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                    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, 2000
OR
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[ ]
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[ ]
TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934
FOR THE TRANSITION PERIOD FROM:

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

            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\mathrm{ 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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\(\qquad\)
```

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 October 18, 2000 |
| :---: | :---: |
| Common | 8,386,131 |

ICU MEDICAL, INC.

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ICU MEDICAL, INC.
                                    Consolidated Balance Sheets
                September 30, 2000 and December 31, 1999
(all dollar amounts in thousands except share data)
ASSETS
CURRENT ASSETS:
    Cash and cash equivalents
    Liquid investments
            Cash and liquid investments
    Accounts receivable, net of allowance for doubtful accounts of \(\$ 432\) and
            \(\$ 368\) as of September 30, 2000 and December 31, 1999, respectively
    Inventories
    Prepaid expenses and other
    Deferred income taxes - current portion
                Total current assets
PROPERTY AND EQUIPMENT, at cost:
    Land, building and building improvements
    Machinery and equipment
    Furniture and fixtures
    Molds
    Construction in process
    Less--Accumulated depreciation
DEFERRED INCOME TAXES
OTHER ASSETS

LIABILITIES AND STOCKHOLDERS' EQUITY
```

CURRENT LIABILITIES:

```
    Accounts payable
    Accrued liabilities
Total current liabilities
STOCKHOLDERS' EQUITY:
    Convertible preferred stock, \(\$ 1.00\) par value
\begin{tabular}{|c|c|c|c|}
\hline \$ & 1,824 & \$ & 965 \\
\hline & 4,299 & & 6,385 \\
\hline & 6,123 & & 7,350 \\
\hline
\end{tabular}
\begin{tabular}{|c|c|}
\hline 9/30/2000 & 12/31/1999 \\
\hline \multicolumn{2}{|l|}{(unaudited)} \\
\hline \$ 2,134 & \$ 1,901 \\
\hline 47,691 & 36,541 \\
\hline 49,825 & 38,442 \\
\hline 7,137 & 7,129 \\
\hline 1,209 & 2,056 \\
\hline 196 & 402 \\
\hline 1,615 & 1,345 \\
\hline 59,982 & 49,374 \\
\hline 12,212 & 12,173 \\
\hline 15,087 & 13,752 \\
\hline 2,599 & 2,524 \\
\hline 5,851 & 5,608 \\
\hline 4,422 & 2,866 \\
\hline \[
\begin{gathered}
40,171 \\
(15,986)
\end{gathered}
\] & \[
\begin{gathered}
36,923 \\
(12,483)
\end{gathered}
\] \\
\hline 24,185 & 24,440 \\
\hline 509 & 806 \\
\hline 863 & 744 \\
\hline \$ 85,539 & \$ 75,364 \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|}
\hline Authorized -- 500,000 shares, issued and outstanding -- none Common stock, \(\$ 0.10\) par value- & - & - \\
\hline Authorized -- \(20,000,000\) shares, issued -- \(8,867,162\) shares & 887 & 887 \\
\hline Additional paid-in capital & 41,534 & 40,843 \\
\hline Treasury stock -- 481,031 and 765,123 shares at & & \\
\hline September 30, 2000 and December 31, 1999, respectively & \((4,756)\) & \((7,153)\) \\
\hline Retained earnings & 41,751 & 33,437 \\
\hline Total stockholders' equity & 79,416 & 68,014 \\
\hline & \$ 85,539 & \$ 75,364 \\
\hline
\end{tabular}

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, 2000 and September 30, 1999
(all dollar amounts in thousands except per share data)
(unaudited)
\begin{tabular}{|c|c|c|c|c|}
\hline NET SALES & \$ & 11,698 & \$ & 10,712 \\
\hline COST OF GOODS SOLD & & 5,517 & & 4,836 \\
\hline Gross profit & & 6,181 & & 5,876 \\
\hline OPERATING EXPENSES: & & & & \\
\hline Selling, general and administrative & & 3,091 & & 2,806 \\
\hline Research and development & & 249 & & 284 \\
\hline Total operating expenses & & 3,340 & & 3,090 \\
\hline Income from operations & & 2,841 & & 2,786 \\
\hline INVESTMENT INCOME & & 532 & & 320 \\
\hline Income before income taxes & & 3,373 & & 3,106 \\
\hline PROVISION FOR INCOME TAXES & & 1,250 & & 1,160 \\
\hline NET INCOME & \$ & 2,123 & \$ & 1,946 \\
\hline NET INCOME PER SHARE & & & & \\
\hline Basic & \$ & 0.25 & \$ & 0.24 \\
\hline Diluted & \$ & 0.23 & \$ & 0.22 \\
\hline WEIGHTED AVERAGE NUMBER OF SHARES & & & & \\
\hline Basic & & 82,922 & & 08,438 \\
\hline Diluted & & 21,757 & & 36,987 \\
\hline
\end{tabular}

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

Net change in current assets and current
liabilities, and other
Net cash provided by operating activities

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, 2000
(All dollar amounts in thousands)
(unaudited)
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 1999 Annual Report to Stockholders.

NOTE 2: Inventories consisted of the following:
\begin{tabular}{|c|c|c|c|c|}
\hline & \multicolumn{2}{|l|}{9/30/00} & \multicolumn{2}{|l|}{12/31/99} \\
\hline Raw material & \$ & 826 & \$ & 962 \\
\hline Work in process & & 261 & & 287 \\
\hline Finished goods & & 122 & & 807 \\
\hline Total & \multicolumn{2}{|l|}{\$ 1,209} & \multicolumn{2}{|l|}{\$ 2,056} \\
\hline
\end{tabular}

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 838,835 and 528,549 for the three months ended September 30, 2000 and 1999, respectively and 675,122 and 594,380 for the nine months ended September 30, 2000 and 1999, respectively. Stock options of subsidiaries did not have a dilutive effect.

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 and state tax credits.

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:
\begin{tabular}{|c|c|c|c|c|c|c|c|}
\hline PRODUCT LINE & 1997 & 1998 & 1999 & Q3-99 & Q3-00 & \[
\begin{gathered}
\text { YTD } \\
\text { Q3-99 }
\end{gathered}
\] & \[
\begin{gathered}
\text { YTD } \\
\text { Q3-00 }
\end{gathered}
\] \\
\hline CLAVE (R) & 65\% & 69\% & 68\% & 64\% & 69\% & 68\% & 70\% \\
\hline CLC2000 (TM) & - & - & 1\% & \(2 \%\) & \(2 \%\) & 1\% & 3\% \\
\hline Click Lock (R) and Piggy Lock (R) & 7\% & 4\% & 3\% & 2\% & 1\% & \(3 \%\) & \(2 \%\) \\
\hline McGaw Protected Needle & 5\% & 4\% & 3\% & 4\% & 1\% & 3\% & \(2 \%\) \\
\hline Lopez Valve(R) and other & 4\% & 5\% & 4\% & 5\% & 3\% & 4\% & 3\% \\
\hline RF100-RF150 ("Rhino") & 7\% & 5\% & 6\% & 6\% & 5\% & 6\% & 5\% \\
\hline Custom I.V. Systems & 6\% & 8\% & 11\% & 13\% & 16\% & 11\% & 13\% \\
\hline B. Braun SafeLine Revenue Sharing & 6\% & 5\% & 4\% & 4\% & \(3 \%\) & 4\% & 2\% \\
\hline Total & 100\% & 100\% & 100\% & 100\% & 100\% & 100\% & 100\% \\
\hline
\end{tabular}

The Company sells its products to independent distributors and through supply and distribution agreements with B.Braun Medical, Inc. ("B.Braun"), Abbott Laboratories ("Abbott") (the "B.Braun 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 and Abbott both purchase CLAVE Products, principally bulk, non-sterile connectors. B. Braun 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, and since July 1999, the CLC2000. Bard purchases the Lopez Valve under a five-year agreement signed in June 1999.

The Abbott Agreement extends to December 2009. The B.Braun Agreement for CLAVE extends to December 2002. Both have extension provisions beyond those dates.

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 protect and expand its market. The price reductions to date have more than been offset by increased volume. 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.

On November 6, 2000, the federal Needlestick Safety and Prevention Act was enacted. The Act modified standards promulgated by the Occupational Safety and Health Administration to require employers to use needleless systems where appropriate to reduce risk of injury to employees from needlesticks. The Company believes the effect of this law will be to accelerate sales of the Company's needleless systems, although it is unable to estimate the amount or timing of such sales.

The Company has commenced two initiatives that, if successful, will reduce its dependence on its current proprietary products. It is seeking to substantially expand its custom I.V. systems business with products sold to medical product manufacturers and independent distributors. The Company is negotiating the terms of an agreement with Abbott under which, if executed, the Company expects to increase its sales of custom I.V. systems. The Company is also launching SETFINDER.COM, which will contract with and distribute commodity-type standard I.V. sets directly to healthcare providers and to group purchasing organizations and independent dealer networks when not in common with the Company's I.V. sets handled by its other distributors. There is no assurance that either one of these initiatives will succeed, or that the anticipated contract with Abbott will be concluded or those expected increases in sales under that contract will occur.

The Company is currently taking steps aimed at improving manufacturing efficiency principally by reducing labor costs and minimizing investment in inventory. The original focus was on production of custom I.V. systems, which is relatively labor intensive; it has now been expanded to include all of the Company's automated and manual manufacturing operations. Substantially all manual assembly is now performed at the facility that the Company opened in December 1998 in Ensenada, Baja California, Mexico. In 1999, the Company made significant investment in automated molding and assembly equipment. Both of these steps have reduced unit production costs. Ongoing steps are aimed at increasing systems capabilities, improving manufacturing efficiency and enhancing distribution, as well as automation of the production of new products, such as the CLC2000 and the 102 Valve(TM), and other products for which volume is growing. Because significant innovation is required to achieve these goals, there is no assurance that these steps will achieve the desired results.

Effective January 1, 2000, the Company reoriented its manufacturing and distribution operations. Marketing and sales operations are now in four groups: medical product manufacturers under the ICU Medical name, independent domestic distributors under the Budget Medical Products ("BMP") name, international manufacturers and distributors under the ICU Medical name, and SetFinder(TM). Manufacturing is in a separate group, producing products for the four marketing and sales groups. BMP, until this reorientation, had been responsible for marketing and sales of only custom I.V. systems to both independent distributors and medical product manufacturers. Because BMP now represents not a product line, but a distribution channel, the custom I.V. systems product line, formerly referred to as the BMP product line, is now referred to as the "custom I.V. systems" product line.

Net sales for each distribution channel, based on the new grouping, were as follows:
\begin{tabular}{|c|c|c|c|c|c|c|c|}
\hline & & & & & & YTD & YTD \\
\hline CHANNEL & 1997 & 1998 & 1999 & Q3-99 & Q3-00 & Q3-99 & Q3-00 \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|c|c|c|c|c|}
\hline Medical product manufacturers & 52\% & 64\% & 71\% & 71\% & 72\% & 70\% & 74\% \\
\hline Independent domestic distributors & 45\% & 33\% & 25\% & 26\% & 23\% & 27\% & 22\% \\
\hline International & 3\% & 3\% & 4\% & 3\% & 5\% & 3\% & 4\% \\
\hline Total & 100\% & 100\% & 100\% & 100\% & 100\% & 100\% & 100\% \\
\hline
\end{tabular}

QUARTER ENDED SEPTEMBER 30, 2000 COMPARED TO THE SAME QUARTER LAST YEAR

NET SALES increased \(\$ 986,000\), or approximately \(9 \%\), to \(\$ 11,698,000\) in the third quarter of 2000 , compared to \(\$ 10,712,000\) during the same period last year. The increase was primarily attributable to a \(20 \%\) increase in sales of CLAVE Products, including custom CLAVE I.V. systems.

Net sales in the third quarter of 2000 fell below Management's expectations and were adversely affected by seasonality and negative fluctuations in ordering patterns, especially by the Company's medical product manufacturer customers. Based on customer orders and market information, Management expects that orders which it had expected in the third quarter of 2000 will be received and filled in the fourth quarter of 2000 , and that net sales for the fourth quarter of 2000 will show strong improvement over those for the third quarter of 2000 and the fourth quarter of 1999. However, there can be no assurance that those expectations will be realized.

Net sales to Abbott in the third quarter of 2000 were \(\$ 6,153,000\), as compared with net sales of \(\$ 3,472,000\) in the third quarter of 1999 . Net sales of CLAVE Products increased to \(\$ 4,921,000\) in the third quarter of 2000 from \(\$ 2,528,000\) in the third quarter of 1999 on a significant increase in unit volume. The balance of the increase in net sales to Abbott was principally in custom CLAVE I.V. systems. Based on terms of the Abbott Agreement, Management expects a substantial increase in CLAVE unit and dollar sales volume with Abbott through the remainder of 2000, although there is no assurance as to the amount of such an increase.

Net sales to B.Braun, including revenue sharing, amounted to \(\$ 2,252,000\) in the third quarter of 2000 , as compared with \(\$ 3,921,000\) in the third quarter of 1999. Net sales of CLAVE Products decreased from \(\$ 2,885,000\) in the third quarter of 1999 to \(\$ 1,757,000\) in the third quarter of 2000 . Fluctuations in the ordering patterns caused sales in the third quarter of 1999 to be unusually high and sales in the third quarter of 2000 to be unusually low. Net sales of CLAVE Products to B. Braun are up \(27 \%\) over the first nine months of 2000 as compared to the first nine months of 1999. Estimated revenue sharing payments due on B. Braun sales of its SafeLine products and sales of McGaw Protected Needle both decreased from last year. Management expects net sales of the McGaw Protected Needle will continue to decline as the market for safe connectors continues its shift to needleless technology. Management expects that SafeLine revenue sharing payments will continue, and although it is unable to accurately forecast such amounts, it does expect the payments to trend downward in the future.

Net sales to independent domestic distributors decreased approximately \(1 \%\) from \(\$ 2,736,000\) in 1999 to \(\$ 2,705,000\) in 2000 . This is attributed to a \(12 \%\) decrease in CLAVE net sales caused principally by a decrease in unit volume and average selling prices of CLAVE Products, partially offset by a \(26 \%\) increase in custom I.V. system sales. Management expects a continued decrease in the net sales of standard CLAVE Products to the independent domestic distributors, but expects later in 2000 and 2001 that the decrease will be partially offset by sales of custom I.V. systems and new products such as the CLC2000 and the 102 Valve. There is no assurance that the Company will achieve increased net sales to independent domestic distributors in the future. Further, the ability of the independent distributors to sustain or increase their sales may be impacted by competition from existing and new competitive products or acquisition of market share by Abbott and B.Braun. Management expects to encounter continued pricing pressure from individual end users, and expects continued declines in net prices to the independent distributors.

Total sales to foreign distributors were \(\$ 551,000\) in the third quarter of 2000 , as compared with \(\$ 351,000\) in the third quarter of 1999 (Those amounts do not include distribution in Canada.). The Company now has distribution arrangements in all of the principal countries in Europe and has recently initiated or expanded distribution in the Middle East, South America and a number of major countries in the Pacific Rim. Net sales to European customers increased moderately from the third quarter of 1999; net sales in the rest of
the world increased substantially and accounted for most of the increase in the sales to foreign distributors. Management expects that its sales to European and other foreign customers will continue to increase in the future, although there is no assurance that those expectations will be realized.

In the fourth quarter of 1999, the Company launched SetFinder, doing business as SETFINDER.COM. Net sales of SetFinder to date have not been significant. The Company believes that, in time, a major portion of the sales of disposable medical products will be initiated on the internet, although the transition to the internet has been slow so far. The Company has and continues to spend a significant effort on the launch and development of SetFinder, although it has temporarily curtailed internet related marketing activities until market opportunities expand. There is no assurance that SetFinder will achieve significant sales and the amount of future operating profits or losses of SetFinder is dependent upon the future development of the SetFinder business, the outcome of which is not known at this time.

Total net sales of CLAVE Products (excluding custom CLAVE I.V. systems) increased from \(\$ 6,849,000\) in the third quarter of 1999 to \(\$ 8,126,000\) in the third quarter of 2000 , or \(19 \%\). The increase in unit shipments was approximately 86\%, almost all of which was accounted for by Abbott. Aggregate average net selling prices decreased approximately \(36 \%\) 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 medical products manufacturers. Management expects unit shipments of CLAVE Products to medical products manufacturers to account for most of the increase in unit shipments of CLAVE Products for the balance of the year 2000 and for 2001 with the balance of the increase to foreign distributors and a small decrease in shipments to domestic distributors.

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. Net sales during the introductory period, which extended through most of 1999, were not significant, but sales to Abbott and the independent domestic distributors started to accelerate in late 1999. Abbott currently accounts for over half of the year-to-date net sales of the CLC2000, although their proportion was somewhat below half in the third quarter of 2000. Management expects continued increases in CLC2000 sales, but there is no assurance as to the amount or timing of future CLC2000 sales.

Net sales of Click Lock and Piggy Lock decreased approximately 41\% in the third quarter of 2000 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 in the third quarter of 2000 decreased 42\% from those in 1999 because there was virtually no sales to Bard in the quarter. Sales to distributors (including foreign distributors) were up approximately \(6 \%\) in the third quarter of 2000 over the third quarter of 1999. Management expects that net sales of the Lopez Valve to distributors will continue to increase, but that total sales of the Lopez Valve for the fourth quarter of 2000 will be less than in the fourth quarter of 1999 because it does not expect any significant purchases by Bard in the fourth quarter.

Net sales of custom I.V. systems increased to \(\$ 1,851,000\) in the third quarter of 2000 , as compared with \(\$ 1,366,000\) in the third quarter of 1999 . Unit sales increased approximately 111\%, with most of that increase with the medical product manufacturers. Management expects continued increase in custom I.V. systems sales for the balance of 2000 and in 2001.

In November 1998, the Company introduced the 102 Valve, the first one-way or two-way drug delivery system. After initial delays in production, the Company actively commenced sales in April 2000. The Company to date has only sold the 102 Valve configured as part of a custom I.V. system, and intends to continue selling it that way for the immediate future. Sales of the lo2 Valve to date have not been significant, but have been increasing monthly. There is no assurance as to the amount or timing of future 102 Valve sales.

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 and Abbott have often offset the expected seasonal sales decline.

Further, those medical product manufacturers order bulk non-sterile product many months before sale to the healthcare facility to allow for normal manufacturing lead-times. Thus, Management believes that the large percentage of sales to medical 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 53\% during the third quarter of 2000 compared to 55\% during the same period last year. Fluctuation in production during the quarter and the relatively low level of sales resulted in unabsorbed overhead. The Company expects the gross margin to increase in the fourth quarter of 2000 as expected increased production volume results in greater absorption of overhead. That, coupled with the benefits of capital equipment added in 1999, is expected to offset the effect of continuing decreases in average selling prices. Management expects that gross margins for custom I.V. systems, SetFinder products and certain other manually assembled products will be lower than those historically recorded by the Company because their production is relatively labor intensive. The Company expects that its unit production costs will continue to decrease in 2001, but that the gross margin percentage will be equal to or slightly lower than that ultimately achieved for the full year 2000, as average unit sales prices continue to decrease, and manually assembled products become a greater percentage of the Company's sales.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES ("SG\&A"), excluding research and development expenses, increased \(10 \%\) to \(\$ 3,091,000\), and were \(26 \%\) of net sales in the third quarter of 2000 compared to \(26 \%\) during the same period last year. Spending increased for administrative and litigation costs, while sales and marketing costs were relatively unchanged. Management expects SG\&A the fourth quarter of 2000 to increase over last year at a higher rate than in the third quarter, but to decline as a percentage of sales if the fourth quarter sales expectations are realized.

In 2001, Management expects SG\&A will be a somewhat higher percentage of sales than in the first three quarters of 2000 because of higher spending in all categories.

RESEARCH AND DEVELOPMENT EXPENSES ("R\&D") were lower in the third quarter of 2000 than in the same quarter of 1999 , principally because of spending on clinical evaluations of the new CLC2000 was less than expected. Management expects that continuing work on the clinical evaluations, as well as software development for SetFinder and the custom I.V. systems business, in addition to work on new products will cause R\&D expenses to increase for the balance of the year. 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.

The Company plans to launch, in limited markets, a new I.V. connector currently under development. The Company expects to apply in early 2001 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. There is no assurance that the FDA will grant marketing clearance, that the company will launch this new product, or that it will achieve sales if and when the company commences marketing it.

INCOME FROM OPERATIONS increased \(\$ 55,000\) or \(2 \%\) and was \(24 \%\) of net sales in the third quarter of 2000 , as compared with \(26 \%\) in the third quarter of 1999. The \(\$ 305,000\) increase in gross profit was substantially offset by the \(\$ 250,000\) increase in operating expenses.

INVESTMENT INCOME increased \(\$ 212,000\), or \(66 \%\), on the third quarter of 2000 as compared with the third quarter of 19999, because of an increase in the investment portfolio as well as an increase in yield, as market rates have generally moved higher.

NET INCOME increased \(9 \%\) to \(\$ 2,123,000\) in the third quarter of 2000 as compared with \(\$ 1,946,000\) in the comparable period last year. NET INCOME PER

SHARE - DILUTED increased \(\$ 0.01\), in the third quarter of 2000 over the third quarter of 1999.

NINE MONTHS ENDED SEPTEMBER 30, 2000 COMPARED TO THE SAME NINE MONTHS LAST YEAR

NET SALES increased \(\$ 5,717,000\), or approximately \(17 \%\), to \(\$ 39,570,000\) in the first nine months of 2000 compared to \(\$ 33,853,000\) during the same period last year. The increase was primarily attributable to increased sales of CLAVE Products including custom CLAVE I.V. sets.

GROSS MARGIN was \(56 \%\) during the first nine months of 2000 as compared to 57\% in the first nine months of 1999. The decrease in average selling prices over the first nine months of 2000 was only partially offset by a decrease in unit manufacturing costs, principally because of unabsorbed overhead in the third quarter.

SELLING, GENERAL AND ADMINISTRATIVE expenses ("SG\&A"), excluding research and development expenses, increased by \(\$ 1,115,000\) to \(\$ 10,387,000\), and decreased as a percentage of net sales to \(26 \%\) during the first nine months of 2000 compared to \(27 \%\) during the first nine months of 1999 . The spending increase was principally for administrative and litigation costs. Sales and marketing costs were approximately the same, in the aggregate in the first nine months of both 1999 and 2000 .

INCOME FROM OPERATIONS increased \(\$ 2,002,000\), or \(22 \%\) principally because of the increase in net sales and the reduction, as a percentage of net sales, in operating expenses.

INVESTMENT INCOME increased \(\$ 493,000\), or \(48 \%\) over the first nine months of 1999. Approximately half the increase is because of an increase in the investment portfolio, and about half is because of an increase in investment yield, principally because of the general increase in market rates.

NET INCOME increased \(\$ 1,615,000\), or \(25 \%\), NET INCOME PER SHARE - DILUTED increased 24\%, a somewhat lower percentage than the increase in net income because of an increase in the weighted average number of shares outstanding.

\section*{LIQUIDITY AND CAPITAL RESOURCES}
--------------------------------------

During the nine months ended September 30, 2000, the Company's cash and cash equivalents and investment securities position increased \(\$ 11,383,000\) to \(\$ 49,825,000\). Cash provided by operating activities and the exercise of stock options was partially offset by the cost of additions to property and equipment.

Management expects that sales of the Company's products will continue to grow in 2000. 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. The decrease in inventory from December 1999 to September 2000 is because of aggressive efforts by the Company to minimize its investment in inventory.

Management currently expects that capital expenditures for property and equipment will be between approximately \(\$ 4\) million and \(\$ 5\) million in 2000 to meet the future growth in CLAVE and other products. All automated production is performed in San Clemente, California, and automated production capacity, after the significant expenditures in 1999, significantly exceeds the Company's current production requirements.

The Company has not purchased treasury stock since October 1999, except for a small amount in March 2000. 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.

\section*{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, SafeLine revenue share, production costs, impact of legislation, gross margins, SG\&A, and research and development expense;
- factors affecting operating results, such as shipments to specific customers, the timing of receipt of orders from customers, product mix, selling prices, the market shift to needleless products, achievement of business expansion goals, development of innovative systems capabilities, introduction and sales of new products, production delays, sales initiated on the internet, manufacturing efficiencies, production volumes, overhead absorption, expansion of markets, seasonality and customers' ordering patterns;
- new contracts with specific customers, buying organizations and dependence on a small number of customers;
- outcome of litigation;
o competitive and market factors, including continuing development of competing products by other manufacturers, consolidation of the healthcare provider market and downward pressure on selling prices and market acceptance of innovative ordering and distribution systems;
o working capital requirements, changes in accounts receivable and inventory, capital expenditures, costs to develop SetFinder and common stock repurchases.

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. Those 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, 1999, 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:
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general economic and business conditions;

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- 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;
- unanticipated market shifts and trends;
o 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 or products incorporating the company's products;
o unanticipated production problems; and
o 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.

PART II
OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS
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In an action filed July 19, 1999, 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 one of its patents 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. On July 29, 1999, the Company 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.

On April 7, 1998, in an action entitled ALLEN PETTY, DBA CARMEL DEVELOPMENT INTERNATIONAL V. ICU MEDICAL, INC., an Orange County, California, Superior Court jury rendered a verdict in favor of the Plaintiff and against the Company. The Company has appealed to have the judgment overturned. The Company accrued a provision for this matter in its June 1998 financial statements.

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

ITEM 2. CHANGES IN SECURITIES
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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
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(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
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Francis J. O'Brien
Chief Financial Officer
(Principal Financial Officer and)
Chief Accounting Officer)
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