```
                FORM 10-Q
                    SECURITIES AND EXCHANGE COMMISSION
                WASHINGTON, D.C. 20549
    -----
            QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF
                        THE SECURITIES EXCHANGE ACT OF 1934
                FOR THE QUARTERLY PERIOD ENDED: SEPTEMBER 30, 1999
                    OR
-----
-----
        TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF
            THE SECURITIES EXCHANGE ACT OF 1934
        FOR THE TRANSITION PERIOD FROM:
```

$\qquad$

``` TO
``` \(\qquad\)
```

            COMMISSION FILE NO.: 0-19974
                ICU MEDICAL, INC.
            (Exact name of Registrant as provided in charter)
            ---------------------------------------------------------
    - Delaware
(State or Other Jurisdiction of Incorporation or Organization)

```
9 5 1 ~ C a l l e ~ A m a n e c e r , ~ S a n ~ C l e m e n t e , ~ C a l i f o r n i a ~
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9 5 1 ~ C a l l e ~ A m a n e c e r , ~ S a n ~ C l e m e n t e , ~ C a l i f o r n i a ~

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(Address of Principal Executive Offices)

33-0022692
--------------------
(I.R.S. Employer Identification No.) 92673
(Zip Code)

```
(949) 366-2183
-----------------------------------------------
(Registrant's Telephone No. Including Area Code)
Indicate by check mark whether the registrant (1) has filed all reports 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:
\begin{tabular}{lc} 
Class & Outstanding at October 29,1999 \\
----- \\
Common & \(8,100,739\)
\end{tabular}
ICU MEDICAL, INC.
INDEX
\begin{tabular}{l|l} 
PART I - FINANCIAL INFORMATION & PAGE NUMBER \\
ITEM 1. FINANCIAL STATEMENTS & \\
Consolidated Balance Sheets, September 30,1999 and & \\
December 31,1998 & \\
Consolidated Statements of Income for the three months \\
ended September 30,1999 and 1998
\end{tabular}
```



|  | $\begin{aligned} & (5,485) \\ & 30,368 \end{aligned}$ |  | $\begin{aligned} & (7,117) \\ & 24,217 \end{aligned}$ |
| :---: | :---: | :---: | :---: |
|  | 66,610 |  | 58,228 |
| \$ | 71,707 | \$ | 62,359 |

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, 1999 and June 30, 1998
(all dollar amounts in thousands except per share data) (unaudited)

|  | For the Three Months Ended |  |  |  |
| :---: | :---: | :---: | :---: | :---: |
|  | 9/30/99 |  | 9/30/98 |  |
| NET SALES | \$ | 10,712 | \$ | 9,618 |
| COST OF GOODS SOLD |  | 4,836 |  | 4,020 |
| Gross profit |  | 5,876 |  | 5,598 |
| OPERATING EXPENSES: |  |  |  |  |
| Selling, general and administrative |  | 2,806 |  | 2,887 |
| Research and development |  | 284 |  | 205 |
| Total operating expenses |  | 3,090 |  | 3,092 |
| Income from operations |  | 2,786 |  | 2,506 |
| INVESTMENT INCOME |  | 320 |  | 367 |
| Income before income taxes |  | 3,106 |  | 2,873 |
| PROVISION FOR INCOME TAXES |  | 1,160 |  | 1,050 |
| NET INCOME | \$ | 1,946 | \$ | 1,823 |
| NET INCOME PER SHARE |  |  |  |  |
| Basic | \$ | 0.24 | \$ | 0.23 |
| Diluted | \$ | 0.22 | \$ | 0.22 |
| WEIGHTED AVERAGE NUMBER OF SHARES |  |  |  |  |
| Basic |  | 208,438 |  | 1,942 |
| Diluted |  | 736,987 |  | 5,717 |

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, 1999 and September 30, 1998 (all dollar amounts in thousands except per share data) (unaudited)

NET SALES
COST OF GOODS SOLD
Gross profit

OPERATING EXPENSES:
Selling, general and administrative Research and development

Total operating expenses


|  | 33,853 | \$ | $\begin{aligned} & 30,030 \\ & 12,555 \end{aligned}$ |
| :---: | :---: | :---: | :---: |
|  | 14,666 |  |  |
| \$ | 19,187 |  | 17,475 |


| 9,272 | 9,415 |
| :---: | ---: |
| 797 | 756 |
| $-\quad-\quad-\quad 10,171$ |  |

Income from operations
INVESTMENT INCOME

Income before income taxes
PROVISION FOR INCOME TAXES

NET INCOME

NET INCOME PER SHARE

## Basic

Diluted

WEIGHTED AVERAGE NUMBER OF SHARES

## Basic

Diluted
$\qquad$
$\qquad$
9,118
$\qquad$
$\qquad$
-------------- 1,038

| 10,150 |  |  | 8,342 |
| :---: | :---: | :---: | :---: |
|  | 3,800 |  | 3,140 |
| \$ | 6,350 | \$ | 5,202 |


| $\$$ | 0.78 | $\$$ | 0.65 |
| :--- | :--- | :--- | :--- |
| $\$$ | 0.72 | $\$$ | 0.62 |
| $============$ | ============ |  |  |


| $8,173,229$ |  |
| :--- | ---: |
| $8,767,609$ |  |
| $============$ | $7,967,903$ |
| $============$ |  |

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

| 9/30/99 | 9/30/98 |
| :---: | :---: |

CASH FLOWS FROM OPERATING ACTIVITIES:
Net Income
Adjustments to reconcile net income to net cash
provided by operating activities --
Depreciation and amortization
Net change in current assets and current liabilities, and other
Net cash provided by operating activities

| $\$$ | 6,350 | $\$$ | 5,202 |
| :--- | :--- | :--- | :--- |


| 2,341 | 1,876 |
| :---: | :---: |
| 777 | (952) |
| 9,468 | 6,126 |

CASH FLOWS FROM INVESTING ACTIVITIES:
Purchases of property and equipment
Net change in liquid investments
Net cash (used in) investing activities

| $(12,432)$ | $(4,914)$ |
| :---: | :---: |
| 2,700 | $(3,891)$ |
| $(9,732)$ | $(8,805)$ |

CASH FLOWS FROM FINANCING ACTIVITIES:
Proceeds from exercise of stock options and related income tax benefits, and other Purchase of treasury stock

| 2,032 | 3,283 |
| :---: | :---: |
| - | (400) |
| 2,032 | 2,883 |

NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS

CASH AND CASH EQUIVALENTS, beginning of the period
2,048 2,962

CASH AND CASH EQUIVALENTS, end of the period
$\$ \quad 3,816$
\$ 3,166

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

ICU MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 1999
(All dollar amounts in thousands)

NOTE 1: The accompanying unaudited interim consolidated 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 consolidated results for the interim periods presented, which adjustments consist of only normal recurring adjustments. 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 consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company's 1998 Annual Report to Stockholders.

NOTE 2: Net inventories consisted of the following:

Raw material
Work in process
Finished goods
Total



NOTE 3: Basic net income per share is computed by dividing net income by the weighted average number of common shares outstanding. Diluted net income per share is computed by dividing net income by the weighted average number of common shares outstanding plus dilutive securities. The Company's dilutive securities are outstanding common stock options (excluding stock options with an exercise price in excess of market value), less the number of shares that could have been purchased with the proceeds from the exercise of the options, using the treasury stock method, and were 528,549 and 348,775 for the three months ended September 30, 1999 and 1998, respectively and 594,380 and 399,180 for the nine months ended September 30, 1999 and 1998, respectively.

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

NOTE 5: The Company is involved in litigation with Medex, Inc. over patent matters. See Part II, Item 1, "Legal Proceedings."

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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 | 1996 | 1997 | 1998 | Q3-98 | Q3-99 | $\begin{gathered} \text { YTD } \\ \text { Q3-98 } \end{gathered}$ | $\begin{gathered} \text { YTD } \\ \text { Q3-99 } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| CLAVE (R) | 68\% | 65\% | 69\% | 67\% | 64\% | 67\% | 68\% |
| Click Lock(R) and Piggy Lock (R) | 12\% | 7\% | $4 \%$ | 4\% | $2 \%$ | 8\% | $3 \%$ |
| McGaw Protected Needle | 8\% | 5\% | 4\% | 4\% | 4\% | 6\% | $3 \%$ |
| Lopez Valve (R) and other | 4\% | 4\% | 5\% | 4\% | 7\% | 4\% | 5\% |
| RF100-RF150 ("Rhino") | 3\% | 7\% | 5\% | 7\% | 6\% | 6\% | 6\% |
| Budget Medical Products | 2\% | 6\% | 8\% | 9\% | 13\% | 5\% | 11\% |
| B. Braun / McGaw SafeLine Revenue Sharing | 3\% | 6\% | 5\% | 5\% | 4\% | 4\% | 4\% |
| Total | 100\% | 100\% | 100\% | 100\% | 100\% | 100\% | 100\% |

The Company sells its products to independent distributors and through supply and distribution agreements with B.Braun Medical, Inc. ("B.Braun / McGaw"), Abbott Laboratories ("Abbott") (the "B.Braun / McGaw Agreement" and the "Abbott Agreement," respectively) and C. R. Bard, Inc. ("Bard"). Most independent distributors handle the full line of the Company's products. B. Braun / McGaw and Abbott both purchase CLAVE products, principally bulk, non-sterile connectors. B.Braun / McGaw also purchases the McGaw Protected Needle and pays the Company revenue sharing payments on its sales of its SafeLine products. Abbott also purchases the Rhino, a low-priced connector specifically designed for Abbott. Bard distributes the Lopez Valve under a five-year agreement signed in June 1999.

The B.Braun / McGaw Agreement extends to December 2002, and has extension provisions beyond then.

In January 1999, the Company and Abbott agreed to a significant expansion of their agreement for CLAVE products. The new agreement has assurances of substantial increases in sales unit volume, accompanied by price reductions. The new agreement was extended from April 2002 to December 2009, and designates the Company as Abbott's preferred supplier for all Abbott's needlefree technology. In July 1999 the contract was amended to add the CLC2000 (TM) to the agreement.

Management believes that as the healthcare provider market continues to consolidate, the Company's success in marketing and distributing CLAVE products will depend, in part, on the Company's ability, either independently or through strategic supply and distribution arrangements, to secure long-term CLAVE contracts with major buying organizations. Further, the Company's marketing and distribution strategy may result in a significant share of the Company's revenues being concentrated among a small number of customers. The loss of a strategic supply and distribution agreement with a customer or the loss of a large contract by such a customer, could have a material adverse effect on operating results.

Management believes the success of the 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, the Company has been reducing prices to its independent distributors, as well as to I.V. product manufacturers, to protect and expand its market. The price reductions to date have more than been offset by increased volume, although this has not occurred to date for independent distributors in the aggregate. Management expects that the average price of its CLAVE products will continue to decline. 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, 1999 COMPARED TO THE SAME QUARTER LAST YEAR

NET SALES increased $\$ 1,094,000$, or approximately $11 \%$, to $\$ 10,712,000$ in the third quarter of 1999 , compared to $\$ 9,618,000$ during the same period last year. The increase was primarily attributable to the increase in sales of CLAVE products, including custom CLAVE I.V. sets sold by the Company's subsidiary, Budget Medical Products ("BMP").

Net sales to Abbott in the third quarter of 1999 were $\$ 3,472,000$, as compared with net sales of $\$ 2,922,000$ in the third quarter of 1998. Substantially all of the increase in net sales was accounted for by CLAVE products, including custom CLAVE I.V. sets. Net sales of the low-priced Rhino were virtually unchanged. Based on communication with Abbott, Management currently expects the monthly net sales rate to Abbott in the fourth quarter of 1999 to approximate what it was in the first half 1999. Management expects continued increases in sales volume with Abbott after 1999. There can be no assurance as to the amount or timing of future sales to Abbott and whether Management's expectations will be realized.

Net sales to B.Braun / McGaw, including revenue sharing, amounted to $\$ 3,921,000$ in the third quarter of 1999, as compared with $\$ 3,154,000$ in the third quarter of 1998. Substantially all of the increase in net sales was accounted for by CLAVE products, including custom CLAVE I.V. sets. Estimated revenue sharing payments due on B. Braun / McGaw sales of its SafeLine products
and sales of McGaw Protected Needle were virtually unchanged. The increase in net sales of CLAVE products to B.Braun / McGaw reflects a return of B.Braun / McGaw to more normal ordering patterns for CLAVE products. Management expects that net sales of the McGaw Protected Needle will decline in the future as the market for safe connectors continues its shift to needleless technology. Management expects that SafeLine revenue sharing payments will continue, although it is unable to accurately forecast such amounts. Management currently expects net sales to B.Braun / McGaw in the fourth quarter of 1999 to approximate those in the third quarter of 1999, although there is no assurance that those expectations will be realized.

Total net sales of CLAVE products (excluding custom CLAVE I.V. sets) increased from $\$ 6,415,000$ in the third quarter of 1998 to $\$ 6,849,000$ in the third quarter of 1999 , or $7 \%$. The increase in unit shipments was approximately $28 \%$, substantially all of which was accounted for by Abbott and B. Braun / McGaw. CLAVE unit shipments to independent distributors were virtually unchanged.

Average net selling prices decreased approximately 16\% on a year-to-year basis in response to market pressures and because a greater proportion of sales were the lower priced bulk non-sterile CLAVEs sold to Abbott and B.Braun / McGaw. Management expects unit shipments of CLAVE products to independent distributors in 1999 to be at or somewhat below those for 1998. Net sales of CLAVE products to independent distributors are expected to decrease as average selling prices continue to decline.

Net sales of Click Lock and Piggy Lock decreased approximately $31 \%$ in the third quarter of 1999 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 the Lopez Valve increased 48\% in the third quarter of 1999 compared to the same period last year due to an increase in unit shipments. Management expects that net sales of the Lopez Valve will continue to increase for the rest of 1999 on increased shipments to independent distributors and to Bard under the new agreement.

Net sales of custom I.v. sets through BMP increased to $\$ 1,366,000$ in the third quarter of 1999 , as compared with $\$ 878,000$ in the third quarter of 1998, principally because of increased unit shipments of custom I.V. sets incorporating the CLAVE, which account for approximately $60 \%$ of BMP's net sales. BMP's production, much of which is performed manually, is relatively labor-intensive, resulting in a generally lower gross profit margin than for the Company's other products. The Company is continuing steps to expand BMP by increasing systems capabilities, improving manufacturing efficiency, reducing labor cost and enhancing distribution. Because significant innovation is required to achieve these goals, there is no assurance that these steps will achieve the desired results. However, even if they are successful, Management expects that gross profit margins in BMP will continue to be lower than the average historical gross profit margins recorded by the Company because production of its products will continue to be relatively labor intensive. BMP has moved substantially all of its manual assembly operations to the facility that the Company opened in December 1998 in Ensenada, Baja California, Mexico. BMP had an improved gross profit in the first, second and third quarters of 1999 and was profitable in all three quarters.

Total sales to foreign distributors, principally in Europe, were $\$ 351,000$ in the third quarter of 1999, as compared with $\$ 190,000$ in the third quarter of 1998. (Those amounts do not include distribution in Canada.) In April 1998, BOC OHMEDA AB ("Ohmeda"), who was the Company's principal distributor in Europe, sold its European distribution to a competitor of the Company, and the Company has terminated substantially all distribution by Ohmeda since August 1998. The Company believes that the loss of distribution through ohmeda had an adverse effect on the amount of European sales. The Company is currently making new distribution arrangements in Europe. Management expects that its sales to European and other foreign distributors will increase in the future, although there can be no assurance that it will succeed in arranging new distribution in Europe or increase sales in Europe or other areas outside the United States.

In November 1997, the Company commenced marketing the CLC2000, a one piece, swabable connector, engineered to prevent the back-flow of blood into the catheter. Although the Company expects CLC2000 sales to increase throughout 1999 based current conditions, sales to date have not been significant and the

Company does not expect CLC2000 sales to make a significant contribution to total sales for 1999. However, there can be no assurance as to the amount or timing of future CLC2000 sales.

In November 1998, the Company introduced the 102 Valve(TM), the first one-way or two-way drug delivery system. The Company continues to work at overcoming delays in production but did commence limited shipments to customers late in the second quarter of 1999. However, there can be no assurance as to when significant shipments will commence.

In the third quarter of 1999, the Company continued development work on SetFinder(TM), which will directly distribute commodity-type standard I.V. sets. Orders can be taken over the internet at a special "web-site" named SETFINDER.COM , and initially will also be accepted by telephone, facsimile and e-mail. Proprietary technology will enable the Company to minimize working capital requirements. SetFinder products will be assembled at BMP's facility in Mexico. Management launched SETFINDER.COM in the fourth quarter of 1999. Because significant innovation is required to launch and operate SETFINDER.COM, there is no assurance that it will be launched successfully or that current plans for SetFinder will not change materially. Further, there can be no assurance that SetFinder will achieve sales and the amount of future operating profits or losses is dependent upon future development of the SetFinder business, the outcome of which is not known at this time.

Historically, the Company has experienced lower usage of its products in the summer months due to lower censuses in healthcare facilities. That would generally cause the Company's sales in the second and third quarters of the year to be lower than sales in the first and fourth quarters. Since 1995, there have been significant departures from that pattern because significant increases in sales volumes with B.Braun / McGaw and Abbott have often offset the expected seasonal sales decline. Further, those I.V. product manufacturers order bulk non-sterile product many months before sale to the healthcare facility to allow for normal manufacturing times. Thus, Management believes that the large percentage of sales to $I . V$. product manufacturers could lead to non-seasonal quarterly fluctuations in net sales because their ordering patterns may not directly reflect their current sales volumes.

GROSS MARGIN was 55\% during the third quarter of 1999 compared to 58\% during the same period last year. The decrease in the gross margin percentage resulted from a decrease in average selling prices that was not entirely offset by a decrease in unit manufacturing costs. Management currently believes that the gross margin percentage for the remainder of 1999 will be slightly better than that for the third quarter of 1999. The future gross margin percentage is dependent upon average selling prices, actual production costs and overhead absorption through production volume. There can be no assurance that the company will be able to maintain production volumes, which are dependent upon fluctuating sales volumes, or selling prices, at levels necessary to realize its expectations as to the gross margin percentage for the remainder of 1999.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES ("SG\&A"), excluding research and development expenses, were $\$ 2,806,000$, a slight decrease from last year's third quarter, and decreased as a percentage of net sales to $26 \%$ during the third quarter of 1999 compared to $30 \%$ during the same period last year. A significant decrease in litigation costs was only partially offset by increased sales and marketing expenses related to the introduction of new products and expansion of the business.

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RESEARCH AND DEVELOPMENT EXPENSES ("R\&D") were higher in the third quarter of 1999 than in the same quarter of 1998, and increased as a percentage of net sales to $3 \%$ from $2 \%$. Management expects $R \& D$ expenses to continue to increase as the year progresses because of the clinical evaluations of the new CLC2000. 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.

INCOME FROM OPERATIONS increased 11\%, because of the increase in net sales and because the decrease in gross margin percentage was substantially offset by the decrease in total operating expenses as a percentage of net sales.
compared with $\$ 1,823,000$ in the comparable period last year. NET INCOME PER SHARE - DILUTED remained the same comparatively between the third quarter of 1999 and the third quarter of 1998.

NINE MONTHS ENDED SEPTEMBER 30, 1999 COMPARED TO THE SAME NINE MONTHS LAST YEAR

NET SALES increased $\$ 3,823,000$, or approximately $13 \%$, to $\$ 33,853,000$ in the first nine months of 1999 compared to $\$ 30,030,000$ during the same period last year. The increase was primarily attributable to increased sales of CLAVE products including custom CLAVE I.V. sets sold by BMP.

GROSS MARGIN was 57\% during the first nine months of 1999 and 58\% during the same period in 1998. Although average selling prices have continued to decrease over the first nine months of 1999, this was partially offset by a decrease in unit manufacturing costs.

SELLING, GENERAL AND ADMINISTRATIVE expenses ("SG\&A"), excluding research and development expenses, decreased slightly to $\$ 9,272,000$, and decreased as a percentage of net sales to $27 \%$ during the nine months of 1999 compared to $31 \%$ during the nine months of 1998. In the nine months of 1998, there were significant costs related to patent litigation in which the Company was the plaintiff and which was settled in the second quarter of 1998 . The costs of that and other litigation in the first half of 1998 was significantly higher than litigation costs in the first half of 1999. The decrease in litigation costs was partially offset by increased sales and marketing costs related to the introduction of new products and the expansion of the business.

## LIQUIDITY AND CAPITAL RESOURCES

During the nine months ended September 30, 1999, the Company's cash and cash equivalents and investment securities position decreased \$932,000 to $\$ 37,157,000$. Cash provided by operating activities and the exercise of stock options was more than offset by the cost of additions to property and equipment.

Management expects that sales of the Company's products will continue to grow after 1999. If sales continue to increase, accounts receivable and inventories are expected to increase as well. As a result of these and other factors, including increased capital expenditures, the Company's working capital requirements may increase in the foreseeable future.

Management currently expects that capital expenditures for property and equipment will be between approximately $\$ 15$ million and $\$ 16$ million in 1999 to meet the future growth in CLAVE and other products, of which approximately $\$ 12.4$ million has been incurred in the nine months ended September 30, 1999. Most of the additions will be in the Company's San Clemente, California production facilities and will be for molding machines, molds and automated assembly machines, which are expected to be placed in service later in 1999 or in 2000 and 2001. In addition, the Company, in April 1999 purchased a 28,000 square foot building near its other two buildings in San Clemente to accommodate its expansion, and costs will be incurred to add improvements to that building and one of the Company's existing buildings. Production capacity provided by these additions significantly exceed the Company's current production requirements.

In October 1999, it purchased 121,000 shares at a cost of approximately $\$ 1.6$ million. The Company had not purchased treasury stock from August 1998 through September 30 , 1999. It may purchase additional shares in the future. However, future acquisitions, if any, will depend on market conditions and other factors.

The Company believes that its existing working capital, supplemented by income from operations, will be sufficient to fund capital expenditures and increased working capital requirements for the foreseeable future.

YEAR 2000 COMPLIANCE
----------------------

Many older computer programs use only the last two digits to refer to a year. Therefore, they do not properly recognize a year that begins with "20"
rather than "19." This is referred to as the Year 2000 , or Y2K problem. The Y2K problem has been eliminated in many new programs and systems, which are said to be "Y2K compliant." The Company does not believe it will encounter any difficulties related to the Y2K problem with its own programs and systems, including its information technology ("IT") systems and applications and related hardware and its non-IT systems (e.g. manufacturing systems). The Company has inquired of parties with whom it deals, such as customers, vendors and governments as to their Y2K compliance; while it is still awaiting some responses, based on responses to date, the Company is not aware of any problems that could affect it. Any such problems, however, could result in interruptions in delivery of services and materials and payments, among other things. The Company has not developed Y2K non-compliance contingency plans, and based upon the results of its assessments to date, does not expect that such plans will be necessary. Costs to assure $Y 2 K$ compliance have so far been and are expected to remain nominal.

While the Company is not currently aware of any Y2K compliance problems in its own systems, the Company cannot assure that the information it receives from third parties about their Y2K compliance is accurate. Failure of the Company's systems to be Y2K compliant, or failure of significant third parties with which the Company deals to be Y2K compliant, could have a material adverse effect on the Company's operations.

## FORWARD LOOKING STATEMENTS

Various portions of this Report, including this Management's Discussion and Analysis, describe trends in the Company's business and finances that Management perceives and state some of its expectations and beliefs about the Company's future. These statements about the future are "forward looking statements," and the Company identifies them by using words such as "believes," "expects," "estimates," "plans," "will," "continue," "could," and by similar expressions and statements about aims, goals and plans. The forward looking statements are based on the best information currently available to Management and assumptions that Management believes are reasonable, but Management does not intend the statements to be representations as to future results. They include, among other things, statements about:

- future operating results and various elements of operating results, including sales and unit volumes of products, production costs, gross margins, and research and development expense;
- factors affecting operating results, such as shipments to specific customers, product mix, selling prices, future revenue sharing payments to the Company, the market shift to needleless products, achievement of business expansion goals, development of innovative systems capabilities, sales of new products, manufacturing efficiencies, production volumes, overhead absorption, expansion of markets, seasonality and customers' ordering patterns;
new contracts with buying organizations and dependence on a small number of customers;
- competitive and market factors, including continuing development of competing products by other manufacturers, consolidation of the healthcare provider market and downward pressure on selling prices;
working capital requirements, capital expenditures and common stock repurchases; and
Y2K issues.

The kinds of statements described above and similar forward looking statements about the Company's 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. These factors are uncertain, and if one or more of them turn out differently than Management currently expects, the Company's operating results may differ materially from Management's current expectations.

Second, one should read the forward looking statements in conjunction with the Risk Factors in the Company's Current Report on Form 8-K to the Securities and Exchange Commission dated November 5, 1998, which is incorporated by reference.

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

```
    general economic and business conditions;
    the effect of price and safety considerations on the healthcare industry;
    competitive factors, such as product innovation, new technologies,
    marketing and distribution strength and price erosion;
    unanticipated market shifts and trends;
    the impact of legislation affecting government reimbursement of healthcare
    costs;
    changes by the Company's major customers and independent distributors in
    their strategies that might affect their efforts to market the Company's
    products;
    unanticipated production problems; and
    the availability of patent protection and the cost of enforcing and of
    defending patent claims.
```

    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.
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PART II
OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS
-------------------------------

In an action entitled MEDEX, INC. V. ICU MEDICAL, INC. pending in the United States District Court for the Southern District of Ohio, Eastern Division, and served on the Company on November 4, 1999, Medex alleges that ICU Medical infringes its patent by the manufacture and sale of the CLAVE connector, and Medex seeks monetary damages and injunctive relief. The Company, based on advice of counsel, believes the suit against the Company is without merit and the Company intends to vigorously defend itself in the action. The Company has brought an action entitled ICU MEDICAL, INC. V. MEDEX, INC. in the United States District Court for the Central District of California against Medex, Inc. for infringing several patents of the Company by the manufacture and sale of certain blood access devices. The Company seeks monetary damages and injunctive relief. The Company intends to vigorously pursue this matter.

The Company is from time to time involved in various other legal proceedings, either as a defendant of plaintiff, most of which are routine litigation in the normal course of business. The Company believes that the resolution of the legal proceedings in which it is involved will not have a material adverse effect on the Company's 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
------------------------------------------------------------------
Inapplicable

ITEM 5. OTHER INFORMATION

None

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K
(a) Exhibits:

27 Financial Data Schedule
(b) Reports on Form 8-K: None

## 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 12, 1999
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Chief Financial Officer
(Principal Financial Officer and)
Chief Accounting Officer)
<ARTICLE> 5
<MULTIPLIER> 1,000


