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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, 2001
                    OR
[ ]
            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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$\qquad$

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                        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 ~
(Address of Principal Executive Offices)
(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 20, 2001
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Outstanding at October 20, 2001
Common
8,662,072
ICU MEDICAL, INC.
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> ICU MEDICAL, INC.
> Consolidated Balance Sheets
> September 30,2001 and December 31,2000
> (all dollar amounts in thousands except share data)
\begin{tabular}{|c|c|c|}
\hline \multicolumn{3}{|l|}{ASSETS} \\
\hline & 9/30/01 & 12/31/00 \\
\hline CURRENT ASSETS: & (unaudited) & \\
\hline Cash and cash equivalents & \$ 2,261 & \$ 1,945 \\
\hline Liquid investments & 65,371 & 48,841 \\
\hline Cash and liquid investments & 67,632 & 50,786 \\
\hline Accounts receivable, net of allowance for doubtful accounts of \(\$ 534\) and \(\$ 505\) as of September 30, 2001 and December 31, 2000, respectively & 10,394 & 12,425 \\
\hline Inventories & 2,411 & 1,435 \\
\hline Prepaid expenses and other & 481 & 402 \\
\hline Deferred income taxes - current portion & 2,356 & 2,150 \\
\hline Total current assets & 83,274 & 67,198 \\
\hline \multicolumn{3}{|l|}{PROPERTY AND EQUIPMENT, at cost:} \\
\hline Land, building and building improvements & 13,584 & 13,505 \\
\hline Machinery and equipment & 15,528 & 15,601 \\
\hline Furniture and fixtures & 3,144 & 2,763 \\
\hline Molds & 7,182 & 6,804 \\
\hline Construction in process & 4,357 & 1,458 \\
\hline Less--Accumulated depreciation & \[
\begin{gathered}
43,795 \\
(19,385)
\end{gathered}
\] & \[
\begin{gathered}
40,131 \\
(16,210)
\end{gathered}
\] \\
\hline & 24,410 & 23,921 \\
\hline DEFERRED INCOME TAXES & 378 & 889 \\
\hline OTHER ASSETS & 895 & 852 \\
\hline & \$ 108,957 & \$ 92,860 \\
\hline
\end{tabular}

LIABILITIES AND STOCKHOLDERS' EQUITY
CURRENT LIABILITIES:
\begin{tabular}{|c|c|c|c|c|}
\hline Accounts payable & \$ & 2,248 & \$ & 1,687 \\
\hline Accrued liabilities & & 8,239 & & 7,793 \\
\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 Nine Months Ended
September 30, 2001 and September 30, 2000
(all dollar amounts in thousands except per share data)
(unaudited)
\begin{tabular}{|c|c|c|c|c|}
\hline & & the Nin & nt & Ended \\
\hline & & 30/01 & & \(30 / 00\) \\
\hline NET SALES & \$ & 48,172 & \$ & 39,570 \\
\hline COST OF GOODS SOLD & & 20,215 & & 17,316 \\
\hline Gross profit & & 27,957 & & 22,254 \\
\hline OPERATING EXPENSES: & & & & \\
\hline Selling, general and administrative & & 11,890 & & 10,387 \\
\hline Research and development & & 872 & & 747 \\
\hline Total operating expenses & & 12,762 & & 11,134 \\
\hline Income from operations & & 15,195 & & 11,120 \\
\hline INVESTMENT INCOME & & 1,626 & & 1,525 \\
\hline Income before income taxes & & 16,821 & & 12,645 \\
\hline PROVISION FOR INCOME TAXES & & 6,205 & & 4,680 \\
\hline NET INCOME & \$ & 10,616 & \$ & 7,965 \\
\hline NET INCOME PER SHARE & & & & \\
\hline Basic & \$ & 1.25 & \$ & 0.96 \\
\hline Diluted & \$ & 1.11 & \$ & 0.89 \\
\hline WEIGHTED AVERAGE NUMBER OF SHARES & & & & \\
\hline Basic & & 509,422 & & 09,507 \\
\hline Diluted & & 53,719 & & 84,629 \\
\hline
\end{tabular}
\begin{tabular}{|c|c|}
\hline 9/30/01 & 9/30/00 \\
\hline \$ 10,616 & \$ 7,965 \\
\hline \[
\begin{aligned}
& 3,475 \\
& 2,292
\end{aligned}
\] & \[
\begin{array}{r}
3,690 \\
\quad(15)
\end{array}
\] \\
\hline 16,383 & 11,640 \\
\hline
\end{tabular}


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, 2001
(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 2000 Annual Report to Stockholders.

NOTE 2: Inventories consisted of the following:
\begin{tabular}{|c|c|c|c|c|}
\hline & \multicolumn{2}{|r|}{9/30/01} & \multicolumn{2}{|r|}{12/31/00} \\
\hline Raw material & \$ & 1,569 & \$ & 1,050 \\
\hline Work in process & & 359 & & 140 \\
\hline Finished goods & & 483 & & 245 \\
\hline Total & \$ & 2,411 & \$ & 1,435 \\
\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 \(1,085,388\) and 838,835 for the three months ended September 30, 2001 and 2000, respectively and 1,064,297 and 675,122 for the nine months ended September 30, 2001 and 2000, 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. and Porex Medical Products, Inc. over patent matters and B. Braun Medical Inc. over contractual and 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 & 1998 & 1999 & 2000 & Q3-00 & Q3-01 & \[
\begin{gathered}
\text { YTD } \\
\text { Q3-00 }
\end{gathered}
\] & \[
\begin{gathered}
\text { YTD } \\
\text { Q3-01 }
\end{gathered}
\] \\
\hline CLAVE (R) & 69\% & 68\% & 71\% & 69\% & 79\% & 70\% & 75\% \\
\hline CLC2000 (TM) & -- & 1\% & 4\% & 2\% & \(2 \%\) & 3\% & 3\% \\
\hline Protected Needle Products & 8\% & 6\% & 3\% & 2\% & 3\% & 4\% & 2\% \\
\hline Lopez Valve (R) and other & 5\% & 4\% & 3\% & 3\% & 3\% & 3\% & 3\% \\
\hline RF100-RF150 ("Rhino") & 5\% & 6\% & 5\% & 5\% & 1\% & 5\% & 3\% \\
\hline Custom I.V. Systems & 8\% & 11\% & 12\% & 16\% & 11\% & 13\% & 13\% \\
\hline B. Braun SafeLine Revenue Sharing & 5\% & 4\% & 2\% & 3\% & 1\% & 2\% & 1\% \\
\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 Abbott Laboratories ("Abbott"), B.Braun Medical Inc. ("B.Braun"), (the "Abbott Agreements" and the "B.Braun Agreements," respectively) and certain other medical product manufacturers. Most independent distributors handle the full line of the Company's products. Abbott and B. Braun both purchase CLAVE Products, principally bulk, non-sterile connectors. Abbott also purchases the Rhino, a low-priced connector specifically designed for Abbott, and since July 1999, the CLC2000, and under an agreement signed February 27, 2001, custom I.V. sets. B. Braun also purchases the McGaw Protected Needle and pays the Company revenue sharing payments on its sales of its SafeLine products. The Company also sells certain of its products to a number of other medical product manufacturers.

The Abbott Agreements extend to December 2009. The B.Braun Agreement for CLAVE products extends to December 2002. All 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 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.

The federal Needlestick Safety and Prevention Act enacted in November 2000, and which became effective in April, 2001 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.

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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. On February 27, 2001, the Company signed an agreement with Abbott under which the Company will manufacture all new custom I.V. sets for sale by Abbott, and the two companies will jointly promote the products under the name SetSource. The Company expects a significant increase in sales of custom I.V. systems under this agreement. The Company has also launched SetFinder, a separate subsidiary, 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. There is no assurance that either one of these initiatives will succeed, or that the expected increases in sales under the February 2001 contract with Abbott will occur.

The Company has been taking steps to improve manufacturing efficiency principally by reducing labor costs, reducing time needed to produce an order, 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, 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.

The Company distributes products through four distribution channels. Net sales for each distribution channel as a percentage of total net sales were as follows:
\begin{tabular}{|c|c|c|c|c|c|c|c|}
\hline CHANNEL & 1998 & 1999 & 2000 & Q3-00 & Q3-01 & \[
\begin{aligned}
& \text { YTD } \\
& \text { Q3-00 }
\end{aligned}
\] & \[
\begin{gathered}
\text { YTD } \\
\text { Q3-01 }
\end{gathered}
\] \\
\hline Medical product manufacturers & 64\% & 71\% & 74\% & 72\% & 78\% & 74\% & 72\% \\
\hline Independent domestic distributors & 33\% & 25\% & 21\% & 23\% & 13\% & 22\% & 19\% \\
\hline International & 3\% & 4\% & 5\% & 5\% & 8\% & 4\% & 8\% \\
\hline SetFinder & -- & ---- & -- & -- & 1\% & 1\% & 1\% \\
\hline
\end{tabular}
\begin{tabular}{|c|c|c|c|c|c|c|c|}
\hline Total & 100\% & 100\% & 100\% & 100\% & 100\% & 100\% & 100\% \\
\hline
\end{tabular}

QUARTER ENDED SEPTEMBER 30, 2001 COMPARED TO THE SAME QUARTER LAST YEAR

NET SALES increased \(\$ 4,516,000\), or approximately \(39 \%\), to \(\$ 16,214,000\) in the third quarter of 2001 , compared to \(\$ 11,698,000\) during the same period last year. The increase was primarily attributable to a 44\% increase in sales of CLAVE Products, including custom CLAVE I.V. systems.

Net sales to Abbott in the third quarter of 2001 were \(\$ 9,229,000\), as compared with net sales of \(\$ 6,153,000\) in the third quarter of 2000 . Net sales of CLAVE Products to Abbott increased to \(\$ 8,550,000\) in the third quarter of 2001 from \(\$ 4,921,000\) in the third quarter of 2000 on a significant increase in unit volume. Sales of the CLC2000, Rhino and custom CLAVE I.V. sets declined, as Abbott balanced its inventory position for those product lines. The Company expects sales of the CLC2000 to Abbott will increase in the future. Sales of the Rhino are expected to continue the decline which started earlier in 2001 as the market shifts to needleless technology. Sales under the new custom I.V. set program, called SetSource, partially offset declines in the other product lines in the third quarter. 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 2001, although there is no assurance as to the amount of such an increase.

Net sales to B.Braun, including revenue sharing, amounted to \(\$ 3,319,000\) in the third quarter of 2001 , as compared with \(\$ 2,252,000\) in the third quarter of 2000. Net sales of CLAVE Products to B. Braun increased from \(\$ 1,757,000\) in the third quarter of 2000 to \(\$ 2,649,000\) in the third quarter of 2001 . Unit volume of CLAVE sales to B. Braun year-to-date is higher than in 2000 , but this has been offset by a decline in average sales price, so the dollar amount of net sales of CLAVE Products to B. Braun year-to-date in 2001 is virtually the same as in 2000. Sales of the McGaw Protected Needle increased from last year, but Management expects future sales to decline, as they have in most recent periods, as the market for safe connectors continues to shift to needleless technology. Estimated revenue sharing payments due on B.Braun sales of its SafeLine products decreased from last year. Management expects that SafeLine revenue sharing payments will continue, although it is unable to accurately forecast such amounts; the SafeLine Agreement was recently extended to December 2001.

Net sales to independent domestic distributors decreased approximately \(20 \%\) from \(\$ 2,705,000\) in 2000 to \(\$ 2,156,000\) in 2001 . This is attributed principally to a \(48 \%\) decrease in CLAVE net sales caused principally by a decrease in unit volume and average selling prices of CLAVE Products. Management expects an increase in the fourth quarter of 2001 over the third quarter in the net sales of standard CLAVE Products to the independent domestic distributors as well as an increase in sales of custom I.V. systems and new products such as the CLC2000 and the 102 Valve(TM), and increases in net sales of the Lopez Valve. However, 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 \(\$ 1,207,000\) in the third quarter of 2001 , as compared with \(\$ 551,000\) in the third quarter of 2000 (Those amounts do not include distribution in Canada.) The Company now has distribution arrangements in all of the principal countries in Western Europe, the Pacific Rim and South America, and in South Africa. Management expects that its sales to 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 spent 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 \(\$ 8,126,000\) in the third quarter of 2000 to \(\$ 12,765,000\) in the third quarter of 2001 , or \(57 \%\). The increase in unit shipments was approximately 83\%, almost all of which was accounted for by medical product manufacturers. Aggregate average net selling prices decreased approximately 14\% 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.

In October 2001, the Company commenced production of the
"MicroCLAVE(TM)." It is smaller than the existing CLAVE but is functionally identical. It will initially be marketed as an extension of the CLAVE Product line for use where its smaller size is advantageous, such as pediatric care.

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. In the third quarter of 2001 , sales to domestic and international distributors accounted for a \(62 \%\) growth in sales of the CLC2000 over the third quarter of 2000 . Abbott accounted for approximately half of the net sales of the CLC2000 in the first quarter of 2001 , but has purchased only a small amount since then as it balanced its inventory position, and sales to Abbott were not significant in the third quarters of 2001 or 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 44\% in the third quarter of 2001 compared to the same period last year. Management expects continued decline in these sales as the safe connector market continues its shift to needleless technology.

Net sales of the Lopez Valve in the third quarter of 2001 decreased 14\% from those in 2000. Management expects that net sales of the Lopez Valve will increase for the remainder of 2001 on increased shipments to independent distributors.

Net sales of custom I.V. systems were \(\$ 1,848,000\) in the third quarter of 2001, as compared with \(\$ 1,851,000\) in the third quarter of 2000 . Unit sales decreased slightly, offset by a small increase in average selling prices. Management believes that the lack of growth in sales in the third quarter was because of normal seasonality as well as inventory balancing in the distribution system, and expects net sales to increase in the fourth quarter of 2001.

In November 1998, the Company introduced the 102 Valve, the first one-way or two-way drug delivery system. After overcoming initial delays in production, the Company re-launched the product in January 2000. Sales to date have not been significant, and 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 \(58 \%\) during the third quarter of 2001 compared to \(53 \%\) during the same period last year. Fluctuation in production during the third
quarter of 2000 and the relatively low level of sales in that quarter resulted in less absorption of overhead in the third quarter of 2000 . In the third quarter of 2001, increases in production volume resulted in greater absorption of overhead, and that offset the effect of lower average selling prices. The Company 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 for the fourth quarter will be equal to or slightly lower than in the third quarter, as average unit sales prices continue to decrease, and manually assembled products become a greater percentage of the Company's sales.

Electrical energy costs at the Company's manufacturing facilities in the third quarter of 2001 continued to moderate somewhat from the first and second quarters of 2001 , but were still approximately double what they were in the first quarter of 2000 , the last quarter before the sharp rate increase experienced since May 2000. Most of the increase was because of rate increases. Electrical energy costs were approximately \(1 \%\) of sales in the third quarter of 2001, down from \(2 \%\) of sales in the first quarter of 2001 and \(2 \%\) in the third quarter of 2000. Management is unable to predict what those costs will be for the balance of 2001, but does not expect them to increase to the levels of the
first half of 2001. There has been no interruption in service. The significant uncertainty as to the availability of electrical energy in California has abated, although there is still uncertainty as to future costs. Any further significant increase in electrical costs or a significant interruption in service could have an adverse effect on the Company.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES ("SG\&A"), excluding research and development expenses, increased \(39 \%\) to \(\$ 4,287,000\), and were \(26 \%\) of net sales in the third quarter of 2001 compared to \(26 \%\) during the same period last year. Spending increased for litigation costs and administrative costs. Sales and marketing costs increased, but decreased as a percentage of sales. Management expects \(S G \& A\) in the fourth quarter of 2001 to increase somewhat from the level in the third quarter, but to decrease as a percentage of sales.

RESEARCH AND DEVELOPMENT EXPENSES ("R\&D") were approximately the same in the third quarters of 2001 and 2000. Spending on software development and on clinical evaluations of the new CLC2000 was higher, offset by decreased new product development costs. Management expects that continuing work on the clinical evaluations of the CLC 2000, as well as software development for the custom I.V. systems business, and work on new products will cause R\&D expenses to increase in the fourth quarter of 2001 . 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 2002 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 \(\$ 1,978,000\) or \(70 \%\) and was \(30 \%\) of net sales in the third quarter of 2001 , as compared with \(24 \%\) in the third quarter of 2000. Gross profit increased \(\$ 3,166,000\) while operating expenses increased only \$1,188, 000 .

INVESTMENT INCOME declined in the third quarter of 2001 as compared with the third quarter of 2000 , notwithstanding the increase in the investment portfolio, because of declines in interest rates since the beginning of 2001.

NET INCOME increased 56\% to \(\$ 3,319,000\) in the third quarter of 2001 as compared with \(\$ 2,123,000\) in the comparable period last year. NET INCOME PER SHARE - DILUTED was \(\$ 0.34\), in the third quarter of 2001 , a \(48 \%\) increase over the third quarter of 2000 . The percentage increase was less than that for net income because there were more shares outstanding and there were more dilutive shares as a result of the higher market price of the Company's common stock.

NET SALES increased \(\$ 8,602,000\), or approximately \(22 \%\), to \(\$ 48,172,000\) in the first nine months of 2001 compared to \(\$ 39,570,000\) 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 58\% during the first nine months of 2001 as compared to \(56 \%\) in the first nine months of 2000 . The decrease in average selling prices over the first nine months of 2001 was more than offset by a decrease in unit manufacturing costs.

SG\&A excluding R\&D increased by \(\$ 1,503,000\) to \(\$ 11,890,000\), and decreased as a percentage of net sales to \(25 \%\) during the first nine months of 2001 compared to \(26 \%\) during the first nine months of 2000 . The spending increase was principally for administrative and litigation costs. Sales and marketing costs increased, but decreased as a percentage of net sales.

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INCOME FROM OPERATIONS increased \(\$ 4,075,000\), or \(37 \%\) principally because of the increase in net sales and the reduction, as a percentage of net sales, in operating expenses.

INVESTMENT INCOME increased \(\$ 101,000\), or \(7 \%\) over the first nine months of 2000. The increase in investment income was less than the increase in the investment portfolio because of the effect of declines in interest rates since the beginning of 2001.

NET INCOME increased \(\$ 2,651,000\), or \(33 \%\), NET INCOME PER SHARE - DILUTED increased 25\%, a somewhat lower percentage than the increase in net income because of an increase in the weighted average number of shares outstanding.

LIQUIDITY AND CAPITAL RESOURCES
----------------------------------

During the nine months ended September 30, 2001, the Company's cash and cash equivalents and investment securities position increased \$16,846,000 to \(\$ 67,632,000\). 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 2001 and 2002. 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 \(\$ 6\) million and \(\$ 7\) million in 2001 principally for production tooling for capacity expansion and new products.

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.

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, future increases in sales of custom I.V. systems, SafeLine revenue share, production costs, gross margins, \(S G \& A\), and R\&D;

\section*{13}
factors affecting operating results, such as shipments to specific customers, product mix, seasonality of sales, selling prices, the market shift to needleless products, impact of safety legislation on buying patterns, achievement of business expansion goals, development of innovative systems capabilities, sales of new products, sales initiated on the internet, direct sales of standard I.V. sets, manufacturing efficiencies, labor costs, unit production costs, electrical energy costs and availability, production automation, and expansion of markets;
new or extended contracts with manufacturers and buying organizations and dependence on a small number of customers; outcome of litigation; competitive and market factors, including continuing development of competing products by other manufacturers, consolidation of the healthcare provider market and downward pressure on selling prices; and working capital requirements, changes in accounts receivable and inventories, capital expenditures 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, 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

\section*{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 or products incorporating 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.

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 believes the suit against it is without merit and has been
vigorously defending 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.

In an action filed May 24, 2001, entitled POREX MEDICAL PRODUCTS, INC.
V. ICU MEDICAL, INC. pending in the United States District Court for the Central District of California, Porex alleges that ICU Medical infringes one of its patents by the offering for sale and selling the CLC 2000 , and Porex seeks monetary damages and injunctive relief. The Company believes the suit against it is without merit and the Company intends to vigorously defend itself in the action.

In an action filed June 29, 2001, entitled ICU MEDICAL, INC. V. B. BRAUN MEDICAL, INC. pending in the Superior Court of the State of California, County of Orange, the Company is seeking certain judicial declarations concerning a controversy over each of the parties rights, duties and obligations under the Manufacture and Supply Agreement for CLAVE Products. On July 27, 2001, the case was removed to the United States District Court for the Central District of California. No monetary damages are sought. Each party has indicated a willingness to attempt a negotiated resolution, although there can be no assurance that such a resolution will be achieved.

In an action filed August 21, 2001 entitled ICU MEDICAL, INC. V. B BRAUN MEDICAL, INC. pending in the United States District Court for the Northern District of California, the Company alleges that B. Braun Medical, Inc. infringes two patents of the Company by the manufacture and sale of its UltraSite medical connector. The Company seeks monetary damages and injunctive relief and intends to vigorously pursue this matter.

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
Inapplicable

ITEM 3. DEFAULT UPON SENIOR SECURITIES
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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: None
(b) Reports on Form 8-K: None

ICU Medical, Inc.
(Registrant)
/s/ Francis J. O'Brien
Date: November 8, 2001
Francis J. O'Brien
Chief Financial Officer
(Principal Financial Officer and Chief Accounting Officer)```

