results of operations, financial position, or cash flows.

In February 2007, the Financial Accounting Standards Board ("FASB") issued SFAS 159, "The Fair Value Option for Financial Assets and Financial Liabilities" which permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. SFAS 159 will be effective on January 1, 2008. The provisions of SFAS 159 are elective, and the Company has not determined whether or to what extent we may implement its provisions or how if implemented, it might affect the Company's financial statements.

**Note 3: Litigation Matters:** In January 2007, the Company received \$8.0 million in settlement of litigation against a law firm that formerly represented the Company in patent litigation matters. This is included in Other Income in the Condensed Consolidated Statements of Income for the nine months ended September 30, 2007.

On June 28, 2007 the United States District Court for the Central District of California ordered ICU Medical, Inc. to pay Alaris Medical Systems, Inc. (now part of Cardinal Health, Inc.), \$4.8 million of fees and costs, plus post judgment interest. The Court's decision was pursuant to a motion brought by Alaris for reimbursement of legal fees following dismissal of the Company's claim of patent infringement against Alaris. The Company intends to appeal the Court's judgment dismissing the Company's claims in the patent case. Because the order is a judgment against the Company and the outcome of the appeal is uncertain, the Company recorded a charge of \$4.8 million in Other Income in the Condensed Consolidated Statement of Income for the nine months ended September 30, 2007. The Company has not paid the judgment, pending outcome of the appeal.

**Note 4: FIN 48 Uncertain Tax Positions:** In July 2006, the FASB issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes," an interpretation of FASB Statement No. 109 ("FIN 48"), which



provides criteria for the recognition, measurement, presentation and disclosure of uncertain tax positions. A tax benefit from an uncertain income tax position may be recognized only if it is “more-likely-than-not” that the position is sustainable based on its technical merits. The provisions of FIN 48 are effective for fiscal years beginning after December 15, 2006.

The Company adopted the provisions of FIN 48 on January 1, 2007. The total amount of unrecognized tax benefits as of the date of adoption was \$2.5 million and as of September 30, 2007 was \$2.8 million, that, if recognized, would affect the effective tax rate. The Company does not anticipate that unrecognized tax benefits will significantly increase or decrease within 12 months of the reporting date.

The Company recognizes interest and penalties related to unrecognized tax benefits and penalties in the tax provision.

The Company is subject to taxation in the United States and various states and foreign jurisdictions. The Company’s United States federal income tax returns for tax years since 2001 are subject to examination by the Internal Revenue Service. The Internal Revenue Service recently concluded their examination of tax years through 2004. The Company’s principal state income tax returns for tax years since 1998 are subject to examination by the state tax authorities.

**Note 5: Inventories** consisted of the following:

	<u>9/30/07</u>	<u>12/31/06</u>
Raw material	\$ 12,320	\$ 9,996
Work in process	2,846	3,258
Finished goods	2,534	3,061
Total	<u>\$ 17,700</u>	<u>\$ 16,315</u>

**Note 6: Property and equipment** consisted of the following:

	<u>9/30/07</u>	<u>12/31/06</u>
Machinery and equipment	\$ 43,150	\$ 38,373
Land, building and building improvements	47,131	38,336
Molds	14,009	10,959
Computer equipment and software	9,065	7,257
Furniture and fixtures	2,236	2,143
Construction in progress	6,126	5,250
Total property and equipment, cost	121,717	102,318
Accumulated depreciation	<u>(50,392)</u>	<u>(43,281)</u>
Net property and equipment	<u>\$ 71,325</u>	<u>\$ 59,037</u>

**Note 7: 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 943,442 and 1,233,160 for the three months ended September 30, 2007 and 2006, respectively and 997,055 and 1,217,820 for the nine months ended September 30, 2007, respectively. Options that are antidilutive because their exercise price exceeded the average market price of its common stock for the period approximated 152,000 for the three months ended September 30, 2007, and 40,000 and 23,000 for the nine months ended September 30, 2007 and 2006, respectively. There were no antidilutive options in the quarter ended September 30, 2006.

**Note 8: Stock Option Grants:** The Company granted 262,500 stock options in the nine months ended September 30, 2007, valued at \$4.8 million. Stock compensation expense will be recognized ratably over 60 months.

**Note 9: Income Taxes:** Income taxes were accrued at an effective tax rate of 33.0% in the first nine months of 2007 as compared to 37.0% in the first nine months of 2006. The effective tax rate differs from that computed at the federal statutory rate of 35% principally because of the effect of state income taxes, and in 2006 losses of a subsidiary not consolidated for income tax purposes, partially offset by the effect of tax-exempt investment income, state and federal tax credits, and deductions for Domestic Production Activities.

**Note 10: Major Customers and Geographic Information:** The Company had revenues equal to ten percent or more of total revenues from one customer, Hospira, Inc. Such revenues were 71% and 77% of total revenue for the quarter ended September 30, 2007 and 2006, respectively, and 73% and 77% of total revenue for the nine months ended September 30, 2007 and 2006, respectively.

As of September 30, 2007, approximately \$39.9 million or 33% of the Company's long-lived assets, principally property and equipment, were located outside the United States: approximately \$33.9 million in Mexico and approximately \$6.0 million in Italy.

**Note 11: Sale of Building:** On September 1, 2006, the Company sold the San Clemente manufacturing building for \$6.1 million, net of fees and expenses. The net book value of the land and building was \$4.0 million, resulting in a gain on the sale of the land and building of \$2.1 million.

**Note 12: Commitments and Contingencies:** The Company is from time to time involved in various legal proceedings, either as a defendant or plaintiff, most of which are routine litigation in the normal course of business. The Company believes that the resolution of the legal proceedings in which it is currently involved will not have a material adverse effect on its financial position or results of operations.

In the normal course of business, the Company has agreed to indemnify officers and directors of the Company, to the maximum extent permitted under Delaware law and to indemnify customers as to certain intellectual property matters related to sales of the Company's products. There is no maximum limit on the indemnification that may be required under these agreements. The Company has never incurred, nor does it expect to incur, any liability for indemnification, and therefore, the Company has not recorded any liability for these arrangements in its financial statements and does not expect to incur any. Except for indemnification agreements, the Company does not have any "off balance sheet arrangements".

## 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 intravenous ("I.V.") therapy applications. Our products are designed to protect patients from potential contamination of their intravenous equipment and catheter which, can otherwise lead to bloodstream infections. Our products also protect healthcare workers from injuries resulting from exposure to hazardous drugs or infectious diseases through accidental needlesticks. We are a leader in the production of custom I.V. systems and we incorporate our proprietary products in many of those custom I.V. systems. With the acquisition of Hospira's Salt Lake City plant in May 2005 and commencement of production under a twenty-year Manufacturing, Commercialization and Development Agreement with Hospira ("MCDA"), we are now also a significant manufacturer of critical care medical devices, including catheters, angiography kits and cardiac monitoring systems.

### Critical Accounting Policies

Our significant accounting policies are summarized in Note 1 to the Consolidated Financial Statements included in our 2006 Annual Report to Shareholders. In preparing our financial statements, we make estimates and assumptions that affect the expected amounts of assets and liabilities and disclosure of contingent assets and liabilities. We apply our accounting policies on a consistent basis. As circumstances change, they are considered in our estimates and judgments, and future changes in circumstances could result in changes in amounts at which assets and liabilities are recorded.

### New Accounting Pronouncements

Statement of Financial Accounting Standards No. 157, "Fair Value Measurements" ("SFAS 157"), defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles, and expands disclosures about fair value measurements. We will adopt the provisions of SFAS 157 effective January 1, 2008. We do not expect SFAS 157 to have a material impact on our results of operations, financial position, or cash flows.

In February 2007, the FASB issued SFAS 159, "The Fair Value Option for Financial Assets and Financial Liabilities" which permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. SFAS 159 will be effective on January 1, 2008. The provisions of SFAS 159 are elective, and we have not determined whether and to what extent we may implement its provisions or how if implemented, it might affect our financial statements.

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.

### 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 I.V. systems, 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 are also increasing our efforts to acquire new products. We made investments in a company developing a new medical device beginning in 2004, acquired Hospira's Salt Lake City, Utah manufacturing facility in May 2005 and entered into the MCDA to produce critical care products for Hospira, and are continuing to seek other opportunities. However, there is no assurance that we will be successful in finding acquisition opportunities, or in acquiring companies or products or that we will successfully integrate them into our existing business.

Custom I.V. systems 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 if we are unsuccessful in enforcing our intellectual property rights. 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 I.V. systems and other products that lend themselves to customization and new products in the U.S. and international markets, and increasing our emphasis on markets outside the U.S.

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 2007 and years ended 2006 and 2005, our revenues from worldwide sales to Hospira were 73%, 77% and 74%, respectively, of total revenues. We expect this percentage will be maintained in the future as a result of sales of CLAVE products, custom I.V. systems, 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.

On May 1, 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 majority of the products under the MCDA are invasive monitoring and angiography products, which include medical devices such as catheters, cardiac monitoring systems and angiography kits. Sales of products manufactured under the MCDA, including custom products, were \$42.9 million and \$56.2 million in the first nine months of 2007 and 2006, respectively. Sales in the first nine months of 2006 include \$8.7 million of products we no longer manufacture. If those sales were excluded, sales under the MCDA for the first nine months of 2006 would have been \$47.5 million. 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.

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.

A substantial portion of the invasive monitoring and angiography critical care products are custom products designed to meet the specific needs of the customer. We believe we can significantly expand the market for custom invasive monitoring and angiography products through cost savings using our proprietary low-cost manufacturing techniques both in Salt Lake City and Mexico.

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. 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	Three months ended September 30,		Nine months ended September 30,		Fiscal Year Ended		
	2007	2006	2007	2006	2006	2005	2004
CLAVE	40 %	34 %	38 %	34 %	34 %	40 %	47 %
Custom products	31 %	28 %	31 %	27 %	28 %	27 %	35 %
Critical Care (excluding custom products)	22 %	25 %	24 %	24 %	25 %	20 %	—
CLC2000 <sup>®</sup>	3 %	3 %	3 %	3 %	3 %	3 %	4 %
Other products	3 %	9 %	2 %	10 %	9 %	8 %	10 %
License, royalty and revenue share	1 %	1 %	2 %	2 %	1 %	2 %	4 %
<b>Total</b>	<b>100 %</b>	<b>100 %</b>	<b>100 %</b>	<b>100 %</b>	<b>100 %</b>	<b>100 %</b>	<b>100 %</b>

Critical care, including critical care custom products, accounted for 30% and 38% of total revenue for the first nine months of 2007 and 2006, respectively. Custom I.V. systems, excluding critical care custom products, were 24% and 19% of total revenues for the first nine months of 2007 and 2006, respectively.

Most custom I.V. systems include one or more CLAVES. Total CLAVE sales including custom I.V. systems with at least one CLAVE were \$26.2 million or 58% of total revenue in the third quarter of 2007 and \$24.1 million or 50% of total revenue in the third quarter of 2006. Total CLAVE sales including custom I.V. systems with at least one CLAVE were \$80.0 million or 56% of total revenue in the first nine months of 2007 and \$72.2 million or 48% of total revenue in the first nine months of 2006.

We sell most of our I.V. administration products to independent distributors 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 and certain other I.V. therapy products. Under a 2001 agreement, we sell custom I.V. systems 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, a 2005 agreement, we sell Hospira invasive monitoring, angiography and other products which it 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 contracts with large healthcare providers and major buying organizations. As a result of this marketing and distribution strategy, we derive most of our revenues from a relatively small number of distributors and manufacturers. The loss of a strategic relationship with a customer or a decline in demand for a manufacturing customer's products could have a material adverse effect on our operating results.

We believe 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. In response to competitive pressure, we have been reducing prices to protect and expand our market, although overall pricing has been stable recently. We expect that the average price of our CLAVE products may continue to decline. 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. We are expanding our custom products business through increased sales to medical product manufacturers and independent distributors. Under one of our Hospira Agreements, we manufacture custom I.V. systems for sale by Hospira and jointly promote the products under the name SetSource™. In 2004, we made our initial investment in a company developing a new medical device and now own 94% of that company. Sales depend on the success of efforts to develop and market the device, and there is no assurance that those efforts will succeed. In 2005, we acquired Hospira's Salt Lake City manufacturing facility and entered into the MCDA to produce Hospira's 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. Custom I.V. systems, custom critical care products and custom oncology products accounted for approximately \$44.1 million or 31% of total revenue in the first nine months of 2007, including sales of custom critical care products of approximately \$9.6 million and Hospira custom I.V. sales of approximately \$13.7 million. We expect continued increases in sales of custom products. There is no assurance that we will be successful in finding acquisition opportunities, or in acquiring companies or products or that we will successfully integrate them into our existing business.

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, expanded our production facility in Mexico and transferred the majority of manual assembly previously done in Salt Lake City to our facility in Mexico. An additional significant expansion of our facility in Mexico was completed in the third quarter of 2007. We may establish other production 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 September 30,		Nine months ended September 30,		Fiscal Year Ended		
	2007	2006	2007	2006	2006	2005	2004
Medical product manufacturers	70 %	74 %	72 %	76 %	76 %	76 %	57 %
Independent domestic distributors	16 %	15 %	15 %	14 %	14 %	16 %	31 %
International customers	14 %	11 %	13 %	10 %	10 %	8 %	12 %
Total	100 %	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 and exported by Hospira. Those sales are included in sales to medical product manufacturers. Other sales to Hospira for destinations outside the U.S. are included in sales to international customers, unless otherwise noted.

**Quarter-to-quarter comparisons:** We present summarized income statement data in Item 1. Financial Statements. The following table shows, for the year 2006, the third quarters of 2007 and 2006 and the first nine months of 2007 and 2006, the percentages of each income statement caption in relation to total revenues.

	Year	Three months ended September 30,		Nine months ended September 30,	
	2006	2007	2006	2007	2006
Revenue					
Net sales	99 %	99 %	99 %	98 %	98 %
Other	1 %	1 %	1 %	2 %	2 %
Total revenues	100 %	100 %	100 %	100 %	100 %
Gross profit	40 %	43 %	39 %	42 %	43 %
Selling, general and administrative expenses	22 %	26 %	23 %	25 %	23 %
Research and development expenses	3 %	5 %	3 %	4 %	4 %
Gain on sale of building	(1) %	0 %	(4) %	0 %	(2) %
Total operating expenses	24 %	31 %	22 %	29 %	25 %
Income from operations	16 %	12 %	17 %	13 %	18 %
Other income	2 %	3 %	3 %	5 %	2 %
Income before income taxes and minority interest	18 %	15 %	20 %	18 %	20 %
Income taxes	5 %	5 %	7 %	6 %	7 %
Minority interest	0 %	0 %	0 %	0 %	0 %
Net income	13 %	10 %	13 %	12 %	13 %

**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 typically causes 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. 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 September 30, 2007 Compared to the Quarter Ended September 30, 2006**

Revenues were \$44.9 million in the third quarter of 2007 compared to \$48.6 million in the third quarter of 2006. Revenues include sales of \$3.2 million in the third quarter of 2006 from a product we discontinued manufacturing under the MCDA in October 2006 and the Punctur Guard products that we terminated in January 2007. Without those sales, revenues for the third quarters of 2007 and 2006 were \$44.9 million and \$45.4 million, respectively.

**Distribution channels:** Net U.S. sales to Hospira in the third quarter of 2007 were \$30.4 million, compared to net sales of \$35.2 million in the third quarter of 2006. The third quarter of 2006 includes \$1.7 million of sales of a product we discontinued manufacturing under the MCDA in October 2006. Excluding the sales of this product, net sales to Hospira decreased \$3.1 million or nine percent. This decrease was primarily comprised of decreases in critical care product sales of \$2.2 million and critical care custom product sales of \$1.2 million due to lower prices charged under the MCDA and lower unit sales in certain products. Custom I.V. systems sales to Hospira approximated \$4.7 million in the third quarter of 2007 compared to \$4.0 million in the third quarter of 2006, an increase of 16%. We expect a decrease in our sales to Hospira in 2007 compared to 2006 because the decline in critical care and custom critical care products will be only partially offset by the growth in custom I.V. systems.

Net sales to independent domestic distributors (including Canada) in the third quarter of 2007 and 2006 were \$7.3 million. Net sales of \$7.3 million is a \$0.7 million, or 11%, increase over sales in the third quarter of 2006 of \$6.6 million, after excluding Punctur Guard sales of \$0.7 million in the third quarter of 2006. This increase was primarily from increased sales in CLAVE and custom products from increased unit volume. We expect that sales to domestic distributors will increase principally from growth in custom products, with modest growth in sales other products, including new products, although there is no assurance that these expectations will be realized.

Net sales to international customers (excluding Canada) were \$6.0 million in the third quarter of 2007, compared to \$5.0 million in the third quarter of 2006, an increase of \$1.0 million or 21%. This increase resulted primarily from \$1.1 million of increased CLAVE sales, \$0.4 million of increased custom I.V. system sales, offset by a decline of \$0.6 million of Punctur Guard sales. Both increases are from increased unit volume. The growth was primarily attributable to increased sales in Europe, Latin America and South Africa. We expect continued increases in sales to international customers across most areas and principal product lines, although there is no assurance that these expectations will be realized.

**Product and other revenue:** Net sales of CLAVE products (excluding custom CLAVE I.V. systems) were \$17.8 million in the third quarter of 2007 compared to \$16.6 million in the third quarter of 2006, an increase of \$1.2 million or seven percent. This increase was primarily due to a 53% increase in international sales of \$1.1 million. Sales of CLAVE products and custom I.V. systems including one or more CLAVE connectors combined were \$26.2 million in the third quarter of 2007 compared with \$24.1 million in the third quarter of 2006. CLAVE and custom CLAVE product sales increased in all distribution channels.



Sales to Hospira of critical care products, excluding custom critical care products and products we no longer manufacture, were \$9.9 million in the third quarter of 2007 compared to \$12.1 million in the third quarter of 2006. This decrease was due to lower unit volume and lower prices under the MCDA. We expect further price decreases in 2008 and 2009.

Net sales of custom products, including custom critical care products, were \$14.1 million in the third quarter of 2007 compared to \$13.7 million in the third quarter of 2006. Custom I.V. system sales increased \$1.3 million across all channels, partially offset by a decline in sales of custom critical care products of \$1.0 million. The increased custom I.V. system revenue was due to higher unit sales. The decrease in custom critical care products was due to lower unit sales and lower prices under the MCDA.

Net sales of CLC2000 in the third quarter of 2007 and the third quarter of 2006 were \$1.2 million and \$1.3 million, respectively.

Sales of other products were \$1.4 million and \$4.5 million in the third quarters of 2007 and 2006, respectively. Other product sales in the third quarter of 2006 include \$1.7 million of sales of a product we no longer manufacture under the MCDA and \$1.5 million of sales of Punctur-Guard products (excluding royalties) which was terminated in the January 2007.

Other revenue consists of license, royalty and revenue share income and was approximately \$0.5 million in the third quarters of 2007 and 2006. 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 margin** for the third quarter of 2007 and 2006 was 43% and 39%, respectively. Production and gross margins were relatively stable in the first and second quarters of 2006. In the third and fourth quarters of 2006, gross margins declined to 39% and 33%, respectively. The decline was caused by temporary production inefficiencies at our factory in Salt Lake City and production inefficiencies at our factory in Mexico because of increased production volumes, turnover of new personnel and changes in production processes and certain non-recurring charges. The production inefficiencies in Salt Lake City and Mexico were reduced in the first three quarters of 2007, but efficiencies have not yet returned to where they were in the first half of 2006. The third quarter of 2007 was favorably impacted by certain government incentives and unfavorably impacted by a decrease in production volumes.

We estimate our gross margin by December of this year will approach 45%. However, there is no assurance as to gross margins in 2007 or when all adverse effects of inefficiencies will be eliminated.

**Selling, general and administrative expenses (“SG&A”)** were \$11.5 million, and were 26% of revenues in the third quarter of 2007, compared with \$11.1 million and 23% in the third quarter of 2006. Increased compensation and benefit expenses of approximately \$1.2 million were offset by lower legal costs of \$1.1 million. The higher compensation and benefits costs were primarily in sales and marketing and increased stock compensation expense. The lower legal fees are primarily due to two legal actions being concluded in the first half of 2007. We expect SG&A in 2007 to approximate 24% of revenue. Increases in costs for sales personnel is expected to be more than offset by a significant decrease in expenses associated with patent and other litigation. There is no assurance that these expectations will be realized.

**Research and development expenses (“R&D”)** were \$2.2 million or five percent of revenue in the third quarter of 2007 compared to \$1.6 million or three percent of revenue in the third quarter of 2006. We expect R&D in 2007 to be four to five percent of revenue, although there is no assurance that these expectations will be realized.

**Other income** was \$1.4 million of in the third quarter of 2007 and \$1.3 million of income in the third quarter of 2006. Interest income was \$1.1 million and \$1.0 million in the third quarter of 2007 and 2006, respectively. Both quarters also include a payment from a legal settlement of \$0.3 million.

**Income taxes** were accrued at an effective tax rate of 33.0% in the third quarter of 2007 compared to 37% in the third quarter of 2006. The effective tax rate differs from that computed at the federal statutory rate of 35% principally because of the effect of state income taxes and, in 2006, losses of a subsidiary not consolidated for income tax purposes, partially offset by the effect of tax-exempt investment income, state and federal tax credits, deductions for Domestic Production Activities. We expect our effective rate to be approximately 33.0% in 2007.

#### **Nine months ended September 30, 2007 Compared to the Nine months ended September 30, 2006**

Revenues were \$142.6 million in the first nine months of 2007 and \$148.8 million in the first nine months of 2006. Revenues include sales of \$12.4 million in 2006 of a product we discontinued manufacturing under the MCDA in October 2006 and the Punctur Guard products that we terminated in January 2007. Revenues for the first nine months of 2007 and 2006 from products other than the discontinued products were \$142.6 million and \$136.4 million, respectively, an increase of five percent.

**Distribution channels:** Net U.S. sales to Hospira in the first nine months of 2007 were \$98.4 million, compared to net sales of \$110.0 million in the first nine months of 2006. The first nine months of 2006 includes \$8.7 million of sales of a product we discontinued manufacturing under the MCDA in October 2006. Excluding the sales of this product, net sales to Hospira decreased \$2.9 million. The change in revenue was primarily from increased custom I.V. system sales of \$1.7 million offset by decreased critical care sales of \$2.3 million and decreased critical care custom sales of \$1.8 million. The increased sales in custom I.V. systems were due to increased unit volumes. The decreases in critical care and critical care custom were due to lower unit sales in most products and lower prices under the MCDA. Custom I.V. system sales approximated \$13.7 million in the first nine months of 2007 compared to \$12.0 million in the first nine months of 2006, an increase of 14%.

Net sales to independent domestic distributors (including Canada) in the first nine months of 2007 were \$21.3 million compared to \$20.3 million in the first nine months of 2006. The first nine months of 2006 includes \$2.2 million of Punctur Guard sales. Excluding Punctur Guard sales, sales in the first nine months of 2006 were \$18.1 million. This increase was primarily comprised of sales increases of \$2.1 in custom products, \$0.4 million increase in CLAVE, and \$0.5 million of new products. All increases are due to increased unit volume.

Net sales to international customers (excluding Canada) were \$18.6 million in the first nine months of 2007, compared with \$14.5 million in the first nine months of 2006, an increase of \$4.1 million or 28%. Approximately \$2.8 million and \$0.7 million of this increase was attributable to increased sales in Europe and the Pacific Rim, respectively. The principal product lines showing increases were custom I.V. systems, with an increase of \$2.1 million and CLAVE products, with an increase of \$2.8 million. 2006 revenue includes \$1.0 million from the discontinued Punctur Guard product line. All revenue product increases were due to increases in unit sales.

**Product and other revenue:** Net sales of CLAVE Products (excluding custom CLAVE I.V. systems) were \$54.1 million in the first nine months of 2007 compared to \$50.8 million in the first nine months of 2006, an increase of \$3.3 million. This increase was primarily due to increased international sales of \$2.8 million and increased domestic distributor sales of \$0.4 million. Sales of CLAVE products and custom I.V. systems including one or more CLAVE connectors combined were \$80.0 million in the first nine months of 2007 compared with \$72.2 million in the first nine months of 2006. CLAVE and custom CLAVE product sales increased from increased unit volume in all our distribution channels.

Sales to Hospira of critical care products, excluding custom critical care products and products we no longer manufacture, were \$33.8 million in the first nine months of 2007 compared to \$36.1 million in the first nine months of 2006. This decrease was primarily due to lower unit volume and lower prices under the MCDA.

Net sales of custom products, including custom critical care products and custom oncology products, were \$44.1 million in the first nine months of 2007 compared to \$39.7 million in the first nine months of 2006. The \$4.4 million or 10% increase was principally from increased unit volume in custom I.V. systems which accounted for an increase of \$5.5 million. The higher custom I.V. system sales were from increases in all channels. The critical care custom decrease of \$1.3 was due to lower unit volume and lower prices in under the MCDA.

Net sales of CLC2000 in the first nine months of 2007 and the first nine months of 2006 were \$3.8 million and \$4.0 million, respectively. The decrease was from modest decreases in all channels.

Sales of other products were \$4.6 million and \$15.9 in the first nine months of 2007 and 2006, respectively. The first nine months of 2006 other product sales include \$8.7 million of sales of a product we no longer manufacture under the MCDA. The first nine months of 2007 and 2006 include \$0.3 million and \$3.7 million, respectively, of sales of Punctur Guard products (excluding royalties) which was terminated in the January 2007.

Other revenue consists of license, royalty and revenue share income and was approximately \$2.2 million in the first nine months of 2007 and \$2.4 million in the first nine months of 2006.

**Gross margin** for the first nine months of 2007 and 2006 was 42% and 43%, respectively. As previously discussed, gross margins declined to 33% in the fourth quarter of 2006. They improved to 39%, 42% and 43% in the first, second and third quarters of 2007, respectively.

**Selling, general and administrative expenses ("SG&A")** were \$35.0 million, and were 25% of revenues in the first nine months of 2007, compared with \$33.9 million and 23% in the first nine months of 2006. The increase in costs was primarily due to increased sales and marketing compensation and benefit expenses of approximately \$1.2 million, \$0.6 million increase in sales and marketing promotion expense, a \$0.8 million increase in travel expenses for our sales and marketing personnel, partially offset by a \$1.8 million decrease in legal expenses.

**Research and development expenses ("R&D")** were \$6.2 million and four percent of revenue in the first nine months of 2007 compared to \$5.5 million and four percent of revenue in the first nine months of 2006.

**Other income** was \$7.4 million in the first nine months of 2007 and \$3.2 million in the first nine months of 2006. Other income in the first nine months of 2007 includes an \$8.0 million payment to us for a settlement of litigation against our former attorneys, a \$0.8 million payment of another legal settlement, partially offset by a \$4.8 million charge for an award against us in our litigation with Alaris Medical Systems. Interest income was \$3.3 million in the first nine months of 2007 compared to \$2.7 million in the first nine months of 2006. The increase in interest income was primarily due to an increase in average invested funds.

**Income taxes** were accrued at an effective tax rate of 33.0% in the first nine months of 2007 as compared to 37.0% in the first nine months of 2006.

### **Liquidity and Capital Resources**

During the first nine months of 2007, our cash, cash equivalents and liquid investments decreased by \$14.3 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, payment of trade and other liabilities and the timing of tax payments.

During the first nine months of 2007 cash provided by operations was \$30.0 million. The first nine months of 2007 cash flow from operations was mainly comprised of \$17.1 million of net income, including \$8.0 million in a legal settlement (\$5.4 million in legal settlements net of taxes), depreciation and amortization of \$8.4 million and changes in our operating assets and liabilities of \$3.6 million.

**Investing Activities:** During the first nine months of 2007, we used \$14.3 million of cash in investing activities. This was principally comprised of cash paid for acquired assets of \$3.2 million, purchases of property and equipment of \$19.1 million which were primarily for the building expansion of our Mexico facility, equipment additions and mold additions, offset by a net \$8.0 million in net investment sales.

We estimate that capital expenditures for all of 2007, including the building improvements in our Mexico facility and new tooling, will be approximately \$23.0 million. Amounts of spending are estimates and actual spending may substantially differ from those amounts.

**Financing Activities:** During the first nine months of 2007, we used cash of \$22.3 million. Cash provided by stock options and the employee stock purchase plan, including tax benefits, was \$3.4 million in the first nine months of 2007 from the sale of 111,159 shares.

In January 2007, we announced an expanded program to purchase up to \$20.0 million of our common stock. In September 2007, we announced another program to purchase up to an additional \$20.0 million of our common stock. We purchased \$25.7 million of our stock during the first nine months of 2007.

We have a substantial cash and liquid investment position generated from profitable operations and stock sales, principally from the exercise of employee stock options. We maintain this position to fund our growth, meet increasing working capital requirements, fund capital expenditures, and to take advantage of acquisition opportunities that may arise. Our primary investment goal is capital preservation, as further described in Item 3. Quantitative and Qualitative Disclosures about Market Risk. Our liquid investments have very little credit risk or market risk. We believe that our existing cash and liquid investments 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.

#### **Off Balance Sheet Arrangements**

In the normal course of business, we have 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 our products. There is no maximum limit on the indemnification that may be required under these agreements. 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 liquid investments 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. There are no obligations past 2009. (In thousands)

	<u>2007</u>	<u>2008</u>	<u>2009</u>
MCDA	\$ 2,426	\$ 5,500	\$ 5,500
Property and equipment	2,760	—	—
Total	<u>\$ 5,186</u>	<u>\$ 5,500</u>	<u>\$ 5,500</u>

## Forward Looking Statements

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 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, 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 custom I.V. systems 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 the effects of new accounting pronouncements;
- 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; 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. 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 Part II, Item 1A of the Annual Report on Form 10-K to the Securities and Exchange Commission for the year ended December 31, 2006 and Part II, Item 1A of this Quarterly Report. 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;
- 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 have a portfolio of corporate preferred stocks and federal-tax-exempt state and municipal government debt securities. The securities are all “investment grade” and we believe that we have virtually no exposure to credit risk. Dividend and interest rates reset at auction for most of the securities at seven to forty-nine day intervals, with some longer but none beyond twelve months, so we have very little market risk, that is, risk that the fair value of the security will change because of changes in market interest rates; they are readily saleable at par at auction dates, and can normally be sold at par between auction dates. As of September 30, 2007, we had no declines in the market values of these 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 and corporate preferred stocks in the portfolio and market conditions specific to the securities in which we invest.

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. 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 Italy, where our net Euro

position at September 30, 2007 was approximately €49 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. We are not dependent upon any single source for any of our principal raw materials and all such materials and products are readily available.

#### **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 Regulations 13a-14(c) and 15a-14(c) 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 Securities Exchange Commission. There were no significant changes in our internal controls or in other factors that could significantly affect our internal controls subsequent to the date of the principal executive officer's and principal financial officer's evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

**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 has 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 February 22, 2007, the Court entered judgment dismissing those remaining claims. The Court's order affected 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, plus post judgment interest. We intend to appeal the Court's decisions. 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 \$4.8 million in our financial statements for the quarter ended June 30, 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 CLC 2000 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. Medegen has stated that it intends to appeal this order. On October 19, 2007, the Court entered judgment of non-infringement and dismissed 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. We intend to defend ourselves in any appeals by Medegen in this action and to vigorously pursue our claims against Medegen.

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 the InVision-Plus valve. We seek monetary damages and injunctive relief and intend to vigorously pursue this matter. RyMed has denied our allegations and sued us 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. We intend to vigorously defend ourselves on this 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 II, Item 1A of our Annual Report to the Securities and Exchange Commission for the year ended December 31, 2006, as well as the information contained in this Quarterly Report and our other reports and registration statements filed with the Securities and Exchange Commission. 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 II, Item 1A of our Annual Report to the Securities and Exchange Commission for the year ended December 31, 2006.

*Continued declines in the market for critical care products could have a material adverse effect on our sales and profits.*

As described in Management's Discussion and Analysis of Financial Condition and Results of Operations, 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 the first nine months of 2007 with further declines expected in the fourth quarter of 2007. If the market for critical care products continues to decline or Hospira does not provide the necessary sales and marketing support to maintain sales, our sales of critical care products to Hospira under the MCDA could continue to decline resulting in a substantial reduction in our sales and profits.

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

### Issuer Repurchase of Equity Securities

The following is a summary of our stock repurchasing activity during the third quarter of 2007:

Period	Shares purchased	Average price paid per share	Shares purchased as part of a publicly announced program	Approximate dollar value that may yet be purchased under the program
07/01/2007 — 07/31/2007	—	\$ —	—	\$ 12,386,700
08/01/2007 — 08/31/2007	201,605	37.48	201,605	4,831,300
09/01/2007 — 09/30/2007	249,086	38.40	249,086	15,265,600
Third quarter 2007 total	450,691	\$ 37.99	450,691	

We had a stock repurchase program, originally announced in July 2006. In August 2006, our Board of Directors authorized a program to purchase \$14.0 million of our common stock. This program was terminated in January 2007 after purchasing shares with a cost of approximately \$8.0 million. Also in January 2007, we announced an expanded program to purchase up to \$20 million of our common stock. The January repurchase program was completed in September 2007. In September 2007, we announced a new program to purchase up to \$20.0 million of our common stock, however, we may purchase less than that amount, as we deem appropriate based on the stock price, prevailing market and business conditions and other considerations. The September 2007 program expires March 14, 2008.

**Item 3. Default Upon Senior Securities**

Inapplicable

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

Inapplicable

**Item 5. Other Information**

None

**Item 6. Exhibits**

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:	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
Exhibit 100.INS	XBRL Instance Document
Exhibit 100.SCH	XBRL Taxonomy Extension Schema Document
Exhibit 100.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
Exhibit 100.LAB	XBRL Taxonomy Extension Label Linkbase Document
Exhibit 100.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

## Signatures

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/ Francis J. O'Brien  
Francis J. O'Brien  
Chief Financial Officer  
(Principal Financial Officer)

Date: October 25, 2007

/s/ Scott E. Lamb  
Scott E. Lamb  
Controller  
(Principal Accounting Officer)

Date: October 25, 2007

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF  
THE SARBANES-OXLEY ACT OF 2002**

I, George A. Lopez, certify that:

1. I have reviewed this quarterly report on Form 10-Q of ICU Medical, Inc.:
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors:
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 25, 2007

/s/ George A. Lopez, M.D.  
Chief Executive Officer

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**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF  
THE SARBANES-OXLEY ACT OF 2002**

I, Francis J. O'Brien, certify that:

1. I have reviewed this quarterly report on Form 10-Q of ICU Medical, Inc.:
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors:
  - a) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 25, 2007

/s/ Francis J. O'Brien  
Chief Financial Officer

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**CERTIFICATION OF CHIEF EXECUTIVE OFFICER  
PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of ICU Medical, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2007 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, George A. Lopez, Chief Executive Officer, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

October 25, 2007

/s/ George A. Lopez, M.D.  
George A. Lopez, M.D.

**CERTIFICATION OF CHIEF FINANCIAL OFFICER  
PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of ICU Medical, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2007 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Francis J. O'Brien, Chief Financial Officer, certify pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

October 25, 2007

/s/ Francis J. O'Brien  
Francis J. O'Brien

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