

ICU MEDICAL INC/DE  
Form 10-Q  
October 31, 2005

## **FORM 10-Q**

**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

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

**For the quarterly period ended: September 30, 2005**

**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.**

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

(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 an accelerated filer (as defined in Rule 12b-2 of the Exchange Act):

Yes

No

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**  
Common

**Outstanding at October 19, 2005**  
13,877,587

*ICU Medical, Inc.*

*Index*

**Part I - Financial Information**

**Item 1. Financial Statements (Unaudited)**

Condensed Consolidated Balance Sheets, September 30, 2005 and December 31, 2004

Condensed Consolidated Statements of Income (Loss) for the three and nine months ended September 30, 2005 and 2004

Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2005 and 2004

Condensed Consolidated Statements of Comprehensive Income (Loss) for the three and nine months ended September 30, 2005 and 2004

Notes to Condensed Consolidated Financial Statements

**Item 2.**

Management's Discussion and Analysis of Financial Condition and Results of Operations

**Item 3.**

Quantitative and Qualitative Disclosures About Market Risk

**Item 4.**

Controls and Procedures

**Part II - Other Information**

**Signatures**

## ICU Medical, Inc.

## Condensed Consolidated Balance Sheets

(all amounts in thousands except share and per share data)

	September 30, 2005 (unaudited)	December 31, 2004 (1)
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 9,623	\$ 5,616
Liquid investments	68,500	81,725
Cash, cash equivalents and liquid investments	78,123	87,341
Accounts receivable, net of allowance for doubtful accounts of \$476 and \$912 as of September 30, 2005 and December 31, 2004, respectively	25,713	8,922
Finance loans receivable - current portion	1,198	2,634
Inventories	13,532	8,429
Prepaid income taxes	1,262	6,576
Prepaid expenses and other current assets	4,069	1,986
Deferred income taxes - current portion	1,435	1,156
Total current assets	125,332	117,044
PROPERTY AND EQUIPMENT, at cost:	89,562	73,702
Less-Accumulated depreciation	(37,074)	(32,768)
	52,488	40,934
FINANCE LOANS RECEIVABLE - non-current portion	2,701	3,613
INTANGIBLE ASSETS - net	11,188	2,780
OTHER ASSETS	382	397
	\$ 192,091	\$ 164,768
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 5,778	\$ 2,693
Accrued liabilities	8,378	4,761
Total current liabilities	14,156	7,454
MINORITY INTEREST	659	966
<b>COMMITMENTS AND CONTINGENCIES</b>		
<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 14,158,612 shares	1,416	1,416
Additional paid-in capital	60,659	61,751
Treasury stock, at cost 281,025 and 583,643 shares at September 30, 2005 and December 31, 2004, respectively	(7,789)	(15,290)
Retained earnings	122,954	107,991
Accumulated other comprehensive income	36	480
Total stockholders equity	177,276	156,348
	\$ 192,091	\$ 164,768

(1) December 31, 2004 balances were derived from the audited consolidated financial statements of ICU Medical, Inc.



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

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

## ICU Medical, Inc.

## Condensed Consolidated Statements of Income (Loss)

(all amounts in thousands except share and per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
<b>REVENUES:</b>				
Net sales	\$ 46,121	\$ 15,894	\$ 111,900	\$ 58,166
Other	403	574	2,402	2,200
<b>TOTAL REVENUE</b>	<b>46,524</b>	<b>16,468</b>	<b>114,302</b>	<b>60,366</b>
<b>COST OF GOODS SOLD</b>	<b>27,248</b>	<b>9,954</b>	<b>63,468</b>	<b>29,368</b>
Gross profit	19,276	6,514	50,834	30,998
<b>OPERATING EXPENSES:</b>				
Selling, general and administrative	9,635	6,807	27,264	19,065
Research and development	1,353	1,763	3,031	2,617
Total operating expenses	10,988	8,570	30,295	21,682
Income (loss) from operations	8,288	(2,056)	20,539	9,316
<b>OTHER INCOME</b>	<b>504</b>	<b>375</b>	<b>2,078</b>	<b>1,083</b>
Income (loss) before income taxes	8,792	(1,681)	22,617	10,399
<b>PROVISION (BENEFIT) FOR INCOME TAXES</b>				
TAXES	3,095	(621)	7,961	3,909
MINORITY INTEREST	(110)	(24)	(307)	(24)
<b>NET INCOME (LOSS)</b>	<b>\$ 5,807</b>	<b>\$ (1,036)</b>	<b>\$ 14,963</b>	<b>\$ 6,514</b>
<b>NET INCOME (LOSS) PER SHARE</b>				
Basic	\$ 0.42	\$ (0.08)	\$ 1.09	\$ 0.47
Diluted	\$ 0.39	\$ (0.08)	\$ 1.00	\$ 0.43
<b>WEIGHTED AVERAGE NUMBER OF SHARES</b>				
Basic	13,861,214	13,685,053	13,764,052	13,731,015
Diluted	15,012,066	13,685,053	14,964,943	14,996,073

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

## ICU Medical, Inc.

## Condensed Consolidated Statements of Cash Flows

(all amounts in thousands)

(unaudited)

	Nine months ended September 30,	
	2005	2004
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net income	\$ 14,963	\$ 6,514
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	6,935	5,564
Provision for doubtful accounts	(428)	(115)
Minority interest	(307)	(24)
Write-off of in-process research and development		1,154
Cash provided (used) by changes in operating assets and liabilities, net of assets acquired		
Accounts receivable	(16,469)	10,621
Inventories	4,978	(6,159)
Prepaid expenses and other assets	(3,360)	(305)
Accounts payable	2,903	(864)
Accrued liabilities	2,818	1,118
Prepaid and deferred income taxes	5,262	(1,135)
	17,295	16,369
Tax benefits from exercise of stock options	2,218	1,923
Net cash provided by operating activities	19,513	18,292
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Cash paid for acquired assets	(31,767)	
Purchases of property and equipment	(3,395)	(5,080)
Advances under finance loans		(1,010)
Proceeds from finance loan repayments	2,348	3,277
Purchases of liquid investments	(34,600)	(17,325)
Proceeds from sale of liquid investments	47,825	13,250
Net cash used in investing activities	(19,589)	(6,888)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from exercise of stock options	3,710	2,645
Proceeds from employee stock purchase plan	482	503
Purchase of treasury stock		(10,133)
Net cash provided by (used in) financing activities	4,192	(6,985)
Effect of exchange rate changes on cash	(109)	(52)
<b>NET INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>4,007</b>	<b>4,367</b>
CASH AND CASH EQUIVALENTS, beginning of period	5,616	1,787
CASH AND CASH EQUIVALENTS, end of period	\$ 9,623	\$ 6,154

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



**ICU Medical, Inc.**

Condensed Consolidated Statements of Comprehensive Income (Loss)

(all amounts in thousands)

(unaudited)

	<b>For the Three Months Ended</b>		<b>For the Nine Months Ended</b>	
	<b>9/30/05</b>	<b>9/30/04</b>	<b>9/30/05</b>	<b>9/30/04</b>
Net income (loss)	\$ 5,807	\$ (1,036)	\$ 14,963	\$ 6,514
<b>Other comprehensive income (loss) net of tax:</b>				
Foreign currency translation adjustment	(6)	49	(444)	(52)
Comprehensive income (loss)	\$ 5,801	\$ (987)	\$ 14,519	\$ 6,462

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

**ICU Medical, Inc.**

**Notes to Condensed Consolidated Financial Statements**

**September 30, 2005**

(All dollar 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 2004 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 are included in the consolidated financial statements. All intercompany balances and transactions have been eliminated.

**Note 2: Asset Purchase:** On May 1, 2005, the Company acquired a Salt Lake City, Utah manufacturing facility, related capital equipment, certain inventories and assumed liabilities from Hospira, Inc. (Hospira) for approximately \$31.8 million in cash and \$0.8 million in acquisition costs. The Company has a twenty-year Manufacturing, Commercialization and Development Agreement (MCDA) with Hospira under which the Company produces for sale to Hospira on an exclusive basis substantially all the products that Hospira had manufactured at that facility. Hospira retains commercial responsibility for the products the Company is producing, including sales, marketing, distribution, customer contracts, customer service and billing. The majority of the products the Company produces under the MCDA are Hospira's critical care products, which include medical devices such as catheters, angiography kits and cardiac monitoring systems. The Company has also committed to fund certain research and development to improve critical care products and develop new products for sale to Hospira, and has also committed to provide certain sales specialist support. The Company's prices and gross margins on the products it sells to Hospira under the MCDA are based on cost savings that it is able to achieve in producing those products over Hospira's cost to manufacture those same products at the purchase date.

The Company is moving all molding and automated assembly to the Salt Lake City location from its San Clemente and Connecticut locations. In addition, the Company is expanding its production facility in Mexico to take over all manual assembly currently done in its Salt Lake City facility. These changes are expected to be completed by early 2007.

Hospira is reimbursing the Company for severance costs and certain other termination costs for workers employed at the Salt Lake City plant at the date of purchase who are involuntarily terminated within two years of the May 1, 2005 date of purchase. The Company will charge to expense as incurred costs of relocating personnel to Salt Lake City, and moving machinery to and installing it in Salt Lake City. Such costs have not been significant to date. The Company expects to pay one-time termination benefits to certain employees in San Clemente and Connecticut who are involuntarily terminated because of the move to Salt Lake City if they continue to render service until terminated and the liability for such benefits is being accrued ratably over the employees' expected service period in accordance with Statement of Financial Accounting Standards ( SFAS ) No. 146 Accounting for Costs Associated with Exit or Disposal Activities. Costs of moving production to Mexico will be capitalized or

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

charged to expense immediately, as appropriate; relocation costs to Mexico are not expected to be material. Total costs of moving, relocation and termination benefits charged to expense are approximately \$0.7 million in the three and nine months ended September 30, 2005 and are included in cost of good sold.

The Company does not expect to incur a significant loss on the disposition of equipment in San Clemente or Connecticut in connection with the move to Salt Lake City. The management of the Company has not yet determined what to do with building space that will no longer needed for production, but the management of the Company does not believe that it will incur any loss on that space.

The purchase price of \$31.8 million and acquisition costs of \$0.8 million were allocated to the assets and liabilities assumed based on their estimated fair market values as follows. This allocation is preliminary.

Property, plant and equipment	\$	14,547
Inventory		10,195
Intangible asset MCDA		8,926
Liabilities assumed		(1,062)
Total	\$	32,606

**Note 3: Stock Options:** The Company accounts for stock options granted to employees and directors under Accounting Principles Board ( APB ) Opinion No. 25 Accounting for Stock Issued to Employees and related interpretations as permitted by SFAS No. 123 Accounting for Stock-Based Compensation , and does not recognize compensation expense because the exercise price of the options equals the fair market value of the underlying shares at the date of grant or as to the 2002 Employee Stock Purchase Plan, the Plan is non-compensatory under the provisions of APB Opinion No. 25. Under SFAS No. 123, the Company is required to present certain pro forma earnings information determined as if employee stock options were accounted for under the fair value method of that Statement. The fair value for options granted in the first nine months of 2005 and 2004 was estimated as of the date of grant using a Black-Scholes option pricing model. The Black-Scholes option valuation model was developed for use in estimating fair value of fully transferable traded options with no vesting restrictions, and, similar to other option valuation models, requires use of highly subjective assumptions, including expected stock price volatility. The characteristics of the Company s stock options differ substantially from those of traded stock options, and changes in the subjective assumptions can materially affect estimated fair values. Therefore, in Management s opinion, existing option valuation models do not necessarily provide a reliable single measure of the fair value of its stock options.

The following information is provided pursuant to SFAS No. 123, as amended.

	Three months ended September 30,		Nine months ended September 30,	
	2005	2004	2005	2004
Net income (loss), as reported	\$ 5,807	\$ (1,036)	\$ 14,963	\$ 6,514
Deduct: stock-based compensation expense determined under fair value method, net of tax	(315)	(1,480)	(693)	(4,153)
Net income (loss), pro forma	\$ 5,492	\$ (2,516)	\$ 14,270	\$ 2,361



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

Net income per share								
Basic, as reported	\$	0.42	\$	(0.08)	\$	1.09	\$	0.47
Diluted, as reported	\$	0.39	\$	(0.08)	\$	1.00	\$	0.43
Basic, pro forma	\$	0.40	\$	(0.18)	\$	1.04	\$	0.17
Diluted, pro forma	\$	0.36	\$	(0.18)	\$	0.95	\$	0.16

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

On December 16, 2004, the Financial Accounting Standards Board ( FASB ) issued FASB Statement No. 123 (revised 2004), Share-Based Payment ( SFAS 123(R) ), a revision of FASB Statement No. 123, which requires expense for all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement over the applicable service period based on their fair values. Pro forma disclosure is no longer an alternative. In April 2005, the Securities and Exchange Commission delayed the effective date of SFAS 123(R) to fiscal years beginning after June 15, 2005. As a result, the Company expects to adopt SFAS 123(R) on January 1, 2006. Statement 123(R) permits public companies to adopt its requirements using one of two methods. The Company plans to adopt the modified prospective method, under which compensation cost is recognized beginning with the effective date. The modified prospective method recognizes compensation cost based on the requirements of SFAS 123(R) for all share-based payments granted after the effective date and based on the requirements of SFAS 123 for all awards granted to employees prior to the effective date that remain unvested on the effective date. The amount of expense recorded under SFAS 123(R) will depend upon the number of options granted in the future and their valuation.

**Note 4: Inventories** consisted of the following:

	9/30/05	12/31/04
Raw material	\$ 7,715	\$ 3,745
Work in process	4,658	507
Finished goods	1,159	4,177
Total	\$ 13,532	\$ 8,429

**Note 5: Property and equipment**, at cost, consisted of the following:

	9/30/05	12/31/04
Land, building and building improvements	\$ 31,561	\$ 22,021
Machinery and equipment	38,207	31,860
Computer equipment and software	6,208	5,020
Furniture and fixtures	2,101	1,678
Molds	9,046	9,345
Construction in process	2,439	3,778
Total	\$ 89,562	\$ 73,702

**Note 6: Finance loans receivable** are commercial loans by ICU Finance, Inc., a wholly-owned consolidated subsidiary. Loans are made only to credit-worthy healthcare entities and are fully secured by real and personal property. The Company plans to hold the loans to maturity or payoff. They are carried at their outstanding principal amount and will be reduced for an allowance for credit losses and charge offs, if any such reductions are determined to be necessary in the future. Interest is accrued as earned based on the stated interest rate and amounts outstanding. Loan fees and costs have not been material. Scheduled maturities are: remainder of 2005 \$0.3 million; 2006 \$1.2 million; 2007 \$1.1 million and 2008 \$1.3 million. Weighted average maturity (principal and interest) at September 30, 2005 was 1.8 years and the weighted average interest rate was 5.1%. In October 2003, the Company discontinued new lending activities. There were no unfunded commitments at September 30, 2005.

**Note 7: Net income per share** is computed by dividing net income by the weighted average number of common shares outstanding. Diluted earnings per share is computed by dividing net income by the weighted average



number of common shares outstanding plus dilutive securities, except in a loss period, when such securities are excluded because they would decrease the diluted loss per share. 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 1,150,852 for the three months ended September 30, 2005 and 1,200,891 and 1,265,058 for the nine months ended September 30, 2005 and 2004, respectively. Potentially dilutive shares from common stock options excluded because of the net loss for the three months ended September 30, 2004 were 1,107,914. Options that are antidilutive because their exercise price exceeded the average market price of its common stock for the period approximated 1,000,000 and 1,400,000 for the three months ended September 30, 2005 and 2004 respectively and 800,000 and 850,000 for the nine months ended September 30, 2005 and 2004, respectively.

**Note 8: Income taxes:** 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 losses of a subsidiary not consolidated for income tax purposes, partially offset by the effect of tax-exempt investment income and state and federal tax credits.

**Note 9: Major customers:** The Company had revenues equal to ten percent or greater of total net revenues from one customer, Hospira, Inc. (formerly a part of Abbott Laboratories). Such revenues were 77% and 56% in the third quarters of 2005 and 2004, respectively, and 72% and 57% in the first nine months of 2005 and 2004, respectively.

**Note 10: Acquisition:** In September 2004, the Company purchased for approximately \$2.5 million in cash an interest of approximately 57% in a corporation developing a new medical device for use in screening for heart disease. The Company had agreed to invest an additional \$1.5 million if certain milestones were achieved by November 30, 2005. In October 2005, the Company elected to waive achievement of the milestones, which will not be met by November 30, 2005, and made the additional investment, thereby increasing its ownership to 68%. The corporation had no operations prior to the initial investment. Its only asset at the date of acquisition was technology related to the device, which will require pre-market submission to the Food and Drug Administration. The corporation has been included in the consolidated financial statements since September 2004, and the interests of the other stockholders, who are founders, are shown as minority interest. Approximately \$1.2 million of the Company's September 2004 investment was allocated to in-process research and development, based in part on an independent appraisal, and that amount was charged to research and development expense in the Company's consolidated financials statements in September 2004. Approximately \$0.4 million of the October 2005 investment will be allocated to in-process research and development and charged to research and development expense in the fourth quarter of 2005. The pro forma effects of this acquisition were not significant. The Company incurred a net loss related to this acquisition of \$0.2 million and \$0.7 million for the three and nine months ended September 30, 2005 respectively.

**Note 11: Commitments and Contingencies:** The Company is from time to time involved in various routine non-material 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 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 made certain indemnities, including indemnities to its 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 the Company's

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

products. There is no limit on the indemnification that may be required under these agreements. The Company has not recorded any liability for these in its financial statements and does not expect to incur any.

## 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 devices are designed to protect patients from Catheter Related Bloodstream Infections and healthcare workers from exposure to infectious diseases through accidental needlesticks. We are also a leader in the production of custom I.V. systems and low cost generic 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 and commencement of production under a 20-year Manufacturing, Commercialization and Distribution Agreement with Hospira ( MCDA ), we are now also a significant manufacturer of critical care medical devices, including catheters, angiography kits and cardiac monitoring systems.

### Risk Factors

In evaluating an investment in our common stock, investors should consider carefully, among other things, the following risk factors, as well as the other information contained in this Quarterly Report and our other reports and registration statements filed with the Securities and Exchange Commission.

*Because we are increasingly dependent on Hospira for a substantial portion of our sales, any change in our arrangements with Hospira causing a decline in our sales to it could result in a significant reduction in our sales and profits.*

We have steadily increased our sales to Hospira in recent years, except for 2004 when sales to Hospira declined as Hospira reduced its inventories of our products. As a result, we depend on Hospira for a high percentage of our sales, and the percentage of our sales attributable to Hospira will increase as we are manufacturing additional products for Hospira as described below. Although we have increased our sales to independent domestic distributors during recent years, most of the increase resulted from our dealers' acquisition of market shares from a manufacturer with whom we terminated our CLAVE distribution agreement and the addition of the Punctur-Guard line in late 2002. The table below shows our net sales to various types of customers for the first nine months of 2005 and for 2004, 2003 and 2002 (dollars in millions):

	Nine Months Ended September 30, 2005		2004		Years Ended December 31, 2003		2002	
Hospira	\$ 82.6	72%	\$ 39.8	53%	\$ 71.3	67%	\$ 50.0	57%
Other manufacturers	3.9	4%	1.5	5%	1.5	5%	10.1	16%
Domestic distributors	18.7	16%	22.4	30%	24.1	23%	17.0	19%
International distributors	9.1	8%	9.0	12%	5.8	5%	7.1	8%

In 2004, Hospira substantially reduced its purchases of CLAVE products because it was reducing its inventories of our products. This caused a significant reduction in our sales and led to a net loss in the third and fourth quarters of 2004. We have taken steps to monitor and control the amount of Hospira's inventory of CLAVE products manufactured in order to mitigate the need for future inventory reductions similar to that in 2004, but there is no assurance that these steps will be successful, or that Hospira will not attempt to reduce its inventory of CLAVE products even further in the future.

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

In the past several years, our prices to Hospira have declined by only a small amount. Any significant decrease in our prices to Hospira, unless accompanied by an offsetting increase in purchasing volume, could have an adverse effect on our sales and profits.

Our sales to Hospira increased as a result of the MCDA that became effective on May 1, 2005. Under the MCDA, we produce for sale to Hospira on an exclusive basis substantially all the products Hospira had manufactured at its Salt Lake City facility. The majority of the products we produce under the MCDA are Hospira's critical care products, which include medical devices such as catheters, angiography kits and cardiac monitoring systems. Although we provide certain sales support to Hospira, our ability to maintain or increase level of sales of these products will depend on Hospira's commitment to and the success of its sales and marketing efforts. The MCDA increases our dependence on Hospira.

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

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

Hospira, a major supplier of I.V. products, was formerly the Hospital Products Division of Abbott Laboratories. On April 30, 2004, Abbott spun off Hospira to its stockholders as an independent company. Since then, Hospira has been a separate entity, independent of Abbott. The principal Hospira agreement, for products other than the MCDA, is a strategic supply and distribution arrangement to market our products in connection with Hospira's I.V. products. The agreement extends through 2014. Our ability to maintain and increase our market penetration may depend on the success of our arrangement with Hospira and Hospira's arrangements with major buying organizations and its ability to renew such arrangements, as to which there is no assurance. If our strategic supply and distribution arrangement proves unsuccessful, our sales would be materially adversely affected. Our business could be materially adversely affected if Hospira terminates its arrangement with us, negotiates lower prices, sells more competing products, whether manufactured by themselves or others, or otherwise alters the nature of its relationship with us. Although we believe that Hospira views us as a source of innovative and profitable products, there is no assurance that our relationship with Hospira will continue in its current form.

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

We intend to continue to expand our marketing and distribution capability internally, by expanding our sales and marketing staff and resources and may expand it externally, by acquisitions both in the United States and foreign markets. We may also consider expanding our product offerings through further acquisitions of companies or product lines. We intend to build additional production facilities or contract for manufacturing in markets outside the United States to reduce labor costs and eliminate transportation and other costs of shipping finished products from the United States and Mexico to customers outside North America. The expansion of our manufacturing, marketing, distribution and product offerings both internally and through acquisitions or by contract may place substantial burdens on our management resources and financial controls. Decentralization of assembly



and manufacturing could place further burdens on management to manage those operations, and maintain efficiencies and quality control.

The performance of the MCDA, under which we produce critical care and certain other products for Hospira, the acquisition of related manufacturing assets, the addition of approximately 750 production personnel (reduced to approximately 500 since May 1, 2005), the relocation of our California and Connecticut manufacturing operations, the expansion of our Mexico facility, the implementation of new manufacturing and assembly processes and techniques and the establishment of financial controls impose a significant burden on our management, human resources, operating and financial and accounting functions. We need to expand our capabilities in each of these areas and devote significant time and effort to integrating the production under the MCDA with our existing operations, all of which divert management's attention from our current operations. In addition, we may require additional expertise, capability and capacity that can best be obtained through other acquisitions.

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

*If we are unable to reduce substantially the cost of manufacturing products that we will sell to Hospira under the MCDA, we may not be able to produce and sell such products profitably, and our profit margins may decline.*

The prices at which we sell products to Hospira and the gross margins that we realize under the MCDA depend on the cost savings that we expect to achieve in producing those products over Hospira's cost to manufacture the same products at the purchase date. Achieving substantial cost reductions require moving manufacturing operations to lower-cost locations and the development and implementation of innovative manufacturing and assembly processes and techniques. There is no assurance that these efforts will be successful. If we are unable to achieve the cost savings that we expect, we may not be able to sell products manufactured under the MCDA profitably, and our profit margins may decline.

*There are significant risks associated with the relocation of our manufacturing facilities.*

We intend to relocate substantial portions of our manufacturing facilities by the end of the second quarter of 2007. We plan to move all manufacturing in San Clemente, consisting of molding and automated assembly, to our Salt Lake City facility. We also plan to move remaining manufacturing operations in Connecticut, consisting of two automated assembly machines, to the Salt Lake City facility. We plan to move all manual assembly operations currently performed in Salt Lake City, to our Ensenada, Mexico facility, although we may move some of them to another low-cost location.

The molding and assembly machines are large and require special handling to move them. Installation in a new location can be very difficult and require specialized engineering expertise. This will tax our existing resources. At the same time, we will be attempting to relocate personnel who are important to our manufacturing processes, and failure to accomplish this could substantially hamper the installation and operation of the equipment in Salt Lake City. While we expect to build extra inventory before moving equipment, and move the equipment in phases and maintain production at both locations for a period of time, failure to successfully complete the move and installation of the equipment and critical personnel could cause production interruptions and production quality issues which could adversely affect our sales.



Certain of the manual assembly operations require expertise that will require significant and ongoing training of the personnel at the location performing the assembly. The products currently made using manual assembly in Salt Lake City are different than the products that we currently make in Mexico. The transfer of production will require a significant transfer of knowledge from Salt Lake City to the new manufacturing location, and if this is not completed successfully, we could experience production interruptions and production quality issues which could adversely affect our sales.

*Because we are dependent on the CLAVE for a major portion of our sales, any decline in CLAVE sales could result in a significant reduction in our sales and profits.*

For the first nine months of 2005, CLAVE products accounted for approximately 42% of our revenue and 57% of our revenue including custom I.V. systems incorporating a CLAVE. We depend heavily on sales of CLAVE products, especially sales of CLAVE products to Hospira. We cannot give any assurance that sales of CLAVE products either to Hospira or other customers will increase indefinitely or that we can sustain current profit margins on CLAVE products indefinitely. Management believes that the success of the CLAVE has motivated, and will continue to motivate, others to develop one piece needleless connectors. In addition to products that emulate the characteristics of the CLAVE, it is possible that others could develop new product concepts and technologies that are functionally equivalent or superior to the CLAVE. If other manufacturers successfully develop and market effective products that are competitive with CLAVE products, CLAVE sales could decline as we lose market share, and/or we could encounter sustained price and profit margin erosion.

*If our efforts to increase substantially our custom products business is not successful or we cannot increase sales of other products and develop new, commercially successful products, our sales may not continue to grow.*

Our continued success may be dependent both on the success of our strategic initiative to increase substantially our custom product business and develop significant market share on a profitable basis and on new product development. Our sales of custom products reached \$26.2 million in 2004, but this was only a 15% increase over 2003 sales, whereas 2003 sales increased 50% over 2002. Our sales of custom products were \$30.3 million in the first nine months of 2005, or a 56% increase from the first nine months of 2004. The success of our custom product sales program will require a larger increase in sales in the future than was achieved in 2004 and the first nine months of 2005. The ability of the custom products to acquire significant market share on a profitable basis depends on whether we are able to continue to develop systems capabilities, improve manufacturing efficiencies, lower inventory carrying costs, reduce labor costs and expand distribution. The accomplishment of each of these objectives will require significant innovation, and we might not succeed in these endeavors. Although we are seeking to continue to develop a variety of new products, there is no assurance that any new products will be commercially successful or that we will be able to recover the costs of developing, testing, producing and marketing such products. Certain healthcare product manufacturers, with financial and distribution resources substantially greater than ours, have developed and are marketing products intended to fulfill the same functions as our products.

*Continuing reductions in the prices of our I.V. connector products could have an adverse effect on profit margins and profits.*

The Hospira agreement establishes the prices that Hospira will pay for our products, which are lower than our average selling prices in most of our other sales channels. In response to competitive pressure, we had steadily reduced selling prices of the CLAVE to protect and expand its market although overall pricing has been stable recently. Reductions in selling prices could adversely affect gross margins and profits if we cannot achieve corresponding reductions in unit manufacturing costs or increased volume.

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

*International sales pose additional risks related to competition with larger international companies and established local companies, our possibly higher cost structure, our ability to open foreign manufacturing facilities that can operate profitably, higher credit risks and exchange rate risk.*

We have undertaken a program to increase significantly our international sales, and have distribution arrangements in all the principal countries in Western Europe, the Pacific Rim and Latin America, and in South Africa. We plan to sell in most other areas of the world. Currently, we export from the United States and Mexico most of the product sold internationally. Our principal competitors are a number of much larger companies as well as smaller companies already established in the countries into which we sell our products. Our cost structure is often higher than that of our competitors because of the relatively high cost of transporting product to the local market as well as low cost local labor in some markets. For these reasons, among others, we expect to open manufacturing facilities in foreign locations. There is no certainty that we will be able to open local manufacturing facilities or that those facilities will operate on a profitable basis.

Our international sales are subject to higher credit risks than sales in the United States. Many of our distributors are small and may not be well capitalized. Payment terms are relatively long. Our prices to our international distributors, outside of Europe, for product shipped to the customers from the United States or Mexico are set in U.S. dollars, but their resale prices are set in their local currency. A decline in the value of the local currency in relation to the U.S. dollar may adversely affect their ability to profitably sell in their market the products they buy from us, and may adversely affect their ability to make payment to us for the products they purchase. Legal recourse for non-payment of indebtedness may be uncertain. These factors all contribute to a potential for credit losses.

In 2003, we acquired a small manufacturer of I.V. systems in northern Italy, and have since transferred our European distribution to this subsidiary. Sales and most other transactions by this subsidiary are denominated in Euros. As the subsidiary increases in size, a decline in the value of the Euro in relation to the U.S. dollar could have an adverse effect on our reported operating results. There is no assurance as to the growth of this subsidiary or its future operating results.

*Continuing pressures to reduce healthcare costs may adversely affect our prices. If we cannot reduce manufacturing costs of existing and new products, our sales may not continue to grow and our profitability may decline.*

Increasing awareness of healthcare costs, public interest in healthcare reform and continuing pressure from Medicare, Medicaid and other payers to reduce costs in the healthcare industry, as well as increasing competition from other protective products, could make it more difficult for us to sell our products at current prices. In the event that the market will not accept current prices for our products, our sales and profits could be adversely affected. We believe that our ability to increase our market share and operate profitably in the long term may depend in part on our ability to reduce manufacturing costs on a per unit basis through high volume production using highly automated molding and assembly systems. If we are unable to reduce unit manufacturing costs, we may be unable to increase our market share for CLAVE products or lose market share to alternative products, including competitors' products. Similarly, if we cannot reduce unit manufacturing costs of new products as production volumes increase, we may not be able to sell new products profitably or gain any meaningful market share. Any of these results would adversely affect our future results of operations.

*Increases in costs of electricity or interruptions in electrical service could have an adverse effect on our operations.*

We use a significant amount of electricity in our molding and automated assembly operations in San Clemente, California. Rates are approximately double what they were five years ago, and there is no certainty that they will not increase further in the future. In addition, public concerns are again being raised about possible interruptions in service because of a lack of availability of electricity. Any significant increase in electrical costs or a significant interruption in service could have an adverse effect on our operations. We believe that the move of our San Clemente production to Salt Lake City will substantially mitigate this risk, but we do not expect that move to be accomplished for at least a year.



*Increases in the cost of petroleum-based products could have an adverse effect on our profitability.*

Most of the material used in our products is resins, plastics and other material that depend upon oil or natural gas as their raw material. Crude oil and natural gas supplies have been restricted by recent hurricanes in the Gulf Coast. If there are related production or supply problems, these may impact our ability to get uninterrupted supply of raw materials, which would impact our ability to deliver timely to our customers. Also crude oil prices in 2005 are at record highs. Our suppliers have passed some of their cost increases on to us, and if crude oil prices are sustained or increase further, our suppliers may pass further cost increases on to us. In addition to the effect on resin prices, transportation costs have increased because of the effect of higher crude oil prices, and at least some of these costs have been passed on to us. Our ability to recover those higher costs may depend upon our ability to raise prices to our customers. In the past, we have rarely raised prices and it is uncertain that we would be able to raise them to recover higher prices from our suppliers. Our inability to raise prices in those circumstances could have an adverse effect on our profitability.

*Our I.V. system products could become obsolete if other companies are successful in developing technologies and products that are superior to ours.*

Many companies are developing products and technologies to address the need for safe and cost effective I.V. connection systems. It is possible that others may develop superior I.V. connection system technologies or alternative approaches that prove superior to our products. Our products could become obsolete as a result of such developments, which could materially and adversely affect our operating results.

*If we are unable to compete successfully on the basis of product innovation, quality, convenience, price and rapid delivery with larger companies that have substantially greater resources and larger distribution networks, we may be unable to maintain market share, in which case our sales may not grow and our profitability may be adversely affected.*

The market for I.V. products is intensely competitive. We believe that our ability to compete depends upon continued product innovation, the quality, convenience and reliability of our products, access to distribution channels, patent protection and price. The ability of our custom I.V. and low-cost system products to compete will depend on our ability to distinguish our products from the competition based on product pricing, quality and rapid delivery. We encounter significant competition in our markets both from large established medical device manufacturers and from smaller companies. Many of these firms have introduced competitive products with protective features not provided by the conventional products and methods they are intended to replace. Most of our current and prospective competitors have economic and other resources substantially greater than ours and are well established as suppliers to the healthcare industry. Several large, established competitors offer broad product lines and have been successful in obtaining full-line contracts with a significant number of hospitals to supply all of their I.V. product requirements. There is no assurance that our competitors will not substantially increase resources devoted to the development, manufacture and marketing of products competitive with our products. The successful implementation of such a strategy by one or more of our competitors could materially and adversely affect us.

*If we were to experience problems with our highly complex manufacturing and automated assembly processes, as we have at times in the past, or if we cannot obtain additional custom tooling and equipment on a timely enough basis to meet demand for our products, we might be unable to increase our sales or might lose customers, in which case our sales could decline.*

We manufacture substantially all of our product components, except for standard components which are available as commodity items, and assemble them into finished products. Automated assembly of components into finished products involves complex procedures requiring highly sophisticated assembly equipment which is custom designed, engineered and manufactured for us. As a result of the critical performance criteria

for our products, we have at times experienced problems with the design criteria for or the molding or assembly of our products. We



believe that we have resolved all design, manufacturing and assembly problems with respect to products manufactured in San Clemente and Connecticut. We are currently assessing design, manufacturing and assembly operations at the Salt Lake City facility and that assessment may result in changes, some of which may be significant. There is no assurance that operations will not be adversely affected by unanticipated problems with current or future products.

We have expanded our manufacturing capacity substantially in recent years, and we expect continuing expansion will be necessary. Molds and automated assembly machines generally have a long lead-time with vendors, often six months or longer. Inability to secure such tooling in a timely manner, or unexpected increases in production demands, could cause us to be unable to meet customer orders. Such inability could cause customers to seek alternatives to our products.

*We may not be able to significantly expand our sales of custom and low-cost, generic I.V. systems, or critical care products, if we are unable to lower manufacturing costs, price our products competitively and shorten delivery times significantly.*

We believe that the success of our I.V. systems operations will depend on our ability to lower per unit manufacturing costs and price our products competitively and on our ability to shorten significantly the time from customer order to delivery of finished product, or both. To reduce costs, we have moved labor intensive assembly operations to our facility in Mexico. To shorten delivery times, we have developed proprietary systems for order processing, materials handling, tracking, labeling and invoicing and innovative procedures to expedite assembly and distribution operations. Many of these systems and procedures require continuing enhancement and development. There is a possibility that our systems and procedures may not continue to be adequate and meet their objectives.

We plan to introduce many of the systems and procedures that we have used in our I.V. systems operations into the production of critical care products. If we are unable to do this successfully, we may not be successful in increasing sales of critical care products.

*If demand for our CLAVE products were to decline significantly, we might not be able to recover the cost of our expensive automated molding and assembly equipment and tooling, which could have an adverse effect on our results of operations.*

Our production tooling is relatively expensive, with each module, which consists of an automated assembly machine and the molds and molding machines which mold the components, costing several million dollars. Most of the modules are for the CLAVE and the integrated Y CLAVE. If the demand for either of these products changes significantly, as might happen with the loss of a customer or a change in product mix, it might be necessary for us to account for the impairment in value of the production tooling because its cost may not be recovered through production of saleable product.

*Because we depend to a significant extent on our founder for new product concepts, the loss of his services could have a material adverse effect on our business.*

We depend for new product concepts primarily on Dr. George A. Lopez, our founder, Chairman of the Board, President and Chief Executive Officer. Dr. Lopez has conceived substantially all of our current and proposed new products and the systems and procedures to be used in the custom I.V. products and their manufacturing. We believe that the loss of his services could have a material adverse effect on our business.

*Because we have substantial cash balances and liquid investments in interest sensitive securities, continued low interest rates would have an adverse effect on our investment income and on our net income.*

We have accumulated a substantial balance of cash and liquid investments principally through profitable operations and the exercise of stock options. These balances amounted to \$78.1 million at September 30, 2005, almost all of which was invested in interest sensitive securities. Such securities consist principally of corporate preferred stocks and federal tax-exempt state and municipal government debt securities. Dividend and interest rates are reset at auction mostly at seven to forty-nine day intervals, with a small portion resetting at longer intervals up to one year.

Short-term interest rates have been the lowest in decades for the past four years and, notwithstanding recent increases, are still low by historic standards. In 2000, our investment income was \$2.1 million on average on cash and liquid investments of approximately \$43.4 million. For the first nine months of 2005, the comparable numbers were approximately \$1.6 million and \$85.6 million, respectively; investment income was approximately \$1.5 million lower than it would have been at the rates in 2000. Continued low interest rates would continue to have an adverse effect on our investment income.

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

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

We are substantially dependent upon the patents on our proprietary products such as the CLAVE to prevent others from manufacturing and selling products similar to ours. In April 2005, we settled litigation against B. Braun Medical Inc. We have ongoing litigation against Alaris Medical Systems, a part of Cardinal Health, Inc., for violating our patents and we are seeking injunctive relief and monetary damages. We believe those violations had and continue to have an adverse effect on our sales. Failure to prevail in this litigation or litigation we may bring against others violating our patents in the future would adversely affect our sales.

We have faced patent infringement claims related to the CLAVE and the CLC-2000. We believe the claims had no merit, and all have been settled or dismissed. We may also face claims in the future. Any adverse determination on these claims related to the CLAVE or other products, if any, could have a material adverse effect on our business.

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

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

*Our ability to market our products in the United States and other countries may be adversely affected if our products or our manufacturing processes fail to qualify under applicable standards of the FDA and regulatory agencies in other countries.*

Government regulation is a significant factor in the development, marketing and manufacturing of our products. Our products are subject to clearance by the United States Food and Drug Administration ( FDA ) under a number of statutes including the Food, Drug and Cosmetics Act ( FDC Act ). Each of our current products has qualified, and we anticipate that any new products we are likely to market will qualify, for clearance under the FDA s expedited pre-market notification procedure pursuant to Section 510(k) of the FDC Act. There is no assurance, however, that new products developed by us or any manufacturers that we might acquire will qualify for expedited clearance rather than a more time consuming pre-market approval procedure or that, in any case, they will receive clearance from the FDA. FDA regulatory processes are time consuming and expensive. Uncertainties as to the time required to obtain FDA clearances or approvals could adversely affect the timing and expense of new product introductions. In addition, we must manufacture our products in compliance with the FDA s Quality System Regulations.

The FDA has broad discretion in enforcing the FDC Act, and noncompliance with the Act could result in a variety of regulatory actions ranging from warning letters, product detentions, device alerts or field corrections to mandatory recalls, seizures, injunctive actions and civil or criminal penalties. If the FDA determines that we have seriously violated applicable regulations, it could seek to enjoin us from marketing our products or we could be otherwise adversely affected by delays or required changes in new products. In addition, changes in FDA, or other federal or state, health, environmental or safety regulations or in their application could adversely affect our business.

To market our products in the European Community ( EC ), we must conform to additional requirements of the EC and demonstrate conformance to established quality standards and applicable directives. As a manufacturer that designs, manufactures and markets its own devices, we must comply with the quality management standards of EN ISO 9001(1994)/ISO 13485 (1996). Those quality standards are similar to the FDA s Quality System Regulations but incorporate the quality requirements for product design and development. Manufacturers of medical devices must also be in conformance with EC Directives such as Council Directive 93/42/EEC ( Medical Device Directive ) and their applicable annexes. Those regulations assure that medical devices are both safe and effective and meet all applicable established standards prior to being marketed in the EC. Once a manufacturer and its devices are in conformance with the Medical Device Directive, the CE Mark maybe affixed to its devices. The CE Mark gives devices an unobstructed entry to all the member countries of the EC. We cannot assure that we will continue to meet the requirements for distribution of our products in Europe.

Distribution of our products in other countries may be subject to regulation in those countries, and there is no assurance that we will obtain necessary approvals in countries in which we want to introduce our products.

*Product liability claims could be costly to defend and could expose us to loss.*

The use of our products exposes us to an inherent risk of product liability. Patients, healthcare workers or healthcare providers who claim that our products have resulted in injury could initiate product liability litigation seeking large damage awards against us. Costs of the defense of such litigation, even if successful, could be substantial. We maintain insurance against product liability and defense costs in the amount of \$10,000,000 per occurrence. There is no assurance that we will successfully defend claims, if any, arising with respect to products or that the insurance we carry will be sufficient. A successful claim against us in excess of insurance coverage could materially and adversely affect us. Furthermore, there is no assurance that product liability insurance will continue to be available to us on acceptable terms.

*Our Stockholder Rights Plan, provisions in our charter documents and Delaware law could prevent or delay a change in control, which could reduce the market price of our common stock.*

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

On July 15, 1997, our Board of Directors adopted a Stockholder Rights Plan (the Plan ) and, pursuant to the Plan, declared a dividend distribution of one Right for each outstanding share of our common stock to stockholders of record at the close of business on July 28, 1997. The Plan was amended in 2002. Under its current

provisions, each Right entitles the registered holder to purchase from us one one-hundredth of a share of Series A Junior participating Preferred Stock, no par value, at a Purchase Price of \$115 per one one-hundredth of a share, subject to adjustment. The Plan is designed to afford the Board a great deal of flexibility in dealing with any attempted takeover of and will cause persons interested in acquiring us to deal directly with the Board, giving it an opportunity to negotiate a transaction that maximizes stockholder values. The Plan may, however, have the effect of discouraging persons from attempting to acquire us.

Investors should refer to the description of the Plan in our Current Report to the Securities and Exchange Commission on Form 8-K dated July 15, 1997 filed July 23, 1997, as updated by our Current Report dated January 30, 1999 filed February 9, 1999, and the terms of the Rights set forth in an Amended and Restated Rights Agreement, dated as of May 10, 2002 between ICU Medical, Inc. and Mellon Investor Services, L.L.C., as Rights Agent, which are filed as an exhibit to the May 14, 2002 Form 8-A/A.

Our Certificate of Incorporation and Bylaws include provisions that may discourage or prevent certain types of transactions involving an actual or potential change of control, including transactions in which the stockholders might otherwise receive a premium for their shares over then current market prices. In addition, the Board of Directors has the authority to issue shares of Preferred Stock and fix the rights and preferences thereof, which could have the effect of delaying or preventing a change of control otherwise desired by the stockholders. In addition, certain provisions of Delaware law may discourage, delay or prevent someone from acquiring or merging with us.

*The price of our common stock has been and may continue to be highly volatile due to many factors.*

The market for small-market capitalization companies can be highly volatile, and we have experienced significant volatility in the price of our common stock in the past. In 2004 and through September 30, 2005, our trading range was from a high of \$41.31 per share to a low of \$19.98 per share. We believe that factors such as quarter-to-quarter fluctuations in financial results, differences between stock analysts' expectations and actual quarterly and annual results, new product introductions by us or our competitors, changing regulatory environments, litigation, changes in healthcare reimbursement policies, sales or the perception in the market of possible sales of common stock by insiders and substantial product orders could contribute to the volatility of the price of our common stock. General economic trends unrelated to our performance such as recessionary cycles and changing interest rates may also adversely affect the market price of our common stock.

Most of our common stock is held by, or included in accounts managed by, institutional investors or managers. Several of those institutions own or manage a significant percentage of our outstanding shares, with the ten largest interests accounting for 59% of our outstanding shares. If one or more of the institutions should decide to reduce or eliminate the position in our common stock, it could cause a decrease in the price of the common stock and such decrease could be significant.

For the past several years there has been a significant short position in our common stock, consisting of borrowed shares sold, or shares sold for future delivery which may not have been borrowed. We do not know whether any of these short positions are covered by long positions owned by the short seller. The short position, as reported by the Nasdaq stock market on October 14, 2005 was 2,226,989 shares, or approximately 16% of our outstanding shares. Any attempt by the short sellers to liquidate their position over a short period of time could cause very significant volatility in the price of our common stock.

*We have outstanding stock options which may dilute the ownership of existing shareholders*

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

At September 30, 2005, we had outstanding stock options to purchase 4.3 million shares, of which 2.9 million had an exercise price below the market price of our stock. Exercise of those options would dilute the ownership interest of existing shareholders.



*Continued compliance with recent securities legislation could be uncertain and could substantially increase our administrative expenses.*

The Sarbanes-Oxley Act of 2002 imposed significant new requirements on public companies. We have complied with most of these without undue effort or expense. However, compliance with Section 404 of the Sarbanes-Oxley Act of 2002 requiring management to document and report on the effectiveness of internal controls and our independent registered public accounting firm to audit and report on the design and effectiveness of our internal controls has been extremely expensive. We expect the expense in 2005 will be less than what we incurred in 2004. Further, there is no certainty that we will continue to receive unqualified reports on our internal controls from our independent registered public accounting firm and what actions might be taken by securities regulators or investors if we are unable to obtain an unqualified report.

### **Critical Accounting Policies**

Our significant accounting policies are summarized in Note 1 to the Consolidated Financial Statements included in our 2004 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.

Investment securities are all marketable and considered available for sale. See Item 3. Quantitative and Qualitative Disclosures about Market Risk. Under our current investment policies, the securities in which we invest have no significant difference between cost and fair value. If our investment policies were to change, and there were differences between cost and fair value, that difference, net of tax effect, would be reflected as a separate component of stockholders' equity.

We record sales and related costs when ownership of the product transfers to the customer and collectibility is reasonably assured. Under the terms of most purchase orders, ownership transfers on shipment, but in some cases it transfers on delivery. If there are significant doubts at the time of shipment as to the collectibility of the receivable, we defer recognition of the sale in revenue until the receivable is collected. Most of our customers are medical product manufacturers or distributors, although some are end-users. Our only post-sale obligations are warranty and certain rebates. We warrant products against defects and have a policy permitting the return of defective products. We record warranty returns as an expense and amounts have been insignificant. Customers, with certain exceptions, do not retain any right of return and there is no price protection with respect to unsold products. Returns from customers with return rights have not been significant. We accrue rebates as a reduction in revenue based on contractual commitments and historical experience. Adjustments of estimates of warranty claims, rebates or returns, which have not been, and are not expected to be material, affect current operating results when they are determined.

Accounts receivable are stated at net realizable value. An allowance is provided for estimated collection losses based on specific past due accounts for which we consider collection to be doubtful. Loss exposure is principally with international distributors for whom normal payment terms are long in comparison to those of our other customers and, to a lesser extent, domestic distributors. Many of these distributors are relatively small and we are vulnerable to adverse developments in their businesses that can hinder our collection of amounts due. If actual collection losses exceed expectations, we could be required to accrue additional bad debt expense, which could have an adverse effect on our operating results in the period in which the accrual occurs.

Inventories are stated at the lower of cost (first in, first out) or market. We need to carry many components to accommodate our rapid product delivery, and if we misestimate demand or if customer requirements change, we



may have components in inventory that we may not be able to use. Most finished products are made only after we receive orders except for certain standard (non-custom) products which we will carry in inventory in expectation of future orders. For finished products in inventory, we need to estimate what may not be saleable. We regularly review inventory for slow moving items and write off all items we do not expect to use in manufacturing, or finished products we do not expect to sell. If actual usage of components or sales of finished goods inventory is less than our estimates, we would be required to write off additional inventory, which could have an adverse effect on our operating results in the period in which the write-off occurs.

Property and equipment is carried at cost and depreciated on the straight-line method over the estimated useful lives. The estimates of useful lives are significant judgments in accounting for property and equipment, particularly for molds and automated assembly machines that are custom made for us. We may retire them on an accelerated basis if we replace them with larger or more technologically advanced tooling. The remaining useful lives of all property and equipment are reviewed regularly and lives are adjusted or assets written off based on current estimates of future use. As part of that review, property and equipment is reviewed for other indicators of impairment. An unexpected shortening of useful lives of property and equipment that significantly increases depreciation provisions, or other circumstances causing us to record an impairment loss on such assets, could have an adverse effect on our operating results in the period in which the related charges are recorded.

#### **New Accounting Pronouncements**

On December 16, 2004, the Financial Accounting Standards Board ( FASB ) issued FASB Statement No. 123 (revised 2004), Share-Based Payment ( SFAS 123(R) ), which is a revision of FASB Statement No. 123, Accounting for Stock-Based Compensation. SFAS 123(R) requires expense for all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. In April 2005, the SEC delayed the effective date of SFAS 123(R) to fiscal years beginning after June 15, 2005. As a result, we expect to adopt SFAS 123(R) on January 1, 2006. SFAS 123(R) permits public companies to adopt its requirements using one of two methods. We plan on adopting the modified prospective method, under which compensation cost is recognized beginning with the effective date. The modified prospective method recognizes compensation cost based on the requirements of SFAS 123(R) for all share-based payments granted after the effective date and, based on the requirements of SFAS 123, for all awards granted to employees prior to the effective date that remain unvested on the effective date. We expect to substantially curtail grants of stock options in the future and do not expect to record any significant expenses under SFAS 123(R) for options currently outstanding. However, the amount of expense recorded under SFAS 123(R) will depend upon the number of options granted in the future and their valuation.

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 acquired the Punctur-Guard line of blood collection needles in 2002, invested in a company developing a new medical device in 2004, acquired Hospira's Salt Lake City, Utah manufacturing facility in May 2005 and entered into an agreement to produce critical care products for Hospira, and are continuing to seek other opportunities. However, there can be 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 slower percentage growth rate than prior to 2004 because of our large market penetration. 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 has been Hospira. Our relationship with Hospira has been and will continue to be of singular importance to our growth. In 2003, approximately 67% of our revenue was from sales to Hospira. While our sales to Hospira declined to approximately 53% of revenue in 2004, this percentage increased in the third quarter of 2005 to 77%. We expect this percentage to increase in the future both as a result of increased sales of CLAVE products and I.V. sets to Hospira and as a result of the new MCDA with Hospira as described below. 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 in the U.S. and also outside the U.S.

On May 1, 2005, we acquired Hospira's Salt Lake City manufacturing facility, related capital equipment, certain inventories and assumed liabilities for \$31.8 million in cash and \$0.8 million of acquisition costs. We entered into a 20 year MCDA with Hospira, under which we produce for sale, exclusively to Hospira, substantially all the products that Hospira had manufactured at that facility. Hospira retains commercial responsibility for the products we are producing, including sales, marketing, 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 from May to September 2005 were \$29.8 million. We have also committed to fund certain research and development to improve critical care products and develop new products for sale to Hospira, and have also committed to provide certain 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 give no assurance as to the amounts of future sales or profits under the MCDA.

Invasive monitoring devices are used to monitor vital signs as well as specific physiologic functions of key organ systems. The invasive monitoring devices that we manufacture for Hospira under the MCDA are all disposable and most are invasive monitoring devices. They are principally hemodynamic monitoring systems used in intensive care and critical care units to measure cardiac output and blood flow. They include (i) pressure-sensing devices that provide continuous blood pressure readings and show the immediate effect of fluid management and drug administration that are most commonly used on patients with suspected pulmonary disease and cardiovascular dysfunction, (ii) needleless blood sampling devices used to obtain a patient's blood sample, and (iii) advanced sensory pulmonary artery catheters used to measure cardiac output and blood oxygen levels. We also manufacture standard hemodynamic monitoring catheters, including central venous and pulmonary artery catheters, angiography kits that are used in the cardiac catheterization laboratory and suction products used to collect fluids in the operating room. Monitoring equipment used with monitoring and measurement devices was not manufactured in Salt Lake City and will continue to be manufactured by Hospira. We manufacture all invasive

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

monitoring devices sold by Hospira in the United States and all catheters sold by Hospira outside the United States. Hospira's principal competitors in invasive monitoring devices and catheters in the United States include Edwards Life Sciences. Hospira's principal competitors in angiography are Merrit Medical and Boston Scientific.

A substantial portion of the invasive monitoring and angiography products made in Salt Lake City 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.

We believe that achievement of our growth objectives, both within the U.S., and outside the U.S., 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 still 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.

### Overview of Operations

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

Product Line	Three months ended September 30,		Nine months ended September 30,		Fiscal Year Ended		
	2005	2004	2005	2004	2004	2003	2002
CLAVE	37%	47%	42%	49%	47%	59%	67%
Custom Products	27%	39%	26%	33%	35%	22%	17%
Critical Care (excluding custom products)	23%		17%				
Punctur-Guard®	2%	3%	3%	5%	5%	7%	1%
CLC2000®	3%	3%	3%	4%	4%	4%	4%
Other Products	7%	5%	7%	6%	5%	4%	7%
License, royalty and revenue share	1%	3%	2%	3%	4%	4%	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>

Salt Lake City products, including critical care, critical care custom products and other products accounts for 36% and 26% of total revenue for the three and nine months ended September 30, 2005, respectively. Custom I.V. systems, excluding critical care custom products, were 19% and 20% of total revenues for the three and nine months ended September 30, 2005, 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 51% of total revenue in the third quarter of 2005 and 74% of total revenue in the third quarter of 2004, and 57% and 72% year-to-date September 30, 2005 and 2004, respectively.

We sell our I.V. administration products to independent distributors 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 since 2004, our Punctur-Guard line of blood collection needles. Under a 2001 agreement, we sell custom I.V. systems to Hospira under a program referred to as SetSource. Under the MCDA, a 2005 agreement, we sell Hospira invasive monitoring, angiography and other products which they formerly manufactured at the Salt Lake City facility. Our 1995 and 2001 agreements with Hospira, excluding the MCDA, with terms to 2014, provide Hospira with conditional exclusive and nonexclusive rights to distribute all existing ICU Medical products worldwide. The terms of the MCDA extends 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.

In June 2004, Cardinal Health, Inc. ( Cardinal ) acquired Alaris Medical Systems, Inc. ( Alaris ). Alaris manufactures a connector that competes with the CLAVE. Cardinal is the largest distributor of healthcare products in the United States, and the companies have announced their intent to increase market share growth beyond what Alaris might be able to achieve on its own. We believe the ownership of Alaris by Cardinal could adversely affect our market share and the prices for our CLAVE products.

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. The price reductions to date have been more than offset by increased volume after excluding the effect of Hospira's inventory reductions in 2004. 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.

The federal Needlestick Safety and Prevention Act, enacted in November 2000, modified standards promulgated by the Occupational Safety and Health Administration to require employers to use safety I.V. systems where appropriate to reduce risk of injury to employees from needlesticks. We believe this law has had and will continue to have a positive effect on sales of our needleless systems and blood collection needles, although we are unable to quantify the current or anticipated effect of the law on our sales.

We are taking steps to reduce our dependence on our current proprietary products. We are seeking to substantially expand our custom products business through increased sales to medical product manufacturers and independent distributors. Under one of our Hospira Agreements, we manufacture all new custom I.V. sets for sale





by Hospira and jointly promote the products under the name SetSource. We also contract with group purchasing organizations and independent dealer networks for inclusion of our non-critical care products among those available to members of those entities. Custom products accounted for approximately \$30.3 million or 26% of total revenue in the first nine months of 2005, including net sales under the Hospira SetSource program of approximately \$10.5 million and custom critical care products that we are manufacturing under the MCDA with Hospira of approximately \$6.9 million. We expect continued increases in sales of custom products. Our Punctur-Guard products, acquired in 2002, are blood collection needles, designed to eliminate exposure to sharp, contaminated needles. Punctur-Guard product revenues in the first nine months of 2005 were \$3.4 million. In 2004, we invested in a company developing a new medical device. Sales depend on the success of efforts to develop and market the device, and there can be no certainty that those efforts will succeed. In 2005, we acquired Hospira's Salt Lake City manufacturing facility and entered into an agreement to produce their invasive monitoring, angiography products and certain other products they had manufactured at that facility. There is no assurance that any of these initiatives will continue to succeed.

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, use of larger molds and molding machines, centralization of all proprietary molding in Salt Lake City, expansion of our production facility in Mexico to take over manual assembly currently done in Salt Lake City, and possibly the establishment of other production facilities outside the U.S.

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

Channel	Three months ended		Nine months ended		2004	Fiscal Year Ended	
	2005	September 30, 2004	2005	September 30, 2004		2003	2002
Medical product manufacturers	79%	59%	76%	61%	57%	71%	73%
Independent domestic distributors	14%	31%	16%	29%	31%	23%	19%
Independent international distributors	7%	10%	8%	10%	12%	6%	8%
<b>Total</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

**Quarter-to-quarter comparisons:** We present summarized income statement data in Item 1. Financial Statements. The following table shows, for the year 2004 and the third quarter and first nine months of 2005 and 2004 and the percentages of each income statement caption in relation to revenues. (We currently calculate our gross profit percentage based on net sales, which includes only product sales and excludes non-product revenue. See below for information on non-product revenue. We present the alternative calculation based on total revenues to give the reader an alternative view of product gross margins.)

	Year 2004	Quarter ended September 30,		Nine months ended September 30,	
		2005	2004	2005	2004
<b>Revenue</b>					
Net sales	96%	99%	97%	98%	96%
Other	4%	1%	3%	2%	4%
Total revenues	100%	100%	100%	100%	100%
<b>Gross profit</b>					
Percentage of net sales	45%	41%	37%	43%	50%
Percentage of total revenues	47%	41%	40%	44%	51%
<b>Operating expenses</b>					
Selling, general and administrative expenses	35%	21%	41%	24%	32%
Research and development expenses	4%	3%	11%	3%	4%
Total operating expenses	39%	24%	52%	27%	36%
<b>Income (loss) from operations</b>					
Income (loss) from operations	8%	18%	(12)%	18%	15%
Other income	2%	1%	2%	2%	2%
<b>Income before income taxes and minority interest</b>					
Income before income taxes and minority interest	10%	19%	(10)%	20%	17%
Income taxes	3%	7%	(4)%	7%	6%
Minority interest	0%	0%	0%	0%	0%
Net income	7%	12%	(6)%	13%	11%

**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, 2005 Compared to the Quarter Ended September 30, 2004**

Revenues increased \$30.1 million to \$46.5 million in the third quarter of 2005, compared to \$16.5 million during the same period last year.

*Distribution channels:* Net sales to Hospira in the third quarter of 2005 were \$35.7 million, compared to net sales of \$8.8 million in the third quarter of 2004. (Hospira sales discussed in this paragraph do not include foreign sales.) Net sales of CLAVE Products to Hospira, excluding custom CLAVE I.V. systems, increased by \$8.6 million, to \$13.8 million, in the third quarter of 2005 from \$5.3 million in the third quarter of 2004. Beginning in the first quarter of 2004, Hospira began decreasing its level of purchases to make a substantial

reduction in its inventory of CLAVE products. Hospira's reduced buying continued through the remainder of 2004. Hospira informed us that it had reduced its inventory to the desired level by the end of December 2004. In 2005 and thereafter, we expect our sales of CLAVE products to Hospira to continue to more closely match its sales to its customers than they have in the past. Sales to Hospira under the SetSource program were \$3.7 million in the third quarter of 2005 compared to \$3.1 million in the third quarter of 2004, an increase of 19%. The SetSource increase is attributed to unit sales increases in the custom set market as hospitals continue to convert from standard sets. Sales of products to Hospira under the MCDA, which began in May 2005, were \$16.6 million or 36% of total revenue. There is no assurance as to the amount of any future sales increases to Hospira.

Net sales to independent domestic distributors were \$6.7 million in the third quarter of 2005 compared to \$5.1 million in 2004. The increase in sales to independent distributors is attributed principally to a \$1.2 million increase in custom sets and a \$0.4 million increase in CLAVE product sales, both on increased unit sales. There is no assurance, however, as to the amount of any future sales increases to the independent domestic distributors.

Net sales to international markets (excluding Canada) were \$3.3 million in the third quarter of 2005, compared to \$1.6 million in the third quarter of 2004 or an increase of \$1.7 million. The increase was primarily attributable to increased sales in Europe, Latin American and the Pacific Rim. The increase, by product line, was primarily comprised of a \$1.1 million increase in sales of CLAVE and Custom I.V. products. We expect increases in foreign sales in the future in response to increased sales and marketing efforts including adding additional business development managers. Also, we believe we will begin to see a positive impact in 2006 from our 2004 amendments to the Hospira contracts, which gave Hospira international distribution. Any such impact may depend on how quickly Hospira expands its international distribution. There is no assurance that those expectations will be realized.

**Product and other revenue:** Net sales of CLAVE Products (excluding custom CLAVE I.V. systems) increased \$9.7 million to \$17.4 million in the third quarter of 2005 from \$7.7 million in the third quarter of 2004. This increase was primarily due to increased unit shipments of CLAVE products to Hospira, discussed above, which increased sales by \$8.6 million from the third quarter of 2004. Sales of CLAVE products and custom I.V. systems including one or more CLAVE connectors combined were \$23.9 million in the third quarter of 2005 as compared with \$12.1 million in the third quarter of 2004. This increase was principally due to increased purchases of CLAVE products by Hospira and increased sales of CLAVE custom products in all channels. We expect growth in CLAVE unit and dollar sales volume in the fourth quarter of 2005 compared to 2004 in all of our distribution channels. However, there is no assurance that these expectations will be realized.

Salt Lake City product sales to Hospira were \$16.6 million in the third quarter of 2005. Critical care sales, including custom critical care sales, were \$14.3 million in the third quarter of 2005.

Net sales of custom and generic I.V. systems, which included custom I.V. sets, both with a CLAVE and without a CLAVE, were \$8.7 million in the third quarter of 2005 compared to \$6.4 million in the third quarter of 2004, or a 36% increase. Increased U.S. distributor sales, international sales and sales to Hospira under the SetSource program accounted for the increase.

Sales of Punctur-Guard products (excluding royalties) were \$0.9 million in the third quarter of 2005 compared to \$0.5 million in the third quarter of 2004, in part due to increased Punctur-Guard product sales to Hospira. We are currently concentrating our sales and marketing efforts for the

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

Winged Set product on outpatient provider contracts and the lab market. However, we have been unable to achieve success with the Blood Collection Needle (BCN), and we are not currently focusing any significant sales and marketing efforts on the BCN. There is no assurance as to future sales of Punctur-Guard products.

Net sales of the CLC2000 were \$1.4 million in the third quarter of 2005 compared to \$0.6 million in the third quarter of 2004. The increase is primarily attributable to increases in sales to Hospira from the relatively low

level of sales of CLC2000 to Hospira in the third quarter of 2004. We expect sales of the CLC2000 to increase moderately in the fourth quarter of 2005 compared with 2004, but there is no assurance as to the amount or timing of future CLC2000 sales.

*Gross margin* for the third quarters of 2005 and 2004, calculated on net sales and excluding other revenue, was 41% and 37%, respectively. Gross margins in the third quarter of 2004 were adversely affected by approximately 13 percentage points because of the curtailment of CLAVE production because of reduced shipments to Hospira and relatively low gross margins on Punctur-Guard products and production in Italy. While gross margin improved in the third quarter of 2005, it is still below our historical level primarily due to the addition of the new Salt Lake City products sold to Hospira under the MCDA, which began in May 2005 and have lower margins than most of our traditional products. Excluding the new Salt Lake City product sales and related cost of goods sold, our gross margin on product sales was 53%. We expect gross margins on our traditional product sales will be in the 53-55% range in the fourth quarter of 2005.

The gross margin on our sales associated with the MCDA was approximately 21% for the third quarter of 2005. This reflects some initial cost savings in relation to Hospira's cost to manufacture these products. We expect the gross profit to increase as we implement our manufacturing processes and relocate production.

Our gross margins can vary depending on both product mix and plant utilization. We give no assurance as to the amount or timing of any future improvements to our gross margins.

*Selling, general and administrative expenses ( SG&A )* in the third quarter of 2005 was \$9.6 million compared to \$6.8 million in the third quarter of 2004, or an increase of \$2.8 million. The increase in costs was partially due to a \$0.8 million increase in expenses associated with patent lawsuits against two companies, of which one was settled in April 2005. Compensation and benefit increases accounted for approximately \$1.4 million, principally from increased compensation, the addition of our Salt Lake City facility and the addition of new sales personnel. We expect SG&A costs to approximate 24% to 26% of revenue for the entire year.

*Research and development expenses ( R&D )* were \$1.4 million in the third quarter of 2005, compared to \$1.8 million in the third quarter of 2004. The decrease is due to a \$1.2 million charge for in-process R&D in the third quarter of 2004 that was not applicable in the third quarter of 2005. This prior year charge was partially offset by a \$0.2 million increase of R&D costs incurred by our majority-owned subsidiary developing a new medical device designed for use in screening for heart disease. The device is in the early design stage and uses new technology. Completion of this device is expected to take several years. There is no assurance as to the timing of or cost of completing a marketable device or whether it will be completed. In October 2005, we invested an additional \$1.5 million in that company. The remaining increase in R&D is primarily from new R&D activity associated with our new products and new R&D activity in our Salt Lake City facility. We estimate R&D costs will increase in the fourth quarter of 2005 compared to 2004 to support on-going new product development and R&D under the MCDA agreement with Hospira and additional R&D expense from the majority-owned company mentioned above and a charge for in-process R&D from our additional \$1.5 million investment of \$0.4 million. We have committed to fund certain R&D under the Salt Lake City MCDA agreement with Hospira, which is included in the Contractual Obligation section of this document.

*Other income* consists of primarily of investment income, which increased from \$0.4 million to \$0.5 million because of an increase in interest rates, offset by a small reduction in the average size of our portfolio.

*Income taxes* were accrued at an effective tax rate of 35.2% in the third quarter of 2005, as compared with 37.5% in the third quarter of 2004. In the second quarter of 2005, we adjusted our annual estimated effective tax rate down to 35.2% for a one-time tax credit that we now expect to receive in 2005. This reduction from the 37.5%



rate in 2004 is partially offset in 2005 by the effect of estimated losses of the majority-owned company developing the new medical device because those losses are not included in our consolidated tax return.

**Nine Months Ended September 30, 2005 Compared to the Nine Months Ended September 30, 2004**

Total revenues increased \$53.9 million, or approximately 89%, to \$114.3 million in the first nine months of 2005 compared to \$60.4 million during the same period last year.

***Distribution channels:*** Net sales to Hospira in the first nine months of 2005 were \$82.6 million, compared to net sales of \$33.3 million in the same period last year. Net sales of CLAVE Products to Hospira, excluding custom CLAVE I.V. systems increased to \$38.3 million in the first nine months of 2005 from \$21.6 million in the first nine months of 2004. As discussed above, Hospira's purchases of CLAVE products was substantially decreased in 2004, but returned to more normal levels in 2005. Sales to Hospira under the SetSource program approximated \$10.5 million in the first nine months of 2005 compared to \$8.9 million in the first nine months of 2004, an increase of 17%. The SetSource increase is attributed to unit sales increases in the custom set market. Sales to Hospira under the MCDA, which began in May 2005, were \$29.8 million or 26% of total revenue.

Net sales to independent domestic distributors increased approximately \$1.4 million, from \$17.3 million in the first nine months of 2004 to \$18.7 million in the first nine months of 2005. Independent domestic distributors had a 17% or \$1.5 million increase in custom I.V. systems and a 21%, or \$0.7 million, increase in CLAVE product sales. Both increases are principally because of an increase in unit volume. These increases were partially offset by a \$0.9 million decrease in sales of Punctur-Guard products due to a decrease in unit sales.

Net sales to international distributors (excluding Canada) were \$9.1 million in the first nine months of 2005, as compared with \$6.4 million in the first nine months of 2004. The increase was primarily attributable to increased sales in Europe, South Africa and the Pacific Rim. The principal product lines showing increases were CLAVE and custom I.V. systems, both on increased unit volumes.

***Product and other revenue:*** Net sales of CLAVE Products (excluding custom CLAVE I.V. systems) increased from \$29.7 million in the first nine months of 2004 to \$48.2 million in the first nine months of 2005, or 62%. This increase was primarily due to increased unit shipments of CLAVE products to Hospira, discussed above, which increased \$16.7 million from the first nine months of 2004. Sales of CLAVE products and custom I.V. systems including one or more CLAVE connectors combined were \$65.1 million in the nine months of 2005 compared with \$43 million in the first nine months of 2004. This increase was due to increased purchases of CLAVE products in all our distribution channels.

Salt Lake City product sales to Hospira were \$29.8 million from May to September 2005, which includes critical care sales and custom critical care sales of \$26.2 million.

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

Net sales of custom and generic I.V. systems increased approximately \$3.9 million, or 20%, to \$23.4 million in the first nine months of 2005 over the first nine months of 2004, principally because of increased unit volume. The SetSource program with Hospira accounted for approximately \$1.5 million of the increase, domestic distributors accounted for approximately \$1.5 million of the increase and international distributors accounted for the balance of the increase. Unit volume accounted for the majority of the increase.

Net sales of Punctur-Guard products (excluding royalties) were \$3.4 million in the first nine months of 2005 compared to \$3.1 million in the first nine months of 2004. Increased sales to Hospira were offset by net declines in other channels.

Net sales of CLC2000 in the first nine months of 2005 were \$4.0 million compared to \$2.5 million from the first nine months of 2004. The increase is primarily attributable to increases in international sales and sales to Hospira. All distribution channels had increases in sales.

Other revenue consists of license, royalty and revenue shares income. It was \$2.4 million in the first nine months of 2005 compared to \$2.2 million in the first nine months of 2004. The increase in 2005 is principally because of the timing of minimum payments due under one of the agreements. We may receive other license fees or royalties in the future for the use of our technology. We give no assurance as to amounts or timing of any future payments, or whether such payments have been received.

*Gross margin* for the first nine months of 2005 and 2004, calculated on net sales and excluding other revenue, was 43% and 50%, respectively. The margin decrease in 2005 is due to the addition of the new Salt Lake City products sold to Hospira under the MCDA, which began in May 2005 and have lower margins than most of our traditional products; average gross margins under the MCDA are 19% for the five months since inception on May 1, 2005. Excluding the new product sales and related cost of goods sold, our margins were 52%. Additionally, gross margins were adversely affected by the new facility in Italy which is still operating below capacity and somewhat lower than normal production levels of CLAVE products in the first quarter of 2005 as we reduced inventories.

*Selling, general and administrative expenses ( SG&A )* increased by \$8.2 million to \$27.3 million, and were 24% of revenues in the first nine months of 2005, as compared with 32% in the first nine months of 2004. The increase in costs was partially due to a \$3.5 million increase in expenses associated with patent lawsuits against two companies, one of which was settled in April 2005. Compensation and benefit increases accounted for approximately \$2.9 million, principally from increased compensation, the addition of our Salt Lake City facility and the addition of new sales personnel. Costs for new product introductions and increased travel costs accounted for approximately \$0.5 million and \$0.8 million, respectively.

*Research and development expenses ( R&D )* were \$3.0 million in the first nine months of 2005 compared to \$2.6 million in the first nine months of 2004. The 2004 total includes a \$1.2 million charge for in-process R&D that was not applicable in the third quarter of 2005. This prior year charge was partially offset by a \$0.7 million increase of R&D costs incurred by our majority-owned subsidiary developing a new medical device designed for use in screening for heart disease. The remaining increase in R&D is primarily from new R&D activity associated with our new products and new R&D activity in our Salt Lake City facility.

*Other income* increased \$1.0 million to \$2.1 million in the first nine months of 2005 compared with the first nine months of 2004. The increase was primarily due to an increase in overall yield and invested funds and a \$0.5 million payment of a settlement agreement

*Income taxes* were accrued at an effective tax rate of 35.2% in the first nine months of 2005 as compared to 37.5% in the first nine months of 2004. In the second quarter of 2005, we adjusted our annual estimated effective tax rate down to 35.2% for a one-time tax credit that we expect to receive in 2005. This reduction from the 37.5% rate in the first

nine months of 2004 is partially offset in 2005 by the effect of estimated losses of the majority-owned company developing the new medical device because those losses are not included in our consolidated tax return.

**Liquidity and Capital Resources**

During the first nine months of 2005, our working capital increased \$1.6 million to \$111.2 million from \$109.6 million at December 31, 2004. Working capital decreased from the purchase of assets from Hospira's Salt Lake City plant of \$23.5 million in non-current assets, the investment of \$3.4 million of property and equipment,

offset by net working capital generated by operations and cash received from employee equity plans. Our cash and cash equivalents and investment securities position decreased during the first nine months of 2005 by \$9.2 million to \$78.1 million. This decrease was primarily due to the \$31.8 million payment for the acquisition of Hospira's Salt Lake City plant, \$3.4 million of other purchases of property and equipment, offset by the aggregate of cash provided by operating activities (including tax benefits from exercise of stock options) of \$19.5 million, cash provided by the company's employee equity plans of \$4.2 million and finance loan payments of \$2.3 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, the timing of tax payments and tax benefits from exercise of stock options.

Accounts receivable increased from \$8.9 million at December 31, 2004 to \$25.7 million at September 30, 2005, an increase of \$16.8 million. Approximately 67% of the increase was due to new receivables with Hospira under the MCDA. The remaining increase is principally because revenue (excluding sales to Hospira under the MCDA) in third quarter of 2005 was 97% more than revenue in the fourth quarter of 2004, offset by cash collections because shipments were spread relatively evenly over each month of the third quarter.

We generally try to maintain a minimal amount of inventory of finished goods and work in process, but will maintain larger amounts of components (classified as raw material) acquired from third parties to avoid production delays if deliveries by our suppliers are late. The Salt Lake City plant will require more raw material and work-in-process inventories in relation to sales because of the relatively large number of different products produced and relatively long production cycles. Our inventory balance increased by \$5.1 million from December 31, 2004. On May 1, 2005, we acquired \$8.9 million of raw material and work in process inventory as part of the purchase of the Salt Lake City facility from Hospira. At September 30, 2005, we had \$7.8 million of raw material and work in process inventory in our Salt Lake facility. Since December 31, 2004, we reduced finished goods inventory by \$3.0 million. Our raw materials and work in process inventories, exclusive of Salt Lake City, increased by \$0.3 million to support an increase in production in the first nine months of 2005.

At the end of 2004, our prepaid income taxes had increased to \$6.6 million because in the first half of 2004 we had overestimated our taxable earnings for the year 2004, resulting in overpayment of estimated taxes. This prepaid amount decreased by \$5.3 million from December 31, 2004 to September 30, 2005, principally because of a \$4.0 million refund received in April 2005 and the net application of overpayments to 2005 taxes due.

The tax benefits from the exercise of stock options, which we believe are more properly related to the sale of our stock which is a financing activity, fluctuates based principally on when employees choose to exercise their vested stock options. Tax benefits from the exercise of stock options in the first nine months of 2005 were \$2.2 million on the exercise of options to acquire 282,352 shares as compared to \$1.9 million in the first nine months of 2004 on the exercise of options to acquire 228,211 shares. On January 1, 2006, when we adopt provisions of SFAS 123(R), on accounting for share based payments, these tax benefits will be reflected in financing activities.

We expect our sales will continue to grow in the fourth quarter of 2005 compared to 2004. As sales increase, working capital is expected to increase to fund the increase in operations.

**Investing Activities:** During the first nine months of 2005, we used cash of \$19.6 million in investing activities. This was comprised of cash paid for acquired assets of \$31.8 million, purchases of property and equipment of \$3.4 million, offset by the net proceeds from sales of liquid investments of \$13.2 million and proceeds from finance loan payments

of \$2.3 million.

We are moving all molding and automated assembly to our Salt Lake City location from our San Clemente and Connecticut locations. In addition, we are expanding our production facility in Mexico to take over all manual

assembly currently done in our Salt Lake City facility. The above moves began in July 2005 and we expect them to be completed by early 2007. These moves require additional expansion or improvements to the existing facilities.

We estimate that capital expenditures, excluding Salt Lake City, for the remainder 2005, will be approximately \$4.6 million, bringing the year's total to approximately \$8.0 million. Amounts of spending are estimates and actual spending may substantially differ from those amounts.

ICU Finance, Inc. is a wholly owned consolidated subsidiary that we established in 2002 as a licensed commercial lender to provide financing to companies involved in distribution of healthcare products and provision of healthcare services. In October 2003, we discontinued new lending activities. Loans were made only to credit-worthy healthcare entities and are fully secured by real and personal property. At September 30, 2005, \$3.9 million in loans were outstanding. Scheduled maturities are: remainder of 2005 \$0.3 million; 2006 \$1.2 million; 2007 \$1.1 million and 2008 \$1.3 million. Weighted average maturity (principal and interest) at September 30, 2005 was 1.8 years and the weighted average interest rate was 5.1%. There were no unfunded commitments at September 30, 2005.

**Financing Activities:** Cash provided by stock options and the employee stock purchase plan, excluding tax benefits, was \$4.2 million in the first nine months of 2005 as compared to \$3.1 million in the first nine months of 2004. Options were exercised to purchase 282,352 shares in the first nine months of 2005 compared with 228,211 in the first nine months of 2004.

In the first nine months of 2004, we acquired our own common stock for \$10.1 million. We did not acquire shares of our common stock in the first nine months of 2005; however, we may purchase our shares in the future. Future purchases of our common stock, if any, will depend on market conditions and other factors.

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 currently 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**

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 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 the following contractual obligations of approximately the following amounts. These amounts exclude purchase orders for goods and services for current delivery; we do not have any long-term purchase commitments for such items. There are no obligations past 2009. (in thousands)

	2005	2006	2007	2008	2009
MCDA	\$ 2,750	\$ 5,500	\$ 5,500	\$ 5,500	\$ 5,500
Property and equipment	1,600				
Total	\$ 4,350	\$ 5,500	\$ 5,500	\$ 5,500	\$ 5,500

**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 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, SG&A, and R&D expense, income, losses, cash flow, new product introductions, 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, expansion in international markets, selling prices, future increases or decreases in sales of certain products and in certain markets and distribution channels, impact of safety legislation, increases in systems capabilities, introduction and sales of new products, manufacturing efficiencies and cost savings, unit manufacturing costs, oil prices, acquisition and use of production equipment and expansion of facilities and assembly capacity, relocation of manufacturing facilities and personnel, expansion of markets and the need for additional facilities, business seasonality and fluctuations in quarterly results, customer ordering patterns and warranty claims, rebates and returns;

new or extended contracts with manufacturers and buying organizations, and dependence on a small number of customers, effect of contract amendments with Hospira, effect of the acquisition of Hospira's Salt Lake City manufacturing facility and the manufacture of products for Hospira under the MCDA, and the outcome of our strategic initiatives;

regulatory approvals; outcome of litigation; competitive and market factors, including continuing development of competing products by other manufacturers, the impact of Cardinal's acquisition of Alaris, consolidation of the healthcare provider market and downward pressure on selling prices; and working capital requirements, foreign currency denominated financial instruments, capital expenditures, acquisitions of other businesses or product lines, indemnification liabilities, contractual liabilities and common stock repurchases.

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 this Quarterly Report to the Securities and Exchange Commission. 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 from between seven and 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, 2005, 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.

At September 30, 2005 we had outstanding commercial loans of approximately \$3.9 million. Loans were made only to credit worthy parties and are fully secured by real and personal property. We plan to hold the loans until maturity or payoff. Maturities are three years or less and the weighted average maturity (principal and interest payments) is 1.8 years. Because of the relatively small amount of the commercial loans, market risk is not significant to our financial statements.

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, British Pound, and Mexican Peso. Cash and receivables in those countries have been insignificant and are generally offset by accounts payable in the same foreign currency. We expect that in the future, with the growth of our European distribution operation, that net Euro denominated instruments will 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 or products for resale, and all such materials and products are readily available.

**Item 4. 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**

In an action filed August 21, 2001 and later amended, entitled ICU Medical, Inc. v. B Braun Medical, Inc. in the United States District Court for the Northern District of California, we alleged that B. Braun infringed ICU's patent by the manufacture and sale of its UltraSite medical connector. On April 20, 2005, ICU Medical, Inc. and B. Braun Medical Inc. settled the patent infringement suit, which was dismissed. The terms of the settlement are confidential.

In an action filed June 16, 2004 entitled ICU Medical, Inc. v. Alaris Medical Systems, Inc. pending in the United States District Court for the Central District of California, we allege that Alaris Medical Systems, Inc. infringes ICU's patent in 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, ICU's Complaint was amended to allege that Alaris infringes three additional patents. We seek monetary damages and injunctive relief and intend to vigorously pursue this matter. The outcome of this matter cannot be determined at this time.

In an action filed September 10, 2004 entitled ICU Medical, Inc. vs. Fulwider Patten Lee & Utecht, LLP, a law firm ( Fulwider ) in the Superior Court of California for the County of Orange, we allege that Fulwider during the course of its representation of us engaged in various matters for our direct competitors including Alaris Medical Systems, Inc. and others which directly conflicted with our interests, and committed other acts of negligence and breaches of the attorney-client relationship. We seek monetary damages and injunctive relief and intend to vigorously pursue this matter. The outcome of this matter cannot be determined at this time.

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

Inapplicable

**Item 3. Default Upon Senior Securities**

Inapplicable

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

Inapplicable

**Item 5. Other Information**

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

**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 31, 2005

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

Date: October 31, 2005