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

WASHINGTON, D.C. 20549 [X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE QUARTERLY PERIOD ENDED: JUNE 30, 2004 OR TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF [] THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM: _____ TO ____ COMMISSION FILE NO.: 0-19974 ICU MEDICAL, INC. (EXACT NAME OF REGISTRANT AS PROVIDED IN CHARTER) DELAWARE 33-0022692 (State or Other Jurisdiction of (I.R.S. Employer Incorporation or Organization) Identification No.) 951 CALLE AMANECER, SAN CLEMENTE, CALIFORNIA 92673 ______ (Address of Principal Executive Offices) (Zip Code) (949) 366-2183 -----(Registrant's Telephone No. Including Area Code) Indicate by check mark whether the registrant (1) has filed all reports 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 [XXX] No [] Indicate the number of shares outstanding in each of the issuer's classes of common stock, as of the latest practicable date: CLASS OUTSTANDING AT JULY 30, 2004 Common 13,728,789 ICU MEDICAL, INC. INDEX PART I - FINANCIAL INFORMATION PAGE NUMBER ITEM 1. FINANCIAL STATEMENTS (UNAUDITED) Condensed Consolidated Balance Sheets, June 30, 2004 and December 31, 2003 Condensed Consolidated Statements of Income for the three and six months ended June 30, 2004 and 2003 4 Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2004 and 2003 5

Condensed Consolidated Statements of Comprehensive Income for the six months ended June 30, 2004 and 2003 $$	6
Notes to Condensed Consolidated Financial Statements	7
ITEM 2.	
Management's Discussion and Analysis of Financial Condition and Results of Operations	10
ITEM 3. Quantitative and Qualitative Disclosures About Market Risk	24
ITEM 4. Controls and Procedures	24
PART II - OTHER INFORMATION	25
SIGNATURES	27

2

ICU MEDICAL, INC. Condensed Consolidated Balance Sheets June 30, 2004 and December 31, 2003 (all dollar amounts in thousands except per share data) (unaudited)

ASSETS

ASSETS		
	6/30/04	12/31/03
CURRENT ASSETS:		
Cash and cash equivalents		\$ 1,787
Liquid investments	88,650 	71,350
Cash, cash equivalents and liquid investments	91,910	73,137
Accounts receivable, net of allowance for doubtful accounts of \$687		
and \$742 as of June 30, 2004 and December 31, 2003, respectively	16,217	24,943
Finance loans receivable - current portion	2,848	4,142
Inventories	9,404	3,398
Prepaid income taxes		1,662
Prepaid expenses and other current assets	1,139	1,927
Deferred income taxes - current portion	2,002	2,008
Total current assets	125,652	
PROPERTY AND EQUIPMENT, at cost: LessAccumulated depreciation		71,615 (30,574)
	39,814	41,041
FINANCE LOANS RECEIVABLE - non-current portion	4,101	4,765
DEFERRED INCOME TAXES - non-current portion	2,738	2,680
INTANGIBLE ASSETS - net	4,011	4,166
OTHER ASSETS	405	419
	\$ 176,721	\$ 164,288
	=======	=======
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 2,727	\$ 3,051
Accrued liabilities	5,769	5,234
Total current liabilities	8,496	8,285

STOCKHOLDERS' EQUITY:

CHIODDENO EQUIII.		
Convertible preferred stock, \$1.00 par value		
Authorized 500,000 shares, issued and outstanding none		
Common stock, \$0.10 par value-		
Authorized 80,000,000 shares, issued 14,158,612 shares		
at June 30, 2004 and December 31, 2003	1,416	1,416
Additional paid-in capital	61,847	63,535
Treasury stock, at cost 235,275 and 471,390 shares at		
June 30, 2004 and December 31, 2003, respectively	(5,655)	(12,116)
Retained earnings	110,541	102,991
Accumulated other comprehensive income	76	177
Total stockholders' equity	168,225	156,003
	\$ 176,721	\$ 164,288
	========	=======

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

3

ICU MEDICAL, INC. Condensed Consolidated Statements of Income For the Three Months and Six Months Ended June 30, 2004 and June 30, 2003 (all dollar amounts in thousands except per share data) (unaudited)

		Months Ended	For the Six Months Ended					
	6/30/04							6/30/03
REVENUES: Net sales Other	\$ 21,001 663	\$ 19,864 1,419	\$ 42,272 1,626	\$ 48,600 3,459				
TOTAL REVENUE	21,664	21,283	43,898	52,059				
COST OF GOODS SOLD	9,600	9,148	19,414	22,172				
Gross profit	12,064	12,135	24,484	29,887				
OPERATING EXPENSES: Selling, general and administrative Research and development	6,603 403	5,543 537	12,258 854	11,630 1,008				
Total operating expenses	7,006	6,080 	13,112	12,638				
Income from operations	5,058	6,055	11,372	17,249				
INVESTMENT INCOME	398	274	708	570				
Income before income taxes	5,456	6,329	12,080	17,819				
PROVISION FOR INCOME TAXES	2,046	2,430	4,530	6,850				
NET INCOME		\$ 3,899 		\$ 10,969				
NET INCOME PER SHARE Basic Diluted	\$ 0.25 \$ 0.23	\$ 0.28 \$ 0.26	\$ 0.55 \$ 0.50	\$ 0.79 \$ 0.72				
WEIGHTED AVERAGE NUMBER OF SHARES Basic Diluted	13,808,661 15,140,606	13,763,120 15,081,815	13,754,326 15,107,214					

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

4

ICU MEDICAL, INC. Condensed Consolidated Statements of Cash Flows For the Six Months Ended June 30, 2004 and June 30, 2003 (all dollar amounts in thousands) (unaudited)

	For the Six Months End		
		6/30/03	
CASH FLOWS FROM OPERATING ACTIVITIES: Net Income Adjustments to reconcile net income to net cash	\$ 7,550		
provided by operating activities Depreciation and amortization	3,742	3,416	
Net change in current operating assets and liabilities, net of effects of acquisitions	3,022	(4,383)	
	14,314	10,002	
Tax benefits from exercise of stock options	1,913	186	
Net cash provided by operating activities	16 , 227	10,188	
CASH FLOWS FROM INVESTING ACTIVITIES: Purchases of property and equipment Cash paid for acquisitions Advances under finance loans Proceeds from finance loan repayments Purchases of investments Proceeds from sale of investments Net cash used in investing activities	(2,272) (1,010) 2,968 (17,300) (17,614)	(5,346) (8,172)	
CASH FLOWS FROM FINANCING ACTIVITIES: Proceeds from exercise of stock options Proceeds from employee stock purchase plan Purchase of treasury stock	2,581 279 	473 271 (10,313)	
Net cash provided by (used in) financing activities	2,860	(9,569)	
NET INCREASE IN CASH AND CASH EQUIVALENTS	1,473	338	
CASH AND CASH EQUIVALENTS, beginning of the period	1,787	4,165 	
CASH AND CASH EQUIVALENTS, end of the period	\$ 3,260 =====	\$ 4,503 ======	

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

Condensed Consolidated Statements of Comprehensive Income For the Three Months and Six Months Ended June 30, 2004 and June 30, 2003 (all dollar amounts in thousands) (unaudited)

		Months Ended	For the Six Months Ended			
	6/30/04	6/30/03	6/30/04	6/30/03		
Net income	\$ 3,410	\$ 3,899	\$ 7,550	\$10,969		
Other comprehensive loss net of tax: Foreign currency translation adjustment	(38)		(101)			
Comprehensive income	\$ 3,372 ======	\$ 3,899 ======	\$ 7,449	\$10,969		

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

6

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.

NOTE 2: INVENTORIES consisted of the following:

	6/30/04	12/31/03		
Raw material Work in process Finished goods	\$ 4,356 729 4,319	\$ 2,699 340 359		
Total	\$ 9,404	\$ 3,398		
	=======	=======		

	6/30/04	
Land, building and building		
improvements	\$ 21 , 577	\$ 16 , 887
Machinery and equipment	29,938	26,429
Furniture and fixtures	7,262	6 , 572
Molds	12,111	11,480
Construction in process	3,076	10,247
Total	\$ 73,964	\$ 71,615

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. 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 2004 \$2,122,000; 2005 \$1,235,000; 2006 \$1,165,000;

7

2007 \$1,157,000 and 2008 \$1,270,000. Weighted average maturity (principal and interest) at June 30, 2004 was 1.5 years and the weighted average interest rate was 5.3%. In October 2003, the Company discontinued new lending activities; the Company will honor existing lending commitments. The maximum that can be borrowed under all commitments, including amounts outstanding, was approximately \$7,052,000 at June 30, 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 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 1,331,945 and 1,318,695 for the three months ended June 30, 2004 and June 30, 2003, respectively and 1,352,888 and 1,324,155 for the six months ended June 30, 2004 and 2003, respectively. Options that are antidilutive because their average exercise price exceeded the average market price of its common stock for the period approximated 600,000 and 500,000 for the three months ended June 30, 2004 and 2003 respectively and 570,000 and 400,000 for the six months ended June 30, 2004 and 2003, respectively.

NOTE 6: STOCK OPTIONS: The Company accounts for stock options granted to employees and directors under Accounting Principles Board ("APB") Opinion No. 25 "Accounting for Stock Issued to Employees" and related interpretations as permitted by SFAS No. 123 "Accounting for Stock-Based Compensation," and does not recognize compensation expense because the exercise price of the options equals the fair market value of the underlying shares at the date of grant. Under SFAS No. 123, the Company is required to present certain pro forma earnings information determined as if employee stock options were accounted for under the fair value method of that Statement. The fair value for options granted in the second guarter 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 its stock options differ substantially from those of traded stock options, and changes in the subjective assumptions can materially affect estimated fair values; therefore, in Management's opinion, existing option valuation models do not necessarily provide a reliable single measure of the fair value of its stock options. The following information is provided pursuant to SFAS No. 123, as amended. The pro forma adjustment reflects stock-based compensation cost calculated under the fair value method, net of related tax effects, calculated pursuant to SFAS No. 123.

	2004	2003 2004		2003
Net Income, as reported	\$3,410	\$3,899	\$7,550	\$10,969
Pro forma adjustment	1,653	1,317	2,673	2,659
Net Income, pro forma	\$1,757	\$2,582	\$4,877	\$ 8,310
	=========	========	========	========
Net Income per share				
Basic, as reported	\$0.25	\$0.28	\$0.55	\$0.79
Diluted, as reported	\$0.23	\$0.26	\$0.50	\$0.72
Basic, pro forma	\$0.13	\$0.19	\$0.36	\$0.61
Diluted, pro forma	\$0.12	\$0.18	\$0.33	\$0.56

8

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 and state tax credits.

NOTE 8: MAJOR CUSTOMERS: The Company had revenues equal to ten percent or greater of total net revenues from one customer, Hospira, Inc. (formerly a part of Abbott Laboratories), of 52% and 67% in the second quarters of 2004 and 2003, respectively, and of 56% and 68% in the first six months of 2004 and 2003, respectively.

NOTE 9: COMMITMENTS AND CONTINGENCIES: The Company is from time to time involved in various routine non-material legal proceedings, either as a defendant or plaintiff, most of which are routine litigation in the normal course of business. The Company believes that the resolution of the legal proceedings in which it is involved will not have a material effect on its financial position or results of operations.

In the normal course of business, the Company has made certain indemnities, including indemnities to its officers and directors, to the maximum extent permitted under Delaware law and intellectual property indemnities to customers in connection with sales of its products. These indemnities do not provide a maximum amount. The Company has not recorded any liability for these in its financial statements and does not expect to incur any.

NOTE 10: ACQUISITIONS: In June 2003, the Company 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 its consolidated financial statements since June 30, 2003. The effect of this acquisition on its financial statements is immaterial.

9

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.

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 and amounts have been insignificant. Customers, with certain exceptions, do not retain any right of return and there is no price protection with respect to unsold products; returns from customers with return rights have not been significant. We accrue rebates as a reduction in revenue based on contractual commitments and historical experience. Adjustments of estimates of warranty claims, rebates or returns, which have not been, and are not expected to be material, affect current operating results when they are determined.

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

Inventories are stated at the lower of cost 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

10

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.

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 and potentially substantial increases in competition 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 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.

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.

11

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.

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	Q2-03	Q2-04	YTD Q2-03	YTD Q2-04
CLAVE	74%	67%	59%	54%	50%	60%	50%
Custom and Generic I.V. Systems	13%	17%	22%	22%	32%	17%	31%
Punctur-Guard (R)	-	1%	7%	8%	6%	6%	6%
CLC2000 (R)	3%	4%	4%	3%	4%	4%	4%
Other Products	10%	7%	4%	6%	5%	6%	6%
License, royalty and revenue share	-	4%	4%	7%	3%	7%	3%
Total	100%	100%	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 70% of net revenue in the second quarter of 2003 and 72% of net revenue in the second quarter of 2004, and 72% and 70% year-to-date June 30, 2003 and 2004, respectively.

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

12

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.

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

We believe the success of the CLAVE has motivated, and will continue to motivate others to develop one-piece, swabbable, needleless connectors that may incorporate many of the same functional and physical characteristics as the CLAVE. We are aware of a number of such products. We have patents covering the technology embodied in the CLAVE and intend to enforce those patents as appropriate. If we are not successful in enforcing our patents, competition from such products could adversely affect our market share and prices for our CLAVE products. In response to competitive pressure, we have been reducing prices to protect and expand our market, although overall pricing has been stable recently. The price reductions to date have been more than offset by increased volume. 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 \$13.3 million of net sales in the first six months of 2004, including net sales under the Hospira SetSource program of approximately \$5.8 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 six months of 2004 were \$2.7 million. There is no assurance that either one of these initiatives will continue to succeed.

13

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.

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

CHANNEL	2001	2002	2003	Q2-03	Q2-04	YTD Q2-03	YTD Q2-04
Medical product manufacturers	72%	73%	71%	73%	56%	75%	60%
Independent domestic distributors	20%	19%	23%	24%	31%	22%	32%
International	8%	8%	6%	3%	13%	3%	8%
Total	100%	100%	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 second quarter and first half 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 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							
	Year	Quarter ended June 30,		Six months	ended Ju	ine 30,			
	2003	2003	2004	CHANGE	2003	2004	CHANGE		
Revenue									
Net sales	96%	93%	97%	6%	93%	96%	-13%		
Other	4%	7%	3%	-53%	7%	4 %	-53%		
Total revenues	100%	100%	100%	2%	100%	100%	-16%		

Cost of sales	47%	43%	44%	5%	43%	44%	-12%
Gross Profit							
Percentage of net sales	53%	54%	54%	0%	54%	54%	-11%
Percentage of all revenues	55%	57%	56%	-1%	57%	56%	-18%
Selling, general and administrative expenses	21%	26%	30%	19%	22%	28%	5%
Research and development expenses	2%	3%	2%	-25%	2%	2 %	-15%
Total operating expenses	23%	29%	32%	15%	24%	30%	4%
Income from operations	32%	28%	23%	-17%	33%	26%	-34%
Investment income	1%	1%	2%	45%	1%	2%	24%
Income before income taxes	33%	29%	25%	-14%	34%	28%	-32%
Income taxes	12%	11%	9%	-16%	13%	11%	-34%
Net income	21%	18%	16%	-13%	21%	17%	-31%

14

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 JUNE 30, 2004 COMPARED TO THE QUARTER ENDED JUNE 30, 2003

Net revenues increased \$381,000, or approximately 2%, to \$21,664,000 in the second quarter of 2004, compared to \$21,283,000 during the same period last year.

DISTRIBUTION CHANNELS: Net sales to Hospira in the second quarter of 2004 were \$11,321,000, as compared with net sales of \$14,046,000 in the second quarter of 2003. (Hospira sales discussed in this paragraph do not include export and foreign sales.) Net sales of CLAVE Products to Hospira, excluding custom CLAVE I.V. systems, decreased by \$2,969,000 in the second quarter of 2004 from \$10,355,000 in the second quarter of 2003 because Hospira has been reducing its inventory of CLAVE products. We believe Hospira's unit sales to their customers have increased in this period. Sales to Hospira under the SetSource program approximated \$3,054,000 in the second quarter of 2004 as compared with approximately \$2,369,000 in the second quarter of 2003, a 29% increase almost entirely because of increased unit volume. We expect a substantial decrease in CLAVE unit and dollar sales volume with Hospira through the balance of 2004 as compared to 2003 as Hospira continues to reduce its inventory. We expect a significant increase in SetSource unit and sales volume through the remainder of 2004 as compared to 2003 as we continue to grow this market. Net sales of CLC2000 decreased approximately 10% to \$409,000 on decreased unit volume. We expect sales of the CLC2000 to Hospira will increase in the future. Net sales of the Rhino were down 60% to approximately \$221,000; 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 increased approximately 27% from \$5,040,000 in the second quarter of 2003 to \$6,411,000 in 2004. This increase in sales to independent distributors is attributed principally to a \$773,000, or 95%, increase in CLAVE product sales to \$1,586,000 and a \$921,000, or 43%, increase in our custom I.V. system sales from approximately \$2,138,000 to approximately \$3,059,000 (this includes all custom I.V. systems, including custom I.V. systems that include CLAVE connectors). The increase in CLAVE product sales was due to an increase in demand through this channel. 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. These increases were partially offset by a decrease in sales of Punctur-Guard products due to a small decrease in unit sales and to pricing concessions on our Punctur-Guard line of products to achieve wider distribution; we anticipate increased unit and dollar volumes in the second half of 2004 through new outpatient provider contracts. 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 continues to contribute to the increase in sales of custom I.V. systems including one or more CLAVEs. Sales of custom I.V. systems including one or more CLAVE products combined were \$2,348,000 in the second quarter of 2003 as compared with \$3,550,000 in the second quarter of 2004. There is no assurance as to the amount of any future sales increases to the independent domestic distributors.

Net sales to international distributors (excluding Canada) were \$2,766,000 in the second quarter of 2004, as compared with \$611,000 in the second quarter of 2003. The increase was principally due to a \$1,493,000 increase in CLAVE product sales and \$526,000 increase in sales of custom I.V. systems. In 2003, we experienced a slowing of distributor orders while they

15

reduced 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. 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. 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 \$10,820,000 in the second quarter of 2004 from \$11,527,000 in the second quarter of 2003. This decrease was due primarily to a decrease in unit shipments of CLAVE products to Hospira, partially offset by an increase in unit shipments to our domestic and international distributors. The aggregate average net selling price of CLAVE products in the second quarter of 2004 changed little from 2003 except for a decrease in selling prices to domestic specialty distributors, and we do not expect any more than minimal decreases for the balance of the year. Sales of custom I.V. systems including one or more CLAVE connectors and CLAVE products combined were \$15,880,000 in the second quarter of 2004 as compared with \$14,976,000 in the second guarter of 2003. We expect a decrease in CLAVE (not including custom sets with CLAVE) unit and dollar volume in the second half of 2004 as compared with the second half of 2003 because of the expected reduction in inventory of CLAVE only products by Hospira, partially offset by increased unit and dollar volume with our domestic and our international distributors. However, there is no assurance that the expectations will be realized.

Net sales of custom I.V. systems were \$7,040,000 in the second quarter of 2004 compared to \$4,620,000 in the second quarter of 2003, a \$2,421,000, or a 52% increase. The SetSource program with Hospira accounted for about \$685,000 of the increase and domestic and international distributors accounted for about \$1,605,000. Unit volume accounted for the majority of the increase.

The 1o2 Valve is the first one-way or two-way drug delivery system in the marketplace. In the third quarter of 2002, we began using automated assembly equipment that will enable us to better meet demand for the 1o2 Valve. We are selling the 1o2 Valve only as a part of our custom I.V. systems, and sales, which are included in that category, were approximately \$1,283,000 in the second quarter of 2004, as compared with approximately \$740,000 in the second quarter of 2003.

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 (excluding royalties) were \$1,183,000 in the second quarter of 2004 as compared to \$1,733,000 in the second quarter of 2003 due to a 6% decrease in unit sales and to pricing concessions on our Punctur-Guard line of products to achieve wider distribution; we anticipate increased unit and dollar volumes in the second half of 2004 through new outpatient provider contracts, but we give no assurance that such increases will be achieved.

Net sales of the CLC2000 were \$943,000 in the second quarter of 2004, a \$220,000, or 30%, increase from the second quarter of 2003 due to an expansion of our business in this product both domestically and internationally. We expect sales of the CLC2000 to increase moderately in the second half 2004 and later years, but there is no assurance as to the amount or timing of future CLC2000 sales

16

Other revenue consists of non-product revenue. 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. These ongoing components account for all of our other revenue in 2004. In the second quarter of 2003, we did not receive the \$235,000 payment, but did receive a \$988,000 initial payment on a license to use certain of our products. 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 second quarter of 2004, calculated on net sales and excluding other revenue, was 54%, the same as for the second quarter of 2003. Gross margins were depressed by about 5 percentage points because of the effect of our Punctur-Guard operations and the new facility in Italy; the remaining operations in San Clemente and Ensenada achieved a gross margin of 59% due to product mix and manufacturing efficiencies. We believe that production in San Clemente in the second half of 2004 will be less than originally anticipated because of the reduced purchases from Hospira as they reduce inventory levels. This reduced production level may have an adverse impact on our gross margins. 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 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 second quarter of 2004 increased 1,060,000, or 19%, to \$6,603,000, and was approximately 30% of revenue in 2004 as compared with 26% of revenue in 2003. The increase in costs was primarily due to increased corporate administrative costs, integration and administrative costs of our operation in Italy, partially offset by elimination of administrative costs related to Bio-Plexus and lower patent litigation costs. Corporate administrative costs have increased principally because of personnel additions, information technology costs and costs related to Sarbanes-Oxley compliance. We expect patent litigation costs will significantly increase in the second half of 2004 as we enforce our patents against B. Braun and Alaris. Sales and marketing costs increased slightly because of the addition of personnel. We expect increased administrative costs as the year progresses and increased selling costs as we add more sales personnel.

RESEARCH AND DEVELOPMENT EXPENSES ("R&D") decreased in the second quarter of 2004 by \$134,000 to \$403,000, and were approximately 2% of revenues in the second quarter of 2004 as compared with 2.5% in the second 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 neared 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 later in 2004. 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 within the third quarter of 2004. 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.

revenues in the second quarter of 2004, as compared with 28% in the second quarter of 2003. The decline in income from operations as a percentage of revenue was because operating expenses increased at a faster rate than revenues and gross margin.

INVESTMENT INCOME increased in the second quarter of 2004 as compared with the second quarter of 2003 by \$124,000, because of an increase in invested funds (including finance loans) and slight increase in overall yield.

17

INCOME TAXES were accrued at an effective tax rate of 37.5% in the second quarter of 2004, as compared with 38.4% in the second quarter of 2003. The decrease is principally because of savings in state income taxes due to organizational changes. We expect our effective tax rate will be approximately 37.5% for the entire year 2004.

NET INCOME decreased 13% to \$3,410,000 in the second quarter of 2004 as compared with \$3,899,000 in the comparable period last year. While revenues increased 2%, gross profit decreased 1%. Operating expenses increased 15%, which caused income from operations to decrease 17%. The slight increase in investment income and a decrease in the effective income tax rate resulted in an overall decrease of 13%. NET INCOME PER SHARE - DILUTED decreased \$0.03 or 13%, in the second quarter of 2004 as compared with the second quarter of 2003 on a comparable number of shares. There was approximately the same number of dilutive shares during each quarter.

SIX MONTHS ENDED JUNE 30, 2004 COMPARED TO THE SIX MONTHS ENDED JUNE 30, 2003

Net revenues decreased \$8,161,000, or approximately 16%, to \$43,898,000 in the first six months of 2004 compared to \$52,059,000 during the same period last year. Approximately \$5.7 million of the decrease is attributable to two items that occurred in the first half of 2003 but did not recur in 2004: 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 \$2.7 million. The balance of the decrease is principally attributable to reduced CLAVE purchases by Hospira, partially offset by increased sales in our independent domestic and international distributors and increases in recurring non-product revenue.

DISTRIBUTION CHANNELS: Net sales to Hospira in the first half of 2004 were \$24,480,000, as compared with net sales of \$34,751,000 in the first half of 2003. Net sales of CLAVE Products to Hospira, excluding custom CLAVE I.V. systems decreased to \$16,360,000 in the first half of 2004 from \$27,697,000 in the first half of 2003 principally due to a decrease in unit volume as Hospira reduced its inventory of CLAVE products and in part because there was nothing comparable in 2004 to the deferment of approximately \$4,000,000 of CLAVE orders to the first quarter of 2003. We believe Hospira's unit sales to their customers have increased. Sales to Hospira under the SetSource program approximated \$5,798,000 in the first half of 2004 as compared with \$4,448,000 in the first half of 2003 on increased unit volume.

Net sales to independent domestic distributors increased approximately \$760,000, or 7%, from \$11,418,200 in the first half of 2003 to \$12,178,000. Independent domestic distributors had a 7%, or \$165,000, increase in CLAVE product sales principally because of an increase in unit volume. Custom I.V. system sales increased 31% from approximately \$4,683,000 to approximately \$6,119,000 (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. These increases were partially offset by a \$668,000, or 21%, decrease in sales of Punctur-Guard products due to a decrease in unit sales and to pricing concessions on our Punctur-Guard line of products to achieve wider distribution; and, a decrease in sales of CLC2000 of 35% on lower unit volume. 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 continues to contribute to the increase in sales 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 \$5,287,000 in the first half of 2003 as compared with \$6,462,000 in the first half of 2004.

Net sales to international distributors (excluding Canada) were \$4,827,000 in the first half of 2004, as compared with \$1,820,000 in the first half of 2003. The increase was principally due to a \$2,120,000 increase in CLAVE product sales and an \$845,000 increase in custom I.V. set sales. 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,

1.8

and this and expansion of our business accounted for the increase in CLAVE sales. The increase in sales of custom I.V. systems was attributable to an increase in unit volume.

PRODUCT AND OTHER REVENUE: Net sales of CLAVE Products (excluding custom CLAVE I.V. systems) decreased from \$31,054,000 in the first half of 2003 to \$21,956,000 in the first half of 2004, or 29%. CLAVE product sales to Hospira decreased \$11,337,000, as Hospira reduced its inventory of CLAVE products. That decrease was partially offset by increases in CLAVE product sales to independent domestic and international distributors.

Net sales of custom and generic I.V. systems increased approximately \$3,902,000, or 41%, to \$13,415,000 in the first half of 2004 over the first half of 2003. The SetSource program with Hospira accounted for about \$1,350,000 of the increase, and domestic distributors accounted for \$1,436,000, and international distributors accounted for the remaining increase. Unit volume accounted for the majority of the increase. We are selling the 1o2 Valve only as a part of our custom I.V. systems, and sales, which are included in that category, were approximately \$2,236,000 in the first half of 2004, as compared with approximately \$1,437,000 in the first half of 2003. Sales of custom I.V. systems including one or more CLAVE connectors and CLAVE products combined were \$31,268,000,000 in the first half of 2004 as compared with \$37,475,000 in the first half of 2003. The decrease was attributable to a decrease in Hospira's purchase of CLAVE products partially offset by increases in CLAVE product sales in all other channels and increases in sales of custom I.V. systems including one or more CLAVE in all channels.

Net sales of Punctur-Guard products (excluding royalties) were \$2,651,000 in the first half of 2004 as compared to \$3,352,000 in the first half of 2003 due to a decrease in unit sales and to pricing concessions on our Punctur-Guard line of products to achieve wider distribution.

Net sales of CLC2000 in the first half of 2004 changed less than 1% from the first half of 2003.

Other revenue consists of non-product revenue and was \$1,436,000 in the first half of 2004 compared to \$3,056,000 in the first half of 2003. 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. These ongoing components account for all of our other revenue in 2004. In the second quarter of 2003, we did not receive the \$235,000 payment, but did receive a \$988,000 initial payment on a license to use certain of our products.

GROSS MARGIN, calculated on net sales and excluding other revenue, was 54% for the first six months of 2004, the same as during the first six months of 2003. The factors impacting our gross margin for the first half of the year are essentially the same as for the second quarter.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES ("SG&A") increased by \$628,000 to \$12,258,000, and were 28% of revenues in the first half of 2004, as compared with 22% in the first half of 2003 on higher revenue. The factors impacting SG&A costs for the first half of the year are increased corporate administrative costs, and integration and administrative costs related to our operation in Italy, partially offset by the elimination of administrative costs related to Bio-Plexus and lower patent litigation costs.

RESEARCH AND DEVELOPMENT EXPENSES ("R&D") decreased in the first half of 2004 by \$154,000 to \$854,000, and were approximately 2% of revenues in the first half of 2004 and higher revenue of 2003. The factors impacting R&D costs for the first half of the year are essentially the same as for the second quarter.

INCOME FROM OPERATIONS decreased \$5,877,000, or 34%, principally because of the decrease in net revenue; the resulting decrease in the gross margin and the growth in operating expenses. The operating margin was 26% of revenues in the first half of 2004 and 33% in the first half of 2003.

INVESTMENT INCOME increased \$138,000, or 24%, as compared with the first half of 2003, because of an increase in invested funds (including finance loans) and a slight increase in overall yield.

INCOME TAXES were accrued at an effective tax rate of 37.5% in the first half of 2004 as compared to 38.4% in the first half of 2003.

NET INCOME decreased \$3,419,000, or 31%, to \$7,550,000 as compared with \$10,969,000 for the first six months of 2003. NET INCOME PER SHARE - diluted decreased 31% to \$0.50 per share in the first six months of 2004 as compared with \$0.72 for the first six months of 2003 on a relatively same number of shares.

LIQUIDITY AND CAPITAL RESOURCES

During the first half of 2004, our working capital increased \$14,224,000 to \$117,156,000 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 six months ended June 30, 2004 by \$18,773,000 to \$91,910,000 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 \$16,227,000, cash provided by the company's employee equity plans of \$2,860,000 and net receipts of \$1,958,000 under finance loans exceeded the purchase of property and equipment of \$2,272,000.

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, investments in capital equipment 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 tends to be higher than the amounts at other times during a quarter.

Accounts receivable decreased from \$24,943,000 at December 31, 2003 to \$16,217,000 at June 30, 2004, or 35%; the decrease was principally because revenue in the second quarter of 2004 was 27% 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 anticipated future orders. Because of Hospira's decision to reduce their inventory levels we expect to reduce production in the second half of 2004.

Inventories increased \$6,006,000 from \$3,398,000 at December 31, 2003 to \$9,404,000 at June 30, 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 which we now believe will be less than originally anticipated. This caused our finished good inventory to increase in the first half of 2004, but we expect finished good inventories to begin to return to levels in line with anticipated sales.

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.

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 half of 2004 were \$1,913,000 on the exercise of options to acquire 224,811 shares as compared to \$186,000 in the first half of 2003 on the exercise of options to acquire 32,064 shares.

We expect that sales of certain products will grow in the second half of 2004. If sales increase, accounts receivable 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 half of 2004 we used cash of \$17,614,000 in investing activities, comprised primarily of the purchase of liquid investments of \$17,300,000 utilizing cash generated by operations in excess of other investing needs and the net cash receipt of \$1,958,000 in finance loans.

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 for our business as it currently exists 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 half of 2004 were \$2,272,000 principally to maintain capacity. We currently estimate that capital expenditures for the remainder 2004 will be approximately \$3,700,000, 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 \$750,000 was committed under contracts at June 30, 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 June 30, 2004, it had \$6,949,000 in loans outstanding. Scheduled maturities are: remainder of 2004 \$2,122,000; 2005 \$1,235,000; 2006 \$1,165,000; 2007 \$1,157,000 and 2008 \$1,270,000. Weighted average maturity (principal and interest) at June 30, 2004 was 1.5 years and the weighted average interest rate was 5.3%. 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 \$7,052,000 at June 30, 2004. This is down from almost \$13,000,000 at the end of the fourth quarter 2003 primarily due to the expiration or reduction of lending agreements.

21

FINANCING ACTIVITIES: Cash provided by stock options and the employee stock purchase plan, including tax benefits, was \$4,773,000 in the first half of 2004 as compared to \$930,000 in the first half of 2003: options were exercised on 224,811 shares in the first half of 2004 as compared with 32,064 in the first half of 2003.

half of 2003, but did not acquire any shares in the first half of 2004. We may purchase our shares in the future. However, future purchases of our common stock, 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. We currently believe that our existing cash and liquid investments along with funds expected to be generated from future operations will provide us with sufficient funds to finance our current operations for the next twelve months.

OFF BALANCE SHEET ARRANGEMENTS

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.

FORWARD LOOKING STATEMENTS

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

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;

22

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 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, the impact of Cardinal's acquisition of Alaris, 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.

23

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.

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 June 30, 2004 we had outstanding commercial loans of approximately \$6,949,000. 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 exchange risk. Sales from the U.S. 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. Translation adjustments to date have not been significant.

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.

24

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

In an action filed June 16, 2004 entitled ICU MEDICAL, INC. V. ALARIS MEDICAL SYSTEMS, INC. pending in the United States District Court for the Central District of California, we allege that Alaris Medical Systems, Inc. infringes ICU's patent in the manufacture and sale of the SmartSite and SmartSite Plus Needle-Free Valves and Systems. We seek monetary damages and injunctive relief and intend to vigorously pursue this matter. On August 2, 2004 the Court denied our request for a preliminary injunction. 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

The following is a description of matters submitted to a vote of our stockholders at our annual Meeting of Stockholders held on May 28, 2004:

A. George A Lopez, M.D. and Robert S. Swinney, M.D. were elected as directors to hold office until the 2007 Annual Meeting. Votes cast for and withheld with respect to the nominee were as follows:

	VOTES FOR	VOTES WITHHELD
George A. Lopez, M.D.	11,881,743	243,030
Robert S. Swinney, M.D.	11,632,548	492,225

The terms of the following directors were continued after the Annual Meeting: Jack W. Brown, John J. Connors, Michael T. Kovalchik, III, M.D., Joseph R. Saucedo, and Richard H. Sherman, M.D.

2.5

B. A proposal to ratify the selection of Deloitte & Touche LLP as our auditors was approved. Votes cast were as follows:

FOR	AGAINST	ABSTAIN	BROKER NON-VOTE
12,106,237	10,698	7,838	-0-

ITEM 5. OTHER INFORMATION

None

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(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

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 9 and 7 - June 16, 2004

Items 9 and 7 - June 25, 2004

26

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

/s/Scott E. Lamb

Scott E. Lamb
Controller
(Principal Accounting Officer)

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;
 - 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.

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;
 - 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.

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 June 30, 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 June 30, 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