#### FORM 10-Q SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

|                              |   | •   |                                   |
|------------------------------|---|---|-----------------------------------|
| [ x ]                        | QUARTERLY REPORT PURSUAN<br>THE SECURITIES E  | T TO SECTION 13 OR 15(d)<br>XCHANGE ACT OF 1934     | OF                                |
|                              | For the quarterly peri  | od ended: March 31, 2004                            |                                   |
|                              |   | OR  |                                   |
| [ ]                          | TRANSITION REPORT PURSUA<br>THE SECURITIES E<br>For the transition period   | XCHANGE ACT OF 1934                                 |                                   |
|                              | Commission Fi   | le No.: 0-19974                                     |                                   |
|                              |   | ICAL, INC.<br>nt as provided in charte              | r)                                |
| 1                            | Delaware  |   | 33-0022692                        |
|                              |   |   |                                   |
| ,                            | ther Jurisdiction of on or Organization)  |   | I.R.S. Employer entification No.) |
| 951 Calle An                 | manecer, San Clemente, Calif  | ornia   | 92673                             |
| (Address                     | of Principal Executive Offic  | es)   | (Zip Code)                        |
|                              |   | 366-2183  |                                   |
|                              |   | No. Including Area Code                             | )                                 |
| filed by Sec<br>preceding 12 | check mark whether the regiction 13 or 15(d) of the Sec 2 months (or for such shorte h reports), and (2) has been days: | urities Exchange Act of<br>r period that the regist | 1934 during the rant was required |
|                              | Yes [XXX]   | No [ ]  |                                   |
|                              | e number of shares outstandi<br>k, as of the latest practica  | _   | 's classes of                     |
|                              | ass   | Outstanding at Apri                                 | 1 30, 2004                        |
|                              | <br>mmon  | 13,783, 44  | 1                                 |
|                              |   | ical, Inc.  |                                   |
|                              | I   | ndex  |                                   |
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## ICU Medical, Inc. Condensed Consolidated Balance Sheets March 31, 2004 and December 31, 2003 (all dollar amounts in thousands except per share data) (unaudited)

| ASSETS  |                      | 12/31/03        |
|---|----------------------|-----------------|
|   |                      |                 |
| CURRENT ASSETS:   |                      |                 |
| Cash and cash equivalents   | s 3.798              | \$ 1,787        |
| Liquid investments  | 81,950               | 71,350          |
|   |                      |                 |
| Cash, cash equivalents and liquid investments   | 85,748               | 73,137          |
|   |                      |                 |
| Accounts receivable, net of allowance for doubtful accounts of \$685  | 17 700               | 24 042          |
| and \$742 as of March 31, 2004 and December 31, 2003, respectively Finance loans receivable - current portion | 17,798<br>3,789      | 24,943<br>4,142 |
| Inventories   | 5,910                | 3,398           |
| Prepaid income taxes  | J, 910               | 1,662           |
| Prepaid expenses and other current assets   | 1,192                | 1,927           |
| Deferred income taxes - current portion   | 2,052                | 2,008           |
|   |                      |                 |
| Total current assets  | 116,489              | 111,217         |
|   |                      |                 |
|   | =0.045               |                 |
| PROPERTY AND EQUIPMENT, at cost:  | 73,045               | 71,615          |
| LessAccumulated depreciation  | (32,183)             | (30,574)        |
|   |                      |                 |
|   |                      | 41,041          |
| FINANCE LOANS RECEIVABLE - non-current portion  | 4,490                | 4,765           |
| DEFERRED INCOME TAXES - non-current portion   | 2,716                | 2,680           |
| INTANGIBLE ASSETS - net   | 4,073                | 4,166           |
| OTHER ASSETS  | 410                  | 419             |
|   | 2 160 040            |                 |
|   | \$ 169,040<br>====== |                 |
|   |                      |                 |
| LIABILITIES AND STOCKHOLDERS' EQUITY  |                      |                 |
| CURRENT LIABILITIES:  |                      |                 |
| Accounts payable  | c 2 0E2              | \$ 3,051        |
| Accrued liabilities   | 5,242                | 5,234           |
| Notified Habilities   |                      |                 |
| Total current liabilities   | 8,295                | 8,285           |
|   |                      |                 |
|   |                      |                 |
| STOCKHOLDERS' EQUITY:   |                      |                 |
| Convertible preferred stock, \$1.00 par value  Authorized 500,000 shares, issued and outstanding none         |                      |                 |
|   |                      |                 |

Authorized -- 500,000 shares, issued and outstanding -- none Common stock, \$0.10 par value-

| Total stockholders' equity   | 160,745<br><br>\$ 169,040 | 156,003<br><br>\$ 164,288 |
|--|---------------------------|---------------------------|
| Accumulated other comprehensive income   | 114                       | 177                       |
| Retained earnings  | 107,131                   | 102,991                   |
| Treasury stock, at cost 441,875 and 471,390 shares at March 31, 2004 and December 31, 2003, respectively | (11,210)                  | (12,116)                  |
| Authorized 80,000,000 shares, issued 14,158,612<br>Additional paid-in capital                            | 1,416<br>63,294           | 1,416<br>63,535           |
|  |                           |                           |

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

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# ICU MEDICAL, INC. Condensed Consolidated Statements of Income For the Three Months Ended March 31, 2004 and March 31, 2003 (all dollar amounts in thousands except share data) (unaudited)

|   | For the Three Months Ended |                          |  |  |
|---|----------------------------|--------------------------|--|--|
|   | 3/31/04                    | 3/31/03                  |  |  |
| REVENUES: Net sales Other   | \$ 21,270<br>963           | \$ 28,736<br>2,040       |  |  |
| TOTAL REVENUE   | 22,233                     | 30,776                   |  |  |
| COST OF GOODS SOLD  | 9,813                      | 13,024                   |  |  |
| Gross profit  | 12,420                     | 17,752                   |  |  |
| OPERATING EXPENSES:  Selling, general and administrative Research and development | 5,655<br>451               | 6,087<br>471             |  |  |
| Total operating expenses  | 6,106                      | 6 <b>,</b> 558           |  |  |
| Income from operations  | 6,314                      | 11,194                   |  |  |
| INVESTMENT INCOME   | 310                        | 296<br>                  |  |  |
| Income before income taxes  | 6,624                      | 11,490                   |  |  |
| PROVISION FOR INCOME TAXES  | 2,484                      | 4,420                    |  |  |
| NET INCOME  | \$ 4,140<br>======         | \$ 7,070                 |  |  |
| NET INCOME PER SHARE  Basic  Diluted  | \$ 0.30<br>\$ 0.28         | \$ 0.50<br>\$ 0.46       |  |  |
| WEIGHTED AVERAGE NUMBER OF SHARES Basic Diluted                                   | 13,699,991<br>15,041,285   | 14,007,731<br>15,337,366 |  |  |

The accompanying notes are an integral part of

# ICU Medical, Inc. Condensed Consolidated Statements of Cash Flows For the Three Months Ended March 31, 2004 and March 31, 2003 (all dollar amounts in thousands) (unaudited)

|  |                        | Months Ended        |
|--|------------------------|---------------------|
|  |                        | 3/31/03             |
| CASH FLOWS FROM OPERATING ACTIVITIES: Net Income Adjustments to reconcile net income to net cash                       | \$ 4,140               |                     |
| provided by operating activities Depreciation and amortization Net change in current operating assets and liabilities, | 1,696                  | 1,633               |
| net of effects of acquisitions   | 6,892<br>              | (4,060)             |
| Tax benefits from exercise of stock options  | 12 <b>,</b> 728<br>122 | 4,643<br>3          |
| Net cash provided by operating activities  | 12,850                 | 4,646               |
| CASH FLOWS FROM INVESTING ACTIVITIES:  |                        |                     |
| Purchases of property and equipment Cash paid for acquisitions   | (1,410)                | (3,017)<br>(1,221)  |
| Advances under finance loans Proceeds from finance loan repayments   | (1,000)<br>1,628       | (2,152)<br>501      |
| Purchases of investments   | (10,600)               | J01<br>             |
| Proceeds from sale of investments  |                        | 9,575               |
| Net cash provided by (used in) investing activities  | (11,382)               | 3,686<br>           |
| CASH FLOWS FROM FINANCING ACTIVITIES:  |                        |                     |
| Proceeds from exercise of stock options Proceeds from employee stock purchase plan                                     | 264<br>279             | 10<br>271           |
| Purchase of treasury stock   |                        | (8,649)             |
| Net cash provided by (used in) financing activities  | 543<br>                | (8,368)             |
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS   | 2,011                  | (36)                |
| CASH AND CASH EQUIVALENTS, beginning of the period   | 1,787                  | 4 <b>,</b> 165      |
| CASH AND CASH EQUIVALENTS, end of the period   | \$ 3,798<br>=======    | \$ 4,129<br>======= |

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

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|   | For the Three          | Months Ended      |
|---|------------------------|-------------------|
|   | 3/31/04                | 3/31/03           |
| Net income  | \$ 4,140               | \$ 7 <b>,</b> 070 |
| Other comprehensive income, net of tax: Foreign currency translation adjustment | (63)                   |                   |
| Comprehensive income  | <br>\$ 4,077<br>====== | \$ 7,070          |

#### ICU Medical, Inc.

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 to 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 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 our 2003 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 designed to protect healthcare workers and patients from the spread of infectious diseases. The Company's devices are sold principally to distributors and medical product manufacturers throughout the United States and a small portion internationally. All subsidiaries are wholly owned and are included in the consolidated financial statements. All intercompany balances and transactions have been eliminated.

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#### NOTE 2: INVENTORIES consisted of the following:

|                 | 3/31/04  | 12/31/03          |
|-----------------|----------|-------------------|
|                 |          |                   |
| Raw material    | \$ 3,139 | \$ 2,699          |
| Work in process | 579      | 340               |
| Finished goods  | 2,192    | 359               |
|                 |          |                   |
| Total           | \$ 5,910 | \$ 3 <b>,</b> 398 |
|                 |          |                   |

#### NOTE 3: PROPERTY AND EQUIPMENT, at cost, consisted of the following:

|                             | 3/31/04  | 12/31/03 |
|-----------------------------|----------|----------|
|                             |          |          |
| Land, building and building |          |          |
| improvements                | \$21,321 | \$16,887 |
| Machinery and equipment     | 29,437   | 26,429   |
| Furniture and fixtures      | 7,031    | 6,572    |
| Molds                       | 11,524   | 11,480   |

NOTE 4: FINANCE LOANS RECEIVABLE are commercial loans by ICU Finance, Inc., a wholly-owned consolidated subsidiary. Loans are made only to credit-worthy healthcare entities and are fully secured by real and personal property. We plan 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 2004 \$3,413,000; 2005 \$1,228,000; 2006 \$1,191,000; 2007 \$1,168,000 and 2008 \$1,279,000. Weighted average maturity (principal and interest) at March 31, 2004 was 1.5 years and the weighted average interest rate was 5.5%. In October 2003, we discontinued new lending activities; we will honor existing lending commitments. The maximum that can be borrowed under all commitments, including amounts outstanding, was approximately \$8,500,000 at March 31, 2004.

NOTE 5: 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. Dilutive securities are outstanding common stock options (excluding stock options with an exercise price in excess of market value), 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 1,341,294 and 1,329,635 for the three months ended March 31, 2004 and 2003, respectively. Options that are antidilutive because their average exercise price exceeded the average market price of our common stock for the period approximated 540,000 and none for the three months ended March 31, 2004 and 2003, respectively.

NOTE 6: STOCK OPTIONS: We account for our stock options granted to employees and directors under Accounting Principles Board ("APB") Opinion No. 25 "Accounting for Stock Issued to Employees" and related interpretations as permitted by SFAS No. 123 "Accounting for Stock-Based Compensation," and do not recognize compensation expense because the exercise price of the options equals the fair market value of the underlying shares at the date of grant or, as to the 2002 Employee Stock Purchase Plan, the plan is non-compensatory under the provisions of APB Opinion No. 25. Under SFAS No. 123, the Company is required to present certain pro forma earnings information determined as if employee stock options were accounted for under the fair value method of that Statement. The fair value

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for options granted in the first quarter of 2004 and 2003 was estimated as of the date of grant using a Black-Scholes option pricing model. The Black-Scholes option valuation model was developed for use in estimating fair value of fully transferable traded options with no vesting restrictions, and, similar to other option valuation models, requires use of highly subjective assumptions, including expected stock price volatility. The characteristics of our stock options differ substantially from those of traded stock options, and changes in the subjective assumptions can materially affect estimated fair values; therefore, in Management's opinion, existing option valuation models do not necessarily provide a reliable single measure of the fair value of our stock options. The following information is provided pursuant to SFAS No. 123, as amended. The pro forma adjustment reflects stock-based compensation cost calculated under the fair value method, net of related tax effects, pursuant to SFAS No. 123.

|     |                              | 2004    | 2003             |
|-----|------------------------------|---------|------------------|
|     |                              |         |                  |
|     | Income, as reported          | \$4,140 | \$7,070          |
| Pro | forma adjustment             | 1,020   | 1,342            |
|     |                              |         |                  |
| Net | <pre>Income, pro forma</pre> | \$3,120 | \$5 <b>,</b> 728 |
|     |                              | ======  | ======           |
| Net | Income per share             |         |                  |
|     | Basic, as reported           | \$0.30  | \$0.50           |
|     | Diluted, as reported         | \$0.28  | \$0.46           |

Ouartor anded March 21

NOTE 7: 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 partially offset by the effect of tax-exempt investment income.

NOTE 8: MAJOR CUSTOMERS: We had revenues equal to ten percent or greater of total net revenues from one customer, Hospira, Inc. (formerly a part of Abbott Laboratories), of 60% and 68% in the first quarters of 2004 and 2003, respectively.

NOTE 9: COMMITMENTS AND CONTINGENCIES: We are from time to time involved in various legal proceedings, either as a defendant or plaintiff, most of which are routine litigation in the normal course of business. 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.

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 amount limit on the indemnification that may be required under these agreements. We have never incurred, nor do we expect to incur, any liabilities for indemnification.

NOTE 10: ACQUISITIONS: In June 2003, we acquired the assets of two affiliated manufacturers of intravenous therapy systems located in northern Italy for a cash payment of approximately \$4.6 million. Principal assets acquired are assembly facilities and related equipment of \$2,443,000 and inventories of \$1,110,000 and an agreement not to compete valued at approximately \$818,000. The acquired assets and related operating results are included in our consolidated financial statements since June 30, 2003. Their effect on our financial statements is immaterial.

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## 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 healthcare workers and their patients from exposure to infectious diseases such as Hepatitis B and C and Human Immunodeficiency Virus ("HIV") 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 on many of those custom I.V. systems. We also manufacture and sell the Punctur-Guard line of blood collection needles, which we acquired in October 2002.

#### Critical Accounting Policies

Our significant accounting policies are summarized in Note 1 to the Consolidated Financial Statements included in our 2003 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. Under the terms of most purchase orders, ownership transfers on shipment, but in some cases it transfers on delivery. If there are significant doubts at the time of shipment as to the collectibility of the receivable, we defer recognition of the sale in revenue until the receivable is collected. Most of our customers are medical product manufacturers or distributors, although some are end-users. Our only post-sale obligations are warranty and certain rebates. We warrant products against defects and have a policy permitting the return of defective products. We record warranty returns as an expense; amounts have been insignificant. Customers, with certain exceptions, do not retain any right of return and there is no price protection with respect to unsold products; returns from customers with return rights have not been significant. We accrue rebates as a reduction in revenue based on contractual commitments and historical experience. Adjustments of estimates of warranty claims, rebates or returns, which have not been, and are not expected to be material, affect current operating results when they are determined.

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

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

Property and equipment is carried at cost and depreciated on the straight-line method over the estimated useful lives. The estimates of useful lives are significant judgments in accounting for property and equipment, particularly for molds and automated assembly machines that are custom made for us. We may retire them on an accelerated basis if we replace them with larger or more technologically advanced tooling. The remaining useful lives of all property and equipment are reviewed regularly and lives are adjusted or assets written off based on current estimates of future use. As part of that review, property and equipment is reviewed for other indicators of impairment, but to date we have not encountered circumstances indicating the carrying amount of an asset, or group of assets, may not be recoverable. 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

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 enables us to capture revenue on the entire I.V. 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 and are continuing to seek other opportunities. However, there can be no assurance that we will be successful in finding acquisition opportunities, or in acquiring companies or products.

Custom I.V. systems and new products will be of increasing importance to us in future years. We expect CLAVE products to continue to grow in the U.S., but at a slower percentage growth rate than in the past because of our large market penetration. Growth for all of our products outside the U.S. could be substantial, although to date it has been modest. Therefore, we will be directing increasing product development, acquisition, sales and marketing efforts to custom I.V. systems and new products in the U.S. and increasing our emphasis on the markets outside the U.S.

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Our largest customer has been Abbott Laboratories ("Abbott"). On April 30, 2004, Abbott spun off its core Hospital Products Division to its stockholders as an independent company named Hospira, Inc. The Hospital Products Division historically accounted for virtually all of our sales to Abbott. Abbott has assigned our agreements with Abbott to Hospira. We believe the spin-off is a positive development for us and will result in new business opportunities with Hospira. For clarity, all historical references to Abbott and its Hospital Products Division have been changed to 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, and we expect this percentage to increase on a yearly basis in the future. 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 I.V. systems, and our other products in the U.S. and also outside the U.S.

We believe that achievement of our growth objectives, both within the U.S., and outside the U.S., will require increased efforts by us in sales and marketing and product development, and we expect to increase expenditures for those during 2004.

There is no assurance that we will be successful in implementing our growth strategy. The custom I.V. systems 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 all these 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 net sales for the periods indicated:

|                                 |      |      |      |       | :======= | = |
|---------------------------------|------|------|------|-------|----------|---|
| Product Line                    | 2001 | 2002 | 2003 | Q1-03 | Q1-04    |   |
|                                 |      |      |      |       |          | - |
| CLAVE                           | 74%  | 67%  | 59%  | 63%   | 50%      |   |
| Custom and Generic I.V. Systems | 13%  | 17%  | 22%  | 16%   | 29%      |   |
| Punctur-Guard (R)               |      | 1%   | 7%   | 68    | 7%       |   |

| CLC2000(R)                         | 3%   | 4%   | 4%   | 4%   | 4%   |
|------------------------------------|------|------|------|------|------|
| Other Products                     | 10%  | 7%   | 4%   | 4%   | 6%   |
| License, royalty and revenue share | -    | 4%   | 4%   | 7%   | 4%   |
| Total                              | 100% | 100% | 100% | 100% | 100% |

Most custom I.V. systems include one or more CLAVEs. Total CLAVE sales including custom I.V. systems with at least one CLAVE were 75% of net revenue in the first quarter of 2003 and 69% of net revenue in the first quarter of 2004.

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We sell our products to independent distributors and through agreements with Hospira (the "Hospira Agreements") and certain other medical product manufacturers. Most independent distributors handle the full line of our products. Hospira purchases CLAVE products, principally bulk, non-sterile connectors, and the CLC2000. In addition, we sell custom I.V. systems to Hospira under a program referred to as SetSource. In January 2004, we announced the execution of amendments to our existing agreements with Hospira. The amendments extend the terms of our agreements to 2014 and provide Hospira with rights to distribute all existing ICU Medical products worldwide. We signed another contract amendment with Hospira in January 2004 to distribute our Punctur-Guard line of blood collection needles in the U.S. and the rest of the world. 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, our success in marketing and distributing CLAVE products will depend, in part, on our ability, either independently or through strategic relationships such as our Hospira relationship, to secure long-term CLAVE contracts with large healthcare providers and major buying organizations. As a result of this marketing and distribution strategy we derive most of our revenues from a relatively small number of distributors and manufacturers. The loss of a strategic relationship with a customer or a decline in demand for a manufacturing customer's products could have a material adverse effect on our operating results.

We believe the success of the CLAVE has motivated, and will continue to motivate others to develop one-piece, swabbable, needleless connectors that may incorporate many of the same functional and physical characteristics as the CLAVE. We are aware of a number of such products. 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. 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 I.V. systems 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 expect continuing significant increases in sales of custom I.V. systems under this agreement. We also contract with group purchasing organizations and independent dealer networks for inclusion of our products among those available to members of those entities. Custom I.V. systems accounted for approximately \$6.6 million of net sales in the first three months of 2004, including net sales under the Hospira SetSource program of approximately \$2.7 million. Also, in the fourth quarter of 2002 we acquired Bio-Plexus. Inc., whose principal products are blood collection needles, under the Punctur-Guard name, that are designed to eliminate exposure to sharp, contaminated needles. Punctur-Guard product revenues in the first quarter of

2004 were \$1.5 million. There is no assurance that either one 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 use of automated assembly equipment for new products and other products for which volume is growing, use of larger molds and molding machines, centralization of all proprietary molding in San Clemente, expansion of our production facility in Mexico, and the establishment of other production facilities outside the U.S.

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

| Channel                           | 2001 | 2002 | 2003 | Q1-03 | Q1-04 |
|-----------------------------------|------|------|------|-------|-------|
| Medical product manufacturers     | 72%  | 73%  | 71%  | 75%   | 65%   |
| Independent domestic distributors | 20%  | 19%  | 23%  | 21%   | 26%   |
| International                     | 8%   | 8%   | 6%   | 4%    | 9%    |
| 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 2003 and the first quarters of 2003 and 2004, the percentages of each income statement caption in relation to revenues, and the percentage change in each caption in each quarter. (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 total revenue for the convenience of readers who prefer to view it that way).

|   | Percentage of Revenues |            |            | -              |  |
|---|------------------------|------------|------------|----------------|--|
|   |                        | Q1-03      |            | Q1-04 v. Q1-03 |  |
| Revenue<br>Net sales<br>Other   | 4%                     | 93%<br>7%  | 4%         | -26%<br>-53%   |  |
| Total revenues<br>Cost of sales   |                        | 100%       |            | -28%<br>-25%   |  |
| Gross Profit Percentage of net sales Percentage of all revenues                   | 53%<br>55%             | 55%<br>58% | 54%<br>56% | -27%<br>-30%   |  |
| Selling, general and administrative expenses<br>Research and development expenses | 2%                     | 20%<br>1%  | 2%         | -8%<br>-4%     |  |
| Total operating expenses  | 23%                    | 21%        |            | -8%            |  |
| Income from operations  |                        | 36%        |            |                |  |
| Investment income   | 1%                     | 1%         | 1%         | 0.5%           |  |
| Income before income taxes Income taxes   | 33%<br>12%             | 37%<br>14% | 30%<br>11% | -42%<br>-44%   |  |
| Net income  | 21%                    |            | 19%        | -41%           |  |

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, 2004 COMPARED TO THE QUARTER ENDED MARCH 31, 2003

Net revenues decreased \$8,543,000, or approximately 28%, to \$22,233,000 in the first quarter of 2004 compared to \$30,776,000 during the same period last year. Approximately \$5.7 million of the decrease is attributable to two items that occurred in the first quarter of 2003 but did not recur in the 2004 quarter; a deferment of approximately \$4.0 million of CLAVE product available for delivery to Hospira on current orders in the fourth quarter of 2002, but for which shipment was deferred until early 2003 by agreement with Hospira, and a one-time license fee of approximately \$1.7 million. The balance of the decrease, representing only a 9.5% decrease, is primarily attributable to the timing of orders from customers.

DISTRIBUTION CHANNELS: Net sales to Hospira in the first quarter of 2004 were \$13,159,000, as compared to net sales of \$20,705,000 in the first quarter of 2003. (Hospira sales discussed in this paragraph do not include export sales.) Net sales of CLAVE products to Hospira, excluding custom CLAVE I.V. systems, in the first quarter of 2004 decreased approximately 48%, to \$8,994,000 due to a decrease in unit volume in part because Hospira reduced its inventory of CLAVE products and in parat because there was nothing comparable in 2004 to this deferment of approximately \$4.0 million of CLAVE orders to the first quarter of 2003. We do not believe Hospira's unit sales to their customers has declined. Sales to Hospira under the SetSource program were \$2,744,000, as compared with approximately \$2,080,000 in the first quarter of 2003. We expect increases in CLAVE unit and dollar sales volume with Hospira for the full year 2004 as compared with 2003, as well as a significant increase in SetSource unit and sales volume as we continue to grow this market. Net sales of CLC2000 increased approximately 22% to \$512,000 on increased unit volume. We expect sales of the CLC2000 to Hospira will increase in the future. Net sales of the Rhino were down 13% to approximately \$414,000; sales of Rhino started to decline in early 2001, and we expect them to decline in the future as the market shifts to one piece, swabbable, needleless technology. There is no assurance as to the amount of any future sales increases to Hospira.

Net sales to independent domestic distributors decreased approximately 10% from \$6,378,000 in the first quarter of 2003 to \$5,766,000 in 2004; this decrease in net sales was generally due to the timing of orders and their fulfillment, as unit volume sold by distributors showed an increase in the first quarter of 2004 as compared with the first quarter of 2003. This decrease in sales to independent distributors is attributed to a \$608,000, or 44% decrease in CLAVE product sales to \$785,000 and a \$261,000, or 17%, decrease in sales of Punctur-Guard products, and a decrease in sales of CLC2000 and the Lopez Valve of 48% and 21%, respectively, on lower unit volume. These decreases were partially offset by a 20% increase in our custom I.V. system sales from approximately \$2,545,000 to approximately \$3,060,000 (this includes all custom I.V. systems, including custom I.V. systems that include CLAVE connectors). The increase in sales of custom I.V. systems was attributable to an increase in unit volume, and we expect increased volume of custom I.V. systems in the future as we continue to penetrate this market. As part of our program to increase sales of custom I.V. systems, we have been encouraging customers to purchase custom I.V. systems that include CLAVE connectors, rather than purchasing only the CLAVE connectors. This has contributed to a drop in CLAVE product sales and an increase in custom I.V. systems including one or more CLAVEs. Sales of custom I.V. systems including one or more CLAVE connectors and CLAVE products combined were \$2,938,000 in the first quarter of 2003 as compared with \$2,855,000 in the first quarter of 2004. The decrease in Punctur-Guard products was due to pricing concessions on our Punctur-Guard line of products to achieve wider distribution. There is no assurance as to the amount of any future sales increases to the independent domestic distributors.

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with \$1,210,000 in the first quarter of 2003. The increase was primarily due to a 94% increase in CLAVE products on increased unit volume. In 2003, we experienced a slowing of distributor orders while they reduced CLAVE inventory levels. Orders in most areas of the world have returned to more normal levels, and this and expansion of our business accounted for the increase in CLAVE sales. We expect increases in foreign sales in the future in response to increased sales and marketing efforts including additional business development managers. Also, we believe we will see a positive impact beginning late in 2004 or 2005 from our recent amendments to the Hospira contracts. There is no assurance that those expectations will be realized.

PRODUCT AND OTHER REVENUE: Net sales of CLAVE products (excluding custom CLAVE I.V. systems) decreased to \$11,136,000 in the first quarter of 2004 from \$19,527,000 in the first quarter of 2003, or 43%. Net sales of CLAVE products including custom I.V. systems with CLAVE decreased from \$22,575,000 in the first quarter of 2003 to \$15,445,000 in the first quarter of 2004, or 32%. This decrease was due primarily to a decrease in unit shipments of CLAVE products to Hospira and our domestic distributors, offset by an increase in unit shipments to our international distributors. The aggregate average net selling price of CLAVE products in the first quarter of 2004 changed little from 2003 except for a decrease in selling prices to specialty distributors, and we do not expect any more than minimal decreases for the balance of the year. We expect growth in CLAVE unit and dollar sales volume in 2004 because of the growth that we expect in all of our distribution channels. However, there is no assurance that the expectations will be realized.

Net sales of custom and generic I.V. systems were \$6,134,000 in the first quarter of 2004 compared to \$4,894,000 in the first quarter of 2003, a \$1,240,000, or 25%, increase. The SetSource program with Hospira accounted for about 54% of the increase, with most of the balance in sales to independent domestic and international distributors. Unit volume accounted for the majority of the increase.

We acquired the Punctur-Guard product line and technology with the purchase of Bio-Plexus on October 31, 2002. After our acquisition of Bio-Plexus on October 31, 2002, we made significant improvements to the Punctur-Guard products and manufacturing processes. We did not actively promote sales of those products until completion of those product improvements. We completed improvements on the Winged Set products and re-launched them on March 1, 2003. We completed improvements on the BCN and started selling the improved product in late September 2003. Sales of Punctur-Guard products were \$1,468,000 in the first quarter of 2004 compared to \$1,548,000 for the first quarter of 2003. The reduction in sales was because of pricing concessions to achieve wider distribution. We expect sales of these products to increase in the future, but we give no assurance that such increases will be achieved.

Net sales of the CLC2000 were \$943,000 in the first quarter of 2004, a \$223,000 or 19% decrease over the first quarter of 2003 principally because of a decrease in sales to independent domestic and international distributors, partially offset by an increase in sales to Hospira. We expect sales of the CLC2000 to increase moderately in 2004 and later years, but there is no assurance as to the amount or timing of future CLC2000 sales.

Other revenue consists of license, royalty and revenue share income. The principal ongoing components are royalties received for other companies' use of Punctur-Guard technology, SafeLine revenue share payments from B. Braun and payments under another license of approximately \$235,000 per quarter for four years starting in the first quarter of 2004. In the first quarter of 2003, we received payment for a fully paid up license to use certain of our patents of \$1,666,000; the absence of a similar payment in 2004, partially offset by increases in other payments, led to the \$1,077,000 decrease on Other Income. 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.

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GROSS MARGIN for the first quarter of 2004, calculated on net sales and excluding other revenue, was 54% as compared with 55% for the first quarter of 2003. The decrease was because of the effect of our Punctur-Guard operations and the new facility in Italy. Punctur-Guard and the new facility in Italy reduced the gross margin by 5 percentage points, otherwise the Company, excluding these recent acquisitions, had a gross margin of 59%. We are working to improve gross margins on the Punctur-Guard products; improvement will depend on increased

sales and full conversion of this product line to our manufacturing techniques. We anticipate that those improvements will result in a modest increase in the gross margin in 2004, but we do not expect it to reach our "benchmark" level of 57% in 2004. We give no assurance as to the amount or timing of future improvements to our gross margins.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES ("SG&A") in the first quarter of 2004 decreased by \$432,000, or 7%, to \$5,655,000, and were 25% of revenue as compared with 20% in 2003 on higher revenue. The decrease in costs was primarily due to the elimination of general and administrative costs related to Bio-Plexus and a reduction in litigation costs, partially offset by increased corporate administrative costs and administrative costs in our new operation in Italy. Selling costs were flat compared to the first quarter of 2003 but we expect to add sales personnel as 2004 progresses, and those personnel and related costs will cause a modest increase in total SG&A costs for 2004. However, actual costs may differ from our expectations.

RESEARCH AND DEVELOPMENT EXPENSES ("R&D") in total were relatively unchanged in the first quarter of 2004 as compared with the first quarter of 2003. Spending was principally on new product development, with a smaller amount being spent on product improvements to Punctur-Guard. Spending on software development decreased as principal development projects reached completion. We estimate that R&D costs will increase during 2004 to support on-going new product development and various product and process improvements. However, R&D costs could differ from these estimates and the R&D may not be completed as expected.

We plan to launch, in limited markets, a new connector in 2004. We have applied to the Food & Drug Administration ("FDA") under Section 510(k) of the Federal Food, Drug and Cosmetics Act for approval to market this new connector. We also expect to launch a new product for the diabetes market for which we have already received marketing approval from the FDA under section 510(k) and which we expect to introduce within the next six months. We are currently developing a new integral check valve for use with all standard and custom I.V. administration sets, which we expect to introduce in the next six months. There is no assurance that the FDA will grant any required marketing clearance, that we will launch any of these new products, or that they will achieve sales if and when we commence marketing them.

INCOME FROM OPERATIONS decreased \$4,388,000 or 43% and was 29% of total revenue in the first quarter of 2004 as compared with 36% in the first quarter of 2003. The decline in income from operations as a percentage of revenue was because of a decline in revenue of 28%, a decrease in the gross profit as a percentage of sales, partially offset by an 8% decrease in operating expenses.

INVESTMENT INCOME increased by \$14,000 in the first quarter of 2004 as compared with the first quarter of 2003 because of a small increase in invested funds (including finance loans) partially offset by a slight decease in overall yield.

INCOME TAXES were accrued at an effective tax rate of 37.5% in the first quarter of 2004, as compared with 38.5% in the first quarter of 2003. The decrease is principally because of savings in state income taxes due to effective state tax planning. We expect our effective tax rate will be approximately 37.5% for the entire year 2004.

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NET INCOME decreased 41% to \$4,140,000 in the first quarter of 2004 as compared with \$7,070,000 in the first quarter of 2003. While revenues decreased 28%, gross profit decreased 30%. Operating expenses decreased less than that, 8%, but because that decrease was less than the percentage decrease in gross margin, income from operations decreased 43%. The slight increase in investment income and a decrease in the effective income tax rate resulted in an overall decrease of 41%. Net income per share - diluted decreased \$0.19 or 40%, in the first quarter of 2004 over the first quarter of 2003. The percentage decrease in earnings per share was less than that of net income because there were fewer shares outstanding due to our stock repurchase of common shares with approximately the same number of dilutive shares during each quarter.

LIQUIDITY AND CAPITAL RESOURCES

\$5,262,000 to \$108,194,000 from \$102,932,000 at December 31, 2003. The increase was principally due to cash generated by operations, cash received from employee equity plans and a reduction in finance loans which was partially offset by investment in property and equipment. Our cash and cash equivalents and investment securities position increased during the three months ended March 31, 2004 by \$12,611,000 to \$85,748,000 from \$\$73,137,000 at December 31, 2003. This is because the aggregate of cash provided by operating activities (including tax benefits from exercise of stock options) of \$12,850,000, cash provided by the company's employee equity plans of \$543,000 and net receipts of \$628,000 under finance loans exceeded the purchase of property and equipment of \$1,410,000.

OPERATING ACTIVITIES: Our cash provided by operating activities tends to increase over time because of increases in our net income. However, it is subject to fluctuations, principally from changes in accounts receivable, inventories, current liabilities and tax benefits from exercise of stock options.

Normally the substantial majority of our accounts receivable are current or no more than thirty days past due. In recent years, the majority of each quarter's sales have been in that last half of the quarter with the result that the amount of accounts receivable reported as of the end of each quarter tend to be higher than the amounts at other times during a quarter.

Accounts receivable decreased from \$24,943,000 at December 31, 2003 to \$17,798,000 at March 31, 2004, or 29%; the decrease was principally because revenue in the first quarter of 2004 was 25% less than revenue in the fourth quarter of 2003.

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. However, in order to avoid production inefficiencies caused by fluctuating production levels, we have begun to level out our production volumes and build finished goods of our standard (non-custom) products to meet future orders. This may cause fluctuations in our quarterly inventory levels.

Inventories increased \$2,512,000, or 74%, from \$3,398,000 at December 31, 2003 to \$5,910,000 at March 31, 2004 principally because of our decision to increase our production volumes beyond current orders and increase our finished goods inventories in anticipation of higher revenues for the second half of 2004. It caused our finished good inventory to increase in the first quarter of 2004, and we anticipate an additional increase in the second quarter of 2004, but we expect finished good inventories to return to historical levels by the end of 2004.

Our current liabilities tend to fluctuate based on the timing of when liabilities are incurred and paid. The largest single source of fluctuation has been income tax liabilities, and those fluctuations are generally a function of the timing and amount of estimated tax payments in relation to actual tax liabilities.

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The tax benefits from the exercise of stock options, which we believe is more properly related to the sale of our stock which is a financing activity, fluctuates based principally on when employees choose to exercise their vested stock options. Tax benefits from the exercise of stock options in the first quarter of 2004 were \$122,000 on the exercise of options to acquire 18,211 shares as compared to \$3,000 in the first quarter of 2003 on the exercise of options to acquire 500 shares.

We expect that sales of our products will grow in the second half of 2004. If sales increase, accounts receivable and inventories are expected to increase as well. As a result of these and other factors, we expect the use of working capital to fund our operations to continue to increase.

INVESTING ACTIVITIES: During the first quarter of 2004 we used cash of \$11,382,000 in investing activities, comprised primarily of the purchase of liquid investments of \$10,600,000 utilizing cash generated by operations in excess of other investing needs.

Capital expenditures were at a relatively high rate in 2003, principally because of our expansion in Mexico, including an electron-beam

sterilizer, and investment in molds, molding equipment, automated assembly equipment, computers and software.

Upon completing an evaluation of the design and capacity of our manufacturing facilities, we estimate that our current facilities will be adequate through 2004, but that production after 2004 may require additional clean room facilities for molding and automated assembly. We expect to decide in the future how to meet the need for any additional facilities and the location of additional clean room facilities for molding and automated assembly.

Capital expenditures in the first quarter 2004 were \$1,410,000 principally to maintain capacity. We currently estimate that capital expenditures for the remainder 2004 will be approximately \$4,600,000, bringing the year total to approximately \$6,000,000 and will be paid from cash we generate from operations. We expect the \$6 million will be spent on molds, molding equipment and automated assembly equipment, computers and software to maintain current capacity including targeted growth for 2004. Of those amounts, approximately \$500,000 was committed under contracts at March 31, 2004, and we expect to commit the balance in 2004. 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 are made only to credit-worthy healthcare entities and are fully secured by real and personal property. At March 31, 2004, it had \$8,279,000 in loans outstanding. Scheduled maturities are: remainder of 2004 \$3,413,000; 2005 \$1,228,000; 2006 \$1,191,000; 2007 \$1,168,000 and 2008 \$1,279,000. Weighted average maturity (principal and interest) at March 31, 2004 was 1.5 years and the weighted average interest rate was 5.5%. In October 2003, we discontinued new lending activities. We will honor existing lending commitments. The maximum that can be borrowed under all commitments, including amounts outstanding, was approximately \$8,500,000 at March 31, 2004. This is down from almost \$13,000,000 at the end of the fourth quarter 2003 primarily due to the expiration of lending agreements.

FINANCING ACTIVITIES: Cash provided by stock options and the employee stock purchase plan, including tax benefits, was \$665,000 in the first quarter of 2004 as compared to \$284,000 in the first quarter of 2003: options were exercised on 18,211 shares in the first quarter of 2004 as compared with 500 in the first quarter of 2003.

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We spent \$8,649,000 to acquire shares of our common stock in the first quarter of 2003, but did not acquire any shares in the first quarter of 2004. We may purchase our shares in the future. However, future acquisitions, if any, will depend on market conditions and other factors.

We have a large 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 potentially 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.

#### 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 the following contractual obligations of approximately the following amounts. These amounts exclude purchase orders for goods and services for current delivery; we do not have any long-term purchase commitments for such items.

Payments due: less than 1 year from

March 31, 2004

Property and equipment

\$500,000

Total

\$500,000 ======

#### FORWARD LOOKING STATEMENTS

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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:

- o future operating results and various elements of operating results, including future expenditures on sales and marketing and product development, sales and unit volumes of products, future license, royalty and revenue share income, production costs, gross margins, SG&A, and R&D expense, new product introductions, changes in working capital items such as receivables and inventory, selling prices and income taxes;
- o factors affecting operating results, such as shipments to specific customers, expansion in international markets, selling prices, the market shift to needleless technology, 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, unit manufacturing

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costs, acquisition and use of production equipment and expansion of facilities and assembly capacity, expansion of markets and the need for additional facilities, business seasonality and fluctuations in quarterly results, customer ordering patterns and warranty claims, rebates and returns;

- o new or extended contracts with manufacturers and buying organizations, and dependence on a small number of customers, effect of Abbott's spin-off of its Hospital Products Division, effect of contract amendments with Hospira, ability to replace distributors, and the outcome of our strategic initiatives;
- o regulatory approval and outcome of litigation; competitive and market factors, including continuing development of competing products by other manufacturers, consolidation of the healthcare provider market and downward pressure on selling prices; and working capital requirements, changes in accounts receivable and inventories, current liabilities, 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 our Current Report on Form 8-K to the Securities and Exchange Commission dated February 15, 2002 which is incorporated by reference.

Third, our actual future operating results are subject to other important factors that we cannot predict or control, including among others the following:

- o general economic and business conditions;
- o the effect of price and safety considerations on the healthcare

industry:

- o competitive factors, such as product innovation, new technologies,
  - marketing and distribution strength and price erosion;
- o unanticipated market shifts and trends;
- o the impact of legislation affecting government reimbursement of healthcare costs;
- o changes by our major customers and independent distributors in their strategies that might affect their efforts to market our products;
- o unanticipated production problems; and
- o the availability of patent protection and the cost of enforcing and of defending patent claims.

We disclaim any obligation to update the statements or to announce publicly the result of any revision to any of the statements contained herein to reflect future events or developments.

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We have a portfolio of corporate preferred stocks and federal-tax-exempt state and municipal government debt securities. The securities are all "investment grade" and we believe that we have virtually no exposure to credit risk. Dividend and interest rates reset at auction for most of the securities from between seven and forty-nine day intervals, with some longer but none beyond twelve months, so we have very little market risk, that is, risk that the fair value of the security will change because of changes in market interest rates; they are readily saleable at par at auction dates, and can normally be sold at par between auction dates.

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Our future earnings are subject to potential increase or decrease because of changes in short-term interest rates. Generally, each one-percentage point change in the discount rate will cause our overall yield to change by two-thirds to three-quarters of a percentage point, depending upon the relative mix of federal-tax-exempt securities and corporate preferred stocks in the portfolio and market conditions specific to the securities in which we invest.

At March 31, 2004 we had outstanding commercial loans of approximately \$8,297,000. Loans are 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 five 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.

We do not have any significant foreign currency risk. Sales to foreign distributors are all denominated in U.S. dollars. Cash and receivables in entities outside the United States, principally in Mexico and Italy, which are denominated in foreign currency are insignificant and are generally offset by accounts payable in the same foreign currency.

#### ITEM 4. CONTROLS AND PROCEDURES

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Our principal executive officer and principal financial officer have concluded, based on their evaluation of our disclosure controls and procedures (as defined in Regulations 13a-14(c) and 15a-14(c) under the Securities Exchange Act of 1934) as of the end of the period covered by this report, that our disclosure controls and procedures are effective to ensure that the information we are required to disclose in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure and that such information is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities Exchange Commission. There were no significant changes in our internal controls or in other factors that could significantly affect our internal controls subsequent to the date of the principal executive officer's and principal financial officer's evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

#### PART II OTHER INFORMATION

#### ITEM 1. LEGAL PROCEEDINGS

In an action filed August 21, 2001 entitled ICU Medical, Inc. v. B Braun Medical, Inc. pending in the United States District Court for the Northern District of California, we allege that B. Braun infringes ICU's patent by the manufacture and sale of its UltraSite medical connector. On December 30, 2003, we were awarded an additional patent and on December 30, 2003 we filed an additional action against B. Braun for patent infringement and moved to amend the 2001 action to include that allegation. The 2001 action has since been amended to include our claim of infringement of the additional patent. We seek monetary damages and injunctive relief and intend to vigorously pursue this matter. The outcome of this matter cannot be determined at this time

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

ITEM 2. CHANGES IN SECURITIES

\_\_\_\_\_

Inapplicable

ITEM 3. DEFAULT UPON SENIOR SECURITIES

\_\_\_\_\_

Inapplicable

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

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Inapplicable

ITEM 5. OTHER INFORMATION

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None

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

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#### (a) Exhibits:

Exhibit 31: Certifications of Chief Executive Officer and 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

#### (b) Reports on Form 8-K:

The Registrant filed the following Report on Form 8-K during the quarter for which this Report is filed:

Items 5 and 7 - January 15, 2004

Items 7 and 12 - February 2, 2004

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#### 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

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Francis J. O'Brien Chief Financial Officer (Principal Financial Officer) Date: May 5, 2004

/s/ Scott E. Lamb

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Scott E. Lamb Controller

(Principal Accounting Officer)

Date: May 5, 2004

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

- I, the Chief Executive Officer, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of ICU Medical, Inc.:
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) [paragraph omitted pursuant to SEC Release Nos. 33-8238 and 34-47986]
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors:
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 5, 2004

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

- I, the Chief Financial Officer, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of ICU Medical, Inc.:
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) [paragraph omitted pursuant to SEC Release Nos. 33-8238 and 34-47986]
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors:
  - a) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 5, 2004

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

In connection with the Quarterly Report of ICU Medical, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, George A. Lopez, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO

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

In connection with the Quarterly Report of ICU Medical, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Francis J. O'Brien, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

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

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