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

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2000 OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES

EXCHANGE ACT OF 1934
FOR THE TRANSITION PERIOD FROM

COMMISSION FILE NO. 0-19974

ICU MEDICAL, INC.

(Exact name of Registrant as specified in its charter)

DELAWARE (State or other jurisdiction of incorporation or organization)

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

951 CALLE AMANECER SAN CLEMENTE, CALIFORNIA (Address of principal executive offices)

92673 (Zip Code)

(Registrant's Telephone Number, Including Area Code): (949) 366-2183

Securities registered pursuant to Section 12(b) of the Act:  $$\operatorname{\textsc{None}}$$ 

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

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 February 28, 2001 was \$217,859,963. \*

The number of shares outstanding of Registrant's Common Stock, \$.10 par value, as of February 28, 2001 was 8,424,523.

Portions of the Proxy Statement for Registrant's 2001 Annual Meeting of Stockholders, filed or to be filed pursuant to Regulation 14A within 120 days following Registrant's fiscal year ended December 31, 2000, are incorporated by reference into Part III of this Report.

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PART I

ITEM 1. BUSINESS.

ICU Medical, Inc. is a leader in the development, manufacture and sale of proprietary, disposable medical connection systems for use in intravenous ("I.V.") therapy applications. The Company's 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

<sup>\*</sup> 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.

needlesticks. In 1993, the Company launched the CLAVE(R), an innovative one-piece, needleless I.V. connection device that has become the Company's largest selling product. The Company believes 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.

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 the Company's needleless I.V. connectors. This awareness has also lead to significant federal and state legislation. On November 6, 2000, the President of the United States signed the federal Needlestick Safety and Prevention Act, which provides for needlestick protections for nurses and other healthcare workers under the Occupational Safety and Health Administration ("OSHA"). The federal legislation, which is to be effective later in 2001, will require hospitals and other healthcare employers to use needleless intravenous systems, like the CLAVE Connector, among other protective technologies to reduce the risk of needlestick injuries to employees. 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 16 other states have enacted similar legislation. ICU Medical's devices will allow a healthcare provider to be compliant with any of these standards.

The Company currently sells its products to I.V. product manufacturers and through independent distributors.

#### BACKGROUND

In 1993, the Company introduced the CLAVE needleless I.V. connection system. 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. This was a successor to the Company's protected needle products first introduced in 1984. The CLAVE was designed 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.

The Company has been manufacturing and distributing custom I.V. systems since late 1995. In 1999, the Company decided to substantially increase its emphasis on marketing and selling custom I.V. systems.

The Company's principal products introduced in recent years are the CLC2000(TM) and the 1o2 Valve(TM).

Effective January 1, 2000, the Company reoriented its manufacturing and distribution operations. Marketing and sales operations are in four groups: medical product manufacturers under the ICU Medical name, independent domestic distributors under the Budget Medical Products name, international manufacturers and distributors under the ICU Medical name and SetFinder(TM). Manufacturing is in a separate group, producing products for the four marketing and sales groups.

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## 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 the Company's 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. The Company's protective I.V. connectors are designed to prevent accidental needlesticks from needles originating from primary and secondary I.V. connections.

### 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 the Company's 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. The Company believes the CLAVE Integrated Y site

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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 Laboratories ("Abbott") and B.Braun Medical, Inc. ("B.Braun") to build directly into their I.V. sets.

The CLAVE is the Company's largest selling product line, and accounted for 71% of the Company's net sales in 2000.

#### CLICK LOCK(R) AND PIGGY LOCK(R) PRODUCTS

The Company's first products, the Click Lock and Piggy Lock, initially introduced in 1984, were designed to overcome the limitations of conventional I.V. connections which use exposed needles that are secured by tape or open luer lock connections. The needles in the Click Lock and Piggy Lock systems are completely recessed into a clear plastic cylindrical housing to reduce the risk of needlesticks and contamination by preventing contact between the needle and other objects. Locking devices which snap closed with an audible click are designed to prevent accidental disconnection but permit immediate and easy disconnection when desired.

The Click Lock housing locks onto the Company's matching injection port located on either piggyback I.V. sets or extension I.V. sets manufactured by the Company. The Piggy Lock was developed as a less expensive, more convenient alternative to using a Click Lock and related I.V. set combination to make a secondary or piggyback I.V. connection.

Recognizing the inherent risks associated with needle handling and disposal, even with protected needle systems, the Company developed the CLAVE, a needleless I.V. connection system that was introduced in 1993. With the availability of the CLAVE and other needleless products sold by competitors, the market is shifting rapidly away from protected needle products to needleless connection systems. Sales of Click Lock and Piggy Lock products are declining both absolutely and as a percentage of net sales.

#### MCGAW PROTECTED NEEDLE AND SAFELINE PRODUCTS

The Company has a Manufacture and Supply Agreement with B.Braun, successor to McGaw, Inc., (the "B.Braun MPN Agreement"), which grants the Company exclusive rights to perform certain assembly of the McGaw Protected Needle which is marketed and distributed by B.Braun. The McGaw Protected Needle is similar to the Click Lock, and competes with the Company's I.V. connection systems. Sales of the McGaw Protected Needle under the B.Braun MPN Agreement accounted for approximately 1% of the Company's net sales in 2000. With the continuing shift in demand from protected needle to needleless products, the Company expects sales of McGaw Protected Needles will continue to decline. Pursuant to another agreement with B.Braun, B.Braun also agreed to pay the Company a share of B.Braun's revenues on SafeLine, a then new needleless I.V. connector designed and manufactured by B.Braun for use with pre-slit injection ports. Such payments commenced in 1996 and accounted for approximately 2% of the Company's net sales in 2000. The Company expects that agreement, which expires in June 2001, will be extended, although there is no certainty as to this matter.

## LOPEZ VALVE(R)

The Company's 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

The Company has 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

housing. The RF150, called the "Rhino," was developed 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 the Company believes that the CLAVE has significant functional advantages over the RF100 and RF150, these products are alternative and less expensive needleless I.V. connectors.

#### CLC2000

The CLC2000 is a one piece, swabable connector 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. lines 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. There are currently no drug treatments available that are recognized by the United States Food and Drug Administration.

The CLC2000 was developed to reduce clotting of catheters because of "back-flow" after the catheter 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 into the primary I.V. line 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.

The Company is currently conducting trials with the objective of receiving FDA approval for certain performance claims for the CLC2000. While the Company believes it can achieve such approval, there is no assurance that it will ultimately receive it.

The Company began marketing the CLC2000 in November 1997. The Company is 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. CLC2000 accounted for 4% of the Company's net sales in 2000.

## 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.

#### 102 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. The Company introduced the 1o2 Valve in November 1998, and after initial delays in production, actively commenced sales in April 2000. Initially, the Company is focusing marketing efforts on anesthesia and critical care usage. Automated production equipment will be installed in the first half of 2001. Sales to date have not been significant.

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## CUSTOM I.V. SYSTEMS

During late 1995, the Company created BMP as a wholly owned subsidiary. BMP was established to service the low end of the safe medical connector market

by distributing custom I.V. sets manufactured by the Company, which incorporate lower priced safe medical connectors, and custom I.V. sets incorporating the CLAVE. Under the reorientation of distribution operations in 2000, BMP will be responsible for all sales to independent domestic distributors, including custom I.V. systems. Custom I.V. systems sold to medical product manufacturers will be distributed under the ICU Medical name.

On February 27, 2001, the Company signed an agreement with Abbott under which the Company will manufacture all new custom I.V. sets for sale by Abbott, and the two companies will jointly promote the products under the name SetSource(TM). The Company expects a significant increase in sales of custom I.V. systems once production under this agreement commences, although there can be no assurance that such increase will be achieved.

During 1998, 1999 and 2000, net sales of custom I.V. systems to medical product manufacturers and independent domestic distributors were approximately \$3,200,000, \$5,300,000, and \$6,700,000, respectively. Most of the growth in 1999 and 2000 net sales was because of increased unit shipments of custom I.V. systems incorporating the CLAVE.

#### SETFINDER

In the fourth quarter of 1999, the Company launched SETFINDER.COM, which will distribute commodity-type standard I.V. sets directly to healthcare providers. This operation will be carried out through SetFinder, Inc., a separate, wholly owned subsidiary. Orders can be taken over the internet at a special "web-site" named SETFINDER.COM, and are also accepted by telephone, facsimile and e-mail. Through use of ICU's manufacturing capability and direct distribution, SetFinder expects to be a low-cost provider with fast order fulfillment times, while offering the customer the convenience of ordering 24 hours a day.

Because significant innovation is required to launch and operate SETFINDER.COM, and because success will depend at least in part on customers' acceptance of using the internet, there is no assurance that its launch will be successful or that current plans for SetFinder will not change materially. Further, there can be no assurance that SetFinder will achieve sales and the amount of future operating profits or losses is dependent upon future development of the SetFinder business, the outcome of which is not known at this time. Sales of SetFinder to date have been minimal.

#### NEW PRODUCTS

The Company is developing several new products that it intends to introduce in 2001 and later. The Company believes innovative products continue to be important to maintaining and increasing its sales levels.

## MARKETING AND DISTRIBUTION

The influence of managed care and the growing trend toward consolidation among healthcare providers are the driving forces behind the Company's 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, the Company believes it is becoming increasingly important to secure contracts with major buying organizations in addition to targeting specific healthcare providers.

The Company's distribution operations are organized into four groups: medical product manufacturers under the ICU Medical name, independent domestic distributors under the Budget Medical Products name, international manufacturers and distributors under the ICU Medical name, and SetFinder.

## MEDICAL PRODUCTS MANUFACTURERS

The Company has entered into 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 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, the Company will have the exclusive right to manufacture all new custom I.V. sets for sale by Abbott, and the two companies 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 certain proprietary products of the Company.

C.R. Bard, Inc. ("Bard") distributes the Lopez Valve under a five-year agreement signed in June 1999.

The Company employs 25 product specialists in the United States and Canada who 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 the Company's products.

Sales to Abbott accounted for approximately 29%, 42% and 48% of net sales in 1998, 1999 and 2000, respectively. Sales to B.Braun accounted for approximately 35%, 28% and 26% of the Company's net sales in 1998, 1999 and 2000, respectively. The loss of Abbott or B.Braun as a customer could have a significant adverse effect on the Company's business and operating results because they have full-line contracts with numerous healthcare providers to supply all I.V. products and solutions to those customers.

### INDEPENDENT DOMESTIC DISTRIBUTORS

The Company currently has approximately 19 independent distributors in the United States and Canada who employ approximately 125 salespeople in the aggregate and accounted for approximately 21% of the Company's net sales in 2000. (Canada is included by the Company as "domestic" for administrative purposes.) In addition, the Company employs 11 product specialists who support the Company's distributors. Distributors purchase and stock the Company's products for resale to healthcare providers.

One independent distributor accounted for approximately 6% of net sales. All other independent distributors account for smaller percentages of net sales. Although the loss of one or more of the several larger distributors could have an adverse affect on the Company's business, the Company believes it could readily locate other distributors in the same territories who could continue to distribute the Company's products to the same customers.

Net sales to independent domestic distributors have been declining over the past several years. The Company has set up a separate sales group to deal only with those distributors in an effort to arrest the decline and increase net sales to specialty distributors. However, there can be no assurance that the decline in net sales will be arrested or that increased net sales to independent domestic distributors will be achieved.

### INTERNATIONAL

The Company's products are distributed in most European countries, Canada, the Middle East, Australia, Japan and other parts of Asia, and South America. Foreign sales (excluding Canada) accounted for approximately 3%, 4% and 5% of the Company's net sales in each of the years 1998, 1999 and 2000, respectively. The Company has four product specialists in Europe and one in New Zealand.

## MANUFACTURING

Manufacturing of the Company's 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. The Company molds all of its proprietary components, and performs all assembly, quality control, inspection, packaging, labeling and shipping of its products. Sterilization is performed under contract by independent companies.

The Company has 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 the Company's molding operation and manufactures certain of the Company's 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 the Company's 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. The assembly systems are custom designed and manufactured for the Company.

The Company's 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, the Company molds its 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. The Company is not dependent on any individual vendor for purchased parts and has no contracts with its suppliers beyond the terms of purchase orders issued.

Virtually all manual assembly is done at the Company's 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 2001.

Over the past several years, the Company has taken significant steps at increasing systems capabilities, improving manufacturing efficiency, reducing labor costs and enhancing 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. The program has now been expanded to include all the Company's automated and manual manufacturing operations. The Company believes it is building expertise that will enable it 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 steps and programs will achieve the desired results beyond those already achieved.

The Company's products are currently sterilized in processes which use either gamma or electronic beam ("e-beam") radiation. Most of the sterilization is by e-beam. E-beam sterilization 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 of the Company's products. The Company and its products are regulated by the FDA under a number of statutes including the Federal Food, Drug and Cosmetics Act ("FDC Act"). 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 the Company's current products has qualified, and the Company anticipates 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 developed by the Company or any manufacturers that

the Company might acquire, or claims that the Company 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

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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 currently manufactured by the Company 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.

The Company 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. The Company is an FDA registered medical device manufacturer, and must demonstrate that the Company and its 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.

The Company believes that its products and procedures are in compliance with all applicable FDA and DHS regulations. There can be no assurance, however, that other products under development by the Company or products developed by the Company in the future will be cleared by the FDA and classified as Class II products, or that additional regulations restricting the sale of its 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 the Company's business.

To market its products in the European Community ("EC"), the Company 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, the Company 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.

The Company has demonstrated conformity to the regulations of both EN ISO 9001 (1994) / EN 46001 (1996) and the Medical Device Directive and affixes the CE Mark to its device labeling for product sold in member countries of the EC.

The Company believes its products and systems are in compliance with all EC requirements. There can be no assurance, however, that other products under development by the Company or products developed by the Company in the

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#### COMPETITION

The market for I.V. products is intensely competitive. The Company believes that its ability to compete depends upon its continued product innovation, the quality, convenience and reliability of its products, access to distribution channels, patent protection, and pricing. The Company encounters significant competition in this market both from large established medical device manufacturers and from smaller companies. The Company's ability to compete effectively depends on its ability to differentiate the products based on safety features, product quality, cost effectiveness, ease of use and convenience, as well as the Company's ability to perceive and respond to changing customer needs. In the long term, the Company's ability to compete may be affected by its 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, the Company's 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 the Company believes that its 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 the Company currently competes, 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 all of their I.V. product requirements. In order to penetrate more of these hospitals, the Company has established strategic supply and distribution relationships with Abbott and B.Braun.

The Company believes the success of the CLAVE has, and will continue to motivate others to develop one piece needleless connectors, which may incorporate many of the same functional and physical characteristics as the CLAVE. The Company is aware of a number of such products. The Company believes most of those products were developed primarily by companies who currently do not have the distribution or financial capabilities of the Company, although some of those products may be distributed in the future by larger companies that do have such capabilities. The Company believes these products have had a modest impact on its CLAVE business to date, but there is no assurance that the Company's current or future products will be able to successfully compete with these or future products developed by others.

The Company believes that its ability to compete in the custom I.V. systems market will be impacted by the same factors affecting its existing products, but will be particularly sensitive to cost to the customer and delivery times. While the Company believes it has advantages in these two areas, there is no assurance that other companies will not be able to compete successfully with the Company's custom I.V. systems.

The Company believes its ability to compete in the commodity-type standard I.V. set business through its e-commerce SETFINDER.COM site will depend on its ability to achieve name recognition among its potential customer base, competitive pricing and rapid order fulfillment, none of which have been proven to date. In addition, the Company expects significant competition from other e-commerce companies, including some newly formed companies, that may have more financial resources than the Company, a broader product line, more name recognition, lower pricing, better order fulfillment, a more attractive or easier-to-use website, or other competitive advantages. The Company does not know whether, or the extent to which, other existing medical product manufacturers will compete directly in the e-commerce arena, but believes that whether or not they compete in that arena, they will continue to be significant competitors. In addition, customers in many cases must be educated to use, and overcome resistance to using, what for many is, new technology. There is no

assurance that the Company will be able to successfully compete in this environment.

#### PATENTS

The Company has United States and certain foreign patents on the CLAVE, Click Lock and Piggy Lock I.V. connectors and has United States patents on the Lopez Valve connector. The Company has 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 the Company's patents range from 2005 to 2016.

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The Company's success may depend in part on its ability to obtain patent protection for its products and to operate without infringing the proprietary rights of third parties. While the Company has obtained certain patents and applied for additional United States and foreign patents covering certain of its 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 the Company's patents will be held valid if subsequently challenged. The Company also believes 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 the Company's products. The loss of patent protection on Click Lock, Lopez Valve or CLAVE products could adversely affect the Company's ability to exclude other manufacturers from producing effective competitive products and could have an adverse impact on the Company's financial results.

The fact that a patent is issued to the Company does not eliminate the possibility that patents owned by others may contain claims which are infringed by the Company's 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 and diversion of resources by the Company, may be necessary to defend the Company against claimed infringement of the rights of others and to determine the scope and validity of the proprietary rights of others. In addition, enforcement of the Company's intellectual property rights through litigation could result in substantial cost and diversion of resources. Adverse determinations in litigation could subject the Company to significant liabilities to third parties or could require the Company to seek licenses from third parties and could prevent the Company from manufacturing, selling or using its products, any of which could have a material adverse effect on the Company's business.

In 1999, the Company became involved in patent litigation with Medex, Inc. See: Item 3 "Legal Proceedings."

## EMPLOYEES

At February 28, 2001, the Company had 419 full-time employees, consisting of 74 engaged in sales, marketing and administration, and 345 in manufacturing, molding, product development and quality control, including 190 in Mexico. The Company contracts with an independent temporary agency to provide certain of its production personnel at its manufacturing facility in San Clemente, California; none of the personnel provided through the agency are employed by the Company. At February 28, 2001, the number of temporary production personnel was approximately 23.

#### ITEM 2. PROPERTIES.

The Company owns two adjacent 39,000 square foot buildings in San Clemente, California, another 28,000 square foot building in the same business park in San Clemente, California 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. pending in the United States District Court for the Southern District of Ohio, Eastern Division, and served on the Company on November 4, 1999, Medex alleges that ICU Medical infringes one of its patents by the manufacture and

sale of the CLAVE connector, and Medex seeks monetary damages and injunctive relief. The Company believes the suit against the Company is without merit and the Company has been vigorously defending itself in the action. On July 29, 1999, the Company brought an action entitled ICU MEDICAL, INC. V. MEDEX, INC. in the United States District Court for the Central District of California against Medex, Inc. for infringing several patents of the Company by the manufacture and sale of certain blood access devices. The Company seeks monetary damages and injunctive relief. The Company intends to vigorously pursue this matter.

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

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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 with the Company held by the executive officers and key employees of the Company. Officers are elected annually by and serve at the pleasure of the Board of Directors.

EXECUTIVE OFFICERS:	Age	Office Held
George A. Lopez, M.D.	53	Chairman of the Board, President and Chief Executive Officer
Richard A. Costello	37	Vice President of Sales
Evelyn L. Foss	45	Vice President of Marketing
Francis J. O'Brien	58	Chief Financial Officer, Secretary and
		Treasurer

Dr. Lopez is the founder of the Company 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.

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.

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

1999	High	Low
First Quarter Second Quarter Third Quarter	\$21 5/16 19 3/4 19 3/4	\$ 15 3/8 14 3/8 13 7/8
Fourth Quarter 2000	16 1/4 High	11 5/8 Low
First Quarter Second Quarter Third Quarter	\$20 3/4 27 30 3/8	\$14 1/4 17 3/4 19 3/8

Fourth Quarter 30 1/8 19 1/2

The Company has never paid dividends and does not anticipate paying dividends in the foreseeable future as the Board of Directors intends to retain future earnings for use in the Company's business. Any future determination as to payment of dividends will depend upon the Company's financial condition, results of operations and such other factors as the Board of Directors deems relevant.

As of February 28, 2001 the Company had 107 stockholders of record and believes it has approximately 1,500 beneficial stockholders.

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### ITEM 6. SELECTED FINANCIAL DATA

ICU MEDICAL, INC.

SELECTED FINANCIAL DATA

Year ended December 31,

	2000	(in thousands, except per share data) 1999 1998 1997 1996
INCOME DATA:		
Net sales Cost of goods sold	23,787	\$ 47,014 \$ 39,842 \$ 30,404 \$ 24,599 19,883 16,687 12,817 10,438
Gross profit Operating expenses	32,404 15,782	13,743 13,141 9,725 8,236
Income from operations Investment income Provision for income taxes	16,622 2,096 6,930	
Net income	\$ 11,788	\$ 9,419 \$ 7,222 \$ 5,681 \$ 4,739
Net income per share		
Basic Diluted	\$ 1.42 \$ 1.30	\$ 1.16 \$ 0.90 \$ 0.71 \$ 0.54 \$ 1.08 \$ 0.86 \$ 0.71 \$ 0.54
Weighted average number of shares Basic Diluted	8,330 9,059	8,155 7,990 7,946 8,722 8,690 8,423 8,029 8,842
CASH FLOW DATA:	=======	
Cash flows from operations	\$ 12,760	\$ 14,767 \$ 6,574 \$ 8,666 \$ 6,513
BALANCE SHEET DATA:  Cash and liquid investments  Working capital  Total assets  Long-term debt  Stockholders' equity	92,860	\$ 38,442 \$ 38,090 \$ 35,112 \$ 31,760 42,024 43,817 37,993 35,587 75,364 62,360 51,186 49,639 68,014 58,229 47,947 46,749

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

## OVERVIEW

The Company's principal product is its 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	2000	1999	1998
CLAVE	71%	68%	69%
CLC2000	4%	1%	
Protected Needle Products	3%	6%	8%

Total	100%	100%	100%	_
B.Braun SafeLine Revenue Sharing	2%	4%	5%	_
Custom I.V. Systems	12%	11%	8%	
RF100-RF150 ("Rhino")	5%	6%	5%	
Lopez Valve and other	3%	4%	5%	

The Company sells its products to independent distributors and through supply and distribution agreements with Abbott, B.Braun, (the "Abbott Agreement" and the "B.Braun Agreement," respectively) and Bard. Most independent distributors handle the full line of the Company's products. Abbott and B.Braun both purchase CLAVE Products, principally bulk, non-sterile connectors. Abbott also purchases the Rhino, a low-priced connector specifically designed for Abbott, and since July 1999, the CLC2000, and under an agreement signed February 27, 2001, custom I.V. sets. B.Braun also purchases the McGaw Protected Needle and pays the Company revenue sharing payments on its sales of its SafeLine products. Bard purchases the Lopez Valve under a five-year agreement signed in June 1999. The Company also distributes the CLC2000 through several other medical product manufacturers for inclusion in catheter kits and trays.

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

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

Management believes the success of the CLAVE has, and will continue to motivate others to develop one piece needleless connectors which may incorporate many of the same functional and physical characteristics as the CLAVE. The Company is aware of a number of such products. In response to competitive pressure, the Company has been reducing prices to protect and expand its market. The price reductions to date have been more than offset by increased volume. Management expects that the average price of its CLAVE products will continue to decline. There is no assurance that the Company's current or future products will be able to successfully compete with products developed by others.

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

The Company has commenced two initiatives that, if successful, will reduce its dependence on its current proprietary products. It is seeking to substantially expand its custom I.V. systems business with products sold to medical product manufacturers and independent distributors. On February 27, 2001, the Company signed an agreement with Abbott under which the Company will manufacture all new custom I.V. sets for sale by Abbott, and the two companies will jointly promote the products under the name SetSource. The Company expects a significant increase in sales of custom I.V. systems once production under this agreement commences. The Company is also launching SETFINDER.COM, which will contract with and distribute commodity-type standard I.V. sets directly to healthcare providers and to group purchasing organizations and independent dealer networks when not in common with the Company's I.V. sets handled by its other distributors. There is no assurance that either one of these initiatives will succeed, or that the expected increases in sales under the February 2001

contract with Abbott will occur.

The Company is currently taking steps aimed at improving manufacturing efficiency principally by reducing labor costs, reducing time needed to produce an order, and minimizing investment in inventory. The original focus was on production of custom I.V. systems, which is relatively labor intensive; it has now been expanded to include all of the Company's automated and manual manufacturing operations. Substantially all manual assembly is now performed at the facility that the Company opened in December 1998 in Ensenada, Baja California, Mexico. In 1999, the Company made significant investment in automated molding and assembly equipment. Both of these steps have reduced unit production costs. Ongoing steps are aimed at increasing systems capabilities, improving manufacturing efficiency and enhancing distribution, as well as automation of the production of new products, such as the CLC2000 and the 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.

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

Net sales for each distribution channel, based on the new grouping, were as follows:

Channel	2000	1999	1998
Medical product manufacturers	74%	71%	64%
Independent domestic distributors	21%	25%	33%
International	5%	4%	3%
Total	100%	100%	100%

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### COMPARISON OF 2000 TO 1999

In 2000, the Company 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 to \$26,956,000 in 2000, compared to \$19,862,000 in 1999. CLAVE unit sales were almost double the amount in 1999. Most of the balance of the sales increase was in the CLC2000 and CLAVE custom I.V. systems. Management expects a substantial increase in CLAVE unit and dollar sales volume with Abbott in 2001, although there is no assurance as to the amount of such increase.

Net sales to B.Braun, including revenue sharing, amounted to \$14,610,000 in 2000, compared to \$12,974,000 in 1999. CLAVE net sales to B.Braun increased approximately 34%, because of increased unit volume partially offset by lower average selling prices. Net sales of the McGaw Protected Needle (a protected needle product) decreased 48%, and management expects those sales to continue to decline in the future as the market for safe connectors continues its shift to needleless technology. Under an agreement with B.Braun, the Company receives revenue sharing payments on B.Braun's sales of its SafeLine products;

such payments commenced in 1996, and the Company recorded estimated revenue sharing of approximately \$1,267,000 in 2000, compared to \$1,751,000 in 1999. The Company expects that the agreement, which expires in June 2001, will be extended, but there is no certainty as to this matter. Management expects that such revenue sharing will continue; the actual amount will depend on the volume and selling prices of B.Braun's SafeLine products, and although Management is unable to accurately forecast such amounts, it does expect the payments to trend downward in the future.

Net sales to independent domestic 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, partially offset by a decline in CLAVE Products and Click-Lock and Piggy Lock Products. The Company believes the decline in sales of CLAVE Products is principally because of acquisition of market share by Abbott and B.Braun. Management expects a continued decrease in the net sales of standard CLAVE Products to the independent domestic distributors, but expects that the decrease will be at least partially offset by sales of custom I.V. systems and new products such as the CLC2000 and the lo2 Valve. There is no assurance that the Company will achieve increased net sales to independent domestic distributors in the future. Further, the ability of the independent distributors to sustain or increase their sales may be impacted by competition from existing and new competitive products or acquisition of market share by Abbott and B.Braun. Management expects to encounter continued pricing pressure from individual end users, and expects continued declines in net prices to the independent distributors.

Total net sales of CLAVE products (excluding custom CLAVE I.V. systems) increased approximately 24% from \$32,059,000 in 1999 to \$39,665,000 in 2000. 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 domestic independent specialty 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 Click Lock and Piggy Lock (protected needle products) decreased 30% in 2000 compared to 1999, because of the safe connector market's continued shift to needleless technology. Management expects that decline to continue.

Net sales of the Lopez Valve in 2000 decreased 6% from those in 1999 because there was virtually no sales to Bard in 2000. Sales to distributors (including foreign distributors) were up approximately 21% in 2000 over 1999. Management expects that net sales of the Lopez Valve to distributors will continue to increase. Bard's sales of Lopez Valves have been less than they originally anticipated, and the amount of future purchases by Bard is uncertain.

Net sales of custom I.V. systems were \$6,737,000 in 2000 compared to \$5,251,000 in 1999. Custom I.V. systems incorporating the CLAVE accounted for substantially all of the increase.

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Total sales to foreign distributors were \$2,437,000 in 2000, as compared with \$1,878,000 in 1999 (Those amounts do not include distribution in Canada.). The Company now has distribution arrangements in all of the principal countries in Europe and has recently initiated or expanded distribution in the Middle East, South America a number of major countries in the Pacific Rim and South Africa. Approximately 60% of sales to foreign distributors are in Europe. Net sales to distributors outside Europe increased substantially in 2000 and accounted for most of the increase in the sales to foreign distributors. Management expects that its sales to European and other foreign customers will continue to increase in the future, although there is no assurance that those expectations will be realized.

In the fourth quarter of 1999, the Company launched SetFinder, doing business as setfinder.com. Net sales of SetFinder to date have not been significant. The Company believes that, in time, a major portion of the sales of disposable medical products will be initiated on the internet, although the transition to the internet has been slow so far. The Company has 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.

Gross margin for 2000 was unchanged from the 58% registered in 1999. The continued increases in the benefits of the Company's extensive efforts to improve manufacturing efficiency, particularly late in 2000, and the increased absorption of overhead by higher production volumes offset the effect of lower average unit selling prices. Management expects that gross margins for custom I.V. systems, SetFinder products and certain other manually assembled products will be lower than those historically recorded by the Company because their production is relatively labor intensive. The Company expects that its unit production costs will continue to decrease in 2001, but that the gross margin percentage will be slightly lower than that ultimately achieved for the full year 2000, as average unit sales prices continue to decrease, and manually assembled products become a greater percentage of the Company's sales.

Electrical energy costs at the Company's manufacturing facilities increased in the second half of 2000 by about one percent of sales. Rates in the second half of 2000 increased to 2 1/2 times what they were in the first quarter of 2000. Management expects a continuation of increased costs through 2001. The Company's principal electrical provider, San Diego Gas & Electric Company, is not subject to the regulatory constraints impacting the other two major providers in California, and there have been no interruptions in service. Any further significant increase in electrical costs or a significant interruption in service could have an adverse effect on the Company.

Selling, general and administrative costs ("SG&A") increased by \$1,773,000, or 14%, to \$14,302,000 in 2000, compared to \$12,529,000 in 1999. SG&A costs were 25% of net sales in 2000 compared to 27% in 1999. Spending increased for administrative and litigation costs, while sales and marketing costs were relatively unchanged. Management expects SG&A costs to increase in 2001, because of growth in the Company, promotional costs of new products and expansion of the custom I.V. system business and SetFinder.

Research and development ("R&D") costs increased in 2000 by approximately \$266,000 to \$1,480,000, or 3% of net sales, compared to approximately \$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. Management estimates that R&D costs in 2001 will continue at approximately the same percentage of net sales as in 2000. However, R&D costs could differ from those estimates and the R&D may not be completed as expected.

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

The Company's effective income tax rate in 2000 was 37%, as compared to 36% in 1999. Management expects its effective tax rate in 2001 to be approximately the same as the 2000 rate.

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.

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## COMPARISON OF 1999 TO 1998

In 1999, the Company had net sales of \$47,014,000 which was \$7,172,000, or 18%, higher than the net sales of \$39,842,000 reported in 1998. The increase was primarily attributable to the increase in sales of CLAVE products, including custom CLAVE I.V. systems.

Net sales to Abbott were \$19,862,000 in 1999, compared to \$11,601,000 in 1998. CLAVE unit sales were 2.4 times the amount in 1998. Most of the balance of the sales increase was in the low-priced Rhino, which increased to \$2,605,000 from \$1,987,000 in 1998.

Net sales to B.Braun, including revenue sharing, amounted to \$12,974,000 in 1999, compared to \$13,961,000 in 1998. CLAVE net sales to B.Braun decreased approximately 9% because of decreased average selling prices; unit shipments were up slightly. Net sales of the McGaw Protected Needle decreased 13%. Revenue sharing payments on B.Braun's sales of its SafeLine products were approximately \$1,751,000 in 1999, compared to \$1,995,000 in 1998.

Total net sales of CLAVE products (excluding custom CLAVE I.V. systems) increased approximately 17% from \$27,508,000 in 1998 to \$32,059,000 in 1999. Unit shipments of CLAVE products in 1999 increased approximately 58% over 1998, with Abbott accounting for the entire unit growth. The aggregate average net selling price of CLAVE products in 1999 decreased approximately 26% as compared with 1998. 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.

CLAVE product sales, excluding custom CLAVE I.V. systems, to independent domestic distributors decreased approximately 32%, caused approximately equally by decreased average selling prices and decreased unit volume.

Net sales of Click Lock and Piggy Lock decreased 22% in 1999 compared to 1998, because of the safe connector market's continued shift to needleless technology.

The Lopez Valve showed a 39% growth in 1999 net sales compared to 1998 principally because of shipments to Bard under the contract signed in June 1999.

Net sales of custom I.V. systems were \$5,251,000 in 1999 compared to \$3,218,000 in 1998. Most of the increase in 1999 net sales was because of increased unit shipments of custom I.V. sets incorporating the CLAVE.

Total sales to foreign distributors were \$1,878,000 in 1999 compared to \$1,364,000 in 1998. (Those amounts do not include distribution in Canada.)

Gross margin for 1999 was unchanged from the 58% registered in 1998. The continued increases in the benefits of the Company's extensive efforts to improve manufacturing efficiency, particularly late in 1999, and the increased absorption of overhead by higher production volumes offset the effect of lower average unit selling prices.

Selling, general and administrative costs ("SG&A") increased by \$435,000, or 4%, to \$12,529,000 in 1999, compared to \$12,094,000 in 1998. SG&A costs were 27% of net sales in 1999 compared to 30% in 1998. The increase in SG&A costs was primarily due to increased sales and marketing costs related to the introduction of new products and expansion of the Company's business, substantially offset by a significant decrease in litigation costs.

Research and development ("R&D") costs increased in 1999 by approximately \$167,000 to \$1,214,000, or 3% of net sales, compared to approximately \$1,047,000, or 3% of net sales, in 1998.

The operating margin increased to 28% in 1999, compared to 25% in 1998, principally because SG&A decreased as a percentage of net sales.

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The Company's effective income tax rate in 1999 was 36%, down from 37% in 1998.

Net income in 1999 increased 30% from 1998 principally because the gross profit increased 17%, but operating expenses increased only 5%. Net income per share (diluted) increased \$0.22, or 26%. The percentage increase in earnings per share was less than that for net income, principally because the increased average number of shares outstanding.

## LIQUIDITY AND CAPITAL RESOURCES

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 and \$3,697,000 from exercise of stock options, partially offset by \$3,994,000 used to purchase property and equipment, and \$119,000 used to acquire treasury stock.

During 1999, working capital decreased approximately \$1,793,000 to \$42,024,000 from \$43,817,000. The Company's cash and cash equivalents and investment securities, including liquid investments, increased by \$352,000 to \$38,442,000 from \$38,090,000. That increase was due primarily to \$14,767,000 of cash flows from operating activities and \$2,016,000 from exercise of stock options, partially offset by \$14,781,000 used to purchase property and equipment, and \$1,650,000 used to acquire treasury stock.

Capital expenditures decreased in 2000 from the relatively high level of 1999, when the Company made substantial investment in molding machines, molds and automated assembly machines in the Company's San Clemente, California production facilities. The Company has adequate facilities to meet its current needs, but expects to purchase additional machinery and molds to meet demand expected in the latter part of 2001 and thereafter.

Management expects that sales of the Company's products will continue to grow in 2001. If sales continue to increase, accounts receivable and inventories are expected to increase as well. As a result of these and other factors, the Company expects the use of working capital to fund its operations to continue to increase. The decrease in inventory from 1999 to 2000 is because of aggressive efforts by the Company to minimize its investment in inventory.

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

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

### FORWARD LOOKING STATEMENTS

Various portions of this Report, including Management's Discussion and Analysis describe trends in the Company's business and finances that Management perceives and states some of its expectations and beliefs about the Company's future. These statements about the future are "forward looking statements," and the Company identifies them by using words such as "believes," "expects," "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 Management and assumptions that Management believes are reasonable, but Management does not intend the statements to be representations as to future results. They include, among other things, statements about:

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- o future operating results and various elements of operating results, including sales and unit volumes of products, future increases in sales of custom I.V. systems, SafeLine revenue share, production costs, gross margins, SG&A, promotional costs, and research and development expense and income taxes;
- costs, and research and development expense and income taxes;
  of actors affecting operating results, such as shipments to
  specific customers, product mix, selling prices, the market
  shift to needleless 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, manufacturing
  efficiencies, labor costs, unit production costs, electrical
  energy costs and service, production automation, expansion of
  markets and distribution costs;
- o new or extended contracts with manufacturers and buying organizations, ability to replace distributors, and dependence on a small number of customers;
- o regulatory approvals and outcome of litigation;
- o competitive and market factors, including continuing development of competing products by other manufacturers, consolidation of the healthcare provider market and downward

pressure on selling prices; and

working capital requirements, changes in accounts receivable
and inventories, capital expenditures and common stock
repurchases.

The kinds of statements described above and similar forward looking statements about the Company's future performance are subject to a number of risks and uncertainties which one should consider in evaluating the statements. First, one should consider the factors and risks described in the statements themselves. These factors are uncertain, and if one or more of them turn out differently than Management currently expects, the Company's operating results may differ materially from Management's current expectations.

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

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

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

The Company disclaims any obligation to update the statements or to announce publicly the result of any revision to any of the statements contained herein to reflect future events or developments.

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

Not Applicable.

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) as of December 31, 2000 and 1999, and the related consolidated statements of income, stockholders' equity and cash flows for the three years ended December 31, 2000. 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. as of December 31, 2000 and 1999, and the consolidated results of its operations and its consolidated cash flows for the three years ended December 31, 2000, 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  $10\,\text{-K}$  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 25, 2001

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ICU MEDICAL, INC.

CONSOLIDATED BALANCE SHEETS \_\_\_\_\_

ASSETS

	Decembe	er 31,
	2000	1999
CURRENT ASSETS:		
Cash and cash equivalents Liquid investments	\$ 1,945,000 48,841,000	\$ 1,901,000 36,541,000
Cash and liquid investments Accounts receivable, net of allowance for doubtful accounts	50,786,000	38,442,000
of \$505,000 in 2000 and \$368,000 in 1999 Inventories Prepaid expenses and other Deferred income taxes - current portion	12,425,000 1,435,000 402,000 2,150,000	7,129,000 2,056,000 402,000 1,345,000
Total current assets	67,198,000	49,374,000
PROPERTY AND EQUIPMENT, at cost: Land, building and building improvements Machinery and equipment Furniture and fixtures Molds Construction in process	13,505,000	12,173,000 13,752,000 2,524,000 5,608,000 2,866,000
LessAccumulated depreciation	40,131,000 (16,210,000) 23,921,000	36,923,000 (12,483,000) 
DEFERRED INCOME TAXES OTHER ASSETS	889,000 852,000	806,000
	\$ 92,860,000	\$ 75,364,000

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

#### ICU MEDICAL, INC. \_\_\_\_\_

## CONSOLIDATED BALANCE SHEETS

## LIABILITIES AND STOCKHOLDERS' EQUITY

	Dec	cember 31,
	2000	1999
CURRENT LIABILITIES:		
Accounts payable Accrued liabilities		\$ 965,000 6,385,000
Total current liabilities	9,480,000	7,350,000
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:  Convertible preferred stock, \$1.00 par value  Authorized500,000 shares;		
Issued and outstandingnone Common stock, \$0.10 par value- Authorized20,000,000 shares;	-	-
Issued 8,867,162 shares in 2000 and 1999 Additional paid-in capital Treasury stock, at cost 472,933 shares in 2000	887,000 41,702,000	887,000 40,843,000
and 765,123 shares in 1999 Retained earnings		(7,153,000) 33,437,000
Total stockholders' equity	83,380,000	68,014,000
	\$ 92,860,000 ======	\$ 75,364,000

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

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ICU MEDICAL, INC.

#### CONSOLIDATED STATEMENTS OF INCOME \_\_\_\_\_

For	the	years	ended	December	31,

	 2000	 1999	 1998
NET SALES COST OF GOODS SOLD	\$ 56,191,000 23,787,000	\$ 47,014,000 19,883,000	\$ 39,842,000 16,687,000
Gross profit	 32,404,000	 27,131,000	 23,155,000

OPERATING EXPENSES:						
Selling, general and administrative		14,302,000		12,529,000		12,094,000
Research and development		1,480,000		1,214,000		1,047,000
Total operating expenses	15,782,000		13,743,000			13,141,000
Income from operations		16,622,000	13,388,000			10,014,000
INVESTMENT INCOME	2,096,000		1,431,000		1,408,00	
Income before income taxes	18,718,000		14,819,000			11,422,000
PROVISION FOR INCOME TAXES	6,930,000		5,400,000			4,200,000
NET INCOME	\$ 11,788,000		\$ 9,419,000		\$	7,222,000
NET INCOME PER SHARE						
Basic	\$	1.42		1.16	\$	0.90
Diluted	\$	1.30	\$	1.08	\$	0.86
	====	=======	====	========	===	
WEIGHTED AVERAGE NUMBER OF SHARES						
Basic		8,330,069		8,154,859		7,989,534
Diluted		9,058,853		8,690,443		8,422,613
	====		====		===	

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

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## ICU MEDICAL, INC.

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Number of Shares Outstanding	Stock	Additional Paid-In Capital	Treasury Stock	Retained Earnings	Total
BALANCE, December 31, 1997	7,766,386	\$887,000	\$39,455,000	\$(9,320,000)	\$ 16,925,000	\$ 47,947,000
Acquire shares for treasury Exercise of stock options and	(32,100)	-	-	(401,000)	-	(401,000)
related income tax benefits, and other Net Income	325,029	-	786,000		71,000 7,222,000	
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 Exercise of stock options and related income tax benefits,	(121,000)	-	-	(1,650,000)	-	(1,650,000)
and other	163,724	-	602,000		(200,000) 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 Exercise of stock options and related income tax benefits,	(6,000)	-	-	(119,000)	-	(119,000)
and other	298,190	-	859,000		385,000	
Net Income	-	-	-	-	11,788,000	11,788,000
BALANCE, December 31, 2000	8,394,229	\$887,000	\$41,702,000		\$ 45,610,000	\$ 83,380,000

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

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## ICU MEDICAL, INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the years ended December	31,		
2000	1999		1998	

CASH FLOWS FROM OPERATING ACTIVITIES:

Net Income \$ 11,788,000 \$ 9,419,000 \$ 7,222,000

Adjustments to reconcile net income to net cash			
provided by operating activities Depreciation and amortization	4 (12 000	3,917,000	2,364,000
Deferred income taxes, non-current	(83,000)	(714,000)	(174,000)
(Increase) decrease in:	(03,000)	(/14,000)	(174,000)
Accounts receivable	(5,409,000)	(637,000)	(3,126,000)
Inventories	621,000	(66,000)	(228,000)
Prepaid expenses and other assets	(94,000)	(17,000)	(184,000)
Increase (decrease) in:	(34,000)	(17,000)	(104,000)
Accounts payable	722,000	282,000	(720,000)
Accrued liabilities	1,408,000	2,937,000	1,694,000
Deferred income taxes, current	(805,000)	(354,000)	(274,000)
· ·			
Net cash provided by operating activities	12,760,000	14,767,000	6,574,000
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property and equipment	(3 004 000)	(14,781,000)	(6 657 000)
Net change in liquid investments	(12,300,000)	(500,000)	(3,891,000)
Net change in riquid investments	(12,300,000)	(300,000)	(3,691,000)
Net cash (used in) investing activities	(16,294,000)	(15,281,000)	(10,548,000)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from exercise of stock			
	3,697,000	2,016,000	3,461,000
Purchase of treasury stock	(119,000)	(1,650,000)	(401,000)
raichase of creasury scook	(113,000)		(401,000)
Net cash provided by financing activities	3,578,000	366,000	3,060,000
NEW THORPING (PROPERTY BY OLDY AND			
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	44,000	(148,000)	(914,000)
CASH AND CASH EQUIVALENTS, beginning of year	1,901,000	2,049,000	2,963,000
CASH AND CASH EQUIVALENTS, end of year	\$ 1,945,000 ======	\$ 1,901,000	\$ 2,049,000
SUPPLEMENTAL DISCLOSURE OF CASH			
FLOW INFORMATION:	2 6 706 000	0 4 555 000	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2
Cash paid during the period for income taxes	\$ 6,706,000	\$ 4,555,000	\$ 3,727,000

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

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## ICU MEDICAL, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2000, 1999 AND 1998

## 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:

	2000	1999		
Raw materials	\$ 1,050,000	\$	962,000	
Work in process	140,000		287,000	
Finished goods	245,000		807,000	

\$ 1,435,000 \$ 2,056,000 ========

========

#### С. 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 30 years Building improvements 15 years Machinery and equipment 5 - 10 years 3 - 5 years Furniture, fixtures and molds

The Company follows the policy of capitalizing expenditures that materially increase the life of the related assets; maintenance and repairs are charged directly to expense 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.

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#### 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, 2000 and 1999, the net book value of patents and licenses was \$350,000 and \$448,000, respectively, net of accumulated amortization of \$551,000 and \$431,000, respectively.

## Research and Development

The Company expenses research and development costs as incurred.

#### Cash Equivalents f. -----

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

## Net Income Per Share

The Company follows Statement of Financial Accounting Standards ("SFAS") No. 128, "Earnings per Share" in calculating net income per share. This statement provides for the presentation of (i) "basic" earnings per share, which is computed by dividing net income by the weighted average number of common shares outstanding and (ii) "diluted" earnings per share which is computed by dividing net income by the weighted average number of common shares outstanding plus dilutive securities. The Company's dilutive securities are outstanding common stock options (excluding stock options with an exercise price in excess of 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.

## 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 can be carried at amortized cost with no accounting for market value fluctuations.

## Income Taxes

"Accounting for Income Taxes," which requires an asset and liability approach in accounting for income taxes payable or refundable at the date of the financial statements as a result of all events that have been recognized in the financial statements as measured by enacted tax laws. Additionally, SFAS No. 109 requires that deferred tax assets be evaluated and a valuation allowance be 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.

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## k. Post-retirement and Post-employment Benefits

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

## 1. 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 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 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:

	2000	1999	1998
Corporate preferred stocks Federal tax-exempt debt securities	\$18,000,000 29,750,000	\$14,800,000 20,650,000	\$14,600,000 20,350,000
Certificate of deposit	1,091,000	1,091,000	1,091,000
	\$48,841,000	\$36,541,000	\$36,041,000
	=========	=========	========

The certificate of deposit is pledged to secure a letter of credit.

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

	2000	1999	1998
Corporate dividends Tax-exempt interest Other interest	\$ 835,000	\$ 699,000	\$ 516,000
	993,000	551,000	758,000
	268,000	181,000	134,000
	\$ 2,096,000	\$ 1,431,000	\$ 1,408,000
	=====	======	======

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#### 3. ACCRUED LIABILITIES

Accrued liabilities consists of the following:

	2000	1999
Accrued incentive compensation	\$ 1,744,000	\$ 1,368,000
Taxes payable	2,523,000	2,299,000
Other accruals	3,526,000	2,718,000
Total accrued liabilities	\$ 7,793,000	\$ 6,385,000
	========	========

#### 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. Options issued after early 2000 vest in equal amounts on the first, second and third anniversary of their issuance. 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.

Of the options outstanding at December 31, 2000, 2,617,257 are time-accelerated options, which were issued under the 1993 Plan. Of those options, 39,700 issued in 1993 at an average exercise price of \$9.56 expire in 2004; 107,500 issued in 1994 at an average exercise price of \$11.05 expire in 2005; 11,000 issued in 1995 at an average exercise price of \$12.66 expire in 2006; 491,509 issued in 1996 at an average exercise price of \$13.73 expire in 2007; 801,201 issued in 1997 at an average exercise price of \$9.47 expire in 2008; 801,138 issued in 1998 at an average exercise price of \$12.32 expire in 2009, 294,630 issued in 1999 at an average exercise price of \$16.80 expire in 2010 and, 70,579 issued in 2000 at an average exercise price of \$15.58 expire in 2011. The remaining 373,797 options that are not time-accelerated are at an average exercise price of \$22.93 and expire in 2001 through 2003.

Dilutive stock options account for the difference in the number of shares used to calculate basic and diluted net income per share and were 728,784 in 2000, 535,584 in 1999 and 433,079 in 1998. 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 100,000, 90,000 and 360,000, in 2000, 1999 and 1998, respectively. At December 31, 2000, all outstanding options had exercise prices less than the market price of the Company's common stock.

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

	Shares		Exer	Rang	е	ice		eighted Average
Outstanding at December 31, 1997	2,147,452	\$	7.19	-	\$	16.25	\$	10.29
Granted	910,229							
Exercised	321,029							8.24
Forfeited	17,500							12.51
Outstanding at December 31, 1998	2,719,152	\$	7.19	-	\$	16.38	\$	11.15
Granted	330,000							16.90
Exercised	158,724		7.19	-		14.28		8.65
Forfeited	27,060		13.00	-				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					19.84
Outstanding at December 31, 2000								
	========	==			==	======	==:	
Exercisable at December 31:					_			
1998	430,621							
1999	1,357,656							
2000	1,923,073		7.63	-		18.31		11.75
Available for grant at December 31, 2000	1,043,503							
	========							

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.

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 2000, 1999 and 1998 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

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; 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 2000, 1999 and 1998 was \$13.36, \$8.36 and \$6.05, 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 \$758,000.

	2000	1999	1998
Proforma:			
Net Income	\$9,481,000	\$7,005,000	\$3,328,000
Net Income per share - basic	\$1.21	\$0.89	\$0.44
- diluted	\$1.10	\$0.83	\$0.42
Weighted average number of			
common shares - basic	7,863,000	7,891,000	7,558,000
- diluted	8,592,000	8,426,000	7,991,000

#### 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 that 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.

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#### 6. INCOME TAXES

The provision for income taxes for the years ended December 31, 2000, 1999 and 1998, is as follows:

	2000	1999	1998
Current:			
Federal	\$ 6,070,000	\$ 5,093,000	\$ 3,694,000

State	1,748,000	1,375,000	954,000
	7,818,000	6,468,000	4,648,000
Deferred:			
Federal	(706,000)	(852,000)	(379,000)
State	(182,000)	(216,000)	(69,000)
	(888,000)	(1,068,000)	(448,000)
	\$ 6,930,000	\$ 5,400,000	\$ 4,200,000
	=========	==========	==========

Current income taxes payable were reduced from the amounts in the above table by \$702,000, \$751,000 and \$843,000 in 2000, 1999 and 1998, 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:

	2000	2000		) 	1998	
	Amount	Percent	Amount	Percent	Amount	Percent
Federal tax at the expected statutory rate	\$ 6,364,000	34.0%	\$ 5,038,000	34.0%	\$ 3,884,000	34.0%
State income tax, net of	1,169,000					6.6
federal benefit Tax-exempt interest and	1,169,000	6.2	794,000	5.3	754,000	0.0
dividends	(537,000)	(2.9)	(353,000)	(2.4)	(380,000)	(3.3)
Tax credits	(66,000)	(0.3)	(79,000)	(0.5)	(58,000)	(0.5)
Provision	\$ 6,930,000	37.0%	\$ 5,400,000	36.4%	\$ 4,200,000	36.8%

The components of the Company's deferred income tax provision for the years ended December 31, 2000, 1999 and 1998 are as follows:

	2000	1999	1998
Allowance for doubtful accounts	\$ (68,000)	\$ (11,000)	\$ (6,000)
Inventory reserves	86,000	_	30,000
Accruals	(810,000)	(317,000)	(367,000)
State income taxes	(13,000)	(26,000)	69,000
Depreciation	(83,000)	(714,000)	(174,000)
	\$ (888,000)	\$(1,068,000)	\$ (448,000)
	========	=========	=========

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

	2000	1999
Current deferred tax benefit:		
Allowance for doubtful accounts	\$ 225 <b>,</b> 000	\$ 157,000
Inventory reserves	184,000	270,000
Accruals	1,609,000	799,000
State income taxes	132,000	119,000
	\$ 2,150,000	\$ 1,345,000
Long-term deferred tax benefit:	=========	=========
Depreciation	\$ 889,000	\$ 806,000

### 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 \$39,665,000 of consolidated net sales in 2000, \$32,059,000 in 1999 and \$27,508,000 in 1998. Custom I.V. systems, many of which incorporate the CLAVE connector, accounted for \$6,877,000 of consolidated net sales in 2000, \$5,251,000 in 1999 and \$3,218,000 in 1998. All other products account for less than 10% 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, 2000, 1999 and 1998, the Company had sales of 10 percent or greater to two manufacturers as follows:

	2000	1999	1998
Manufacturer A	26%	28%	35%
Manufacturer B	48	42	29

#### 8. COMMITMENTS AND CONTINGENCIES

In June 1998, the Company suffered a judgment against it in the amount of \$728,000 after a jury verdict in favor of a plaintiff for commissions alleged owed him. The Company is appealing the judgment, but in view of the uncertainties of the appeal process, accrued a provision for this matter in its 1998 financial statements.

In November 1999, a medical products manufacturer commenced a patent infringement action against the Company over the CLAVE connector. The Company believes the action against it is without merit and has been vigorously defending itself. The Company has also brought a patent infringement action against that Company and intends to vigorously pursue this matter.

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.

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

	Quarter Ended			
	March 31	June 30	Sept. 30	Dec. 31
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
1999				
Net Sales	\$11,442	\$11,699	\$10,712	\$13,161
Gross Profit	6,709	6,602	5,876	7,944

Net Income	2,184	2,220	1,946	3,069
Net Income Per Share:				
Basic	\$0.27	\$0.27	\$0.24	\$0.38
Diluted	\$0.25	\$0.25	\$0.22	\$0.36

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, 2000, 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, 2000, and such information is incorporated herein by this reference.

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#### 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:

FORM 10-K PAGE NO.

### 1. Financial Statements

The financial statements listed below are set forth in Item 8 of this  $\mbox{\it Annual Report.}$ 

Report of Independent Public Accountants	21
Consolidated Balance Sheets at December 31, 2000 and 1999	22-23
Consolidated Statements of Income for the Years Ended December 31, 2000,	
1999 and 1998	24
Consolidated Statements of Stockholders' Equity for the Years Ended	
December 31, 2000, 1999 and 1998	25
Consolidated Statements of Cash Flows for the Years Ended December 31,	
2000, 1999 and 1998	26
Notes to Consolidated Financial Statements	27-35

### 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	Registrant's Directors' Stock Option Plan.(3)
10.4	Manufacture and Supply Agreement dated September 13, 1993 between Registrant and B.Braun, Inc. relating to the Protected Needle product.(4)
10.5	Supply and Distribution Agreement dated April 3, 1995 between Registrant and Abbott Laboratories, Inc. relating to the CLAVE product.(5)
10.6	Registrant's Director's Stock Award Plan.(6)
10.7	Rights Agreement dated July 15, 1998 between Registrant and ChaseMellon Shareholder Services, L.L.C. as Rights Agent.(7)
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10.8	Manufacture and Supply Agreement dated January 1, 1999 by and between Registrant and B.Braun Medical, Inc. relating to the CLAVE product.(8)
10.9	SafeLine Agreement effective October 1, 1999 by and between Registrant and B.Braun Medical, Inc.(8)
10.10	Amendment to Abbott and ICU Medical Agreement, dated January 1, 1999 between Registrant and Abbott Laboratories.(9)
10.11	Amendment No. 1 to Rights Agreement, dated January 30, 1999, between Registrant and ChaseMellon Shareholder Services, L.L.C. as Rights Agent.(10)
10.12	Co-Promotion and Distribution Agreement, dated February 27, 2001 between Registrant and Abbott Laboratories.(11)
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 May 4, 1996 and incorporated herein by reference.
(3)	Filed as an exhibit to Registrant's definitive Proxy Statement filed pursuant to Regulation 14A on March 22, 1993 and incorporated herein by reference.

(4) 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.

- (5) 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.
- (6) Filed as exhibit to Registrant's definitive Proxy Statement filed pursuant to Regulation 14A on April 11, 1998 and incorporated herein by reference.
- (7) Filed as an exhibit to Registrant's Registration Statement on Form 8-A dated July 23, 1998 and incorporated herein by reference.
- (8) Filed as an exhibit to Registrant's Current Report on Form 8-K dated June 18, 1999, and incorporated herein by reference.
- (9) Filed as an exhibit to Registrant's Current Report on Form 8-K dated February 23, 1999, and incorporated herein by reference.
- (10) Filed as an exhibit to Registrant's Registration Statement on Form 8-A/A dated February 9, 1999 and incorporated herein by reference.
- (11) 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

Jack W. Brown

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#### 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

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Dated: March 7, 2001

## 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. George A. Lopez, M.D.	Chairman of the Board, President, and Chief Executive Officer, (Principal Executive Officer)	March 7,	2001
, - ,	Francis J. O'Brien Francis J. O'Brien	Chief Financial Officer and Principal Accounting Officer	March 7,	2001
/s/	Jack W. Brown	Director	March 7,	2001

/s/ John J. Connors	Director	March 7, 2001
John J. Connors		
/s/ Michael T. Kovalchik, III, M.D.	Director	March 7, 2001
Michael T. Kovalchik, III, M.D.		
/s/ Richard H. Sherman, M.D.	Director	March 7, 2001
Richard H. Sherman, M.D.		
/s/ Robert S. Swinney, M.D.	Director	March 7, 2001
Robert S. Swinney, M.D.		

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SCHEDULE II

## ICU MEDICAL, INC.

## VALUATION AND QUALIFYING ACCOUNTS

Additions Charged to Balance at Balance Beginning Costs and Charged to Write-offs/ at End Expenses Other Accounts Description of Period Disposals of Period For the year ended December 31, 1998: Allowance for doubtful accounts \$ 324,000 \$ 40,000 \$ 22,000 \$ 342,000 Inventory reserves \$ 500,000 62,000 96,000 \$ 466,000 For the year ended December 31, 1999: Allowance for doubtful accounts \$ 342,000 \$ 100,000 \$ 74,000 \$ 368,000 Inventory reserves \$ 466,000 \$ 466,000 For the year ended December 31, 2000: Allowance for doubtful accounts \$ 368,000 \$ 195,000 \$ 58,000 \$ 505,000 Inventory reserves \$ 466,000 \$ 201,000 \$ 265,000

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## EXHIBIT INDEX

Exhibit Number	Description	Sequentially Numbered Page
21.1	Subsidiaries of Registrant	41
23.1	Consent of Arthur Andersen LLP	42

## 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

## CONSENT OF INDEPENDENT PUBLIC ACCOUNTANTS

As independent public accountants, we hereby consent to the incorporation of our report dated January 25, 2001 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, 2000 or performed any audit procedures subsequent to the date of our report.

/s/ Arthur Andersen LLP ARTHUR ANDERSEN LLP

Orange County, California January 25, 2001