SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2001 OR

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

COMMISSION FILE NO. 0-19974

ICU MEDICAL, INC.
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

| | |
|---|---|
| DELAWARE | 33-0022692 |
| (STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION) | (I.R.S. EMPLOYER IDENTIFICATION NO.) |
| 951 CALLE AMANECER<br>SAN CLEMENTE, CALIFORNIA | 92673 |
| (ADDRESS OF PRINCIPAL EXECUTIVE OFFICES) | (ZIP CODE) |

(REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE): (949) 366-2183

Securities registered pursuant to Section 12(b) of the Act:
None

Securities Registered Pursuant to Section 12 (g) of the Act:
Common Stock, $.10 par value
Preferred Stock Purchase Rights

Indicate by check mark whether Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ ]

The aggregate market value of the voting stock held by non-affiliates of Registrant as of January 31, 2002 was $369,789,239. *

The number of shares outstanding of Registrant's Common Stock, $.10 par value, as of January 31, 2002 was 8,777,388.

Portions of the Proxy Statement for Registrant's 2002 Annual Meeting of Stockholders, filed or to be filed pursuant to Regulation 14A within 120 days following Registrant's fiscal year ended December 31, 2001, are incorporated by reference into Part III of this Report.

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* Without acknowledging that any persons other than Dr. George A. Lopez and Dr. Diana K. Lopez are affiliates, all directors and executive officers have been included as affiliates solely for purposes of this computation.

## PART I

### ITEM 1. BUSINESS.

We are a leader in the development, manufacture and sale of proprietary, disposable medical connection systems for use in intravenous ("I.V.") therapy applications. Our devices are designed to protect healthcare workers and their patients from exposure to infectious diseases such as Hepatitis B and C and Human Immunodeficiency Virus ("HIV") through accidental needlesticks. We also produce custom I.V. systems that incorporate our proprietary products and low-cost generic I.V. systems.

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 currently sell our products to I.V. product manufacturers and through independent distributors. Our largest customers are Abbott Laboratories ("Abbott") and B.Braun Medical Inc. ("B.Braun"), who accounted for 53% and 19%, respectively, of our sales in 2001.

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

BACKGROUND

In 1993, we launched the CLAVE(R), an innovative one-piece, needleless I.V. connection device that has become our largest selling product. We believe that the CLAVE offers healthcare providers a combination of safety, ease of use, reliability and cost effectiveness that is superior to any other protective I.V. connection system on the market. It allows protected, secure and sterile I.V. connections without needles and without failure-prone mechanical valves used in the I.V. connection systems of some competitors. The CLAVE is a successor to our protected needle products first introduced in 1984. We designed the CLAVE to eliminate needles from certain applications by acute care hospitals, home healthcare providers, ambulatory surgical centers, nursing homes, convalescent facilities, physicians' offices, medical clinics, and emergency services. Reduction in the use of needles not only decreases needlesticks but also reduces the number of needles to be disposed of and certain safety risks inherent in needle handling and disposal.

We have been manufacturing and distributing custom and generic I.V. systems since late 1995. In 1999, we decided to substantially increase our emphasis on marketing and selling custom and generic I.V. systems. 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.

The principal products that we have introduced in recent years are the CLC2000(R) and the 1o2 Valve(TM).

I.V. USAGE AND INFECTION CONTROL

Primary I.V. therapy lines, used in hospitals, nursing homes, emergency units and in home healthcare, consist of a tube running from a bottle or plastic bag containing an I.V. solution to a catheter inserted in a patient's vein. The tube typically has several injection ports or Y sites (conventionally, entry tubes covered by latex caps) to which a secondary I.V. line can be connected to permit constant intravenous administration of medications, fluids and nutrients, and to allow instantaneous intravenous administration of emergency medication.



In conventional practice, primary I.V. system connections are made by inserting an exposed steel needle attached to the primary I.V. line into an injection port connected to the catheter. Conventional secondary I.V. connections, so called piggyback connections, are made by inserting an exposed

steel needle attached to a secondary I.V. line into an injection port or other I.V. connector. In a conventional I.V. connection the needle, which typically is secured only with tape, can detach from the catheter or injection port resulting in disconnection and a serious and sometimes fatal interruption of the flow of the I.V. solution to the patient. The exposed needles can easily be contaminated by contact with unsterile objects or through contact with fluid in the I.V. lines. A contaminated needle can result in infection to healthcare workers and, less frequently, patients, as a result of accidental needlesticks. Increasing awareness of the risk of infection from needlesticks and the substantial and increasing expense to healthcare providers of complying with regulatory protocols when needlesticks occur have led to a growing demand for safe medical devices such as our protective I.V. connectors.

Hepatitis B and C and HIV are transmitted through blood and other body fluids, and workers who come in contact with such infectious materials are at risk of contracting these diseases. Transmissions may occur from needlesticks by contaminated needles or exposure of mucous membranes to infectious body fluids containing blood traces. Following each needlestick, the healthcare employer is required to perform a series of tests on the healthcare worker for both Hepatitis B and C and HIV, as well as track and record each needlestick incident. Thus, needlesticks result in time lost from work and substantial expense regardless of whether transmission of an infectious disease is detected. Our protective I.V. connectors are designed to prevent accidental needlesticks from needles originating from primary and secondary I.V. connections.

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 needleless I.V. connectors. This awareness has also lead to significant federal and state legislation. In addition, the federal Needlestick Safety and Prevention Act, enacted in 2000, modified standards promulgated by the Occupational Safety and Health Administration, to require employers to use needle-safe systems where appropriate to reduce risk of injury to employees from needlesticks. This is a significant expansion of the previous OSHA mandate that "universal precautions" be observed to minimize exposure to blood and other body fluids. In September 1998, the State of California enacted the bloodborne pathogen standard under the state's occupational safety and health statute. The standard mandates use of needlestick prevention controls, including needleless systems. California was the first state to enact such legislation, and since then 19 other states have enacted similar legislation. Our devices will allow a healthcare provider to be compliant with any of these standards.

## PRODUCTS

### CLAVE PRODUCTS

A conventional I.V. line terminates with a male luer connector to which a needle would be attached to penetrate a latex or non-latex rubber covered injection port to make a primary or secondary I.V. connection. With the CLAVE system, instead of attaching a needle to the male luer, a CLAVE is used in place of the injection port and the male luer, without a needle, is simply threaded into the CLAVE with a half turn. The CLAVE consists of a cylindrical housing, which contains a silicone compression seal and a recessed plastic piercing element. As the luer tip enters the CLAVE housing, it depresses the silicone seal back into the housing and slides over the piercing element, which penetrates through the compressed silicone. Fluid channels in the piercing element create a continuous fluid pathway from the I.V. line, through the CLAVE into the primary I.V. line and into the catheter. The luer tip creates a tight seal against the top of the silicone thereby preventing contaminants from entering the fluid pathway. When the I.V. line is disconnected from the CLAVE, the silicone compression seal expands to again fill the housing and reseal the opening. When the CLAVE is not in use, the silicone compression seal fills the opening in the housing and covers the plastic piercing element, thus completely sealing the connector and presenting a flush surface which can be cleansed with an alcohol swab. The CLAVE contains no natural rubber latex.



Emergency medications can be administered through the CLAVE by using a standard syringe without a hypodermic needle attached. The CLAVE can be used with any conventional primary I.V. system, acute and chronic central venous I.V. system, acute care catheter, multi-lumen catheter, peripheral catheter and a variety of other standard devices. The resilience of the silicone compression seal permits repeated connections and disconnections without replacing the

CLAVE.

The CLAVE Integrated Y site is designed to be integrated directly into primary and secondary I.V. sets, thus eliminating the need for special adapters, pre-slit injection ports, or metal needles when making piggyback I.V. connections. Currently, most popular I.V. connection systems that compete with our systems require either a metal needle, a pre-slit injection port or a special adapter to make piggyback connections. The original CLAVE can be used to make a piggyback connection, but it also requires a special adapter when used in piggyback applications. We believe the CLAVE Integrated Y site offers a lower cost alternative to existing systems by eliminating the need for multiple parts. The healthcare professional simply inserts the male luer of any secondary I.V. set, without a needle, into the CLAVE Integrated Y site and twists to make the connection. The CLAVE Integrated Y site will not replace CLAVE products used in non-piggyback connections. Unlike the original CLAVE site, the CLAVE Integrated Y site is marketed exclusively to I.V. set manufacturers, such as Abbott and B.Braun to build directly into their I.V. sets.

The CLAVE is our largest selling product line, and accounted for 74% of the Company's net sales in 2001.

In October 2001, we commenced production of the "MicroCLAVE(R)." It is smaller than the existing CLAVE but is functionally similar. We will initially market it as an extension of the CLAVE product line for use where its smaller size is advantageous, such as pediatric care.

CUSTOM AND GENERIC I.V. SYSTEMS

During late 1995, we entered the low end of the safe medical connector market by manufacturing and distributing I.V. sets which incorporated lower priced safe medical connectors, and also commenced manufacturing and distributing custom I.V. sets incorporating the CLAVE. In 1999, we decided to substantially increase our emphasis on marketing and selling these systems. To promote the growth of the business, we have developed innovative software systems and manufacturing processes that permit us to design 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. sets to the customer generally within three days of receipt for smaller orders to approximately two weeks for larger orders. This is a fraction of the time required by other custom set manufacturers and we can generally produce the custom sets at a lower cost. The use of sophisticated design, ordering and order tracking systems and streamlined assembly and distribution processes allows us to sell custom I.V. sets at prices substantially lower than those charged by other producers of custom I.V. 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.

On February 27, 2001, we signed an agreement with Abbott under which we 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(TM). We expect a significant increase in sales of custom I.V. systems, although there can be no assurance that such increase will be achieved.

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. To date, most of the I.V. set sales volume is in custom I.V. systems, and we expect this to continue.

During 1999, 2000 and 2001, net sales of custom and generic I.V. systems were approximately $5,300,000, $6,700,000, and $9,300,000, respectively. Most of the growth in 2001 net sales was because of the SetSource program and increased unit shipments of non-propriety custom I.V. systems.

The CLC2000 is a one piece, swabable connector used to connect I.V. lines to catheters, which is engineered to prevent the back-flow of blood into the catheter. The CLC2000 does not permit the use of needles, thereby ensuring compliance with needle-free policies of healthcare providers. The CLC2000 also contains no natural rubber latex.

The CLC2000 is used on those I.V. catheters where catheter occlusion is most prevalent. Generally, when an I.V. line is disconnected, there is a back-flow of blood into the catheter that is in the patient's vein. That blood in time coagulates and occludes the catheter. Occlusion ("clotting off") of catheters requires expensive drugs and procedures to "flush" the catheter, or if those procedures are not effective, replacement of the catheter. Flushing carries the risk of infection from bacteria in the occluded blood.

The CLC2000 was developed to reduce clotting of catheters because of "back-flow" after the I.V. line is disconnected. The CLC2000 consists of a "T" shaped cylindrical housing, which contains a poppet that is depressed as the luer tip enters the CLC2000. Fluid flows around the poppet and through the housing and into the catheter. When the luer is removed from the CLC2000, a portion of the fluid remaining in the housing is expelled out through the tip of the catheter while a constant positive pressure is maintained to prevent any back-flow into the catheter.

We began marketing the CLC2000 in November 1997. We are concentrating the marketing of the CLC2000 where its "no back-flow" features are of maximum benefit in patient care. These are generally therapies which use long-term indwelling catheters such as oncology, dialysis and long-term infusion of medication. We recently took delivery of automated assembly equipment and expect to commence production on that equipment by the second quarter of 2002. CLC2000 accounted for 3% of our net sales in 2001.

POSI-LINK(TM)

The Posi-Link is a device which is functionally the same as the CLC2000 but designed for use on systems accessed by a blunt cannula, rather than a standard male luer. The Posi-Link was introduced in 2000. Sales to date have not been significant.

1o2 VALVE

The 1o2 Valve is the first one-way or two-way drug delivery system. It functions as a single unit or in multiple "ganged" units as a manifold, for use throughout a hospital. It provides the safety features of an automatic one-way valve, yet allows aspiration, or two-way function by simply pushing a button. The 1o2 Valve can be used in place of products such as stopcocks and check valve manifolds. We actively commenced sales in April 2000. Initially, we are focusing marketing efforts on anesthesia and critical care usage and we are selling the 1o2 Valve only as part of I.V. sets that we manufacture. We recently took delivery of automated assembly equipment and expect to commence production on that equipment by the second quarter of 2002. Sales to date, while not yet significant, have been increasing.

LOPEZ VALVE(R)

The Lopez Valve is a small "T" valve designed to be connected into nasogastric, gastric or jejunostomy tube systems. The valve permits intermittent injection of medications, irrigation or suction without having to disconnect the line and thereby opening the system. By eliminating the need to open the system, the Lopez Valve helps prevent the splashing of and risk of contact with potentially infectious stomach fluids and also saves valuable time.

RF100 AND RF150

We have developed a family of inexpensive single-use needleless connectors for use in both piggyback and non-piggyback applications. The RF100, designed for use in piggyback applications, is a one-piece, needleless I.V. connector comprised of a small plastic piercing element that is recessed into a plastic housing. The RF100 locks onto any standard Y site reducing the potential for accidental disconnection. The RF150 is similar to the RF100 in that it is comprised of a small plastic piercing element that is recessed into a plastic housing. We developed the RF150, called the "Rhino," specifically for Abbott for use with pre-slit injection ports in piggyback and non-piggyback applications. Once the injection port is pierced, the protective housing opens much like a clothes pin, and locks over the pre-slit injection port thus reducing the

potential for accidental disconnections. Although we believe that the CLAVE has significant functional advantages over the RF100 and RF150, these products are alternative and less expensive needleless I.V. connectors.

PROTECTED NEEDLE AND OTHER PRODUCTS

We manufacture and sell Click Lock and Piggy Lock products, which were our first products, introduced in 1984. They use needles recessed in a clear plastic shroud. We also manufacture the McGaw Protected Needle, which is similar to the Click Lock, for B.Braun. B.Braun also pays us a share of its revenues on its SafeLine products. The market for all of these products has been declining as the market shifts to swabable needleless products, and in the aggregate they accounted for less than 5% of our net sales in 2001.

NEW PRODUCTS

We are developing several new products that we intend to introduce in 2002 and later. We believe innovative products continue to be important to maintaining and increasing our sales levels.

We plan to launch, in limited markets, a new I.V. connector currently under development. We expect to apply in the first half of 2002 to the Food & Drug Administration ("FDA") under Section 510(k) of the Federal Food, Drug and Cosmetics Act ("FDC Act") for approval to market this new connector. There is no assurance that the FDA will grant marketing clearance, that we will launch this new product, or that it will achieve sales if and when we commence marketing it.

MARKETING AND DISTRIBUTION

The influence of managed care and the growing trend toward consolidation among healthcare providers are the driving forces behind our sales and marketing strategies. Many healthcare providers are consolidating to create economies of scale and to increase negotiating power with suppliers. In an effort to further control costs, many of these consolidated groups are entering into long-term contracts with medical suppliers at fixed pricing. In this changing market place, we believe it is becoming increasingly important to secure contracts with major buying organizations in addition to targeting specific healthcare providers.

Our distribution operations are organized into four groups: medical product manufacturers under the ICU Medical(R) name, independent domestic distributors under the Budget Medical Products name, international manufacturers and distributors under the ICU Medical name, and SetFinder(TM).

MEDICAL PRODUCTS MANUFACTURERS

We have strategic supply and distribution relationships with Abbott and B.Braun, two major I.V. product suppliers, each of whom has a significant share of the I.V. set market under contract. The agreement with Abbott extends to December 2009, and the agreement with B.Braun extends to December 2002. The agreements confer to Abbott and B.Braun conditional exclusive and nonexclusive rights to distribute certain CLAVE products to certain categories of customers.

Abbott and B.Braun purchase CLAVE products packaged separately and in bulk for distribution to healthcare providers. CLAVE products purchased in bulk are assembled into Abbott's and B.Braun's full range of I.V. products. Both Abbott and B.Braun purchase other CLAVE products, which are sold as accessories.

Under an agreement signed with Abbott on February 27, 2001, and running to December 2009, we have the exclusive right to manufacture all new custom I.V. sets for sale by Abbott, and Abbott and ourselves will jointly promote the products under the name SetSource. Abbott is the exclusive and non-exclusive distributor and co-promoter of SetSource products to certain categories of customers, including SetSource products containing both companies' proprietary products.



We employ 26 product specialists in the United States and Canada to support the Abbott and B.Braun salespeople, calling on prospective customers,

demonstrating products and supporting programs to train the salespeople and customers' staffs in the use of our products.

Sales to Abbott accounted for approximately 53%, 48% and 42% of net sales in 2001, 2000 and 1999, respectively. Sales to B.Braun accounted for approximately 19%, 26% and 28% of our net sales in 2001, 2000 and 1999, respectively. The loss of Abbott or B.Braun as a customer could have a significant adverse effect on our business and operating results because they have full-line contracts with numerous healthcare providers to supply substantially all I.V. products and solutions to those customers.

In 2001, we became involved as plaintiff in litigation with B.Braun over contractual and patent matters. See Item 3. Legal Proceedings. While we hope to resolve the matters which are the subject of the litigation, even if they are resolved, the effect on our relationship with B.Braun is not known at this time. B.Braun does have a product, called UltraSite, that is directly competitive with the CLAVE, and 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 the UltraSite and it erodes B.Braun's sales of CLAVE Products, there could be an adverse effect on us, even if we ultimately prevail on the patent matters. We believe many of B.Braun's customers have a strong preference for the CLAVE over competitive products, including the UltraSite, and that many of them will continue to buy CLAVE Products through B.Braun or other distribution channels.

INDEPENDENT DOMESTIC DISTRIBUTORS

We currently have approximately 20 independent distributors in the United States and Canada who employ approximately 125 salespeople in the aggregate and accounted for approximately 19% of our net sales in 2001. We include Canada as "domestic" for administrative purposes. In addition, we employ 10 product specialists to support our distributors. Distributors purchase and stock our products for resale to healthcare providers.

No independent distributor accounts for as much as 5% of net sales. Although the loss of one or more of our larger distributors could have an adverse affect on our business, we believe we could readily locate other distributors in the same territories who could continue to distribute our products to the same customers.

For several years before 2001, our sales to independent distributors had been declining. In 2001, they showed a modest 6% increase, after we established a separate sales group at the beginning of 2000 to deal only with the independent distributors and attempt to increase our net sales to them. It is too soon for us to determine whether the declining trend in sales to the independent distributors has been reversed, and there is no assurance that sales to them will not decline in the future.

INTERNATIONAL

We distribute products in the principal countries in Western European countries, the Pacific Rim and South America and in South Africa. Foreign sales (excluding Canada) accounted for approximately 4%, 5% and 8% of the Company's net sales in each of the years 1999, 2000 and 2001, respectively. The International division currently has approximately 60 distributors. We have two business development managers in Europe, one in New Zealand serving the entire Pacific Rim, and one in South America. We expect to add several more business development managers in 2002. Administrative operations are in Rome and San Clemente.

Currently, we export from the United States substantially all the products sold internationally. All sales are denominated in U.S. dollars. We believe it will be necessary for us to establish production facilities in a number of locations outside North America to meet local demands and avoid high transportation costs. We are currently investigating opportunities in Europe and the Far East.



SETFINDER

In the fourth quarter of 1999, we launched SetFinder, doing business as SETFINDER.COM. Net sales of SetFinder to date have not been significant. We believe 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. We have 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.

MANUFACTURING

Manufacturing of our products involves injection molding of plastic and silicone parts, manual and automated assembly of the molded plastic parts, needles and other components, quality control inspection, packaging and sterilization. We mold all of our proprietary components, and perform all assembly, quality control, inspection, packaging, labeling and shipping of our products. Sterilization is performed under contract by independent companies. Our manufacturing operations function as a separate group, producing products for the four marketing and sales groups.

We have a fully integrated medical device manufacturing facility in two adjacent buildings totaling 78,000 square feet in San Clemente, California. A mold maintenance shop supports the repair and maintenance needs of our molding operation and manufactures some of our production molds. In addition, the mold maintenance shop serves as a research and development prototype shop, and utilizes advanced computer assisted design systems and automated machining equipment. The state-of-the-art medical device molding facility includes a 20,000 square foot class 100,000 clean room in which all molding and automated assembly of our proprietary medical components is performed. The clean room is equipped with 30 injection molding machines and ancillary equipment including robots designed to minimize human intervention, and sophisticated, highly automated assembly systems to assemble the CLAVE, CLAVE Integrated Y site, Click Lock, RF150 and the McGaw Protected Needle products. We are currently expanding the clean room to accommodate 40 injection molding machines. The assembly systems are custom designed and manufactured for us.

Our state-of-the-art injection molding technology and highly automated assembly systems are designed to maintain a high level of product quality and achieve high volume production at low unit manufacturing costs. To achieve these advantages and to gain greater control over raw material and finished product delivery times, we mold our entire requirements of proprietary molded components. Generic, "off-the-shelf" items are purchased from outside vendors unless significant cost savings can be achieved by molding in-house. We are not dependent on any individual vendor for purchased parts and have no contracts with our suppliers beyond the terms of purchase orders issued.

Virtually all manual assembly is done at our facility in Ensenada, Baja California, Mexico. Products assembled manually are I.V. sets, the Lopez Valve, Piggy Lock and CLAVE ancillary products and accessories. The CLC2000 and 1o2 Valve are currently assembled manually pending installation of automated assembly, currently scheduled for 2002.

Over the past several years, we have been conducting a program to increase systems capabilities, improve manufacturing efficiency, reduce labor costs and enhance distribution. These steps were initially focused on production of custom I.V. systems and, in part, led to the transfer of most manual assembly to a new 20,000 square foot facility in Ensenada, Baja California, Mexico. Establishment of production facilities outside North America is a continuing part of this process, and will build off the manufacturing, systems and software expertise that we have developed in recent years. The program also includes molding and automated assembly operations, where the focus is on improving manufacturing efficiency, aggressive control of material and labor costs, and control of inventory costs.

We believe we are building expertise that will enable us to reduce labor costs and minimize investment in inventory, while at the same time reducing to a bare minimum the time from when an order is received to when it is shipped. Because significant innovation is required to achieve these goals, there is no assurance that the programs will achieve the desired results beyond those already achieved.

Our products are currently sterilized in processes which use either gamma or electron beam ("e-beam") radiation. Most of the sterilization is by e-beam, which is less expensive and quicker than gamma radiation sterilization. Sterilization is performed by independent companies.

GOVERNMENT REGULATION

Government regulation is a significant factor in the development, marketing and manufacturing our products. The FDA regulates medical product manufacturers and their products under a number of statutes including the FDC Act, and we and our products are subject to the regulations of the FDA. The FDC Act provides two basic review procedures for medical devices. Certain products may qualify for a submission authorized by Section 510(k) of the FDC Act, under which the manufacturer gives the FDA a pre-market notification of the manufacturer's intention to commence marketing the product. The manufacturer must, among other things, establish that the product to be marketed is substantially equivalent to another legally marketed product. Marketing may commence when the FDA issues a letter finding substantial equivalence. If a medical device does not qualify for the Section 510(k) procedure, the manufacturer must file a pre-market approval ("PMA") application. This requires substantially more extensive pre-filing testing than the Section 510(k) procedure and involves a significantly longer FDA review process. FDA approval of a PMA application occurs only after the applicant has established safety and efficacy to the satisfaction of the FDA. Each of our current products has qualified, and we anticipate that any new products that it is likely to market will qualify, for the expedited Section 510(k) clearance procedure. There is no assurance, however, that new products that we develop or any manufacturers that we might acquire, or claims that we may make concerning those products, will qualify for expedited clearance rather than the more time consuming PMA procedure or that, in any case, they will receive clearance from the FDA. Certain product performance claims for the CLC2000 require FDA approval after extensive testing that is not yet completed. FDA regulatory processes are time consuming and expensive. Uncertainties as to time required to obtain FDA clearances or approvals could adversely affect the timing and expense of new product introductions. All of the regulated products that we currently manufacture are classified as Class II medical devices by the FDA. Class II medical devices are subject to performance standards relating to one or more aspects of the design, manufacturing, testing and performance or other characteristics of the product in addition to general controls involving compliance with labeling and record keeping requirements.

We must comply with FDA regulations governing medical device manufacturing practices. The FDA and the California Department of Health Services ("DHS") require manufacturers to register and subject them to periodic FDA and DHS inspections of their manufacturing facilities. We are an FDA registered medical device manufacturer, and must demonstrate that we and our contract manufacturers comply with the FDA's current Quality System Regulations ("QSR") regulations. Under these regulations, the manufacturing process must be regulated and controlled by the use of written procedures and the ability to produce devices which meet the manufacturer's specifications must be validated by extensive and detailed testing of every critical aspect of the process. They also require investigation of any deficiencies in the manufacturing process or in the products produced and detailed record keeping. Further, the FDA's interpretation and enforcement of these requirements has been increasingly strict in recent years and seems likely to be even more stringent in the future. Failure to adhere to QSRs would cause the products produced to be considered in violation of the applicable law and subject to enforcement action. The FDA monitors compliance with these requirements by requiring manufacturers to register with the FDA, and by subjecting them to periodic FDA inspections of manufacturing facilities. If an FDA inspector observes conditions that might be violative, the manufacturer must correct those conditions or explain them satisfactorily, or face potential regulatory action that might include physical removal of the product from the marketplace.

We believe that our products and procedures are in compliance with all applicable FDA and DHS regulations. There can be no assurance, however, that other products we are developing or products that we may develop in the future will be cleared by the FDA and classified as Class II products, or that additional regulations restricting the sale of our present or proposed products will not be promulgated by the FDA or DHS. In addition, changes in FDA, DHS or other federal or state health, environmental or safety regulations or their applications 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 QSR regulations but incorporate the quality requirements for product design and development.

Manufacturers of medical devices must also conform to 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 may be affixed to its devices. The CE Mark gives devices an unobstructed entry to all the member countries of the EC.

We have demonstrated conformity to the regulations of both EN ISO 9001 (1994) / EN 46001 (1996) and the Medical Device Directive and we affix the CE Mark to our device labeling for product sold in member countries of the EC.

We believe our products and systems are in compliance with all EC requirements. There can be no assurance, however, that other products we are developing or products that we may develop in the future will conform or that additional regulations restricting the sale of our present or proposed products will not be promulgated by the EC.

COMPETITION

The market for I.V. products is intensely competitive. We believe that our ability to compete depends upon our continued product innovation, the quality, convenience and reliability of our products, access to distribution channels, patent protection, and pricing. We encounter significant competition in this market both from large established medical device manufacturers and from smaller companies. Our ability to compete effectively depends on our ability to differentiate our products based on safety features, product quality, cost effectiveness, ease of use and convenience, as well as our ability to perceive and respond to changing customer needs. In the long term, our ability to compete may be affected by our ability to reduce unit manufacturing costs through higher volume production.

In addition to competing with conventional needle I.V. connection systems and protected needle connection systems marketed by companies such as Baxter Healthcare Corporation ("Baxter") and Abbott, our present and future products will compete with needleless I.V. connection systems like those marketed by Baxter, Becton-Dickinson and Company, B.Braun, Alaris Corporation and others. Although we believe that our needleless CLAVE has distinct advantages over competing systems, there is no assurance that it will be able to compete successfully with these products.

Manufacturers of products with which we currently compete, or might compete in the future, include large companies with an established presence in the healthcare products market and substantially greater financial, marketing and distribution, managerial and other resources. In particular, Baxter, Abbott and B.Braun are leading distributors of I.V. therapy systems, while Becton-Dickinson and Company and Sherwood Medical Company dominate the hypodermic needle market. Several of these competitors have broad product lines and have been successful in obtaining full-line contracts with a significant number of hospitals to supply substantially all of their I.V. product requirements. In order to penetrate more of these hospitals, we have established strategic supply and distribution relationships with Abbott and B.Braun.

We believe 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. We are aware of a number of such products. We believe most of those products were developed primarily by companies who currently do not have the distribution or financial capabilities that we have, although some of those products may be distributed in the future by larger companies that do have such capabilities. We believe these products have had a modest impact on our CLAVE business to date, but there is no assurance that our current or future products will be able to successfully compete with these or future products developed by others.

We believe that our ability to compete in the custom I.V. systems market will be impacted by the same factors affecting our existing products, but will be particularly sensitive to cost to the customer and delivery times. While we believe we have advantages in these two areas, there is no assurance that other companies will not be able to compete successfully with our custom I.V. systems.

PATENTS

We have United States and certain foreign patents on the CLAVE, CLC2000, Click Lock, and Piggy Lock I.V. connectors and have United States patents on the Lopez Valve connector. We have applications pending for additional United States and foreign patents on the 1o2 Valve, CLC2000, Posi-Link, CLAVE, Click Lock and Piggy Lock I.V. connectors. The expiration dates of our patents range from 2003 to 2017.

Our success may depend in part on our ability to obtain patent protection for our products and to operate without infringing the proprietary rights of third parties. While we have obtained certain patents and applied for additional United States and foreign patents covering certain of our products, there is no assurance that any additional patents will be issued, that the scope of any patent protection will prevent competitors from introducing similar devices or that any of our patents will be held valid if subsequently challenged. We also believe that patents on the Click Lock and the Lopez Valve products may have been, and that patent protection on the CLAVE may be, important in preventing others from introducing competing products which are as effective as our products. The loss of patent protection on CLAVE, CLC2000, Click Lock or Lopez Valve products could adversely affect our ability to exclude other manufacturers from producing effective competitive products and could have an adverse impact on our financial results.

The fact that a patent is issued to us does not eliminate the possibility that patents owned by others may contain claims which are infringed by our products.

There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. Litigation, which would result in substantial cost to us and in diversion of our resources, may be necessary to defend us against claimed infringement of the rights of others and to determine the scope and validity of the proprietary rights of others. In addition, our enforcement of our intellectual property rights through litigation could result in substantial cost and diversion of resources. Adverse determinations in litigation could subject us to significant liabilities to third parties or could require us to seek licenses from third parties and could prevent us from manufacturing, selling or using our products, any of which could have a material adverse effect on our business.

In 1999, we became involved in patent litigation with Medex, Inc., which was settled in early 2002. In 2001we became involved in patent litigation with Porex Medical Products, Inc., which is in the process of being dismissed. Also, in 2001, we became involved in patent litigation with B.Braun. See: Item 3 "Legal Proceedings."

EMPLOYEES

At January 31, 2002, we had 476 full-time employees, consisting of 88 engaged in sales, marketing and administration, and 388 in manufacturing, molding, product development and quality control, including 250 in Mexico. We contract with an independent temporary agency to provide certain of its production personnel at our manufacturing facility in San Clemente, California; we employ none of the personnel provided through the agency. At January 31, 2002, the number of temporary production personnel was approximately 43.

ITEM 2. PROPERTIES.

We own two adjacent 39,000 square foot buildings in San Clemente, California, another 28,000 square foot building in the same business park and a 20,000 square foot building on approximately 94 acres of land in Ensenada, Baja California, Mexico.



ITEM 3. LEGAL PROCEEDINGS.

In an action filed July 19, 1999, entitled Medex, Inc. v. ICU Medical, Inc. in the United States District Court for the Southern District of Ohio, Eastern Division, Medex alleged that we infringe one of its patents by the manufacture and sale of the CLAVE connector, and Medex sought monetary damages and injunctive relief. On July 29, 1999, we 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 or our patents by the manufacture and sale of certain blood access devices. We sought monetary damages and injunctive relief. We reached agreement with Medex to settle and dismiss these actions with prejudice in early 2002, and final documents are currently being prepared.

In an action filed May 24, 2001, entitled Porex Medical Products, Inc. v. ICU Medical, Inc. in the United States District Court for the Central District of California, Porex alleged that ICU Medical infringes one of its patents by the offering for sale and selling the CLC 2000, and Porex sought monetary damages and injunctive relief. Porex has agreed to dismiss this action without prejudice.

In an action filed June 29, 2001, entitled ICU Medical, Inc. v. B.Braun Medical, Inc. filed originally in the Superior Court of the State of California, County of Orange, we are 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. On December 3, 2001, B.Braun filed a counter-claim against us alleging that we breached the Manufacture and Supply Agreement and seeking specific performance, a preliminary injunction and damages. We are not seeking monetary damages at this time. Attempts at mediation in November 2001 to resolve these issues were not successful.

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, we allege that B.Braun Medical, Inc. infringes two of our patents by the manufacture and sale of its UltraSite medical connector. We seek monetary damages and injunctive relief and intend to vigorously pursue this matter.

From time to time we are involved in various other legal proceedings, either as a defendant or plaintiff, most of which are routine litigation in the normal course of business. We believe that the resolution of the legal proceedings in which we are involved will not have a material adverse effect on our financial position or results of operations.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

Not Applicable.

EXECUTIVE OFFICERS OF REGISTRANT.

The following table lists the names, ages, certain positions and offices held by our executive officers and key employees. Officers serve at the pleasure of the Board of Directors.

| EXECUTIVE OFFICERS: | Age | Office Held |
|---|---|---|
| George A. Lopez, M.D. | 54 | Chairman of the Board, President and Chief Executive Officer |
| Richard A. Costello | 38 | Vice President of Sales |
| Evelyn L. Foss | 46 | Vice President of Marketing. |
| Francis J. O'Brien | 59 | Chief Financial Officer, Secretary and Treasurer |



Dr. Lopez is our founder and has served as Chairman of the Board, President and Chief Executive Officer since August 1989.

Mr. Costello became Vice President of Sales in December 1997, after having been National Sales Manager since August, 1996 and a product specialist since 1992.

Ms. Foss became Vice President of Marketing in 1992. She resigned from

the position in February 2002 and continues as an officer of SetFinder, Inc., a wholly-owned subsidiary of ICU Medical, Inc.

Mr. O'Brien became Chief Financial Officer in November 1996 and was elected as Secretary in December 1996. From October 1994 to November 1996, he was an independent consultant and prior to 1994 he was a partner with Ernst & Young LLP.

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

Our Common Stock has been traded on the Nasdaq Stock Market National Market Tier under the symbol "ICUI" since our initial public offering on March 31, 1992. The following table sets forth, for the quarters indicated, the high and low closing prices for our Common Stock quoted by the Nasdaq:

| 2000 | High | Low |
|---|---|---|
| First Quarter | $20 3/4 | $14 1/4 |
| Second Quarter | 27 | 17 3/4 |
| Third Quarter | 30 3/8 | 19 3/8 |
| Fourth Quarter | 30 1/8 | 19 1/2 |

| 2001 | High | Low |
|---|---|---|
| First Quarter | $35 3/8 | $25 15/16 |
| Second Quarter | 42.10 | 32 9/16 |
| Third Quarter | 41.41 | 35.35 |
| Fourth Quarter | 47.00 | 37.70 |

We have never paid dividends and do not anticipate paying dividends in the foreseeable future as the Board of Directors intends to retain future earnings for use in our business. Any future determination as to payment of dividends will depend upon our financial condition, results of operations and such other factors as the Board of Directors deems relevant.

As of December 31, 2001 we had 104 stockholders of record and believe we have approximately 2,000 beneficial stockholders.



### ITEM 6. SELECTED FINANCIAL DATA

ICU MEDICAL, INC.

SELECTED FINANCIAL DATA

| | Year ended December 31, (in thousands, except per share data) | | | | |
|---|---|---|---|---|---|
| | 2001 | 2000 | 1999 | 1998 | 1997 |
| INCOME DATA: | | | | | |
| Net sales | $ 69,055 | $ 56,191 | $ 47,014 | $ 39,842 | $ 30,404 |
| Cost of goods sold | 28,932 | 23,787 | 19,883 | 16,687 | 12,817 |
| Gross profit | 40,123 | 32,404 | 27,131 | 23,155 | 17,587 |
| Operating expenses | 18,004 | 15,782 | 13,743 | 13,141 | 9,725 |
| Income from operations | 22,119 | 16,622 | 13,388 | 10,014 | 7,862 |
| Investment income | 1,988 | 2,096 | 1,431 | 1,408 | 1,269 |
| Provision for income taxes | 8,720 | 6,930 | 5,400 | 4,200 | 3,450 |
| Net income | $ 15,387 | $ 11,788 | $ 9,419 | $ 7,222 | $ 5,681 |
| Net income per share | | | | | |
| Basic | $ 1.80 | $ 1.42 | $ 1.16 | $ 0.90 | $ 0.71 |

| | | | | | |
|---|---|---|---|---|---|
| Diluted | $ 1.60 | $ 1.30 | $ 1.08 | $ 0.86 | $ 0.71 |
| Weighted average number of shares | | | | | |
| Basic | 8,560 | 8,330 | 8,155 | 7,990 | 7,946 |
| Diluted | 9,636 | 9,059 | 8,690 | 8,423 | 8,029 |
| CASH FLOW DATA: | | | | | |
| Cash flows from operations, excluding tax benefits from exercise of stock options | $ 20,565 | $ 12,760 | $ 14,767 | $ 6,574 | $ 8,666 |
| Total cash flows from operations | $ 24,329 | $ 13,462 | $ 15,518 | $ 7,417 | $ 8,674 |
| BALANCE SHEET DATA: | | | | | |
| Cash and liquid investments | $ 73,027 | $ 50,786 | $ 38,442 | $ 38,090 | $ 35,112 |
| Working capital | 79,736 | 57,718 | 42,024 | 43,817 | 37,993 |
| Total assets | 117,342 | 92,860 | 75,364 | 62,360 | 51,186 |
| Long-term debt | -- | -- | -- | -- | -- |
| Stockholders' equity | 106,677 | 83,380 | 68,014 | 58,229 | 47,947 |



ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

OVERVIEW

Our principal product is our CLAVE needleless I.V. connection system. The following table sets forth, for the periods indicated, net sales by product as a percentage of total net sales:

| Product Line | 2001 | 2000 | 1999 |
|---|---|---|---|
| CLAVE | 74% | 71% | 68% |
| Custom and Generic I.V. Systems | 13% | 12% | 11% |
| CLC2000 | 3% | 4% | 1% |
| Lopez Valve | 2% | 3% | 4% |
| RF100-RF150 ("Rhino") | 3% | 5% | 6% |
| Protected Needle and Other Products | 5% | 5% | 10% |
| Total | 100% | 100% | 100% |

We sell our products to independent distributors and through agreements with Abbott, 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 our 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 the CLC2000, and under an agreement signed February 27, 2001, custom I.V. sets. B.Braun also purchases the McGaw Protected Needle and pays us revenue sharing payments on its sales of its SafeLine products. We also sell certain other products to a number of other medical product manufacturers.

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

We believe that as the healthcare provider market continues to consolidate, our success in marketing and distributing CLAVE products will depend, in part, on our ability, either independently or through strategic supply and distribution arrangements, to secure long-term CLAVE contracts with major buying organizations. Further, our marketing and distribution strategy may result in a significant share of our revenues being concentrated among a small number of distributors and manufacturers. 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 our operating results.

We believe 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. We are aware of a number of such products. In response to competitive pressure, we have been reducing prices to protect and expand our market. The price reductions to date have been more than offset by increased volume. We expect that the average price

of our CLAVE products will continue to decline. There is no assurance that our 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 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. We believe the effect of this law will be to accelerate sales of our needleless systems, although we are unable to estimate the amount or timing of such sales.

We are taking steps to reduce our dependence on our current proprietary products. We are seeking to substantially expand our custom I.V. systems business with products sold to medical product manufacturers and independent distributors and expand selectively into the production of generic I.V. sets. On February 27, 2001, we signed an agreement with Abbott under which we will



manufacture all new custom I.V. sets for sale by Abbott, and we will jointly promote the products under the name SetSource. We expect a significant increase in sales of custom I.V. systems under this agreement. We 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 when not in common with our I.V. sets handled by our other distributors. 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.

We have an ongoing program to increase systems capabilities, improve manufacturing efficiency, reduce labor costs, reduce time needed to produce an order, and minimize investment in inventory. The original focus was on production of custom I.V. systems, which is relatively labor intensive; it now includes all automated manufacturing operations as well. Manual assembly is now performed at the facility 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 also include automation of the production of new products, such as the CLC2000 and the 1o2 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.

We distribute products through four distribution channels. Net sales for each distribution channel were as follows:

| Channel | 2001 | 2000 | 1999 |
|---|---|---|---|
| Medical product manufacturers | 72% | 74% | 71% |
| Independent domestic distributors | 19% | 21% | 25% |
| International | 8% | 5% | 4% |
| SetFinder | 1% | - | - |
| Total | 100% | 100% | 100% |

COMPARISON OF 2001 TO 2000

In 2001, we had net sales of $69,055,000 which was $12,864,000, or 23%, higher than the net sales of $56,191,000 reported in 2000. The increase was primarily attributable to the increase in sales of CLAVE products, including custom CLAVE I.V. systems.

Net sales to Abbott were $36,793,000 in 2001, compared to $26,956,000 in 2000. CLAVE sales increased to $32,282,000 from $21,337,000 because of an increase in unit volume somewhat offset by lower average selling prices. Sales under the SetSource program approximated $1,200,000 for the year; they have been increasing monthly and exceeded $250,000 for the month of December 2001. We expect a substantial increase in CLAVE unit and dollar sales volume with Abbott in 2002, as well as a significant increase in SetSource unit and dollar sales volume. Net sales of the CLC2000 and Rhino declined as Abbott balanced its inventory position. We expect sales of the CLC2000 to Abbott will increase in the future. Sales of the Rhino are expected to continue the decline which started in early 2001 as the market shifts to swabable technology. Sales of

custom CLAVE I.V. sets declined as production of several high-volume sets was transferred to Abbott. There is no assurance as to the amount of any of the future sales increases to Abbott.

Net sales to B.Braun, including revenue sharing, amounted to $12,872,000 in 2001, compared to $14,610,000 in 2000. The decrease was principally because of a decrease in CLAVE sales. Unit sales of CLAVE products to B.Braun increased, but a decrease in average selling prices, in part because of a decrease in prices and in part because of a change in the product mix to lower priced products, more than offset the effect of higher unit volume. We expect a decrease in CLAVE and dollar sales to B.Braun in 2002, particularly in the first half of the year, at least in part because we believe that their



purchase of CLAVE products in the latter half of 2001 exceeded their sales to their customers. Sales of the McGaw Protected Needle increased from last year, but we expect sales to decline in the future, as they have in most recent periods, as the market for safe connectors continues to shift to needleless swabable technology. SafeLine revenue sharing payments decreased from last year; such payments depend on the volume and selling prices of B.Braun's SafeLine products, and although we cannot accurately forecast such amounts, we do expect payments to trend downward in the future.

Net sales to independent domestic distributors increased approximately 6% to $12,748,000 in 2001 from $11,980,000 in 2000. The increase was due principally to a 35% increase in custom and generic I.V. systems partially offset by a 16% decrease in CLAVE product sales because of lower unit volume. The increase in sales of custom and generic I.V. systems was attributable to an increase in unit volume; approximately one-third of the increase was from increased sales of custom I.V. systems incorporating the 1o2 Valve. The decrease in CLAVE product sales was because of lower unit volume. We believe the decline in sales of CLAVE products is principally because of acquisition of market share by Abbott and B.Braun. We expect a continued decrease in the net sales of standard CLAVE Products to the independent domestic distributors, but expect that the decrease will be at least partially offset by sales of custom and generic I.V. systems, including custom I.V. systems incorporating the 1o2 Valve, and new products such as the CLC2000. There is no assurance that we 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.

Total sales to foreign distributors were $5,384,000 in 2001, as compared with $2,437,000 in 2000 (Those amounts do not include distribution in Canada.). We now have distribution arrangements in the principal countries in Western Europe, the Pacific Rim and South America and in South Africa. Approximately 30% of international sales in 2001 were to distributors selling in Western Europe, approximately 30% in South Africa, approximately 25% in the Pacific Rim and approximately 15% in Latin America. We expect significant increases in sales to foreign customers will continue in the future, although there is no assurance that those expectations will be realized.

Total net sales of CLAVE products (excluding custom CLAVE I.V. systems) increased approximately 29% to $51,130,000 in 2001 from $39,665,000 in 2000. Unit shipments of CLAVE products in 2001 increased approximately 63% over 2000. Abbott accounted for 95% of the growth in dollar sales of CLAVE, International approximately 24%, partially offset by the decline in B.Braun and independent domestic distributors. The aggregate average net selling price of CLAVE products in 2001 decreased approximately 15% as compared with 2000. That decrease reflects lower prices on bulk, non-sterile CLAVE products sold to Abbott and B.Braun, as well as a higher percentage of the sales mix being accounted for by bulk, non-sterile CLAVEs. We expect continued significant growth in CLAVE unit and dollar sales volume in 2002, notwithstanding any decline in sales to B.Braun or independent domestic distributors because of the large growth that we expect with Abbott and international distribution. Further, we expect the decline in average selling prices to abate somewhat from the decline rates of the past several years. However, we give no assurance that the expectations will be realized.

Net sales of custom and generic I.V. systems were $9,263,000 in 2001 compared to $6,737,000 in 2000. Sales of non-proprietary and generic I.V. sets accounted for substantially all of the net increase.

Net sales of the CLC2000 were approximately the same in 2001 as they were in 2000. The decline in sales to Abbott was offset by increased sales to domestic and foreign distributors. We expect sales of the CLC2000 to increase in 2002 and later years, but there is no assurance as to the amount or timing of future CLC2000 sales.

Net sales of the Lopez Valve decreased 14% in 2001 to $1,444,000, on lower unit volume to domestic and international distributors. We had expected sales to increase in 2001, but we believe that the focus of the sales and marketing efforts of our personnel and those of our distributors on other products diluted the sales of the Lopez Valve. We are making improvements to the product and expect sales to increase in 2002.

Net sales of protected needle products increased slightly, as increased sales of the McGaw Protected Needle offset decreased sales of Click Lock and Piggy Lock products. We expect sales of these products will decrease in the future as the safe connector market continues its shift to needleless technology.



Gross margin for 2001 was unchanged from the 58% registered in 2000. The results of our continuing extensive efforts to improve manufacturing efficiency and the increased absorption of overhead by higher production volumes offset the effect of lower average unit selling prices. We expect that gross margins for custom and generic I.V. systems and certain other manually assembled products will be lower than those we have historically achieved because their production is relatively labor intensive. We expect that our unit production costs will continue to decrease in 2002, but that the gross margin percentage will be slightly lower than that ultimately achieved for the full year 2001, 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 our manufacturing facilities in the second half 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 second half of 2001, down from 2% of sales in the third and fourth quarters of 2000 and the first quarter of 2001. We are unable to predict what those costs will be in 2002, but do 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 our operations.

Selling, general and administrative ("SG&A") costs increased by $2,514,000, or 18%, to $16,816,000 in 2000, compared to $14,302,000 in 2000. SG&A costs were 24% of net sales in 2001 compared to 25% in 2000. Spending increased for litigation and administrative costs. Sales and marketing costs increased, but decreased as a percentage of sales. We expect SG&A costs to increase in 2002, because of growth in the Company, promotional costs of new products, international expansion, and expansion of the custom and generic I.V. system business.

Research and development ("R&D") costs decreased in 2001 by $292,000 to $1,188,000, or 2% of net sales, as compared to $1,480,000, or 3% of net sales in 2000. Spending on new product development including development of automated production machinery in 2001 was lower than in 2000, as was spending on clinical evaluations of the CLC2000, which we believe are nearing completion. Costs of software development to support manufacturing and distribution of custom and generic I.V. systems increased in 2001. We estimate that R&D costs will continue in 2002 at approximately the same percentage of net sales as in 2001. However R&D costs could differ from those estimates and the R&D may not be completed as expected.

We plan to launch, in limited markets, a new I.V. connector currently under development. We expect to apply in the first half of 2002 to the FDA under Section 510(k) of the FDC Act for approval to market this new connector. There is no assurance that the FDA will grant marketing clearance, that we will launch this new product, or that it will achieve sales if and when we commence marketing it.

The operating margin increased to 32% in 2001, compared to 30% in 2000, principally because operating expenses decreased as a percentage of net sales.

Investment income decreased by $108,000 in 2001, notwithstanding an increase in the investment portfolio, because of the effect of declines in interest rates since the beginning of 2001.

Our effective income tax rate in 2001 was 36%, down from 37% in 2000 principally because of state tax credits. We expect our effective tax rate in 2002 to be approximately the same as the 2000 rate.

Net income in 2001 increased 31% from 2000 principally because the gross profit increased 24%, but operating expenses increased only 14%. Net income per share (diluted) increased $0.30, or 23%. The percentage increase in earnings per share was less than that for net income, principally because the increased average number of shares outstanding.



COMPARISON OF 2000 TO 1999

In 2000, we had net sales of $56,191,000 which was $9,177,000, or 20%, higher than the net sales of $47,014,000 reported in 1999. The increase was primarily attributable to the increase in sales of CLAVE products, including custom CLAVE I.V. systems.

Net sales to Abbott were $26,956,000 in 2000, compared to $19,862,000 in 1999. The increase was principally because of an increase in unit sales of CLAVE products, with most of the balance of the increase in the CLC2000 and CLAVE custom I.V. systems.

Net sales to B.Braun, including revenue sharing, amounted to $14,610,000 in 2000, compared to $12,974,000 in 1999. Net sales of CLAVE products increased approximately 34%, while sales of the McGaw Protected Needle decreased 48% and SafeLine revenue sharing payments decreased approximately $484,000, or 28%.

Net sales to independent distributors increased approximately 1% from $11,846,000 in 1999 to $11,980,000 in 2000. Increases were registered in sales of custom I.V. systems, CLC2000 and Lopez Valves, offset by a decline in CLAVE products and protected needle products.

Total sales to foreign distributors were $2,437,000 in 2000 compared to $1,878,000 in 1999. (Those amounts do not include distribution in Canada.) Approximately 60% of international sales were to distributors in Europe.

Total net sales of CLAVE products (excluding custom CLAVE I.V. systems) increased approximately 24% to $39,665,000 in 2000 from $32,059,000 in 1999. Unit shipments of CLAVE products in 2000 increased approximately 56% over 1999. Abbott accounted for 66% of the growth in dollar sales of CLAVE, B.Braun accounted for 40% and International approximately 2%, partially offset by the decline in independent domestic distributors. The aggregate average net selling price of CLAVE products in 2000 decreased approximately 21% as compared with 1999. That decrease reflects lower prices from independent distributors and lower prices on bulk, non-sterile CLAVE products sold to Abbott and B.Braun, as well as a higher percentage of the sales mix being accounted for by bulk, non-sterile CLAVEs.

Net sales of custom I.V. systems were $6,737,000 in 2000 compared to $5,251,000 in 1999. Most of the increase in 2000 net sales was because of increased unit shipments of custom I.V. sets incorporating the CLAVE.

Net sales of the CLC2000 increased from $747,000 in 1999 to $2,080,000 in 2000. Most of the increase was sales to Abbott, with most of the balance of the increase on sales to independent domestic distributors.

Net sales of the Lopez Valve in 2000 decreased 6% from those in 1999, because C.R. Bard, Inc., who had signed a contract to buy Lopez Valves in 1999 purchased virtually no Lopez Valves in 2000. Sales to domestic and foreign distributors were up approximately 21% in 2000 over 1999.

Net sales of protected needle products decreased approximately 40% because of the safe connector market's continued shift to needleless technology.

Gross margin for 2000 was unchanged from the 58% registered in 1999. The results of our continuing extensive efforts to improve manufacturing efficiency and the increased absorption of overhead by higher production volumes offset the effect of lower average unit selling prices.

SG&A costs increased by $1,773,000, or 14%, to $14,302,000 in 2000, compared to $12,529,000 in 1999. Spending increased for administrative and litigation costs, while sales and marketing costs were relatively unchanged.

R&D costs increased in 2000 by $266,000 to $1,480,000, or 3% of net sales, compared to $1,214,000, or 3% of net sales, in 1999. Spending in 2000 was principally on clinical evaluations of the CLC2000, software development for the custom I.V. systems business and SetFinder and work on new products including development of automated production machinery.



The operating margin increased to 30% in 2000, compared to 28% in 1999, principally because SG&A costs decreased as a percentage of net sales.

The Company's effective income tax rate in 2000 was 37%, as compared with 36% in 1999.

Net income in 2000 increased 25% from 1999 principally because the gross profit increased 19%, but operating expenses increased only 15%. Net income per share (diluted) increased $0.22, or 20%. The percentage increase in earnings per share was less than that for net income, principally because the increased average number of shares outstanding.

ACCOUNTING POLICIES

Our significant accounting policies are summarized in Note 1 to the Consolidated Financial Statements. In applying those policies, estimates and judgments affect the amounts at which accounts receivable and inventory and certain liabilities are recorded and the useful lives of property and equipment.

We apply our accounting policies on a consistent basis. As circumstances change, they are considered in our estimates and judgments, and future changes in circumstances could result in changes in amounts at which assets and liabilities are recorded. They could also affect the estimated useful levels of property and equipment, which could result in changes in depreciation expense or write-offs or write downs of such assets.

LIQUIDITY AND CAPITAL RESOURCES

During 2001, working capital increased approximately $22,018,000 to $79,736,000 from $57,718,000. The Company's cash and cash equivalents and investment securities, including liquid investments, increased by $22,241,000 to $73,027,000 from $50,786,000. That increase was due primarily to $20,565,000 of cash flows from operating activities (excluding tax benefits from exercise of stock options) and $7,910,000 from exercise of stock options (including tax benefits), partially offset by $6,234,000 used to purchase property and equipment.

During 2000, working capital increased approximately $15,694,000 to $57,718,000 from $42,024,000. The Company's cash and cash equivalents and investment securities, including liquid investments, increased by $12,344,000 to $50,786,000 from $38,442,000. That increase was due primarily to $12,760,000 of cash flows from operating activities (excluding tax benefits from exercise of stock options) and $3,697,000 from exercise of stock options (including tax benefits), partially offset by $3,994,000 used to purchase property and equipment, and $119,000 used to acquire treasury stock.

Capital expenditures increased in 2001 principally for investment in molding machines, molds and automated assembly machines, as well as recurring facilities improvements and acquisition of computer equipment and software. We expect that capital expenditures in 2002 will be somewhat above those in 2001 for additional investments in molding machines, molds and automated assembly machines in San Clemente, continuing acquisition of computer equipment and software, and new facilities outside of North America.

We expect that sales of our products will continue to grow in 2002. If sales continue to increase, accounts receivable and inventories are expected to

increase as well. As a result of these and other factors, we expect the use of working capital to fund our operations to continue to increase.

We have not purchased treasury stock since October 1999, except for a small amount in March 2000. We may purchase additional shares in the future. However, future acquisitions, if any, will depend on market conditions and other factors.

We believe that our existing working capital, supplemented by income from operations, will be sufficient to fund our capital expenditures and increased working capital requirements for the foreseeable future.



FORWARD LOOKING STATEMENTS

In various portions of this Report, including Management's Discussion and Analysis, we describe trends in our business and finances that we perceive and state some of our expectations and beliefs about our future. These statements about the future are "forward looking statements," and we identify them by using words such as "believes," "expects," "anticipates," "estimates," "intends," "plans," "will," "continuing," "could," and similar expressions and by statements about aims, goals and plans. The forward looking statements are based on the best information currently available to us and assumptions that we believe are reasonable, but we do 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 and generic I.V. systems, SafeLine revenue share, production costs, gross margins, SG&A, promotional costs, and R&D expense and income taxes;
- factors affecting operating results, such as shipments to specific customers, product mix, selling prices, the market shift to needleless products, declines in sales of certain products, impact of legislation, achievement of business expansion goals, development of innovative systems capabilities, introduction and sales of new products, sales initiated on the internet, direct sales of commodity type standard I.V. sets, manufacturing efficiencies, labor costs, unit production costs, electrical energy costs and service, production automation, expansion of markets and establishment of production facilities outside North America;
- new or extended contracts with manufacturers and buying organizations, ability to replace distributors, and dependence on a small number of customers;
- regulatory approvals and 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 our future performance are subject to a number of risks and uncertainties which one should consider in evaluating the statements. First, one should consider the factors and risks described in the statements themselves. These factors are uncertain, and if one or more of them turn out differently than we currently expect, our operating results may differ materially from our 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 February 15, 2002, which is incorporated by reference.

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

- general economic and business conditions;

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

We disclaim 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.



ITEM 7a. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We invest in corporate preferred stocks and federal-tax-exempt state and municipal government debt securities. The securities are all "investment grade" and we believe that we have virtually no exposure to credit risk. Dividend and interest rates reset at auction for most of the securities from between seven and forty-nine day intervals, with some longer but none beyond twelve months, so we have very little market risk, that is, risk that the fair value of the security will change because of changes in market interest rates.

Our future earnings are subject to potential increase or decrease because of changes in short-term interest rates. Generally, each one-percentage point change in the discount rate will cause our overall yield to change by two-thirds to three-quarters of a percentage point, depending upon the relative mix of federal-tax-exempt securities and corporate preferred stocks in the portfolio and market conditions specific to the securities in which we invest.

We do not have any significant foreign currency risk. Sales to foreign distributors are all denominated in U.S. dollars. Cash and receivables in entities outside the United States, principally in Mexico, which are denominated in foreign currency are insignificant and are generally offset by accounts of payable in the same foreign currency.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

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REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To the Board of Directors and Stockholders
of ICU Medical, Inc.:

We have audited the accompanying consolidated balance sheets of ICU MEDICAL, INC. (a Delaware corporation) and subsidiaries as of December 31, 2001 and 2000, and the related consolidated statements of income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2001. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated

financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of ICU Medical, Inc. and subsidiaries as of December 31, 2001 and 2000, and the consolidated results of their operations and their consolidated cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

Our audits were made for the purpose of forming an opinion on the basic consolidated financial statements taken as a whole. The schedule listed in Item 14(a)2 of this Form 10-K is presented for purposes of complying with the Securities and Exchange Commissions rules and is not part of the basic consolidated financial statements. This schedule has been subjected to the auditing procedures applied in our audits of the basic consolidated financial statements and, in our opinion, fairly states in all material respects the consolidated financial data required to be set forth therein in relation to the basic consolidated financial statements taken as a whole.

/s/ Arthur Andersen LLP
ARTHUR ANDERSEN LLP

Orange County, California
January 29, 2002



ICU MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

ASSETS

| | December 31, 2001 | December 31, 2000 |
|---|---|---|
| CURRENT ASSETS: | | |
| Cash and cash equivalents | $ 3,901,000 | $ 1,945,000 |
| Liquid investments | 69,126,000 | 48,841,000 |
| Cash and liquid investments | 73,027,000 | 50,786,000 |
| Accounts receivable, net of allowance for doubtful accounts of $581,000 in 2001 and $505,000 in 2000 | 13,062,000 | 12,425,000 |
| Inventories | 1,594,000 | 1,435,000 |
| Prepaid expenses and other | 605,000 | 402,000 |
| Deferred income taxes - current portion | 2,113,000 | 2,150,000 |
| Total current assets | 90,401,000 | 67,198,000 |
| PROPERTY AND EQUIPMENT, at cost: | | |
| Land, building and building improvements | 13,584,000 | 13,505,000 |
| Machinery and equipment | 15,663,000 | 15,601,000 |
| Furniture and fixtures | 3,568,000 | 2,763,000 |
| Molds | 8,566,000 | 6,804,000 |
| Construction in process | 3,566,000 | 1,458,000 |

| | | |
|---|---|---|
| | 44,947,000 | 40,131,000 |
| Less--Accumulated depreciation | (19,825,000) | (16,210,000) |
| | 25,122,000 | 23,921,000 |
| DEFERRED INCOME TAXES - non current portion | 963,000 | 889,000 |
| OTHER ASSETS - net | 856,000 | 852,000 |
| | $ 117,342,000 | $ 92,860,000 |

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



ICU MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

LIABILITIES AND STOCKHOLDERS' EQUITY

| | December 31, | |
|---|---|---|
| | 2001 | 2000 |
| CURRENT LIABILITIES: | | |
| Accounts payable | $ 2,401,000 | $ 1,687,000 |
| Accrued liabilities | 8,264,000 | 7,793,000 |
| Total current liabilities | 10,665,000 | 9,480,000 |
| COMMITMENTS AND CONTINGENCIES | | |
| STOCKHOLDERS' EQUITY: | | |
| Convertible preferred stock, $1.00 par value Authorized--500,000 shares; Issued and outstanding--none | -- | -- |
| Common stock, $0.10 par value- Authorized--20,000,000 shares; Issued -- 8,867,162 shares in 2001 and 2000 | 887,000 | 887,000 |
| Additional paid-in capital | 45,765,000 | 41,702,000 |
| Treasury stock, at cost -- 116,459 shares in 2001 and 472,933 shares in 2000 | (987,000) | (4,819,000) |
| Retained earnings | 61,012,000 | 45,610,000 |
| Total stockholders' equity | 106,677,000 | 83,380,000 |
| | $ 117,342,000 | $ 92,860,000 |

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



ICU MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF INCOME

For the years ended December 31,

| | 2001 | 2000 | 1999 |
|---|---|---|---|
| NET SALES | $69,055,000 | $56,191,000 | $47,014,000 |
| COST OF GOODS SOLD | 28,932,000 | 23,787,000 | 19,883,000 |
| Gross profit | 40,123,000 | 32,404,000 | 27,131,000 |
| OPERATING EXPENSES: | | | |
| Selling, general and administrative | 16,816,000 | 14,302,000 | 12,529,000 |
| Research and development | 1,188,000 | 1,480,000 | 1,214,000 |
| Total operating expenses | 18,004,000 | 15,782,000 | 13,743,000 |
| Income from operations | 22,119,000 | 16,622,000 | 13,388,000 |
| INVESTMENT INCOME | 1,988,000 | 2,096,000 | 1,431,000 |
| Income before income taxes | 24,107,000 | 18,718,000 | 14,819,000 |
| PROVISION FOR INCOME TAXES | 8,720,000 | 6,930,000 | 5,400,000 |
| NET INCOME | $15,387,000 | $11,788,000 | $ 9,419,000 |
| NET INCOME PER SHARE | | | |
| Basic | $ 1.80 | $ 1.42 | $ 1.16 |
| Diluted | $ 1.60 | $ 1.30 | $ 1.08 |
| WEIGHTED AVERAGE NUMBER OF SHARES | | | |
| Basic | 8,560,371 | 8,330,069 | 8,154,859 |
| Diluted | 9,636,058 | 9,058,853 | 8,690,443 |

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



ICU MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

| | Number of Shares Outstanding | Common Stock Amount | Additional Paid-In Capital | Treasury Stock | Retained Earnings | Total |
|---|---|---|---|---|---|---|
| BALANCE, December 31, 1998 | 8,059,315 | $ 887,000 | $ 40,241,000 | $ (7,117,000) | $ 24,218,000 | $ 58,229,000 |
| Acquire shares for treasury | (121,000) | -- | -- | (1,650,000) | -- | (1,650,000) |
| Exercise of stock options and related income tax benefits, and other | 163,724 | -- | 602,000 | 1,614,000 | (200,000) | 2,016,000 |
| Net Income | -- | -- | -- | -- | 9,419,000 | 9,419,000 |
| BALANCE, December 31, 1999 | 8,102,039 | 887,000 | 40,843,000 | (7,153,000) | 33,437,000 | 68,014,000 |
| Acquire shares for treasury | (6,000) | -- | -- | (119,000) | -- | (119,000) |
| Exercise of stock options and related income tax benefits, and other | 298,190 | -- | 859,000 | 2,453,000 | 385,000 | 3,697,000 |
| Net Income | -- | -- | -- | -- | 11,788,000 | 11,788,000 |
| BALANCE, December 31, 2000 | 8,394,229 | 887,000 | 41,702,000 | (4,819,000) | 45,610,000 | 83,380,000 |
| Exercise of stock options and related income tax benefits, and other | 356,474 | -- | 4,063,000 | 3,832,000 | 15,000 | 7,910,000 |
| Net Income | -- | -- | -- | -- | 15,387,000 | 15,387,000 |
| BALANCE, December 31, 2001 | 8,750,703 | $ 887,000 | $ 45,765,000 | $ (987,000) | $ 61,012,000 | $ 106,677,000 |

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

CONSOLIDATED STATEMENTS OF CASH FLOWS

| | For the years ended December 31, | | |
|---|---|---|---|
| | 2001 | 2000 | 1999 |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | | |
| Net Income | $ 15,387,000 | $ 11,788,000 | $ 9,419,000 |
| Adjustments to reconcile net income to net cash provided by operating activities -- | | | |
| Depreciation and amortization | 5,034,000 | 4,612,000 | 3,917,000 |
| Deferred income taxes, non-current | (74,000) | (83,000) | (714,000) |
| (Increase) decrease in: | | | |
| Accounts receivable | (637,000) | (5,409,000) | (637,000) |
| Inventories | (159,000) | 621,000 | (66,000) |
| Prepaid expenses and other assets | (208,000) | (94,000) | (17,000) |
| Increase (decrease) in: | | | |
| Accounts payable | 714,000 | 722,000 | 282,000 |
| Accrued liabilities | 471,000 | 1,408,000 | 2,937,000 |
| Deferred income taxes, current | 37,000 | (805,000) | (354,000) |
| | 20,565,000 | 12,760,000 | 14,767,000 |
| Tax benefits from exercise of stock options | 3,764,000 | 702,000 | 751,000 |
| Net cash provided by operating activities | 24,329,000 | 13,462,000 | 15,518,000 |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | | |
| Purchases of property and equipment | (6,234,000) | (3,994,000) | (14,781,000) |
| Net change in liquid investments | (20,285,000) | (12,300,000) | (500,000) |
| Net cash (used in) investing activities | (26,519,000) | (16,294,000) | (15,281,000) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | | |
| Proceeds from exercise of stock options and other | 4,146,000 | 2,995,000 | 1,265,000 |
| Purchase of treasury stock | -- | (119,000) | (1,650,000) |
| Net cash provided by (used in) financing activities | 4,146,000 | 2,876,000 | (385,000) |
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS | 1,956,000 | 44,000 | (148,000) |
| CASH AND CASH EQUIVALENTS, beginning of year | 1,945,000 | 1,901,000 | 2,049,000 |
| CASH AND CASH EQUIVALENTS, end of year | $ 3,901,000 | $ 1,945,000 | $ 1,901,000 |
| SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION: | | | |
| Cash paid during the year for income taxes | $ 5,685,000 | $ 6,706,000 | $ 4,555,000 |

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



ICU MEDICAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2001, 2000 AND 1999

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

a. General

ICU Medical, Inc. (the "Company" - a Delaware corporation) operates principally in one business segment engaged in the development and marketing of disposable medical devices designed to protect healthcare workers and patients

from the spread of infectious diseases. The Company's devices are sold principally to distributors and medical product manufacturers throughout the United States. All wholly owned subsidiaries are included in the consolidated financial statements.

b. Inventories

Inventories are stated at the lower of cost or market with cost determined using the first-in, first-out method. Inventory costs include material, labor and overhead related to the manufacturing of medical devices.

Inventories at December 31, consist of the following:

| | 2001 | 2000 |
|---|---|---|
| Raw materials | $1,290,000 | $1,050,000 |
| Work in process | 179,000 | 140,000 |
| Finished goods | 125,000 | 245,000 |
| | $1,594,000 | $1,435,000 |

c. Property and Equipment

The Company uses the straight-line method for depreciating property and equipment over their estimated useful lives. Estimated useful lives are:

| | |
|---|---|
| Buildings | 15 - 30 years |
| Building improvements | 15 years |
| Machinery and equipment | 5 - 10 years |
| Furniture, fixtures and molds | 3 - 5 years |

The Company follows the policy of capitalizing expenditures that materially increase the life of the related assets; maintenance and repairs are expensed as incurred. The costs and related accumulated depreciation applicable to property and equipment sold or retired are removed from the accounts and any gain or loss is reflected in the statements of income.



d. Patents and Licenses

Patents and licenses, which are shown in other assets in the accompanying consolidated balance sheets, are stated at cost and are amortized using the straight-line method over 10 years which is the estimated useful life of the patent or license. At December 31, 2001 and 2000, the net book value of patents and licenses was $348,000 and $350,000, respectively, net of accumulated amortization of $671,000 and $551,000, respectively.

e. Research and Development

The Company expenses research and development costs as incurred.

f. Cash Equivalents

Cash equivalents include certificates of deposit and money market funds with initial maturities of three months or less.

g. Net Income Per Share

"Basic" earnings per share is computed by dividing net income by the weighted average number of common shares outstanding. "Diluted" earnings per share is computed by dividing net income by the weighted average number of common shares outstanding. Dilutive securities are outstanding common stock options (excluding stock options with an exercise price in excess of average 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.

h. Investment Securities

The Company accounts for investments in accordance with SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities." This statement addresses the accounting and reporting for investments in equity securities that have readily determinable fair values and for all investments in debt securities. It requires that securities classified as available for sale be carried at their market values and changes in the securities market values be recorded, net of income tax effect, as a separate component of stockholders' equity. Debt securities that the Company intends to hold to maturity are carried at amortized cost with no accounting for market value fluctuations.

i. Income Taxes

The Company accounts for income taxes using the asset and liability approach. Under this approach, deferred taxes are determined based on the differences between the financial statements and the tax bases using rates as enacted in tax laws. A valuation allowance is established if it is "more likely than not" that all or a portion of the deferred tax asset will not be realized.

j. Revenue Recognition

Sales and related costs are recorded by the Company upon shipment of products to non-related distributors and end-users. Distributors and end-users do not retain any right of return or price protection with respect to unsold product. The Company warrants products against defects and has a policy permitting the return of products under such circumstances. The Company provides a reserve for future returns and price adjustments (including rebates) based on historical experience. Revenue sharing payments are estimated and recorded in the period earned, and adjusted to actual amounts when reports are received from payers; if there is insufficient data to make such estimates, the revenue sharing is not recorded until reported by the payers.



k. Post-retirement and Post-employment Benefits

The Company does not provide post-retirement or post-employment benefits to employees.

l. Stock Options

The Company accounts for its stock options under Accounting Principles Board ("APB") Opinion No. 25 "Accounting for Stock Issued to Employees" and related interpretations as permitted by SFAS No. 123 "Accounting for Stock-Based Compensation".

m. Accounting Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

2. LIQUID INVESTMENTS

The Company's liquid investments, all of which are marketable and are considered "available for sale," consist principally of corporate preferred stocks and federal-tax-exempt state and municipal government debt securities that reset dividend or interest rates at auction, principally from between seven and forty-nine day intervals. They are carried at cost, which closely approximates both fair value and par value throughout the period they are held. Balances consist of:

| | 2001 | 2000 |
|---|---|---|

| | | |
|---|---|---|
| Corporate preferred stocks | $12,400,000 | $18,000,000 |
| Federal tax-exempt debt securities | 55,635,000 | 29,750,000 |
| Certificate of deposit | 1,091,000 | 1,091,000 |
| | $69,126,000 | $48,841,000 |

Investment income, including interest on certificates of deposit and money market funds, consisted of:

| | 2001 | 2000 | 1999 |
|---|---|---|---|
| Corporate dividends | $ 527,000 | $ 835,000 | $ 699,000 |
| Tax-exempt interest | 1,330,000 | 993,000 | 551,000 |
| Other interest | 131,000 | 268,000 | 181,000 |
| | $1,988,000 | $2,096,000 | $1,431,000 |



3. ACCRUED LIABILITIES

Accrued liabilities consists of the following:

| | 2001 | 2000 |
|---|---|---|
| Accrued incentive compensation | $2,353,000 | $1,744,000 |
| Taxes payable | 1,939,000 | 2,523,000 |
| Other accruals | 3,972,000 | 3,526,000 |
| | $8,264,000 | $7,793,000 |

4. COMMON STOCK AND COMMON STOCK OPTIONS GRANTED

In 1993, the Company adopted the 1993 Stock Incentive Plan (the "1993 Plan"). In 1996, the 1993 Plan was amended to increase the number of shares reserved for issuance to employees from 1,275,000 to 3,275,000, and in 1999 it was again amended to increase the number of shares reserved for issuance to employees to 4,775,000. Options granted under the 1993 Plan expire eleven years from issuance and all options issued through early 2000 are time-accelerated options which vest upon the earlier of the Company attaining specific operating performance levels or ten years from the date of grant. Almost all options issued after early 2000 vest in equal amounts on the first, second and third anniversary of their issuance ("time vested"). The 1993 Plan includes conditions whereby options not vested are canceled if employment is terminated. All options have been granted at the fair market value of the Company's stock on the date of grant. Upon exercise of options, the Company is generally entitled to a tax deduction for an amount equal to the excess over the exercise price of the fair market value of the shares at the date of exercise.

In 1997, the Directors' Stock Award Plan, under which each non-employee Director is awarded 1,000 shares of Common Stock annually, was adopted. Further, grants under the Directors' Stock Option Plan, which had been adopted in 1993 and under which all options granted had vested, were discontinued.

The 2,925,732 options outstanding at December 31, 2001 were all issued under the 1993 Plan. 2,133,998 of those options are vested. Of the 791,734 unvested options, 226,247 options are time-accelerated options issued from 1996 to 2001 and 565,487 options are time vested with vesting dates through 2004. Of the options outstanding at December 31, 2001, 117,700 were issued in 1993 to 1995 at an average exercise price of $10.93 and expire in 2004 through 2006; 448,000 issued in 1996 at an average exercise price of $14.26 expire in 2007; 568,187 issued in 1997 at an average exercise price of $9.44 expire in 2008; 778,118 issued in 1998 at an average exercise price of $12.29 expire in 2009, 275,989 issued in 1999 at an average exercise price of $16.69 expire in 2010; 384,238 issued in 2000 at an average exercise price of $28.12 expire in 2011; and 353,500 issued in 2001 at an average exercise price of $34.88 expire in 2012.

Dilutive stock options account for the difference in the number of

shares used to calculate basic and diluted net income per share and were 1,075,687 in 2001, 728,784 in 2000, and 535,584 in 1999. Stock options of subsidiaries did not have a dilutive effect. Options which are anti-dilutive because their average exercise price exceeded the average market price of the Company's common stock approximated 20,000, 100,000, and 90,000 in 2001, 2000, and 1999, respectively. At December 31, 2001, all outstanding options had exercise prices less than the market price of the Company's common stock.



A summary of the Company's stock option activity is as follows:

| | Shares | Exercise Price Range | | | Weighted Average |
|---|---|---|---|---|---|
| Outstanding at December 31, 1998 | 2,719,152 | $ 7.19 | - | $ 16.38 | $ 11.15 |
| Granted | 330,000 | 12.75 | - | 21.44 | 16.90 |
| Exercised | 158,724 | 7.19 | - | 14.28 | 8.65 |
| Forfeited | 27,060 | 13.00 | - | 21.31 | 16.14 |
| Outstanding at December 31, 1999 | 2,863,368 | 7.63 | - | 21.44 | 11.91 |
| Granted | 438,876 | 14.38 | - | 28.46 | 21.98 |
| Exercised | 293,190 | 7.63 | - | 18.31 | 9.72 |
| Forfeited | 18,000 | 13.50 | - | 26.34 | 19.84 |
| Outstanding at December 31, 2000 | 2,991,054 | 7.63 | - | 28.46 | 13.55 |
| Granted | 365,710 | 25.50 | - | 43.75 | 34.85 |
| Exercised | 351,307 | 7.63 | - | 27.00 | 11.27 |
| Forfeited | 79,725 | 10.94 | - | 38.13 | 13.63 |
| Outstanding at December 31, 2001 | 2,925,732 | $ 7.63 | - | $ 43.75 | $ 16.43 |
| Exercisable at December 31: | | | | | |
| 1999 | 1,357,656 | 7.63 | - | 16.13 | 10.84 |
| 2000 | 1,923,073 | 7.63 | - | 18.31 | 11.75 |
| 2001 | 2,133,998 | 7.63 | - | 28.47 | 13.21 |
| Available for grant at December 31, 2001 | 757,518 | | | | |

In 2000, two of the Company's wholly owned subsidiaries, Budget Medical Products, Inc. and SetFinder, Inc. adopted stock option plans. Options are granted at fair market value and expire ten years from issuance, except Incentive Stock Options which expire five years from issuance, and all options issued to date vest over a three-year period, except options issued to non-employee members of the Company's Board of Directors which vest six months after issuance. The terms of the plans are similar to those of the Company's 1993 Plan, and also provide the subsidiaries with certain rights to repurchase shares issued under options. In 2000, options were issued for approximately fifteen percent of the outstanding shares of those subsidiaries. At December 31, 2001, approximately one-third of outstanding options are exercisable.

The Company applies APB Opinion No. 25 and related interpretations in accounting for stock options granted to employees and directors, and does not recognize compensation expense because the exercise price of the options equals the fair market value of the underlying shares at the date of grant.

Under SFAS No. 123, the Company is required to present certain pro forma earnings information determined as if employee stock options were accounted for under the fair value method of that Statement. The fair value for options granted in 2001, 2000 and 1999 was estimated as of the date of grant using a Black-Scholes option pricing model. For options under the Company's 1993 Plan, the following weighted-average assumptions in the respective years were used: risk-free interest rate of 4.9, 6.1 and 5.4 percent, respectively; expected option life of 6.2, 7.4 and 4.1 years, respectively; expected volatility of 50, 54 and 58 percent, respectively; and, no dividends. The



Black-Scholes option valuation model was developed for use in estimating fair value of fully transferable traded options with no vesting restrictions, and, similar to other option valuation models, requires use of highly subjective

assumptions, including expected stock price volatility. The characteristics of the Company's stock options differ substantially from those of traded stock options, and changes in the subjective assumptions can materially affect estimated fair values; therefore, in Management's opinion, existing option valuation models do not necessarily provide a reliable single measure of the fair value of the Company's stock options.

The fair value of the options of the subsidiaries was estimated using the same methodology as for grants by the Company; substantially all options were granted in 2000, when assumptions were a 6.8 percent risk free interest rate, option life of 6.9 years, and expected volatility of 53 percent. Volatility was estimated using the Company's volatility since there is no market for the subsidiaries' shares.

For purposes of the following required pro forma information, the weighted average fair value of stock options granted under the 1993 Plan in 2001, 2000 and 1999 was $18.73, $13.36 and $8.36, respectively. The total estimated fair value is amortized to expense over the vesting period. The effect of the pro forma amortization of the value of the subsidiaries' options on pro forma income was a net reduction of approximately $400,000 in 2001 and $758,000 in 2000.

| | | 2001 | 2000 | 1999 |
|---|---|---|---|---|
| Pro forma: | | | | |
| Net Income..... | | $11,417,000 | $9,481,000 | $7,005,000 |
| Net Income per share | - basic..... | $1.38 | $1.21 | $0.89 |
| | - diluted... | $1.22 | $1.10 | $0.83 |
| Weighted average number of common shares | - basic..... | 8,287,000 | 7,863,000 | 7,891,000 |
| | - diluted... | 9,362,000 | 8,592,000 | 8,426,000 |

5. STOCKHOLDER RIGHTS PLAN

In July 1997, the Board of Directors adopted a Stockholder Rights Plan. The Company distributed a Preferred Share Purchase Right (a "Right") for each share of the Company's Common Stock outstanding. The Rights generally will not be exercisable until a person or group has acquired 15% or more of the Company's Common Stock in a transaction that is not approved in advance by the Board of Directors or ten days after the commencement of a tender offer which could result in a person or group owning 15 percent or more of the Common Stock.

On exercise, each Right entitles the holder to buy one share of Common Stock at an exercise price of $50.00. In the event a third party or group were to acquire 15 percent or more of the Company's outstanding Common Stock without the prior approval of the Board of Directors, each Right will entitle the holder, other than the acquirer, to buy Common Stock with a market value of twice the exercise price, for the Right's then current exercise price. In addition, if the Company were to be acquired in a merger, shareholders with unexercised Rights could purchase common stock of the acquirer with a value of twice the exercise price of the Rights.

The Company's Board of Directors may redeem the Rights for a nominal amount at any time prior to the tenth business day following an event that causes the Rights to become exercisable. The Rights will expire unless previously redeemed or exercised on August 7, 2007.



6. INCOME TAXES

The provision for income taxes for the years ended December 31, 2001, 2000 and 1999, is as follows:

| | 2001 | 2000 | 1999 |
|---|---|---|---|
| Current: | | | |
| Federal | $ 7,165,000 | $ 6,070,000 | $ 5,093,000 |

| | | | |
|---|---|---|---|
| State | 1,592,000 | 1,748,000 | 1,375,000 |
| | 8,757,000 | 7,818,000 | 6,468,000 |
| Deferred: | | | |
| Federal | (85,000) | (706,000) | (852,000) |
| State | 48,000 | (182,000) | (216,000) |
| | (37,000) | (888,000) | (1,068,000) |
| | $ 8,720,000 | $ 6,930,000 | $ 5,400,000 |

Current income taxes payable were reduced from the amounts in the above table by $3,764,000, $702,000 and $751,000 in 2001, 2000 and 1999, respectively, equal to the tax benefit that the Company receives upon exercise of stock options by employees and directors. That benefit is allocated to stockholders' equity.

A reconciliation of the provision for income taxes at the statutory rate to the Company's effective rate is as follows:

| | 2001 | | 2000 | | 1999 | |
|---|---|---|---|---|---|---|
| | Amount | Percent | Amount | Percent | Amount | Percent |
| Federal tax at the expected statutory rate | $8,196,000 | 34.0 % | $6,364,000 | 34.0% | $5,038,000 | 34.0% |
| State income tax, net of federal benefit | 1,347,000 | 5.7 | 1,169,000 | 6.2 | 794,000 | 5.3 |
| Tax-exempt interest and dividends | (553,000) | (2.4) | (537,000) | (2.9) | (353,000) | (2.4) |
| Tax credits | (270,000) | (1.1) | (66,000) | (0.3) | (79,000) | (0.5) |
| Provision | $8,720,000 | 36.2% | $6,930,000 | 37.0% | $5,400,000 | 36.4% |

The components of the Company's deferred income tax provision for the years ended December 31, 2001, 2000 and 1999 are as follows:

| | 2001 | 2000 | 1999 |
|---|---|---|---|
| Allowance for doubtful accounts | $ (24,000) | $ (68,000) | $ (11,000) |
| Inventory reserves | (32,000) | 86,000 | -- |
| Accruals | 363,000 | (810,000) | (317,000) |
| State income taxes | (270,000) | (13,000) | (26,000) |
| Depreciation | (74,000) | (83,000) | (714,000) |
| | $ (37,000) | $ (888,000) | $(1,068,000) |



The components of the Company's deferred income tax benefit are as follows:

| | 2001 | 2000 |
|---|---|---|
| Current deferred tax benefit: | | |
| Allowance for doubtful accounts | $ 249,000 | $ 225,000 |
| Inventory reserves | 216,000 | 184,000 |
| Accruals | 1,246,000 | 1,609,000 |
| State income taxes | 402,000 | 132,000 |
| | $2,113,000 | $2,150,000 |
| Non-current deferred tax benefit: | | |
| Depreciation | $ 963,000 | $ 889,000 |

7. PRODUCTS, MAJOR CUSTOMERS AND CONCENTRATIONS OF CREDIT RISKS

All the Company's products are disposable medical devices. Its principal product is its CLAVE needleless I.V. connection system which accounted for $51,130,000 of consolidated net sales in 2001, $39,665,000 in 2000 and $32,059,000 in 1999. Custom I.V. systems, many of which incorporate the CLAVE connector, accounted for $9,263,000 of consolidated net sales in 2001, $6,737,000 in 2000 and $5,251,000 in 1999. All other products account for less than 3% of net sales.

The Company sells products, which are sold on credit terms principally throughout the United States to medical product manufacturers, independent medical supply distributors, and in selected cases to hospitals and homecare providers. The manufacturers and distributors, in turn, sell the Company's products to healthcare providers. For the years ended December 31, 2001, 2000 and 1999, the Company had sales of 10 percent or greater to two manufacturers as follows:

| | 2001 | 2000 | 1999 |
|---|---|---|---|
| Manufacturer A | 19% | 26% | 28% |
| Manufacturer B | 53 | 48 | 42 |

8. COMMITMENTS AND CONTINGENCIES

The Company is from time to time involved in various legal proceedings, most of which are routine litigation, in the normal course of business. In the opinion of management, the resolution of the legal proceedings in which the Company is involved will not have a material adverse impact on the Company's financial position or results of operations.



9. QUARTERLY FINANCIAL DATA -- UNAUDITED -- (DOLLARS IN THOUSANDS, EXCEPT PER SHARE DATA)

| | Quarter Ended | | | |
|---|---|---|---|---|
| | March 31 | June 30 | Sept. 30 | Dec. 31 |
| 2001 | | | | |
| Net Sales | $15,006 | $16,952 | $16,214 | $20,883 |
| Gross Profit | 8,549 | 10,061 | 9,347 | 12,166 |
| Net Income | 3,533 | 3,764 | 3,319 | 4,771 |
| Net Income Per Share: | | | | |
| Basic | $0.42 | $0.44 | $0.39 | $0.55 |
| Diluted | $0.38 | $0.39 | $0.34 | $0.49 |
| 2000 | | | | |
| Net Sales | $14,249 | $13,623 | $11,698 | $16,621 |
| Gross Profit | 8,230 | 7,843 | 6,181 | 10,150 |
| Net Income | 2,872 | 2,970 | 2,123 | 3,823 |
| Net Income Per Share: | | | | |
| Basic | $0.35 | $0.36 | $0.25 | $0.46 |
| Diluted | $0.33 | $0.33 | $0.23 | $0.41 |

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF REGISTRANT.

The information about Registrant's directors and disclosure of Form 3, 4 or 5 delinquent filers called for by Item 10, Part III of Form 10-K is set

forth in Registrant's definitive Proxy Statement filed or to be filed pursuant to Regulation 14A within 120 days of Registrant's fiscal year ended December 31, 2001, and such information is incorporated herein by this reference. Pursuant to Instruction G(3) to Form 10-K and Instruction 3 to Item 401(b) of Regulation S-K, information about Registrant's executive officers called for by Item 10, Part III of Form 10-K is set forth in Part I of this Report in a separate item captioned "Executive Officers of Registrant."

ITEMS 11 THOUGH 13.

The information called for by Part III of Form 10-K (Item 11 - Executive Compensation, Item 12 - Security Ownership of Certain Beneficial Owners and Management and Item 13 - Certain Relationships and Related Transactions) is set forth in Registrant's definitive Proxy Statement filed or to be filed pursuant to Regulation 14A within 120 days of Registrant's fiscal year ended December 31, 2001, and such information is incorporated herein by this reference.



PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 10-K.

(a) The following documents are filed as part of this Report:

1. Financial Statements



2. Financial Statement Schedules

The Financial Statement Schedules required to be filed as a part of this Report are:



Schedules other than those listed above are omitted since they are not applicable, not required or the information required to be set forth therein is included in Consolidated Financial Statements or Notes thereto included in this Report.

3. Exhibits

Exhibits required to be filed as part of this report are:

| EXHIBIT NUMBER | DESCRIPTION |
|---|---|
| 3.1 | Registrant's Certificate of Incorporation, as amended.(1) |
| 3.2 | Registrant's Bylaws, as amended.(1) |
| 10.1 | Form of Indemnity Agreement with Executive Officers.(1) |
| 10.2 | Registrant's Amended and Restated 1993 Incentive Stock Plan.(2) |
| 10.3 | Manufacture and Supply Agreement dated September 13, 1993 between Registrant and B.Braun, Inc. relating to the Protected Needle product.(3) |
| 10.4 | Supply and Distribution Agreement dated April 3, 1995 between Registrant and Abbott Laboratories, Inc. relating to the CLAVE product.(4) |

10.5 Registrant's Director's Stock Award Plan.(5)

10.6 Rights Agreement dated July 15, 1998 between Registrant and ChaseMellon Shareholder Services, L.L.C. as Rights Agent.(6)



10.7 Manufacture and Supply Agreement dated January 1, 1999 by and between Registrant and B.Braun Medical, Inc. relating to the CLAVE product.(7)

10.8 SafeLine Agreement effective October 1, 1999 by and between Registrant and B.Braun Medical, Inc.(7)

10.9 Amendment to Abbott and ICU Medical Agreement, dated January 1, 1999 between Registrant and Abbott Laboratories.(8)

10.10 Amendment No. 1 to Rights Agreement, dated January 30, 1999, between Registrant and ChaseMellon Shareholder Services, L.L.C. as Rights Agent.(9)

10.11 Co-Promotion and Distribution Agreement, dated February 27, 2001 between Registrant and Abbott Laboratories.(10)

21.1 Subsidiaries of Registrant.

23.1 Consent of Arthur Andersen LLP.

(1) Filed as an exhibit to Registrant's Registration Statement Form S-1 (Registration No. 33-45734) filed on February 14, 1992, and incorporated herein by reference.

(2) Filed as an Exhibit to Registrant's definitive Proxy Statement filed pursuant to Regulation 14A on March 4, 1999 and incorporated herein by reference.

(3) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended September 30, 1993, and incorporated herein by reference.

(4) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended March 31, 1995, and incorporated herein by reference.

(5) Filed as exhibit to Registrant's definitive Proxy Statement filed pursuant to Regulation 14A on April 11, 1998 and incorporated herein by reference.

(6) Filed as an exhibit to Registrant's Registration Statement on Form 8-A dated July 23, 1998 and incorporated herein by reference.

(7) Filed as an exhibit to Registrant's Current Report on Form 8-K dated June 18, 1999, and incorporated herein by reference.

(8) Filed as an exhibit to Registrant's Current Report on Form 8-K dated February 23, 1999, and incorporated herein by reference.

(9) Filed as an exhibit to Registrant's Registration Statement on Form 8-A/A dated February 9, 1999 and incorporated herein by reference.

(10) Filed as an exhibit to Registrant's Current Report on Form 8-K dated March 7, 2001 and incorporated herein by reference.

(b) Reports on Form 8-K.

None



SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

ICU MEDICAL, INC.

By: /s/ George A. Lopez, M.D.
George A. Lopez, M.D.
Chairman of the Board

Dated: February 25, 2002

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of Registrant and in the capacities and on the dates indicated.

| Signature | Title | Date |
|---|---|---|
| /s/ George A. Lopez, M.D.<br>George A. Lopez, M.D. | Chairman of the Board, President, and Chief Executive Officer, (Principal Executive Officer) | February 25, 2002 |
| /s/ Francis J. O'Brien<br>Francis J. O'Brien | Chief Financial Officer and Principal Accounting Officer | February 25, 2002 |
| /s/ Jack W. Brown<br>Jack W. Brown | Director | February 25, 2002 |
| /s/ John J. Connors<br>John J. Connors | Director | February 25, 2002 |
| /s/ Michael T. Kovalchik, III, M.D.<br>Michael T. Kovalchik, III, M.D. | Director | February 25, 2002 |
| /s/ Joseph R. Saucedo<br>Joseph R. Saucedo | Director | February 25, 2002 |
| /s/ Richard H. Sherman, M.D.<br>Richard H. Sherman, M.D. | Director | February 25, 2002 |
| /s/ Robert S. Swinney, M.D.<br>Robert S. Swinney, M.D. | Director | February 25, 2002 |



SCHEDULE II

ICU MEDICAL, INC.

VALUATION AND QUALIFYING ACCOUNTS

Additions

| Description | Balance at Beginning of Period | Charged to Costs and Expenses | Charged to Other Accounts | Write-offs/ Disposals | Balance at End of Period |
|---|---|---|---|---|---|
| For the year ended December 31, 1999: | | | | | |
| Allowance for doubtful accounts | $342,000 | $100,000 | $ - | $74,000 | $368,000 |
| For the year ended December 31, 2000: | | | | | |
| Allowance for doubtful accounts | $368,000 | $195,000 | $ - | $ 58,000 | $505,000 |
| For the year ended December 31, 2001: | | | | | |
| Allowance for doubtful accounts | $505,000 | $100,000 | $ - | $24,000 | $581,000 |



## EXHIBIT INDEX

EXHIBIT 21.1

SUBSIDIARIES OF REGISTRANT

| NAME | STATE OF INCORPORATION |
|---|---|
| Budget Medical Products, Inc. | California |
| ICU MedEurope Limited | United Kingdom |
| SetFinder, Inc. | Delaware |
| BMP de Mexico, S.A. de C.V. | Mexico |

EXHIBIT 23.1

CONSENT OF INDEPENDENT PUBLIC ACCOUNTANTS

As independent public accountants, we hereby consent to the incorporation of our report dated January 29, 2002 included in this Form 10-K, into the Company's previously filed Form S-8 Registration Statement File No. 33-49822. It should be noted that we have not audited any financial statements of the Company subsequent to December 31, 2001 or performed any audit procedures subsequent to the date of our report.

/s/ Arthur Andersen LLP
ARTHUR ANDERSEN LLP

Orange County, California
February 19, 2002