

FORM 10-Q  
SECURITIES AND EXCHANGE COMMISSION  
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: SEPTEMBER 30, 1997

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)

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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)

(714) 366-2183  
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(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  
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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 November 6, 1997
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Common	7,766,386

ICU MEDICAL, INC.

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PART I - FINANCIAL INFORMATION  
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ICU MEDICAL, INC.  
Consolidated Balance Sheets  
September 30, 1997 and December 31, 1996  
(all dollar amounts in thousands except share data)

ASSETS	9/30/97	12/31/96
	(unaudited)	
CURRENT ASSETS:		
Cash and cash equivalents	\$ 4,219	\$ 2,060
Liquid investments	27,650	29,700
Accounts receivable, net of allowance for doubtful accounts of \$324 and \$293 as of September 30, 1997 and December 31, 1996, respectively.	3,249	3,043
Inventories	1,742	2,234
Prepaid expenses and other and other	898	763
Deferred income taxes	335	450
Total current assets	38,093	38,250
PROPERTY AND EQUIPMENT, AT COST		
Machinery and equipment	6,646	6,762
Furniture and fixtures	1,467	1,320
Molds	2,725	2,679
Land, building and building improvements	5,001	4,993
Construction in process	597	417
	16,436	16,171
Less - Accumulated depreciation	(6,715)	(5,242)
	9,721	10,929
Other assets	509	460
	\$48,323	\$49,639
	=====	
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	\$ 1,000	\$ 1,902
Accrued liabilities	766	761
Total current liabilities	1,766	2,663
Deferred income taxes	270	227

## STOCKHOLDERS' EQUITY

Convertible preferred stock, \$1.00 par value, Authorized 500,000 shares, issued and outstanding - none		
Common stock, \$0.10 par value, authorized, 20,000,000 shares; issued, 8,867,162 shares.	887	887
Additional capital	39,452	39,447
Treasury stock - 1,102,276 and 566,711 shares at September 30, 1997 and December 31, 1996, respectively.	(9,335)	(4,848)
Retained earnings	15,283	11,263
	-----	-----
Total stockholders' equity	46,287	46,749
	-----	-----
	\$48,323	\$49,639
	=====	=====

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

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ICU MEDICAL, INC.  
Consolidated Statements of Income  
For the Three Months Ended  
September 30, 1997 and September 30, 1996  
(all dollar amounts in thousands except per share data)  
(unaudited)

	For the Three Months Ended	
	9/30/97	9/30/96
	-----	-----
Net sales	\$ 7,700	\$ 5,972
Cost of goods sold	3,306	2,772
	-----	-----
Gross profit	4,394	3,200
Selling, general and administrative expenses	2,126	1,809
Research and development expenses	280	191
	-----	-----
Income from operations	1,988	1,200
Investment income	342	330
	-----	-----
Income before income taxes	2,330	1,530
Provision for income taxes	885	566
	-----	-----
Net income	\$ 1,445	\$ 964
	=====	=====
Net income per share	\$ 0.18	\$ 0.11
	=====	=====
Weighted average number of common and common equivalent shares outstanding	7,853,002	8,907,056
	=====	=====

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

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ICU MEDICAL, INC.  
Consolidated Statements of Income  
For the Nine Months Ended  
September 30, 1997 and September 30, 1996  
(all dollar amounts in thousands except per share data)  
(unaudited)

	For the Nine Months Ended	
	9/30/97	9/30/96
Net sales	\$ 21,714	\$ 18,127
Cost of sales	9,276	7,751
Gross profit	12,438	10,376
Selling, general and administrative expenses	5,976	4,778
Research and development expenses	931	535
Income from operations	5,531	5,063
Interest and other income	950	1,003
Income before tax	6,481	6,066
Provision for income taxes	2,445	2,244
Net income	\$ 4,036	\$ 3,822
Net income per share	\$ 0.50	\$ 0.43
Weighted average number of common and common equivalent shares outstanding	8,038,076	8,992,433

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

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ICU MEDICAL, INC.  
Consolidated Statements of Cash Flows  
For the Nine Months Ended  
September 30, 1997 and September 30, 1996  
(all dollar amounts in thousands)  
(unaudited)

	For the Nine Months Ended	
	9/30/97	9/30/96
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	\$ 4,036	\$ 3,822
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	1,679	1,524
Net change in current asset and current liabilities, and other	(542)	(950)
Net cash provided by operating activities	5,173	4,396
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment and other	(534)	(818)
Proceeds from sales of investment securities	-	508
Net change in liquid investments	2,050	(4,125)

Net cash provided by (used in) investing activities	1,516	(4,435)
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CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from stock options exercised and related tax benefits	76	1,399
Purchase of treasury stock	(4,606)	-
-----		
Net cash provided by (used in) financing activities	(4,530)	1,399
-----		
NET INCREASE IN CASH AND CASH EQUIVALENTS	2,159	1,360
Cash and cash equivalents, beginning of the period	2,060	2,014
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CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 4,219	\$ 3,374
=====		

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

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ICU MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
SEPTEMBER 30, 1997  
(All dollar amounts in thousands)  
(unaudited)

NOTE 1: The accompanying unaudited interim financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission and reflect all adjustments which are, in the opinion of Management, necessary to a fair statement of the results for the interim periods presented, which adjustments consist of only normal recurring adjustments. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. The financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company's 1996 Annual Report to Stockholders. Certain reclassifications have been made to the 1996 consolidated financial statements to conform with the current presentation.

NOTE 2: Inventories consisted of the following:

Description	9/30/97	12/31/96
-----	-----	-----
Raw material	\$ 798	\$ 1,179
Work in process	353	458
Finished goods	591	597
-----		
Total	\$ 1,742	\$ 2,234
=====		

NOTE 3: Net income per share was computed by dividing net income by the weighted average number of shares of common stock and common stock equivalents outstanding during the periods. Common stock equivalents consist of the shares issuable on exercise of the outstanding dilutive common stock options, less the shares that could have been purchased with the proceeds from the exercise of the options, using the treasury stock method.

NOTE 4: The effective tax rate differs from that computed at the federal statutory rate of 34% principally because of the effect of tax-exempt investment income offset by the effect of state income taxes.

NOTE 5: In October 1996, the Company announced a new CLAVE/(R)/ pricing strategy under which prices to independent distributors are adjusted through rebates of up to approximately 40%, depending on the type of customer to which the distributor is reselling the CLAVE product. Through June 30, 1997, management had estimated the accrued rebate by approximating the maximum rebate that might be available to the distributors. In the third quarter, the Company has reduced this estimate based upon additional historical data. The Company will continue to accumulate historical data and may adjust this estimate in future periods.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION  
AND RESULTS OF OPERATIONS

General  
- - - - -

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

PRODUCT LINE	1994	1995	1996	Q3-96	YTD Q3-96	Q3-97	YTD Q3-97
CLAVE	45%	61%	68%	67%	67%	69%	67%
Click Lock and Piggy Lock	41%	20%	12%	11%	13%	8%	8%
McGaw Protected Needle	9%	13%	8%	9%	10%	5%	6%
Lopez Valve and other	5%	4%	4%	4%	4%	4%	4%
RF100-RF150 ("Rhino")	-	2%	3%	4%	2%	7%	6%
Budget Medical Products	-	-	2%	-	1%	5%	5%
McGaw SafeLine Revenue Sharing	-	-	3%	5%	3%	2%	4%
Total	100%	100%	100%	100%	100%	100%	100%

The Company sells its products to independent distributors and through strategic supply and distribution agreements with McGaw, Inc. ("McGaw") and Abbott Laboratories ("Abbott") (the "McGaw Agreement" and the "Abbott Agreement," respectively). Most independent distributors handle the full line of the Company's products. McGaw and Abbott both purchase CLAVE/(R)/ products, principally bulk, non-sterile connectors; McGaw also purchases the McGaw Protected Needle and Abbott also purchases the Rhino, a low-priced connector specifically designed for Abbott. Through the third quarter of 1997, both agreements establish minimum transfer prices which are lower than historical average selling prices, which the Company negotiated in anticipation of significant sales, and a revenue sharing formula under which the Company could receive more than the minimum transfer prices based on selling prices of products incorporating the Company's products. The McGaw Agreement provides for revenue sharing based on McGaw's selling prices of CLAVE products and the Abbott Agreement provides for revenue sharing based on Abbott's selling prices of both CLAVE products and Rhinos. Effective August 1, 1997, the Abbott Agreement was amended to establish fixed selling prices for Rhinos and eliminate revenue sharing for all orders of Rhinos after August 1, 1997.

On June 25, 1997, B.Braun Melsungen AG (B.Braun) acquired McGaw from IVAX Corporation. B.Braun's U.S. operation markets an I.V. connection system that competes with I.V. connection systems of the Company and others. The McGaw Agreement extends to July 2000, and the Company expects B.Braun-McGaw to abide by the Agreement. The Company cannot predict the ultimate impact of the acquisition, although it does expect the relationship with B.Braun-McGaw to change over time. The Company is currently discussing significant modifications of the McGaw Agreement, including pricing changes and extension of the term of the Agreement. The Company does not expect any significant change in the pattern of sales to McGaw, at least through the balance of 1997. However, there is no assurance that there will not be a significant change in the pattern of sales and there is no assurance as to the outcome of current discussions of the McGaw Agreement.

Management believes the success of CLAVE has, and will continue to motivate others to develop one piece needleless connectors which may incorporate many of

the same functional and physical characteristics as the CLAVE. The Company is aware of a number of such products. In response to competitive pressure felt in the third quarter of 1996, the Company in mid-October 1996 announced to its independent distributors a new aggressive pricing strategy to protect and expand its market. Under this strategy, prices to independent distributors will eventually be reduced by up to approximately 40%, depending on the type of customer to which the distributor is reselling the CLAVE product (See Note 5 to the Consolidated Financial Statements). The average price reduction through the third quarter of 1997 was less than the maximum 40%, although Management expects that the average price of its CLAVE products will continue to decline over the next several quarters. Management expects that the price decline eventually will be more than offset by increased volume, although this has not occurred to date for independent distributors in the aggregate. There is no assurance that such increased volume will be achieved by the independent distributors, and there is no assurance that the Company's current or future products will be able to successfully compete with products developed by others.

Quarter Ended September 30, 1997 Compared to the Same Quarter Last Year  
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Net sales increased \$1,728,000, or approximately 29%, to \$7,700,000 in the third quarter compared to \$5,972,000 during the same period last year. The increase was primarily attributable to a 34% increase in sales of CLAVE products, increased sales by the Budget Medical Products subsidiary ("BMP"), and increased sales of the low-priced Rhino. Those increases were partially offset by continuing decreases in Click Lock, Piggy Lock and McGaw Protected Needle sales, and decreased revenue sharing due from McGaw, Inc. ("McGaw") based on sales of its SafeLine products.

Net sales to McGaw, including revenue sharing, amounted to \$2,391,000 in the third quarter of 1997, as compared with \$1,992,000 in the third quarter of 1996. The increase was accounted for principally by increased unit shipments of CLAVE products. That increase was partially offset by a 25% decrease in McGaw Protected Needle sales because of lower unit shipments, as expected, and a decrease in estimated revenue sharing payments due under the McGaw Agreement on McGaw's sales of its SafeLine products. Management expects that overall CLAVE selling prices to McGaw will decrease through the balance of 1997, and also expects that those decreases will cause it to receive declining amounts of revenue sharing on CLAVE products sold to McGaw; further, there is no assurance that McGaw's pricing in the future will result in any revenue sharing under the formula in the McGaw Agreement. The Company has had sufficient data to estimate and record CLAVE revenue sharing payments from McGaw in the period earned through the first quarter of 1997. Commencing in the second quarter of 1997, and until pricing stabilizes sufficiently, the Company began recording revenue sharing due from McGaw on CLAVE products only when reported by McGaw and will no longer estimate and accrue revenue sharing payments before they are reported. Based on McGaw's forecasts, Management expects increases in unit shipments to McGaw to continue during the remainder of 1997, although there is no assurance that McGaw's forecasts will be realized. Management expects that SafeLine revenue sharing payments will continue, although it is unable to accurately forecast such amounts. Management expects McGaw Protected Needle sales to decline for the remainder for 1997 compared to the third quarter this year, as the market continues to shift to needleless technology.

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The Company began production-quantity shipments of the Rhino to Abbott in late 1995 and the CLAVE in the third quarter of 1996. Net sales to Abbott in the third quarter of 1997 were \$1,555,000, as compared with net sales of \$584,000 in the third quarter of 1996. The increase in net sales of CLAVE products was 187% and the increase in net sales of the Rhino was 134% including revenue sharing. Commencing in the second quarter of 1997, there has been a substantial increase in marketing of CLAVE products to Abbott and to Abbott customers, and the Company expects the order volume from Abbott to increase in the fourth quarter of 1997. There is no assurance that Abbott will be successful in promoting and selling CLAVE against its other safe connector offerings, or against other competitors' current or future products. Further, there is no assurance that Abbott's selling prices will result in any significant revenue sharing with the Company under the Abbott Agreement.

Total CLAVE net sales increased approximately 34% from \$3,950,000 in the third quarter of 1996 to \$5,299,000 in the third quarter of 1997. Unit shipments of CLAVE products increased approximately 67%, substantially all of which was accounted for by McGaw and Abbott, offset by a decrease with

independent distributors. Average selling prices continued to decrease.

Net sales of CLAVE products to independent distributors in the third quarter of 1997 decreased approximately 19% from the third quarter of 1996, principally because of lower unit volumes, and to a lesser degree, lower average selling prices. Management expects that unit sales of CLAVE products to its independent distributors will have little, if any, increase for the remainder of 1997, and may continue to decrease, causing net sales of CLAVE products to the independent distributors to continue to decrease, and resulting in unit sales and net sales below 1996 levels. Sales to the independent distributors have been adversely impacted by acquisition of CLAVE market share by Abbott and McGaw and have been temporarily adversely impacted by the termination of several distributor arrangements and in the future may be impacted by competition from existing and new competitive products. Management expects to encounter continued pricing pressure from individual end users, but believes that its new pricing strategy is and will continue to improve its competitive position.

Net sales of Click Lock and Piggy Lock decreased approximately 8% in the third quarter of 1997 compared to the same period last year. The decline is because of the safe-connector market's continued shift to needleless technology. Management expects the trend to continue.

Net sales of Lopez Valve and Swiss System increased 10% in the third quarter compared to the same period last year due to an increase in unit shipments. Management expects sales of the Lopez Valve to be at the same or slightly higher levels as in the third quarter of 1997 for the remainder of the year.

Net sales of Budget Medical Products increased to \$413,000 in the third quarter of 1997 principally because of increased unit shipments of custom I.V. sets incorporating the CLAVE.

Total sales to foreign distributors were \$201,000 in the third quarter of 1997, as compared with \$278,000 in the third quarter of 1996. The decrease was due to lower unit shipments. Foreign distributors have not yet achieved consistent ordering patterns, but Management expects that the Company's sales to foreign distributors will increase over the balance of the year.

Historically, the Company has experienced lower usage of its products in the summer months due to lower censuses in healthcare facilities. The table below illustrates the effect this phenomenon has on the Company's net sales:

NET SALES (000'S)	Q1	Q2	Q3	Q4	TOTAL
1993	\$2,914	\$2,335	\$2,495	\$3,637	\$11,381
1994	\$4,180	\$3,842	\$3,484	\$5,036	\$16,542
1995	\$5,427	\$5,966	\$4,617	\$5,272	\$21,282
1996	\$6,008	\$6,147*	\$5,972*	\$6,472*	\$24,599
1997	\$6,824*	\$7,190*	\$7,700*		

\* Includes McGaw SafeLine Revenue Sharing In Q2, Q3, Q4 1996 and Q1, Q2, Q3 1997 of \$229,000, \$300,000, \$300,000 and \$359,000, \$418,000, \$182,000 respectively.

As illustrated above, the second and third quarters tend to be weaker than the first and fourth. The exceptions are the second quarter of 1995, in which McGaw was building significant inventory of CLAVE; the second quarter of 1997, in which sales increases occurred in most of the Company's product lines; and the third quarter of 1997, in which sales increases occurred principally because of increased net sales of CLAVE products to Abbott and independent distributors, offset by lower net sales of CLAVE products to McGaw.

Gross margin was 57% during the third quarter of 1997 compared to 54%



during the same period last year. Although average selling prices have continued to decrease, increases in production volume resulted in greater absorption of overhead and a decrease in unit manufacturing costs.

Management believes that the continuing decrease in average selling prices for CLAVE products, including the effect of its new pricing strategy to independent distributors, could adversely effect the gross margin percentage for the next several quarters, but that as volume increases, including increasing production of CLAVE products for McGaw and Abbott, gross margin percentages should not deteriorate significantly. This is because a large portion of the Company's manufacturing costs are fixed and the Company has adequate existing fixed-asset capacity to handle increased volumes. Any such improvement could be offset, however, by a continuation of the shift in sales mix from independent distributors to McGaw and Abbott at lower average selling prices. Also, management is currently evaluating further upgrading the efficiency of its manufacturing operations by replacing certain fixed assets and adding others; the effect of this would be to expand its capacity and lower per unit production costs as production volume increases.

Selling, general and administrative expenses ("SG&A"), excluding research and development expenses, increased \$317,000 to \$2,126,000, but decreased as a percentage of sales to 28% of sales during the third quarter of 1997 compared to 30% during the same period last year. The principal component of the increase in SG&A expenses was sales and marketing costs, including those related to BMP and international markets. Management expects continuing increases in sales and marketing costs in the fourth quarter of 1997 and in 1998 as it works to expand sales of current products and launch new products.

Costs of patent litigation in which the Company is the plaintiff were approximately 2% of net sales in the third quarter of 1997, as compared with 7% in the third quarter of 1996. Management

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expects the amount of those costs to increase in the fourth quarter of 1997, but to be at a level lower than those incurred in the fourth quarter of 1996. The amount of such costs will depend on the progress of the litigation, and that is difficult to predict.

Research and development expenses ("R&D") increased from 3% of net sales in the third quarter of 1996 to 4% of net sales in the third quarter of 1997, reflecting increased efforts to complete R&D on a number of new products. Management currently expects those efforts to continue through the end of 1997 and into 1998, with R&D expense at approximately the same level as in the third quarter of 1997. However, no assurance can be given that such costs will not differ materially from those estimates or that the R&D will be completed as expected.

Net income increased 50% to \$1,444,000 in the third quarter of 1997 as compared with \$964,000 in the comparable period last year. Net sales and gross profit increased 29% and 37%, respectively. SG&A and R&D combined, increased 20% from the third quarter of 1996, and income from operations increased 65%.

Net income per share increased \$0.07, or 64%, in the third quarter of 1997 over the third quarter of 1996. This increase was more than the percentage increase in net income because of a 12% decrease in the weighted average number of common and common equivalent shares outstanding. Had the decrease in shares not occurred, the increase in net income per share would have been approximately 55%.

Nine Months Ended September 30, 1997 Compared to the Same Nine Months Last Year  
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Net sales increased approximately 20% for the nine months ended September 30, 1997 compared to the same nine month period last year. The growth in net sales was due to increased net sales to McGaw and Abbott, partially offset by a decline in net sales to independent distributors. The increase resulted primarily from increased CLAVE sales, Rhino sales, and BMP sales. Those were offset in part by declining Click Lock, Piggy Lock and McGaw Protected Needle sales. During the period, net sales of CLAVE increased approximately 19% due primarily to higher unit sales offset in part by lower average selling prices. Net sales of Click Lock and Piggy Lock decreased 28% and McGaw Protected Needles decreased approximately 27%, due to lower unit sales compared to the same period last year. For the nine months ended September 30, 1997 net sales

of Rhino increased to approximately \$1,309,000 compared with \$429,000 for the same period last year. BMP net sales increased to \$1,109,000 compared with \$156,000 for the same period last year.

Net sales to McGaw for the first nine months of 1997 were \$8,325,000, as compared to \$6,797,000 for the first nine months of 1996. Comparable amounts for Abbott were \$2,933,000 and \$810,000, respectively.

Gross margin for the nine months ended September 30, 1997 and 1996 was 57%. Increased unit volumes and lower per unit manufacturing costs offset the effect of lower average selling prices.

SG&A expenses excluding R&D, for the nine months ended September 30, 1997 were 28% of sales compared to 26% during the same period of 1996. The increase is principally because of increased sales and marketing costs, and general corporate expenses partially offset by a decrease in the continuing costs of patent litigation in which the Company is the plaintiff.

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R&D expenses increased for the nine months ended September 30, 1997 as compared to the same period in 1996 for the same reason as they increased in the third quarter as described above.

#### Liquidity and Capital Resources

During the nine months ended September 30, 1997, the Company's cash and cash equivalents and investment securities position increased \$109,000 to \$31,869,000. Cash provided by operating activities was offset by the cost of treasury stock purchases and additions to working capital and property and equipment.

If sales of the Company's products increase, accounts receivable and inventories are expected to increase as well. As a result of these and other factors, the Company's working capital requirements may increase in the foreseeable future.

The Company believes that its existing working capital, supplemented by income from operations, will be sufficient for the foreseeable future.

Since October 1996, the Company has purchased 1,146,000 shares of its common stock at a cost of \$9.7 million, of which 52,500 shares were purchased in the quarter ended September 30, 1997, at a cost of \$446,000. The Company is not currently repurchasing its Common Stock, but may again repurchase its Common Stock from time to time in the future depending on market prices and other factors.

#### Forward Looking Statements

In this Management's Discussion and Analysis, Management has made numerous statements about perceived trends and its expectations and beliefs about various matters, which reflect the best information currently available to Management and assumptions which Management believes to be reasonable. They include without limitation statements about: sales to and revenue sharing from McGaw and Abbott; McGaw's compliance with the McGaw Agreement; the relationship with McGaw; the pattern of sales to McGaw; the development by others of competing products; decline in average selling prices and the possibility of increased volume offsetting such declines; decreases in Click Lock, Piggy Lock and McGaw protected needle sales; decreases in selling prices to and revenue sharing from McGaw; the volume of unit shipments to McGaw; SafeLine revenue sharing; order volume from Abbott; unit sales volume to independent distributors; decreases in net sales to independent distributors and the possible temporary nature of such decreases; the effect on sales to independent distributors of competitive products; pricing pressure from end users; Lopez Valve sales; foreign sales; the effect of decreases in average selling prices on gross margins and the possible offsetting effects of volume increases; shift in the balance between sales to independent dealers and sales to McGaw and Abbott and the effects of any such shift; sales, marketing and patent litigation costs; research and development expenses and results; working capital requirements; and, repurchases of the Company's common stock. These statements and similar statements are forward

looking statements that involve a number of risks and uncertainties including the possible failure of the factors described in such statements to materialize and the caveats which accompany the statements. The Company

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further cautions that actual future results of operations are subject to other important factors including, among others, the following: general economic and business conditions; the effect of price and safety considerations on the healthcare industry; competitive factors such as product innovation, new technologies, marketing and distribution strength and price erosion; unanticipated market shifts and trends; the impact of legislation effecting government reimbursement of healthcare costs; any changes in corporate strategies and practices of McGaw, Abbott and the Company's independent distributors that might effect the resources and efforts that they devote to marketing the Company's products; the possible impact of the acquisition of the Company's customers (including McGaw) by other entities; production problems; changes in product mix; changes in marketing strategy; the availability of patent protection and the cost of enforcing or defending patent claims; and other risks described from time to time in the Company's registration statements and reports filed with the Securities and Exchange Commission, including the Company's Current Report on Form 8-K dated November 14, 1996. Results of operations actually achieved in the future may thus differ materially from Management's current expectations. The Company disclaims 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.

#### New Accounting Pronouncement

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In February 1997, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 128, "Earnings per Share." As it effects the Company under its current capital structure, it provides for the presentation of "basic" earnings per share, which excludes the dilutive effect of outstanding common stock options, and "diluted" earnings per share, which includes the dilutive effect of such common stock options and is the same as "net income per share" as currently presented by the Company. Both basic and diluted earnings per share, as calculated under SFAS No. 128, for the quarters ended September 30, 1997 and 1996 are \$0.18 and \$0.11, respectively, and for the nine months ended September 30, 1997 and 1996 are \$0.50 and \$0.43, respectively. Those are the same amounts as presented as net income per share in the consolidated financial statements.

## PART II OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

- -----

In an action entitled ICU Medical, Inc. v. Tri-State Hospital Supply Corporation, pending in the United States District Court for the Northern

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District of California, the Company alleges infringement of two patents by defendant's protected needle connector and Y-style extension sets. The Company is seeking an injunction, and monetary damages in an amount to be determined. On February 28, 1996, the Court ruled on a number of motions filed by the parties. It denied a number of motions for summary judgment brought by the defendant, including the motion for partial summary judgment of non-infringement of one of the patents, and issued rulings on matters of

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enforceability that were generally favorable to the Company. The case remains pending and a number of motions remain to be brought by the Company. Trial date is presently scheduled for February 1998.

In an action entitled Allen Petty, dba Carmel Development International v. ICU Medical, Inc., pending in the Superior Court for Orange County, State of

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California, Plaintiff alleges breach of contract and seeks at least \$500,000 in commissions allegedly related to sales of the CLAVE/(R)/ to various O.E.M. manufacturers. The Company believes the claim is without merit and intends to defend the action vigorously. The Company has asserted counter claims against the Plaintiff alleging breach of contract and misappropriation and conversion of trade secrets and fraud. Trial date is scheduled for March 1998.

In an action entitled Hinck Medical, Inc. v. ICU Medical, Inc., pending in -----  
the United States District Court for the District of Oregon, the plaintiff alleges that the Company breached a distribution agreement by imposing different payment terms on the plaintiff, Hinck Medical, Inc. ("Hinck") than were required of other distributors, and makes several other allegations. The Company has denied the allegations of the complaint and has asserted counterclaims against Hinck for breach of the distribution agreement and is seeking damages. The parties have agreed to submit the matter to binding arbitration. Accordingly, the action pending in the federal court has been stayed pending resolution of the matter through arbitration. The Company believes the claim against it is without merit and intends to defend the action vigorously.

ITEM 2. CHANGES IN SECURITIES  
-----

Inapplicable

ITEM 3. DEFAULT UPON SENIOR SECURITIES  
-----

Inapplicable

ITEM 4. OTHER INFORMATION  
-----

None

ITEM 5. EXHIBITS AND REPORTS ON FORM 8-K  
-----

(a) Exhibits:

10.1 Amendment to Abbott and ICU Medical Agreement, dated September 9, 1997  
between Registrant and Abbott Laboratories \*

27 Financial Data Schedule

\* Portions of the Agreement have been redacted. Registrant has requested that the Securities and Exchange Commission grant confidential treatment to the redacted portions of the Agreement.

(b) Reports on Form 8-K:

Registrant filed the following Report on Form 8K during the quarter for which this Report is filed.

Item 5 - July 23, 1997

15

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  
-----

Date: November 14, 1997

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

Item 601 of Regulation

CONFIDENTIAL TREATMENT

Portions of the attached Amendment 1 to Abbott and ICU Medical Agreement have been redacted. The Company has applied to the Securities and Exchange Commission for confidential treatment of the redacted portions.

AMENDMENT 1  
TO  
ABBOTT AND ICU MEDICAL AGREEMENT

This Amendment is made to the Agreement dated April 3, 1995 by and between ICU Medical and Abbott Laboratories for the purchase and sale of certain products (the "Agreement").

Premises

The parties desire to modify prices and make other changes to the Agreement. Therefore, in consideration of the premises and mutual promises and agreements contained herein, ICU Medical and Abbott agree to amend the Agreement as follows:

1. The correct interpretation of paragraph 6.4 for the calculation of Price of Product is documented in Exhibit E of the Agreement.
2. The High Pressure Clave/TM/ will be covered by the Revenue Sharing formula in the Agreement, same as the Clave/TM/. The ICU Billing Price for the High Pressure Clave/TM/ will be the same as for the Clave/TM/.
3. The R-F 150 Connector will be given a fixed price and will not be on a Revenue Share basis. The packaged and sterile product will be ---- and the bulk non-sterile product will be ---- effective for orders placed after 8/1/97. No change in price will be made for product already in inventory.
4. Abbott agrees to reimburse ICU Medical ---- for implementation of the bulk non-sterile R-F 150 within 30 days of the date of this Amendment.
5. The minimum price on the Clave/TM/ and Integral Clave/TM/ paid to ICU Medical on a quarterly revenue sharing basis will be \$ ---- for 1997 and then negotiated for any changes from this level if the average selling price to the customer is below ---- . This calculation is based on average selling price to all accounts and is net of certain adjustments such as hospital dividends.
6. Except as expressly modified by this Amendment, all terms and conditions in the Agreement shall continue in full force and effect.
7. The provisions of paragraph 6.4 of the Agreement regarding pump administration sets is amended as follows; the price of the Clave/TM/ is ----per pump administration set, based on the agreed mix of ---- percent single Clave/TM/ sets, and ---- percent dual Clave/TM/ sets, and ---- percent triple Clave/TM/ sets. Both parties agree to negotiate changes from this level, as appropriate, based on market conditions.

The parties intending to be bound by the terms and conditions hereof, have caused this Amendment to be signed by their duly authorized representatives the 9 day of September 1997.

- -----

Abbott Laboratories  
  
By /s/  
-----  
Title /s/  
-----

ICU Medical  
  
By /s/ Francis J. O'Brien  
-----  
By Francis J. O'Brien  
-----

Title \_\_\_\_\_

Title Chief Financial Officer  
\_\_\_\_\_

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