

ICU MEDICAL INC/DE
Form 10-Q
April 26, 2006

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: March 31, 2006

OR

0

**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 ☐

Yes ☒

No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act:

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

Indicate by check mark whether or not the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act):

Yes ☐

No ☒

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

Class
Common

Outstanding at April 15, 2006
14,282,815

ICU Medical, Inc.

Index

Part I - Financial Information

Item 1. Financial Statements (Unaudited)

Condensed Consolidated Balance Sheets, March 31, 2006 and December 31, 2005

Condensed Consolidated Statements of Income for the three months ended March 31, 2006 and 2005

Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2006 and 2005

Condensed Consolidated Statements of Comprehensive Income for the three months ended March 31, 2006 and 2005

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. and Subsidiaries

Condensed Consolidated Balance Sheets

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

	March 31, 2006 (unaudited)	December 31, 2005 (1)
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 9,171	\$ 6,854
Liquid investments	86,684	79,888
Cash, cash equivalents and liquid investments	95,855	86,742
Accounts receivable, net of allowance for doubtful accounts of \$844 and \$593 as of March 31, 2006 and December 31, 2005, respectively	26,594	23,644
Finance loans receivable - current portion	1,153	1,178
Inventories	16,664	15,435
Prepaid income taxes	1,207	3,768
Prepaid expenses and other current assets	2,670	3,522
Deferred income taxes - current portion	3,070	3,473
Total current assets	147,213	137,762
PROPERTY AND EQUIPMENT, net	53,666	52,194
FINANCE LOANS RECEIVABLE, non-current portion	2,137	2,422
INTANGIBLE ASSETS, net	10,761	10,963
DEFERRED INCOME TAXES, non-current portion	743	723
OTHER ASSETS	473	473
	\$214,993	\$204,537
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 6,337	\$ 5,078
Accrued liabilities	8,057	8,809
Total current liabilities	14,394	13,887
DEFERRED INCOME TAXES	352	529
MINORITY INTEREST	780	923
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS EQUITY:		
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 14,282,815 shares at March 31, 2006 and 14,158,612 at December 31, 2005	1,428	1,416
Additional paid-in capital	63,389	60,154
Treasury stock, at cost - 0 and 22,314 shares at March 31, 2006 and December 31, 2005, respectively		(609)
Retained earnings	134,631	128,265
Accumulated other comprehensive income (loss)	19	(28)
Total stockholders equity	199,467	189,198
	\$ 214,993	\$ 204,537

(1) December 31, 2005 balances were derived from audited consolidated financial statements.

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. and Subsidiaries

Condensed Consolidated Statements of Income

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

(unaudited)

	Three Months Ended March 31,	
	2006	2005
REVENUES:		
Net sales	\$ 47,457	\$ 25,663
Other	1,324	1,422
TOTAL REVENUE	48,781	27,085
COST OF GOODS SOLD		
	27,431	11,860
Gross profit	21,350	15,225
OPERATING EXPENSES:		
Selling, general and administrative	10,591	8,023
Research and development	1,569	674
Total operating expenses	12,160	8,697
Income from operations	9,190	6,528
OTHER INCOME	761	588
Income before income taxes and minority interest	9,951	7,116
PROVISION FOR INCOME TAXES	3,728	2,771
MINORITY INTEREST	(143)	(72)
NET INCOME	\$ 6,366	\$ 4,417
NET INCOME PER SHARE		
Basic	\$ 0.45	\$ 0.32
Diluted	\$ 0.41	\$ 0.30
WEIGHTED AVERAGE NUMBER OF SHARES		
Basic	14,218,346	13,613,636
Diluted	15,394,787	14,762,038

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

ICU Medical, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

(Amounts in thousands)

(unaudited)

	Three months ended March 31,	
	2006	2005
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	\$ 6,366	\$ 4,417
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	2,531	1,531
Provision for doubtful accounts	209	(280)
Minority interest	(143)	(72)
Stock compensation	126	
Cash provided (used) by changes in operating assets and liabilities		
Accounts receivable	(3,130)	(2,591)
Inventories	(1,215)	1,056
Prepaid expenses and other assets	672	(9)
Accounts payable	1,248	(12)
Accrued liabilities	(764)	1,472
Prepaid and deferred income taxes	2,762	1,269
	8,662	6,781
Tax benefits from exercise of stock options in 2005		1,077
Net cash provided by operating activities	8,662	7,858
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(3,577)	(1,233)
Proceeds from finance loan repayments	310	306
Purchases of liquid investments	(12,096)	(7,900)
Proceeds from sale of liquid investments	5,300	
Net cash used in investing activities	(10,063)	(8,827)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	2,282	1,620
Proceeds from employee stock purchase plan	576	243
Tax benefits from exercise of stock options in 2006	852	
Net cash provided by financing activities	3,710	1,863
Effect of exchange rate changes on cash	8	(58)
NET INCREASE IN CASH AND CASH EQUIVALENTS	2,317	836
CASH AND CASH EQUIVALENTS, beginning of period	6,854	5,616
CASH AND CASH EQUIVALENTS, end of period	\$ 9,171	\$ 6,452

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

ICU Medical, Inc. and Subsidiaries

Condensed Consolidated Statements of Comprehensive Income

(Amounts in thousands)

(unaudited)

	Three months ended March 31,	
	2006	2005
Net income	\$ 6,366	\$ 4,417
Other comprehensive income (loss) net of tax: Foreign currency translation adjustment	47	(209)
Comprehensive income	\$ 6,413	\$ 4,208

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

ICU Medical, Inc.

Notes to Condensed Consolidated Financial Statements

March 31, 2006

(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 2005 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: New Accounting Policy - Share Based Awards Prior to the January 1, 2006 adoption of the Financial Accounting Standards Board ("FASB") Statement No. 123(revised 2004), "Share-Based Payment" ("SFAS 123R"), the Company accounted for stock-based compensation 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" ("SFAS 123"). Accordingly, because the exercise price of the options equaled the fair market value of the underlying shares at the date of grant or as to the 2002 Employee Stock Purchase Plan ("ESPP") is non-compensatory under the provisions of APB Opinion No. 25, no compensation cost was recognized by the Company for stock-based compensation. As required by SFAS No. 123, the Company presented certain proforma information for stock-based compensation in the notes to the consolidated financial statements.

Effective January 1, 2006, the Company adopted the fair value recognition provisions of SFAS 123R, using the modified-prospective transition method. Under this transition method, stock-based compensation cost was recognized in the consolidated financial statements for all share based payments after January 1, 2006. These include stock options, and the ESPP, since the related purchase discounts for the ESPP exceeded the amount allowed under SFAS 123R for non-compensatory treatment. Compensation cost recognized includes the estimated expense for the portion of the vesting period after January 1, 2006 for share based payments prior to, but not vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS 123. Results for prior periods have not been restated, as provided for under the modified-prospective method. Shares to be issued to satisfy future share option exercises and share purchases from the ESPP will

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

be issued either from new common stock grants from previously authorized shares or from treasury shares. While the company does not currently have any treasury shares, the Company has purchased shares on the open market in the past.

Total stock-based compensation cost recognized in the three months ended March 31, 2006 was \$0.1 million for stock options and the ESPP. The effect of adoption SFAS 123R on the Company's basic and diluted earning per share was less than \$.01 per share. Prior to the adoption of SFAS 123R, the Company presented all tax benefits resulting from the exercise of stock options as operating cash inflows in the consolidated statements of cash flows, in accordance with the provisions of the Emerging Issues Task Force (EITF) Issue No. 00-15, Classification in the Statement of Cash Flows of the Income Tax Benefit Received by a Company upon Exercise

of a Nonqualified Employee Stock Option. In the Company's case, all tax benefits received were the tax benefits of tax deductions in excess of stock compensation cost recognized because no stock compensation cost was recognized under APB Opinion No. 25. SFAS 123R requires the benefits of tax deductions in excess of the compensation cost recognized for those options to be classified as financing cash inflows rather than operating cash inflows, on a prospective basis. This amount is shown as tax benefits from exercise of stock options on the consolidated statement of cash flows. Other than this classification change, the effect of adopting SFAS 123R had no effect on the Company's Condensed Consolidation Statement of Cash Flows.

The following information shows the effect on net earnings and earnings per share for the three months ended March 31, 2005 had compensation cost been recognized based upon the estimated fair value on the grant date of stock options, and ESPP, in accordance with SFAS 123R.

Net income, as reported	\$	4,417
Deduct: stock-based compensation expense determined under fair value method, net of tax		(109)
Net income, pro forma	\$	4,308
Net income per share		
Basic, as reported	\$	0.32
Diluted, as reported	\$	0.30
Basic, pro forma	\$	0.32
Diluted, pro forma	\$	0.29

Note 3: Stock-Based Compensation

Stock Option Plans

The 2003 Stock Option Plan (2003 Plan) has 1,500,000 shares of common stock reserved for issuance to employees. Options may be granted with exercise prices at no less than fair market value at date of grant. Options granted under the 2003 Plan may be nonstatutory stock options which expire no more than ten years from date of grant or incentive stock options as defined in Section 422 of the Internal Revenue Code of 1986, as amended. Upon exercise of nonstatutory stock options, the Company is generally entitled to a tax deduction on the exercise of the option for an amount equal to the excess over the exercise price of the fair market value of the shares at the date of exercise; the Company is generally not entitled to any tax deduction on the exercise of an incentive stock option. The 2003 Plan includes conditions whereby options not vested are cancelled if employment is terminated. As of March 31, 2006, the Company has one unvested performance based grant of 15,000 options and three unvested time-based grants totaling 1,668 options, which vest in 2006 and 2007.

The Company also has the 2001 Directors' Stock Option Plan (the Directors' Plan), which had 750,000 shares reserved for issuance. Options not vested terminate if the directorship is terminated. All further grants under the Directors' Plan have been suspended. As of March 31, 2006, the Company has one unvested performance based grant of 15,000 options and three unvested time-based grants totaling 1,668 options, which vest in 2006 and 2007.

The fair value of stock grants is calculated using the Black-Scholes option valuation model. Grants for the first quarter of 2005 used the following weighted-average assumptions: risk-free interest rate of 4.3 percent, expected option life of 4.0 years, expected volatility of 52 percent and no dividends. There were no option grants in 2006. As of March 31, 2006, the Company has \$0.1 million of unamortized stock

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

compensation cost, the majority of which will be amortized in the remainder of 2006. As of March 31, 2006, the Company has one unvested performance based grant of 15,000 options and three unvested time-based grants totaling 1,668 options, which vest in 2006 and 2007. Vested and expected to vest stock options equal the Company's total outstanding options at March 31, 2006.

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

A summary of the Company's stock option activity for the three months ended March 31, 2006 is as follows:

	Shares	Exercise Price Range	Weighted Average
Outstanding at December 31, 2005	4,019,958	\$ 5.08 - \$ 39.56	\$ 19.26
Granted			
Exercised	(124,074)	5.08 - 37.08	18.40
Forfeited	(1,000)	39.04 - 39.04	39.04
Outstanding at March 31, 2006	3,894,884	\$ 5.08 - \$ 39.56	\$ 19.28
Exercisable at March 31, 2006	3,878,216	\$ 5.08 - \$ 39.56	\$ 19.26

Available for grant at March 31, 2006:

2003 Plan	1,251,000
Director's Plan	513,750
	1,764,750

The intrinsic value of stock options exercised in the quarter ended March 31, 2006 was \$2.3 million. The intrinsic value of options outstanding and options exercisable at March 31, 2006 was \$66.4 million and \$66.1 million, respectively. The above intrinsic values are before applicable taxes, based on the Company's closing stock price of \$36.20 on March 31, 2006. The weighted average remaining contractual term of options outstanding and options exercisable at March 31, 2006 was 5.34 and 5.33 years, respectively.

Options Outstanding				Options Exercisable			
Range of Exercise Price	Number Outstanding	Weighted Average Exercise Price		Number Exercisable	Weighted Average Exercise Price		
\$ 5.08 - 7.29	380,030	\$ 6.01		380,030	\$ 6.01		
\$ 8.04 - 12.00	1,315,635	\$ 8.48		1,315,635	\$ 8.48		
\$ 12.92 - 18.88	425,487	\$ 15.61		425,487	\$ 15.61		
\$ 19.46 - 28.86	477,108	\$ 24.84		460,440	\$ 24.87		
\$ 29.11 - 39.56	1,296,624	\$ 33.29		1,296,624	\$ 33.29		
\$ 5.08 - 39.56	3,894,884	\$ 19.28		3,878,216	\$ 19.26		

A majority-owned subsidiary of the Company has adopted a stock option plan under which 300,000 shares are reserved for issuance to employees and directors. The terms are similar to the Company's 2003 Plan. The subsidiary options were granted with exercise prices at fair market value at the date of grant and have been issued for approximately 8.5% of the outstanding shares of the subsidiary. As of March 31, 2006, 255,000 stock options are outstanding under this plan and 100,000 are exercisable. All outstanding and exercisable stock options have an average exercise price of \$2.00 and a weighted average remaining contractual life of 9.2 years. There were no option grants, forfeitures or exercises under this plan in the first quarter of 2006.

Employee Stock Purchase Plan

The Company has an ESPP under which U.S. employees other than executive officers of the Company may purchase up to \$25,000 annually of Common Stock at 85% of its fair market value at the beginning or the end of a six-month offering period, whichever is lower. There are 750,000 shares of Common Stock reserved for issuance under the ESPP, which number is subject to annual increase. The Board of Directors determined that the annual increase due January 1, 2003, 2004, 2005 and 2006 would not take place. The ESPP is intended to constitute an employee stock purchase plan within the meaning of Section 423 of the Internal Revenue Code. Employees purchased 22,443 and 11,077 shares of Common Stock under the ESPP Plan in the first quarter of 2006 and 2005, respectively. As of March 31, 2006, there are 663,917 shares available for future issuance.

The fair value of rights to purchase shares under the ESPP shares is calculated using the Black-Scholes option valuation model. Shares for the August 2005-February 2006 and February 2006-August 2006 purchase periods used the following weighted-average assumptions: risk-free interest rate of 3.46 and 4.52 percent, respectively; expected option life of 0.5 years, expected volatility of 28 and 31 percent which is based on the historical volatility of the Company and no dividends. As of March 31, 2006, the Company has \$0.2 million of unamortized stock compensation expense from ESPP which will be recognized in the second and third quarters of 2006.

Note 4: 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, pricing, 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 records revenue net of any such reductions.

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 substantially 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. As of March 31, 2006, the Company has \$0.9 million accrued for these exit costs. The total estimated exit costs associated with these terminations is \$1.2 million. Costs of

moving production to Mexico will be capitalized or 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 in the first quarter of 2006 were approximately \$0.4 million 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 decided to sell one building, but has not yet determined what to do with other building space that will no longer be needed for production. The management of the Company does not believe that it will incur any loss on any of its San Clemente or Connecticut building 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.

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

Note 5: Inventories consisted of the following:

	3/31/06	12/31/05
Raw material	\$ 8,722	\$ 9,746
Work in process	4,694	4,323
Finished goods	3,248	1,366
Total	\$ 16,664	\$ 15,435

Note 6: Property and equipment consisted of the following:

	3/31/06	12/31/05
Machinery and equipment	\$ 38,814	\$ 38,421
Land, building and building improvements	31,630	31,588
Molds	9,418	9,123
Computer equipment and software	6,476	6,369
Furniture and fixtures	2,049	2,042
Construction in progress	6,305	3,577
Total property and equipment, cost	94,692	91,120
Accumulated depreciation	(41,026)	(38,926)
Net property and equipment	\$ 53,666	\$ 52,194

Note 7: Finance loans receivable are commercial loans by ICU Finance, Inc., a wholly-owned consolidated subsidiary. Loans were 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 2006 \$0.9 million; 2007 \$1.1 million and 2008 \$1.3 million. Weighted average maturity (principal and interest) at March 31, 2006 was 1.5 years and the weighted average interest rate was 5.6%. In October 2003, the Company discontinued new lending activities. There were no unfunded commitments at March 31, 2006.

Note 8: 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 1,176,441 and 1,148,402 for the three months ended March 31, 2006 and 2005, respectively. Options that are antidilutive because their exercise price exceeded the average market price of its common stock for the period approximated 200,000 and 1,200,000 for the three months ended March 31, 2006 and 2005, respectively.

Note 9: 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 10: Major customers: The Company had revenues equal to ten percent or greater of total net revenues from one customer, Hospira, Inc. Such revenues were 75% and 61% in the three months ended March 31, 2006 and 2005, respectively.

Note 11: Commitments and Contingencies: The Company is 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. 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 agreed to indemnify officers and directors of the Company, to the maximum extent permitted under Delaware law and to indemnify customers as to certain intellectual property matters related to sales of the Company's products. There is no maximum limit on the indemnification that may be required under these agreements. The Company has never incurred, nor does it expect to incur, any liability for indemnification, and therefore, the Company has not recorded any liability for these in its financial statements and does not expect to incur any. Except for indemnification agreements, the Company does not have any off balance sheet arrangements.

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

We are a leader in the development, manufacture and sale of proprietary, disposable medical connection systems for use in intravenous (I.V.) therapy applications. Our 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 Development Agreement with Hospira (MCDA), we are now also a significant manufacturer of critical care medical devices, including catheters, angiography kits and cardiac monitoring systems.

Critical Accounting Policies

Our significant accounting policies are summarized in Note 1 to the Consolidated Financial Statements included in our 2005 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 all our purchase orders, ownership transfers on shipment. 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 a few 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. With certain exceptions, customers 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. We rely on prior payment trends, financial status and other factors to estimate the cash which ultimately will be received. Such amounts cannot be known with certainty at the financial statement date. We regularly review individual past due balances for collectibility. 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 could 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

As described in Note 2 and Note 3 to the Condensed Consolidated Financial Statements, we implemented FASB Statement No. 123 (revised 2004) Share Based Payment as of January 1, 2006. The effect of adoption was not significant to our financial statements.

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

Business Overview

Until the late 1990s, our primary emphasis in product development, sales and marketing was disposable medical connectors for use in I.V. therapy, and our principal product was the CLAVE®. In the late 1990s, we commenced a transition from a product-centered company to an innovative, fast, efficient, low-cost manufacturer of custom I.V. systems, using processes that we believe can be readily applied to a variety of disposable medical devices. This strategy has enabled us to capture revenue on the entire I.V. delivery system, and not just a component of the system.

We are also increasing our efforts to acquire new products. We acquired the Punctur-Guard® line of blood collection needles in 2002, invested in a company developing a new medical device in 2004 and increased our investment in this company in 2005, 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 is no assurance that we will be successful in finding acquisition opportunities, or in acquiring companies or products or that we will successfully integrate them into our existing business.

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

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 further penetration of markets available to our existing customers in the U.S. becomes increasingly difficult. 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 2005 to 73% and was 75% in the first quarter of 2006. We expect this percentage to remain significant 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.

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 primary commercial responsibility for the products we are producing, including sales, marketing, pricing, distribution, customer contracts, customer service and billing. The majority of the products under the MCDA are invasive monitoring and angiography products, which include medical devices such as catheters, cardiac monitoring systems and angiography kits. Sales of products manufactured under the MCDA from May to December 2005 were \$46.7 million and in the first quarter of 2006 were \$19.2 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 record revenue net of any such reductions. We give no assurance as to the amounts of future sales or profits under the MCDA.

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 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 March 31,		Fiscal Year Ended		
	2006	2005	2005	2004	2003
CLAVE	33%	58%	40%	47%	59%
Custom Products	25%	25%	27%	35%	22%
Critical Care (excluding custom products)	24%		20%		
Punctur-Guard	2%	4%	3%	5%	7%
CLC2000®	3%	4%	3%	4%	4%
Other Products	10%	4%	5%	5%	4%
License, royalty and revenue share	3%	5%	2%	4%	4%
Total	100%	100%	100%	100%	100%

Salt Lake City products, including critical care, critical care custom products and other products account for 39% of total revenue for the quarter ended March 31, 2006. Custom I.V. systems, excluding critical care custom products, were 18% of total revenues for the quarter ended March 31, 2006.

Most custom I.V. systems include one or more CLAVE. Total CLAVE sales including custom I.V. systems with at least one CLAVE were \$22.6 million or 46% of total revenue in the first quarter of 2006 and \$20.4 million or 75% of total revenue in the first quarter of 2005.

We sell our I.V. administration products to independent distributors and through agreements with Hospira and certain other medical product manufacturers. Most independent distributors handle the full line of our I.V. administration products. We sell our invasive monitoring, angiography and I.V. administration products through three agreements with Hospira (the Hospira Agreements). Under a 1995 agreement, Hospira purchases CLAVE products, principally bulk, non-sterile connectors, and the CLC2000 and 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. Our 1995 and 2001 agreements with Hospira provide Hospira with conditional exclusive and nonexclusive rights to distribute all existing ICU Medical products worldwide with terms that extend to 2014. Under the MCDA, a 2005 agreement, we sell Hospira invasive monitoring, angiography and other products which they formerly manufactured at the Salt Lake City facility. The term 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 (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 \$12.0 million or 25% of total revenue in the first quarter of 2006, including sales under the Hospira SetSource program of approximately \$3.8 million and custom critical care products that we manufactured for Hospira under the MCDA of approximately \$3.2 million. We expect continued increases in sales of custom products. Punctur-Guard product revenues in the first quarter of 2006 were \$1.1 million. In 2004 and 2005, 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 the MCDA 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. Product revenues for each distribution channel were as follows:

Channel	Three months ended March 31,		Fiscal Year Ended		
	2006	2005	2005	2004	2003
Medical product manufacturers	78%	68%	76%	57%	71%
Independent domestic distributors	13%	22%	16%	31%	23%
Independent international distributors	9%	10%	8%	12%	6%
Total	100%	100%	100%	100%	100%

Quarter-to-quarter comparisons: We present summarized income statement data in Item 1. Financial Statements. The following table shows, for the year 2005 and the first quarter of 2006 and 2005, 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 such as license fees. See below for more information on non-product revenue. We present the alternative calculation based on net product revenue for the convenience of readers.)

	Year	Quarter ended March 31,	
	2005	2006	2005
Revenue			
Net sales	98%	97%	95%
Other	2%	3%	5%
Total revenues	100%	100%	100%
Gross profit			
Percentage of net sales	43%	42%	54%
Percentage of total revenues	44%	44%	56%
Selling, general and administrative expenses	24%	22%	30%
Research and development expenses	3%	3%	2%
Total operating expenses	27%	25%	32%
Income from operations	18%	19%	24%
Other income	2%	1%	2%
Income before income taxes and minority interest	20%	20%	26%
Income taxes	7%	8%	10%
Minority interest	0%	0%	0%
Net income	13%	13%	16%

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 March 31, 2006 Compared to the Quarter Ended March 31, 2005

Revenues increased \$21.7 million to \$48.8 million in the first quarter of 2006, compared to \$27.1 million in the first quarter of 2005.

Distribution channels: Net U.S. sales to Hospira in the first quarter of 2006 were \$36.6 million, compared to net sales of \$16.4 million in the first quarter of 2005. Net sales of CLAVE Products to Hospira, excluding custom CLAVE I.V. systems were \$12.6 million in the first quarter of 2006, compared to \$12.4 million in the first quarter of 2005.

Sales to Hospira under the SetSource program approximated \$3.8 million in the first quarter of 2006 compared to \$3.2 million in the first quarter of 2005, an increase of 19%. The SetSource increase is attributed to unit sales increases in the custom set market. Sales to Hospira under the MCDA were \$19.2 million or 39% of total revenue in the first quarter of 2006. There were no sales in the first quarter of 2005 under the MCDA, which began in May of 2005. We expect a significant increase in our sales to Hospira in 2006 from the inclusion of critical care products for a full year, continuing growth in sales of custom I.V. systems and a modest percentage growth in CLAVE and other product sales, although there is no assurance that these expectations will be realized.

Net sales to independent domestic distributors (including Canada) were \$6.2 million and \$6.0 million in the first quarters of 2006 and 2005, respectively. We expect that sales to domestic distributors will increase principally from growth in custom I.V. system business, with modest growth in sales of other products, although there is no assurance that these expectations will be realized.

Net sales to international distributors (excluding Canada) were \$4.3 million in the first quarter of 2006, compared with \$2.6 million in the first quarter of 2005, an increase of 65%. Approximately 65% of the increase was attributable to increased sales in Europe and 30% of the increase was from increased sales in Latin America. The principal product lines showing increases were custom I.V. systems, which accounted for 62% of the increase and CLAVE, which accounted for 27% of the increase. Both increases were due to increased unit volumes. We expect significant increases in sales to international distributors across all areas and all principal product lines, although there is no assurance that these expectations will be realized.

Product and other revenue: Net sales of CLAVE Products (excluding custom CLAVE I.V. systems) increased from \$15.7 million in the first quarter of 2005 to \$16.1 million in the first quarter of 2006. Sales of CLAVE products and custom I.V. systems including one or more CLAVE connectors combined were \$22.6 million in the first quarter of 2006 compared with \$20.4 million in the first quarter of 2005. This increase was due to increased purchases of CLAVE products in all our distribution channels.

Sales to Hospira of critical care products, excluding custom critical care products sales were \$11.9 million in the first quarter of 2006.

Net sales of custom products, including custom critical care products, were \$12.0 million in the first quarter of 2006 as compared with \$6.8 million for the first quarter of 2005, an increase of \$5.2 million. \$3.2 million of this increase was from the inclusion of critical care products. Net sales of custom and generic I.V. systems increased approximately \$2.0 million, or 28%, to \$8.8 million in the first quarter of 2006 compared to

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

the first quarter of 2005, principally because of increased unit volume. The SetSource program with Hospira accounted for approximately \$0.6 million of the increase, international distributors accounted for approximately \$1.0 million of the increase and domestic distributors accounted for the balance of the increase.

Net sales of Punctur-Guard products (excluding royalties) were \$1.1 million in the first quarter of 2006 and 2005. Increased unit volume was offset by lower prices.

Net sales of the CLC2000 were \$1.2 million in the first quarter of 2006 and \$1.0 million in the first quarter of 2005. The increase in sales was due to modest unit volume increases in all distribution channels.

Sales of other products were \$5.2 million in 2006 and \$1.1 million in 2005. The first quarter of 2006 other product sales include \$4.1 million of products manufactured under the MCDA related to a product line that we will no longer manufacture under the MCDA after 2006, as anticipated when we entered into the MCDA. We did not purchase the production equipment for this product line. This amount of sales in the first quarter is almost double the amounts in prior quarters as production was accelerated in anticipation of moving the majority of the production equipment out of the plant in the first quarter. All production of that product is scheduled to cease in September 2006.

Other revenue consists of license, royalty and revenue share income and was approximately \$1.3 million in the first quarter of 2006 and \$1.4 million in the first quarter of 2005. 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 will be received.

Gross margin for the first quarter of 2006 and 2005, calculated on net sales and excluding other revenue, was 42% and 54%, respectively. The margin decrease in the first quarter of 2006 is due to the addition of the new critical care products sold to Hospira under the MCDA, which began in May 2005 and have lower margins than most of our traditional products. The gross margin, at 42%, was the same as in the fourth quarter of 2005. We expect overall gross margins including other revenue in the remainder of 2006 to improve to 45% to 46% as we make improvements in the Salt Lake City plant and progress on the relocation of manufacturing, although there is no assurance that these expectations will be realized.

Selling, general and administrative expenses (SG&A) increased by \$2.6 million to \$10.6 million, and were 22% of revenues in the first quarter of 2006, as compared with 30% in the first quarter of 2005. The increase in costs was partially due to \$1.2 million of increased compensation and benefit expenses, including increased bonuses, the addition of our Salt Lake City facility, the addition of new sales personnel and increased pay rates. Amortization of intangibles and depreciation accounted for a \$0.5 million increase from the first quarter of 2005. Bad debt expense accounted for \$0.5 million of the increase from the first quarter of 2005. We expect SG&A in 2006 to be approximately 22% to 23% of revenue. There is no assurance that these expectations will be realized.

Research and development expenses (R&D) were \$1.6 million in the first quarter of 2006 compared to \$0.7 million in the first quarter of 2005. The increase was comprised of a \$0.3 million increase from our majority owned subsidiary developing a new medical device being designed for use in screening for heart disease and \$0.6 million of costs from new R&D activity associated with our new products, including new R&D activity in our Salt Lake City facility.

Other income is primarily from investment earnings and was \$0.8 million and \$0.6 million for the first quarters of 2006 and 2005, respectively.

Minority interest was \$0.1 million in the first quarters of 2006 and 2005 and represents the minority interest share of the net loss of the company developing a new medical device for use in screening heart disease.

Income taxes were accrued at an effective tax rate of 37.5% and 38.9% in the first quarter of 2006 and 2005, respectively. We expect our effective tax rate to remain at approximately 37.5% in 2006.

Liquidity and Capital Resources

In the first quarter of 2006, our cash and liquid investments increased by \$9.1 million. Operating activities generated \$8.7 million in cash and we received \$3.7 million from our stock plans. This was offset by \$3.6 million in purchases of property and equipment.

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

Accounts receivable increased \$3.1 million from December 31, 2005, which is primarily due to higher sales in the last month of the first quarter of 2006 compared to the last month of the fourth quarter of 2005.

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 requires 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 \$1.2 million from December 31, 2005 because of an increase of \$2.2 million in work-in-process and finished goods, partially offset by a decrease of \$1.0 million in raw materials. We are increasing our finished goods as we build a buffer stock of inventory in preparation for our move of production from San Clemente to Salt Lake City. We expect to increase inventories further through the second quarter of 2006 to provide additional buffer stocks before moving production.

The \$0.7 million decrease in prepaid expenses and other assets includes \$1.0 million non-trade receivable payment, remitted to us by the broker associated with December 2005 stock option exercises.

Prepaid income taxes declined by \$2.6 million as prepayments were applied to taxes due.

Tax benefits from stock options, which were the tax benefits of tax deductions in excess of compensation cost recognized, are no longer be classified in Cash Flows from Operating Activities, but are included in Cash Flows from Financing Activities commencing January 1, 2006 under the newly effective SFAS 123R. It has been our long-standing belief that these benefits should be classified as financing activities, but that classification was precluded by prior accounting pronouncements.

We expect our sales will continue to grow in the remainder of 2006 compared to 2005. As sales increase, working capital is expected to increase to fund the increase in operations.

Investing Activities: During the first quarter of 2006, we used cash of \$10.0 million in investing activities. This was comprised of purchases of property and equipment of \$3.6 million, and net purchases of liquid investments of \$6.8

million and proceeds from finance loan payments of \$0.3 million.

We are moving all molding and automated assembly to our Salt Lake City facility from our San Clemente and Connecticut facilities, which requires improvements to our Salt Lake City facility. In addition, we have expanded our production facility in Mexico by 45,000 square feet to take over most of the manual assembly currently done in our Salt Lake City facility. The moves from Salt Lake City to Mexico began in July 2005 and we expect them to be completed by early 2007. The moves from San Clemente to Salt Lake City began in April 2006 and are expected to be completed by the end of the summer in 2006.

We estimate that capital expenditures in 2006, including the building improvements in our Salt Lake City and Mexico facilities, will be approximately \$13.5 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. Loans were made only to credit-worthy healthcare entities and are fully secured by real and personal property. At March 31, 2006, \$3.3 million in loans were outstanding. Scheduled maturities are: remainder of 2006 \$0.9 million; 2007 \$1.1 million and 2008 \$1.3 million. Weighted average maturity (principal and interest) at March 31, 2006 was 1.5 years and the weighted average interest rate was 5.6%. There were no unfunded commitments at March 31, 2006.

Financing Activities: Cash provided by stock options and the employee stock purchase plan, including tax benefits, was \$3.7 million in the first quarter of 2006 at an average exercise price of \$19.51 to purchase 146,517 shares compared to \$2.9 million to purchase 144,538 shares in the first quarter of 2005 at an average exercise price of \$12.98. The tax benefits from the exercise of stock options fluctuates based principally on when employees choose to exercise their vested stock options. Tax benefits from the exercise of stock options in the first quarter of 2006 were \$0.9 million. The amount in the first quarter of 2005 was \$1.1 million, and, as explained above, is included in Cash Flows from Operating Activities.

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

Off Balance Sheet Arrangements

In the normal course of business, we have agreed to indemnify officers and directors of the Company to the maximum extent permitted under Delaware law and to indemnify customers as to certain intellectual property matters related to sales of our products. There is no maximum limit on the indemnification that may be required under these agreements. We have never incurred, nor do we expect to incur, any liability for indemnification. Except for indemnification agreements, we do not have any off balance sheet arrangements.

Contractual Obligations

We have contractual obligations of approximately the amounts set forth in the table below. These amounts exclude purchase orders for goods and services for current delivery. The majority of our purchase orders are blanket purchase orders that represent an estimated forecast of goods and services. We do not have a commitment liability on the blanket purchase orders. Since we do not have the ability to separate out blanket purchase orders from non-blanket purchase orders for goods and services for current delivery, these amounts are excluded from the table below. The commitments under the MCDA are those to fund certain research and development to improve critical care products and develop new products for sale to Hopsira and to provide sales specialists focused on critical care. We believe that our existing cash and liquid investments along with funds expected to be generated from future operations will provide us with sufficient funds to meet commitments under all of our contractual obligations. There are no obligations past 2009. (in thousands)

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

	2006		2007		2008		2009	
MCDA	\$	5,556	\$	5,500	\$	5,500	\$	5,500
Property and equipment		3,102						
Total	\$	8,658	\$	5,500	\$	5,500	\$	5,500

Forward Looking Statements

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

Various portions of this Report, including this Management's Discussion and Analysis, describe trends in our business and finances that we perceive and state some of our expectations and beliefs about our future. These statements about the future are forward looking statements, and we identify them by using words such as believe, expect, estimate, plan, will, continue, could, may, and by similar expressions and statements about aims, goals and plans. The forward looking statements are based on the best information currently available to us and assumptions that we believe are reasonable, but we do not intend the statements to be representations as to future results. They include, among other things, statements about:

future operating results and various elements of operating results, including future expenditures on sales and marketing and product development, future sales and unit volumes of products, future license, royalty and revenue share income, production costs, gross margins, SG&A, and R&D expense, income, losses, cash flow, changes in working capital items such as receivables and inventory, selling prices, and income taxes;

factors affecting operating results, such as shipments to specific customers, reduced dependence on current proprietary products, expansion in international markets, selling prices, future increases or decreases in sales of certain products and in certain markets and distribution channels, 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, and personnel, 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, cost savings and use of our systems and procedures under the MCDA, and the outcome of our strategic initiatives;

regulatory approvals and compliance; outcome of litigation; competitive and market factors, including continuing development of competing products by other manufacturers, the impact of Cardinal's acquisition of Alaris, consolidation of the healthcare provider market and downward pressure on selling prices; factors impacting our stock price; future stock option grants; 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 Item 1A of 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 at seven to forty-nine day intervals, with some longer but none beyond twelve months, so we have very little market risk, that is, risk that the fair value of the security will change because of changes in market interest rates; they are readily saleable at par at auction dates, and can normally be sold at par between auction dates. As of March 31, 2006, 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.

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

At March 31, 2006, we had outstanding commercial loans of approximately \$3.3 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 1.5 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 and accruals in the same foreign currency, except for Italy, where our net Euro position at March 31, 2006 was approximately 1.7 million. We expect that in the future, with the growth of our European distribution operation, that net Euro denominated instruments will continue to increase. We currently do not hedge our foreign currency exposures.

Our exposure to commodity price changes relates primarily to certain manufacturing operations that use resin. We manage our exposure to changes in those prices through our procurement and supply chain management practices and the effect of price changes has not been material. We are not dependent upon any single source for any of our principal raw materials 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 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 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. This case is currently scheduled for trial in February 2007. The outcome of this matter cannot be determined at this time.

In an action filed on September 10, 2004 entitled ICU Medical, Inc. v. Fulwider Patton Lee & Utecht, LLP (Fulwider), in the Superior Court of California for the County of Orange, we allege that during the course of its representation of us and continuing thereafter, Fulwider engaged in various matters for our direct competitors, including Alaris and others, and committed other acts of negligence and breaches of the attorney-client relationship. On November 16, 2005, the Court enjoined Fulwider from advising or representing Alaris in connection with the matter of ICU Medical, Inc. v. Alaris Medical Systems, Inc. On December 2, 2005, with leave of the Court, we filed an amended complaint naming Cardinal Health 303, Inc. (formerly Alaris Medical Systems, Inc.) as an additional defendant. On March 27, 2006, the Court sustained Alaris' demurrers to an amended complaint without leave to amend, effectively removing Alaris as a defendant. We intend to seek appellate review of the Court's ruling sustaining Alaris' demurrers without leave to amend. In the Fulwider action, we seek monetary damages and injunctive relief and intend to vigorously pursue this matter. This case is currently scheduled for trial date in February 2007. 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 1A. 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.

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

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. Sales to Hospira increased by approximately \$20.2 million in the first quarter of 2006 compared to the first quarter of 2005. Approximately \$19.2 million of the first quarter increase was attributable to the purchase of Hospira's Salt Lake City plant and commencement of production under a twenty-year MCDA as of May 1, 2005. The table below shows our total revenue attributable to various types of customers for the first quarter of 2006, and for 2005, 2004 and 2003 (dollars in millions):

	Three Months Ended March 31, 2006			2005			Years Ended December 31, 2004			2003		
Hospira (U.S.)	\$	36.6	75%	\$	115.0	73%	\$	39.8	53%	\$	71.3	67%
Other manufacturers		0.4	0%		2.2	1%		1.5	2%		1.5	1%
Domestic distributors		6.2	13%		24.4	16%		22.4	30%		24.1	23%
International distributors		4.3	9%		13.0	8%		9.0	12%		5.8	5%
Other revenue		1.3	3%		2.9	2%		2.8	3%		4.6	4%

Our principal agreements with Hospira are the MCDA, a strategic supply and distribution agreement for most of our other medical devices in the domestic and international markets and an agreement to sell Hospira custom I.V. systems to Hospira; the latter two agreements extend through 2014.

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

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.

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, and exclusive rights to sell products we produce under the MCDA. 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.

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

In contrast to our dependence on Hospira, our principal competitors in the market for protective I.V. connection systems are much larger companies that dominate the market for I.V. products and have broad product lines and large internal distribution networks. In many cases, these

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

competitors are able to establish exclusive relationships with large hospitals, hospital chains, major buying organizations and home healthcare providers to supply substantially all of their requirements for I.V. products. In addition, we believe that there is a trend among individual hospitals and alternate site healthcare providers to consolidate into or join large major buying organizations with a view to standardizing and obtaining price advantages on disposable medical products. These factors may limit our ability to gain market share through our independent dealer network, resulting in continued concentration of sales to and dependence on Hospira.

If we are unable to reduce substantially the cost of manufacturing products that we will sell to Hospira under the MCDA, our financial performance may be adversely affected.

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 date we purchased the Salt Lake City facility from Hospira. Achieving substantial cost reductions requires 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, our profits on products manufactured under the MCDA will be adversely affected.

The relocation of our manufacturing and assembly operations imposes a significant burden on our resources, will require specialized expertise, will result in interruption of production and will require relocation and training of personnel, any of which could have an adverse effect on our operations and financial results.

We intend to relocate substantial portions of our manufacturing facilities by early 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 to the Salt Lake City facility. We plan to move most of the 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 and expect that some highly skilled processes may stay in Salt Lake City.

Our performance under the MCDA, 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 other operations. In addition, we may require additional expertise, capability and capacity that can best be obtained through other acquisitions.

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 and income.

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 and income.

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

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 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.

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 2005, CLAVE products accounted for approximately 40% of our revenue and 55% of our revenue including custom I.V. systems incorporating a CLAVE. For the first quarter of 2006, CLAVE products accounted for approximately 33% of our revenue and 46% of our revenue including custom I.V. systems. We depend heavily on sales of CLAVE products, especially sales of CLAVE products to Hospira. Most of our CLAVE sales are in the United States, where we expect our growth in sales to moderate in the future as further penetration of markets available to our existing customers in the United States becomes increasingly difficult. Future significant sales increases for CLAVE products may depend on increases in sales of custom I.V. systems expansion in the international markets, which we are aggressively pursuing, or acquisition of new customers in the United States. We cannot give any assurance that sales of CLAVE products 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 needless 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 total sales of custom products including custom I.V. products and custom critical care products reached \$12.0 million in the first quarter of 2006, an increase of 75% over the same quarter in 2005; however, only 28% of this increase was in custom I.V. products. Sales of custom I.V. products increased by 22% in 2005 over 2004, 15% in 2004 over 2003 and 50% in 2003 over 2002. The success of our custom product sales program will require a larger increase in sales in the future than was achieved in 2005 and 2004 and there is no assurance that such an increase will be achieved or sustained. 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.

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 our products sold internationally. Our principal competitors in international markets 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 our competitors' lower local labor costs 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.

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 pricing. The ability to compete effectively depends on our ability to differentiate our products based on safety features, product quality, cost effectiveness, ease of use and convenience, as well as our ability to perceive and respond to changing customer needs. 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.

We may not be able to significantly expand our sales of custom 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.

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 continuing our assessment of design, manufacturing and assembly operations at the Salt Lake City facility and that assessment has resulted in changes and will result in future 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 are increasingly dependent on manufacturing in Mexico. Any political or economic disruption in Mexico or a change in the local economy could have an adverse effect on our operations

We continue to expand our production in Mexico. In 2005, production costs in Mexico were approximately \$19.0 million. Most of the material we use in manufacturing is imported into Mexico, and substantially all the production in Mexico is exported. We depend on our ability to move goods across the border quickly. Any disruption in the free flow of goods across the border could have an adverse effect on our business.

As of March 31, 2006, we employed 618 people in our plant in Ensenada, Mexico, and expect this to increase in the future. Business activity in the Ensenada area is expanding significantly, providing increasing employment opportunities. This could have an adverse effect on our ability to hire or retain necessary personnel and increase amounts we must pay them. We continue to take steps to compete for labor through attractive employment conditions and benefits, but there is no assurance that these steps will continue to be successful or that we will not face increasing labor costs in the future.

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 substantially higher than what they were six 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 in California could have an adverse effect on our operations.

Increases in the cost of petroleum-based and natural gas-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 continue to be negatively impacted by damage caused by the hurricanes in the Gulf Coast in 2005. Related production and supply problems have had a small impact our ability to get uninterrupted supplies of raw materials, which has caused some minor delay in

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

deliveries of certain products under the MCDA. There is no assurance that these supply problems will not persist or get worse. Also, crude oil and natural gas prices in 2006 are at record highs. Our suppliers have passed some of their cost increases on to us, and if such 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.

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 on Dr. George A. Lopez, our founder, Chairman of the Board, President and Chief Executive Officer for new product concepts and manufacturing innovation. 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 \$95.9 million at March 31, 2006, of which substantially all was invested in interest bearing instruments. Such instruments 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 2005, the comparable numbers were approximately \$2.2 million and \$82.5 million, respectively; investment income was approximately \$1.8 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. We have ongoing litigation against Alaris, a part of Cardinal, 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

could 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.

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

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

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 (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.

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. From the beginning of 2005 through March 2006, our trading price ranged from a high of \$43.09 per share to a low of \$23.01 per share. We believe that factors such as quarter-to-quarter fluctuations in financial results, differences between stock analysts

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

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 in 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 56% of our outstanding shares. If one or more of the institutions should decide to reduce or eliminate its position in our common stock, it could cause a decrease in the price of the common stock that 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 March 15, 2006 was 2,092,851 shares, or approximately 15% 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

At March 31, 2006, we had outstanding stock options to purchase 3.9 million shares, of which 3.6 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 of financial reporting and our independent registered public accounting firm to audit and report on the design and effectiveness of our internal controls of financial reporting has been extremely expensive. Further, there is no certainty that we will continue to receive unqualified reports on our internal controls of financial reporting 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.

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: April 26, 2006

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

Date: April 26, 2006