SECURITIES AND EXCHANGE COMMISSIONS

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported) February 15, 2002

ICU MEDICAL, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	0-19974	33-0022692
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

951 Calle Amanecer, San Clemente, California	92673
(Address of principal executive offices)	(Zip Code)

(949) 366-2183

Registrant's telephone number, including area code

N/A

(Former name or former address, if changed since last report)

ITEM 5. OTHER EVENTS.

ICU Medical, Inc. from time to time makes forward looking statements, as that term is defined in the Private Securities Litigation Reform Act of 1995, in reports and registration statements that we file with the Securities and Exchange Commission and in our communications with our stockholders and the investing public. Such forward looking statements involve a number of risks and uncertainties. We have briefly summarized our business below and described certain risks associated with our business. Investors should carefully read and consider the risk factors when evaluating the forward looking statements in our reports, registration statements and public communications.

First person pronouns used in this Report, such as "we," "us" and "our" refer to ICU Medical, Inc. and its subsidiaries unless the context indicates otherwise.

THE COMPANY

We develop, manufacture, sell and distribute disposable medical products. Our principal products are proprietary safe medical connection devices for use in intravenous ("I.V.") therapy applications. We also produce custom I.V. systems that incorporate our proprietary products and low-cost, generic I.V. systems.

We pioneered the development of safe I.V. connectors designed to protect healthcare workers and their patients from the spread of infectious diseases, such as Hepatitis B and C and Human Immunodeficiency Virus ("HIV"), by significantly reducing the risk of accidental needlesticks. The CLAVE(R), a one-piece, needleless I.V. connection device, accounts for approximately 74% of our sales (excluding custom I.V. systems).

Although CLAVE sales have increased steadily since we introduced it in 1993, we have undertaken a strategic initiative to reduce our dependence on the CLAVE. The initiative involves a planned transition from being primarily a manufacturer of I.V. system components to producing and distributing complete

I.V. systems, both custom and low-cost, generic systems. Many of the I.V. systems include our I.V. connection products.

A key element of our strategy to expand our custom and generic I.V. system business has been the development and implementation of our proprietary software for customer orders and order tracking, combined with an innovative system to coordinate manufacture of components in the U.S., assembly of components into sets in Mexico and distribution of finished products. We believe that we offer customers substantially shorter delivery times and lower costs than other manufacturers of I.V. systems can currently offer.

We have strategic supply and distribution agreements with two of the largest worldwide suppliers of I.V. products, Abbott Laboratories ("Abbott") and B.Braun Medical, Inc. ("B.Braun"). The agreements (as currently amended, referred to as the "Abbott Agreement" and the "B.Braun Agreement") provide that Abbott and B.Braun may sell our I.V. connectors as components, and in certain prepackaged I.V. systems incorporating our components. Under these agreements, Abbott and B.Braun may offer these products to large hospitals, hospital chains and home healthcare providers, including those with which they have established full-line supply contracts for I.V. products. The Abbott Agreement extends to December 2009 and the B.Braun Agreement extends to December 2002, and both have renewal provisions beyond those dates. We also distribute our products through a network of independent distributors in the United States and internationally. In February 2001, we entered into an agreement with Abbott under which we will manufacture all new custom I.V. sets for sale by Abbott, and we and Abbott will jointly promote the products under the name SetSource. This agreement also extends to December 2009.

Heightened awareness of the risk of infection from needlesticks and the substantial expense to healthcare providers of complying with regulatory protocols when needlesticks occur, have led to growing demand for safe medical devices such as our protective I.V. connectors. In addition, the federal Needlestick and Safety Prevention Act, enacted in November 2000, 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.

Our I.V. connector products offer various combinations of features including needleless or enclosed needle connection systems and positive locking mechanisms. The Lopez Valve(R), designed to be connected into nasogastric, gastric or jejunostomy tube systems, creates a closed system to prevent contact with body fluids during therapy. The CLC 2000(TM) is a one piece, swabbable connector engineered to prevent the backflow of blood into a catheter. The 1o2 Valve(TM), a drug delivery system incorporating a one-way check valve and a button for the infusion and aspiration of I.V. fluids. We have several new products under development, including new versions of the CLAVE. We have patents or pending patent applications on each of our current connector products and the 1o2 Valve.

The CLAVE and our other I.V. connectors currently account for approximately 84% of our sales (excluding custom I.V. systems), and CLAVE sales continue to grow. The success of the CLAVE has motivated other manufacturers to attempt to develop competing needleless products, which may incorporate many of the same functional and physical characteristics as the CLAVE. In addition, I.V. connectors using older technologies still account for the majority of I.V. connectors in the market and many of these purport to offer lower prices than the CLAVE. While we believe that the CLAVE offers healthcare providers an advantageous combination of safety, ease of use, reliability and cost effectiveness, we nevertheless encounter competition from manufacturers of other protective devices. Several of these manufacturers have substantially greater financial and other resources and larger marketing and distribution systems than we do. A combination of competitive and economic factors has resulted in continuing pricing pressure on the CLAVE, and we have steadily reduced prices on the CLAVE and expect to continue to do so if conditions continue to warrant it. To reduce dependence on the CLAVE and add greater value to our products, we are seeking to expand substantially our custom I.V. systems and generic I.V. systems business. Hospitals and other healthcare providers purchase I.V. sets that are both standard manufacturers' catalog items and custom sets where the hospital, or possibly the individual doctor, specifies the desired features such as tubing size and length and the number, spacing and type of ports, connectors, clamps,

and other devices.

We have developed innovative software systems and manufacturing processes that permit us to design, produce and ship custom I.V. sets in a fraction of the time required by other custom set manufacturers and generally at a lower cost. We can design a custom I.V. set to a hospital's or physician's exact specifications, commence production within less than a day after we receive the customer order, and ship the custom I.V. set generally within three days of receipt for smaller orders to approximately two weeks for larger orders. The use of sophisticated design, ordering and order tracking systems and streamlined assembly and distribution processes allows us to sell custom sets at prices substantially lower than those charged by other producers of custom sets.

We have also developed proprietary internet-based electronic ordering, order tracking, invoicing and payment systems. This was originally designed for use by a subsidiary formed in 1999, SetFinder, Inc., which operates a "web site" named SETFINDER.COM. Hospitals and other healthcare providers have been slow to change from traditional methods of ordering products and supplies to ordering over the internet, and to date we receive most of our orders by facsimile or telephone. We believe, however, that customers will gradually make the transition from traditional ordering methods to Internet ordering.

We have committed significant resources to the strategic initiative to expand our custom and generic I.V. system businesses and expect to incur additional expenses for continuing software development and enhancements in the manufacturing process. Sales of custom I.V. sets and low-cost generic I.V. sets have grown as a result of these efforts, and they currently account for approximately 13% of our net sales.

We conduct our marketing and sales operations in four groups: domestic medical product manufacturers under the ICU Medical name, independent domestic distributors under the Budget Medical Products(TM) name, international manufacturers and distributors under the ICU Medical name, and SetFinder(TM).

We conduct manufacturing in two locations. We do molding and automated assembly in San Clemente, California, and manual assembly in a plant in Ensenada, Baja California, Mexico, opened in December 1998. We constructed the assembly facility in Mexico to reduce the costs of the labor-intensive assembly of I.V. sets and other products whose assembly is not automated. We also expect to open additional assembly plants outside the United States to meet local demands and avoid high transportation costs.

Because the above description of our business is a summary, it does not contain all the information about our business and products that may be important to investors. Investors should read the more extensive descriptions in our Registration Statements and Annual Reports on Form 10-K filed from time to time with the Securities and Exchange Commission. In those statements and reports, we more extensively describe our products, markets, marketing and distribution efforts, manufacturing processes, government regulatory issues, competition, patents, management and management compensation.

RISK FACTORS

In evaluating a transaction in our common stock, investors should consider carefully, among other things, the following risk factors, as well as the other information contained in our registration statements and reports filed with the Securities and Exchange Commission.

BECAUSE WE ARE DEPENDENT ON ABBOTT AND B.BRAUN FOR A SUBSTANTIAL PORTION OF OUR SALES, ANY CHANGE IN OUR ARRANGEMENTS WITH THOSE TWO COMPANIES OR DECLINE IN OUR SALES TO THEM COULD RESULT IN A SIGNIFICANT REDUCTION IN OUR SALES AND PROFITS.

In recent years, we have steadily increased our sales to Abbott. Until recently, we have also increased sales to B.Braun. During the same period, we have not significantly increased our sales to our independent domestic distributors that historically accounted for most of our sales. As a result, we depend on fewer customers for a higher percentage of our sales than in the past. The table below shows our sales to various types of customers for 2001, 2000 and 1999:

	Year Ended December 31,		
	2001	2000	1999
Abbott Laboratories	53%	48%	42%
B.Braun	19%	26%	28%
Independent distributors	20%	21%	25%
International	8%	5%	4%

In contrast to our dependence on Abbott and B.Braun, our principal competitors in the market for protective I.V. connection systems (including Abbott and B.Braun) are much larger companies that dominate the market for I.V. products and have broad product lines and large internal distribution networks. In many cases, these competitors are able to establish exclusive relationships with large hospitals, hospital chains, major buying organizations and home healthcare providers to supply substantially all of their requirements for I.V. products. In addition, we believe that there is a trend among individual hospitals and home healthcare providers to consolidate into or join large major buying organizations with a view to standardizing and obtaining price advantages on disposable medical products. These factors may limit our ability to gain market share through our independent dealer network, resulting in continued concentration of sales among and dependence on a small number of customers.

Abbott and B.Braun are major suppliers of I.V. products. The Abbott Agreement and the B.Braun Agreement are strategic supply and distribution arrangements to market our products in connection with each supplier's I.V. products. Our ability to maintain and increase our market penetration may depend on the success of our arrangements with Abbott, B.Braun and major buying organizations and the ability to renew such arrangements, as to which there is no assurance. If our strategic supply and distribution arrangements prove unsuccessful, our sales would be materially adversely affected. Our business could be materially adversely affected if Abbott or B.Braun terminate their arrangements with us, negotiate lower prices, sell more competing products, whether manufactured by themselves or others, or otherwise alter the nature of their relationships with us. Although we believe that both Abbott and B.Braun view us as a source of innovative and profitable products, there is no assurance that our relationships Abbott and B.Braun will continue in their current form.

We are currently in litigation, as plaintiff, with B.Braun over contractual and patent matters. While we hope to resolve the matters which are subject to the litigation, even if they are resolved, the effect on the relationship with B.Braun is not known at this time. B.Braun does have a product directly competitive with the CLAVE, which we have alleged is being marketed and sold in violation of two of our patents and the provisions of our agreement with B.Braun. However, if B.Braun continues to market that product and it erodes B.Braun's sales of products incorporating our CLAVE, there could be an adverse effect on us, even if we ultimately prevail on the patent matters.

BECAUSE WE ARE DEPENDENT ON THE CLAVE FOR 74% OF OUR SALES (EXCLUDING CUSTOM I.V. SYSTEMS), ANY DECLINE IN CLAVE SALES COULD RESULT IN A SIGNIFICANT REDUCTION IN OUR SALES AND PROFITS.

During the 2001, CLAVE products accounted for approximately 74% of our net sales (excluding custom I.V. systems). As the demand for protective I.V. connection systems moved from protected needle to needleless products, net sales of our protected needle products declined from approximately 50% of net sales in 1994, to approximately 3% of net sales in the year ended December 31, 2001. We depend heavily on sales of CLAVE products and expect sales of protected needle products to continue to diminish and eventually terminate. We cannot give any assurance that sales of CLAVE products will continue to increase indefinitely or that we can sustain current profit margins on CLAVE products indefinitely. Management believes that the success of the CLAVE has motivated, and will continue to motivate, others to develop one piece needleless connectors. In addition to products that emulate the characteristics of the CLAVE, it is possible that others could develop new product concepts and technologies that are functionally equivalent or superior to the CLAVE. If other manufacturers

successfully develop and market effective products that are competitive with CLAVE products, CLAVE sales could decline as we lose market share, and/or we could encounter sustained price and profit margin erosion.

IF OUR EFFORTS TO INCREASE SUBSTANTIALLY OUR CUSTOM I.V. SYSTEM AND LOW-COST, GENERIC I.V. SYSTEM BUSINESSES ARE NOT SUCCESSFUL OR WE CANNOT INCREASE SALES OF OTHER PRODUCTS AND DEVELOP NEW, COMMERCIALLY SUCCESSFUL PRODUCTS, OUR SALES MAY NOT CONTINUE TO GROW.

Our continued success may be dependent both on the success of our strategic initiative to increase substantially our custom I.V. set and low-cost, generic I.V. set businesses and develop significant market share on a profitable basis and on new product development The ability of the custom I.V. system and low-cost I.V. system products to acquire significant market share on a profitable basis depends on whether we are able to continue to develop systems capabilities, improve manufacturing efficiencies, lower inventory carrying costs, reduce labor costs and expand distribution. The accomplishment of each of these objectives will require significant innovation, and we might not succeed in these endeavors. Although we are seeking to develop a variety of new products, there is no assurance that any new products will be commercially successful or that we will be able to recover the costs of developing, testing, producing and marketing such products. Certain healthcare product manufacturers with financial and distribution resources substantially greater than ours have developed and are marketing products intended to fulfill the functions of our products.

CONTINUING REDUCTIONS IN THE PRICES OF OUR I.V. CONNECTOR PRODUCTS COULD HAVE AN ADVERSE EFFECT ON PROFIT MARGINS AND PROFITS.

The Abbott Agreement and the B.Braun Agreement establish the prices that Abbott and B.Braun will pay for our products, which are lower than our historical average selling prices. In response to competitive pressure, we have steadily reduced selling prices of the CLAVE to protect and expand its market. Management expects that we will continue to reduce average selling prices. Reductions in average selling prices could adversely affect gross margins and profits if we cannot achieve corresponding reductions in unit manufacturing costs through increased volume.

INTERNATIONAL SALES POSE ADDITIONAL RISKS RELATED TO COMPETITION WITH LARGER INTERNATIONAL COMPANIES AND ESTABLISHED LOCAL COMPANIES, OUR POSSIBLY HIGHER COST STRUCTURE, OUR ABILITY TO OPEN FOREIGN MANUFACTURING FACILITIES THAT CAN OPERATE PROFITABLY, HIGHER CREDIT RISKS AND EXCHANGE RATE RISK.

We have undertaken a program to increase significantly our international sales, and have distribution arrangements in all the principal countries in Western Europe, the Pacific Rim and South America, and in South Africa. We plan to go into most other areas of the world. Currently, we export from the United States substantially all product sold internationally. Our principal competitors are a number of much larger companies as well as smaller companies already established in the countries into which we sell our products. Our cost structure is often higher than that of our competitors because of the relatively high cost of transporting product from the United States to the local market as well as low cost local labor in some markets. For these reasons, among others, we expect to open manufacturing facilities in foreign locations. There is no certainty that we will be able to open local manufacturing facilities or that those facilities will operate on a profitable basis.

Our international sales are subject to higher credit risks than sales in the United States. Many of our distributors are small and may not be well capitalized. Payment terms are relatively long. Our prices to our international distributors are set in U.S. dollars, but their resale prices are set in their local currency. A decline in the value of the local currency in relation to the U.S. dollar may adversely affect their ability to profitably sell in their market the products they buy from us, and may adversely affect their ability to make payment to us for the product they purchase. Legal recourse for non-payment of indebtedness may be uncertain. These factors all contribute to a potential for credit losses.

IF WE ARE UNABLE TO PERSUADE CUSTOMERS TO PAY HIGHER PRICES OF OUR I.V. CONNECTORS AND RELATED PRODUCTS THAN FOR THE CONVENTIONAL PRODUCTS THEY ARE DESIGNED TO REPLACE, AND IF WE CANNOT REDUCE MANUFACTURING COSTS OF EXISTING AND NEW PRODUCTS, OUR SALES MAY NOT CONTINUES TO GROW AND OUR PROFITABILITY MAY DECLINE.

Manufacturing costs and pricing for our products are higher than for their conventional counterparts that are not designed to provide the protection afforded by our products. Selling prices of CLAVE system components are also higher than other competitive needleless systems on a per unit basis. The CLC 2000 and the 1o2 Valve, and other new products under development will also initially cost more to manufacture than the existing devices they are designed to replace, and we will charge higher prices for such new products than customers would pay for conventional devices. We believe that the CLAVE, the CLC 2000, the 1o2 and other new products are and will be cost effective on an actual use basis and offer advantages that will offset their higher selling prices, but prospective customers must be persuaded to pay premium prices for CLAVE products.

Increasing awareness of healthcare costs, public interest in healthcare reform and continuing pressure from Medicare, Medicaid and other payors to reduce costs in the healthcare industry, as well as increasing competition from other protective products, could make it more difficult for us to sell our products at premium prices. In the event that the market will not accept premium prices for our products, our sales and profits could be adversely affected. We believe that our ability to increase our market share and operate profitably in the long term may depend in part on our ability to reduce manufacturing costs on a per unit basis through high volume production using highly automated molding and assembly systems. If we are unable to reduce unit manufacturing costs, we may be unable to increase our market share for CLAVE products or lose market share to alternative products, including competitors' products. Similarly, if we cannot reduce unit manufacturing costs of new products as production volumes increase, we may not be able to sell new products profitably or gain any meaningful market share. Any of these results would adversely affect our future results of operations.

INCREASES IN COSTS OR ELECTRICITY OR INTERRUPTIONS IN ELECTRICAL SERVICE COULD HAVE AN ADVERSE EFFECT ON OUR OPERATIONS.

We use a significant amount of electricity in our molding and automated assembly operations in San Clemente, California. In the second quarter of 2000, we began experiencing a substantial increase in electrical energy costs because of increases in rates. There has been significant uncertainty as to the future cost and availability of electrical energy in California. While rates have moderated since early 2001, rates are still approximately double what they were in early 2000. While we have not experienced any interruption in electrical service to date, there continues to be significant uncertainty as to future costs of electricity and some continuing concern as to availability. Any significant increase in electrical costs or a significant interruption in service could have an adverse effect on our operations.

OUR PRODUCTS COULD BECOME OBSOLETE IF OTHER COMPANIES ARE SUCCESSFUL IN DEVELOPING TECHNOLOGIES AND PRODUCTS THAT ARE SUPERIOR TO OURS.

Many companies are developing products and technologies to address the need for safe and cost effective I.V. connection systems. It is possible that others may develop superior I.V. connection system technologies or alternative approaches that prove superior to our products. Our products could become obsolete as a result of such developments, which could materially and adversely affect our operating results.

IF WE ARE UNABLE TO COMPETE SUCCESSFULLY ON THE BASIS OF PRODUCT INNOVATION, QUALITY, CONVENIENCE, PRICE AND RAPID DELIVERY WITH LARGER COMPANIES THAT HAVE SUBSTANTIALLY GREATER RESOURCES AND LARGER DISTRIBUTION NETWORKS, WE MAY BE UNABLE TO MAINTAIN MARKET SHARE, IN WHICH CASE OUR SALES MAY NOT CONTINUE TO GROW AND OUR PROFITABILITY MAY BE ADVERSELY AFFECTED.

The market for I.V. products is intensely competitive. We believe that

our ability to compete depends upon continued product innovation, the quality, convenience and reliability of our products, access to distribution channels, patent protection and price. The ability of our custom I.V. and low-cost system products to compete will depend on our ability to distinguish our products from the competition based on product pricing, quality and rapid delivery. We encounter significant competition in our markets both from large established medical device manufacturers and from smaller companies. Many of these firms have introduced competitive products with protective features not provided by the conventional products and methods they are intended to replace. Most of our current and prospective competitors have economic and other resources substantially greater than ours and are well established as suppliers to the healthcare industry. Several large, established competitors offer broad product lines and have been successful in obtaining full-line contracts with a significant number of hospitals to supply all of their I.V. product requirements. There is no assurance that our competitors will not substantially increase resources devoted to the development, manufacture and marketing of products competitive with our products. The successful implementation of such a strategy by one or more of our competitors could materially and adversely affect us.

IF WE WERE TO EXPERIENCE PROBLEMS WITH OUR HIGHLY COMPLEX MANUFACTURING AND AUTOMATED ASSEMBLY PROCESSES, AS WE HAVE AT TIMES IN THE PAST, OR IF WE CANNOT OBTAIN ADDITIONAL CUSTOM TOOLING AND EQUIPMENT ON A TIMELY ENOUGH BASIS TO MEET DEMAND FOR OUR PRODUCTS, WE MIGHT BE UNABLE TO INCREASE OUR SALES OR MIGHT LOSE CUSTOMERS, IN WHICH CASE OUR SALES COULD DECLINE.

We manufacture substantially all of our product components, except for standard components which are available as commodity items, and assemble them into finished products. Automated assembly of components into finished products involves complex procedures requiring highly sophisticated assembly equipment which is custom designed, engineered and manufactured for us. As a result of the critical performance criteria for its products, we have at times experienced problems with the design criteria for or the molding or assembly of our products. While we believe that we have resolved all design, manufacturing and assembly problems with respect to current products, there is no assurance that operations will not be adversely affected by unanticipated problems with current products or if such problems are experienced with future products.

We have expanded our manufacturing capacity substantially in recent years, and we expect continuing expansion will be necessary. Molds and automated assembly machines generally have a long lead-time with vendors, often six months or longer. Inability to secure such tooling in a timely manner, or unexpected increases in production demands, could cause us to be unable to meet customer orders. Such inability could cause customers to seek alternatives to our products.

WE MAY NOT BE ABLE TO SIGNIFICANTLY EXPAND OUR SALES OF CUSTOM AND LOW-COST, GENERIC I.V. SYSTEMS IF WE ARE UNABLE TO LOWER MANUFACTURING COSTS, PRICE OUR PRODUCTS BELOW OUR COMPETITORS' PRICES AND SHORTEN DELIVERY TIMES SIGNIFICANTLY.

Our custom I.V. and low-cost, generic I.V. system products do not have any inherent competitive advantage over other competitors' products. We believe that the success of our custom and generic I.V. systems operations will depend on our ability to lower per unit manufacturing costs and price our products

below our competitors' prices and on our ability to shorten significantly the time from customer order to delivery of finished product, or both. To reduce costs, we have moved labor intensive assembly operations to our facility in Mexico. To shorten delivery times, we have developed proprietary systems for order processing, materials handling, tracking, labeling and invoicing and innovative procedures to expedite assembly and distribution operations. Many of these systems and procedures are new and innovative, and will require continuing enhancement and development. There is a possibility that our systems and procedures may not continue to be adequate and meet their objectives.

IF DEMAND FOR OUR CLAVE PRODUCTS WERE TO DECLINE SIGNIFICANTLY, WE MIGHT NOT BE ABLE TO RECOVER THE COST OF OUR EXPENSIVE AUTOMATED MOLDING AND ASSEMBLY EQUIPMENT AND TOOLING, WHICH COULD HAVE AN ADVERSE EFFECT ON OUR RESULTS OF OPERATIONS.

Our production tooling is relatively expensive, with each "module,"

which consists of an automated assembly machine and the molds and molding machines which mold the components, costing several million dollars or more. Most of the modules are for the CLAVE and the integrated Y CLAVE. If the demand for either of these products changes significantly, as might happen with the loss of a customer or a change in product mix, it might be necessary for us to account for the impairment in value of the production tooling because its cost may not be recovered through production of saleable product.

BECAUSE WE DEPEND TO A SIGNIFICANT EXTENT ON OUR FOUNDER FOR NEW PRODUCT CONCEPTS, THE LOSS OF HIS SERVICES COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS.

We depend for new product concepts primarily on Dr. George A. Lopez, our founder, Chairman of the Board, President and Chief Executive Officer. Dr. Lopez has conceived of substantially all of our current and proposed new products and the systems and procedures to be used in the custom I.V. products and their manufacturing. We believe that the loss of his services could have a material adverse effect on our business.

BECAUSE WE HAVE SUBSTANTIAL CASH BALANCES AND LIQUID INVESTMENTS IN INTEREST SENSITIVE SECURITIES, DECLINES IN INTEREST RATES HAVE AN ADVERSE EFFECT ON OUR INVESTMENT INCOME AND COULD HAVE A SIGNIFICANT ADVERSE EFFECT ON OUR NET INCOME.

We have accumulated a substantial balance of cash and liquid investments principally through profitable operations and exercises of stock options. These amounted to $73.0 million at December 31, 2001, almost all of which was invested in interest sensitive securities. Such securities consist principally of corporate preferred stocks and federal tax-exempt state and municipal government debt securities. Dividend and interest rates are reset at auction mostly at seven to forty-nine day intervals, with a small portion resetting at longer intervals up to one year.

For the year ended December 31, 2000, investment income was $2.1 million, or approximately 11% of our income before income taxes, and the cash and liquid investments were $50.8 million. Since then, short-term interest rates have declined substantially, causing our investment income to decrease for the year ended December 31, 2001, notwithstanding continuing increases in cash and liquid investments. Any further additional reductions in interest rates will reduce the rate of return on our investments and may cause the total investment income to continue to decrease.

OUR BUSINESS COULD BE MATERIALLY AND ADVERSELY AFFECTED IF WE FAIL TO DEFEND AND ENFORCE OUR PATENTS, IF OUR PRODUCTS ARE FOUND TO INFRINGE PATENTS OWNED BY OTHERS OR IF THE COST OF PATENT LITIGATION BECOMES EXCESSIVE.

We have patents on certain products, software and business methods, and pending patent applications on other intellectual property and inventions. There is no assurance, however, that patents pending will issue or that the patent protection from patents which have issued or may issue in the future will be broad enough to prevent competitors from introducing similar devices, that such patents, if challenged, will be upheld by the courts or that we will be able to prove infringement and damages in litigation.

We face patent infringement claims related to the CLAVE and the CLC 2000. We believe the claims have no merit, and all have been settled or are in the process of being dismissed. We may also face claims in the future. Any adverse determination on these claims related to the CLAVE or other products, if any, could have a material adverse effect on our business.

We from time to time receive newly issued patents on medical devices which we review to evaluate any infringement risk. We are aware of a number of patents for I.V. connection systems that have been issued to others. While we believe these patents will not affect our ability to market our products, there is no assurance that these or other issued or pending patents might not interfere with our right or ability to manufacture and sell our products.

There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. Patent infringement litigation, which may be necessary to enforce patents issued to us or to defend ourselves against claimed infringement of the rights of others, can be expensive

and may involve a substantial commitment of our resources which may divert resources from other uses. Adverse determinations in litigation or settlements could subject us to significant liabilities to third parties, could require us to seek licenses from third parties, could prevent us from manufacturing and selling our products or could fail to prevent competitors from manufacturing products similar to ours. Any of these results could materially and adversely affect our business.

OUR ABILITY TO MARKET OUR PRODUCTS IN THE UNITED STATES AND OTHER COUNTRIES MAY BE ADVERSELY AFFECTED IF OUR PRODUCTS OR OUR MANUFACTURING PROCESSES FAIL TO QUALIFY UNDER APPLICABLE STANDARDS OF THE FDA AND REGULATORY AGENCIES IN OTHER COUNTRIES.

Government regulation is a significant factor in the development, marketing and manufacturing of our products. Our products are subject to clearance by the United States Food and Drug Administration ("FDA") under a number of statutes including the Food, Drug and Cosmetics Act ("FDC Act"). Each of our current products has qualified, and we anticipate that any new products we are likely to market will qualify, for clearance under the FDA's expedited premarket notification procedure pursuant to Section 510(k) of the FDC Act. There is no assurance, however, that new products developed by us or any manufacturers that we might acquire will qualify for expedited clearance rather than a more time consuming premarket approval procedure or that, in any case, they will receive clearance from the FDA. FDA regulatory processes are time consuming and expensive. Uncertainties as to the time required to obtain FDA clearances or approvals could adversely affect the timing and expense of new product introductions. In addition, we must manufacture our products in compliance with the FDA's Quality System Regulations.

The FDA has broad discretion in enforcing the FDC Act, and noncompliance with the Act could result in a variety of regulatory actions ranging from warning letters, product detentions, device alerts or field corrections to mandatory recalls, seizures, injunctive actions and civil or criminal penalties. If the FDA determines that we have seriously violated applicable regulations, it could seek to enjoin us from marketing our products or we could be otherwise adversely affected by delays or required changes in new products. In addition, changes in FDA, or other federal or state, health, environmental or safety regulations or in their application could adversely affect our business.

To market our products in the European Community ("EC"), we must conform to additional requirements of the EC and demonstrate conformance to established quality standards and applicable directives. As a manufacturer that designs, manufactures and markets its own devices, we must comply with the quality management standards of EN ISO 9001(1994)/EN 46001 (1996). Those quality standards are similar to the FDA's Quality System Regulations but incorporate the quality requirements for product design and development. Manufacturers of medical devices must also be in conformance with EC Directives such as Council Directive 93/42/EEC ("Medical Device Directive") and their applicable annexes. Those regulations assure that medical devices are both safe and effective and meet all applicable established standards prior to being marketed in the EC. Once a manufacturer and its devices are in conformance with the Medical Device Directive, the "CE" Mark maybe affixed to its devices. The CE Mark gives devices an unobstructed entry to all the member countries of the EC. We cannot assure that we will continue to meet the requirements for distribution of our products in Europe.

Distribution of our products in other countries may be subject to regulation in those countries, and there is no assurance that we will obtain necessary approvals in countries in which we wants to introduce our products.

PRODUCT LIABILITY CLAIMS COULD BE COSTLY TO DEFEND AND COULD EXPOSE US TO LOSS.

The use of our products exposes us to an inherent risk of product liability. Patients, healthcare workers or healthcare providers who claim that our products have resulted in injury could initiate product liability litigation seeking large damage awards against us. Costs of the defense of such litigation, even if successful, could be substantial. We maintain insurance against product liability and defense costs in the amount of $5,000,000 per occurrence. There is no assurance that we will successfully defend claims, if any, arising with

respect to products or that the insurance we carry will be sufficient. A successful claim against us in excess of insurance coverage could materially and adversely affect us. Furthermore, there is no assurance that product liability insurance will continue to be available to us on acceptable terms.

IF WE ARE UNABLE TO MANAGE EFFECTIVELY OUR INTERNAL GROWTH OR GROWTH THROUGH ACQUISITIONS OF COMPANIES OR PRODUCTS, OUR FINANCIAL PERFORMANCE MAY BE ADVERSELY AFFECTED.

We intend to expand our marketing and distribution capability internally, by expanding our marketing staff and resources and possibly externally, by acquisitions both in the United States and foreign markets. We may also consider expanding our product offerings through acquisitions of companies or product lines. We intend to build additional production facilities or contract for manufacturing in markets outside the United States to reduce labor costs and eliminate transportation and other costs of shipping finished products from the United States to customers outside the United States. The expansion of our manufacturing, marketing, distribution and product offerings both internally and through acquisitions or by contract may place substantial burdens on our management resources and financial controls. Decentralization of assembly and manufacturing could place further burdens on management to manage those operations, and maintain efficiencies and quality control. There is no assurance that the increasing burdens on our management resources and financial controls will not adversely affect our operating results. In addition, acquisitions may involve a number of special risks, including adverse short-term effects on our reported operating results, diversion of management's attention, dependence on retention, hiring and training of key personnel, risks associated with unanticipated problems or legal liabilities and amortization of acquired intangible assets, some or all of which could materially and adversely affect our operations and financial performance.

OUR STOCKHOLDER RIGHTS PLAN, PROVISIONS IN OUR CHARTER DOCUMENTS AND DELAWARE LAW COULD PREVENT OR DELAY A CHANGE IN CONTROL, WHICH COULD REDUCE THE MARKET PRICE OF OUR COMMON STOCK.

On July 15, 1997, our Board of Directors adopted a Stockholder Rights Plan (the "Plan") and, pursuant to the Plan, declared a dividend distribution of one Right for each outstanding share of our common stock to stockholders of record at the close of business on July 28, 1997. Each Right entitles the registered holder to purchase from us one one-hundredth of a share of Series A Junior participating Preferred Stock, no par value, at a Purchase Price of $50 per one one-hundredth of a share, subject to adjustment. The Plan is designed to afford the Board a great deal of flexibility in dealing with any attempted takeover of and will cause persons interested in acquiring us to deal directly with the Board, giving it an opportunity to negotiate a transaction that maximizes stockholder values. The Plan may, however, have the effect of discouraging persons from attempting to acquire us. Investors should refer to the description of the Plan in our Current Report to the Securities and Exchange Commission on Form 8-K dated July 15, 1997 filed July 23, 1997, as updated by our Current Report dated January 30, 1999 filed February 9, 1999, and the terms of the Rights set forth in a Rights Agreement between us and Chase Mellon Shareholder Services, L.L.C., as Rights Agent, as amended by Amendment No. 1 to the Rights Agreement, which are filed as exhibits to the July 15, 1997 Form 8-K and the January 30, 1999 Form 8-K.

Our Certificate of Incorporation and Bylaws include provisions that may discourage or prevent certain types of transactions involving an actual or potential change of control, including transactions in which the stockholders might otherwise receive a premium for their shares over then current market prices. In addition, the Board of Directors has the authority to issue shares of Preferred Stock and fix the rights and preferences thereof, which could have the effect of delaying or preventing a change of control otherwise desired by the stockholders. In addition, certain provisions of Delaware law may discourage, delay or prevent someone from acquiring or merging with us.

THE PRICE OF OUR COMMON STOCK HAS BEEN AND MAY CONTINUE TO BE HIGHLY VOLATILE DUE TO MANY FACTORS.

The market for small-market capitalization companies can be highly volatile, and we have experienced significant volatility in the price of our

common stock in the past. We believe that factors such as quarter-to-quarter fluctuations in financial results, differences between stock analysts' expectations and actual quarterly and annual results, new product introductions by us or our competitors, changing regulatory environments, litigation, changes in healthcare reimbursement policies, sales or the perception in the market of possible sales of common stock by insiders and substantial product orders could contribute to the volatility of the price of our common stock. General economic trends unrelated to our performance such as recessionary cycles and changing interest rates may also adversely affect the market price of our common stock.

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 hereunto duly authorized, in the City of San Clemente, State of California on February 15, 2002.

ICU MEDICAL, INC.

/s/ Francis J. O'Brien

Francis J. O'Brien
Chief Financial Officer