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

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 1999 OR

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

EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM TO

COMMISSION FILE NO. 0-19974

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

DELAWARE

(STATE OR OTHER JURISDICTION OF
INCORPORATION OR ORGANIZATION)
951 CALLE AMANECER
SAN CLEMENTE, CALIFORNIA
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES)

33-0022692 (I.R.S. EMPLOYER IDENTIFICATION NO.)

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  $_{\rm X}$  No  $_{\rm max}$ 

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 29, 2000 was \$109,027,884. \*

The number of shares outstanding of Registrant's Common Stock, \$.10 par value, as of February 29, 2000 was 8,304,039.

Portions of the Proxy Statement for Registrant's 2000 Annual Meeting of Stockholders, filed or to be filed pursuant to Regulation 14A within 120 days following Registrant's fiscal year ended December 31, 1999, are incorporated by reference into Part III of this Report.

\* 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.

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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 I.V. connectors are designed to prevent accidental disconnection of I.V. lines and to protect healthcare workers

and their patients from the spread of infectious diseases such as Hepatitis B and C and Human Immunodeficiency Virus ("HIV") by significantly reducing the risk of accidental needlesticks. 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 protective I.V. connectors. In addition, healthcare regulations promulgated by 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. Since then, four other states have enacted similar legislation, and legislation is pending is approximately 26 other states and in the U.S. Congress. 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

The Company's first products, the Click Lock(R) and Piggy Lock(R), feature protected needles to prevent accidental contact with needles and include locking mechanisms to prevent accidental disconnections. These products were designed to replace conventional products and methods, such as I.V. connectors with exposed needles that are secured by tape or open luer lock connections.

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. The CLAVE needleless I.V. connection system allows protected, secure and sterile I.V. connections without needles and without failure-prone mechanical valves used in the I.V. connection systems of some competitors. The CLAVE 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. While the Company continues to manufacture and sell protected needle products, sales of those products are declining as the market penetration of needleless systems such as the CLAVE and other competitive needleless products increases.

The Company has been manufacturing and distributing custom I.V. systems through its wholly owned subsidiary, Budget Medical Products, Inc. ("BMP"), since it established BMP in late 1995. In 1999, the Company decided to substantially increase its emphasis on marketing and selling custom I.V. systems.

Effective January 1, 2000, the Company reoriented its manufacturing and distribution operations. Marketing and sales operations will be 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 to independent distributors, the custom I.V. systems product line, formerly referred to as the BMP product line, will now be referred to as the "custom I.V. systems" product line.

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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 an infectious disease is transmitted. 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.

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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 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 B.Braun Medical, Inc. ("B.Braun") and Abbott Laboratories ("Abbott") to build directly into their I.V. sets. Sales of the CLAVE Integrated Y site to date have only been to Abbott.

The CLAVE is the Company's largest selling product line, and accounted for 68% of the Company's net sales in 1999.

### CLICK LOCK AND PIGGY LOCK PRODUCTS

The Company's first products, the Click Lock and Piggy Lock, were designed to overcome the limitations of conventional I.V. connections which use exposed needles. 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.

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. The B.Braun MPN Agreement provides that the Company release B.Braun from any claims for patent infringement resulting from the sale of McGaw Protected Needles prior to the effective date of the B.Braun MPN Agreement, and for as long as the B.Braun MPN Agreement is in effect. The Company began assembly of the McGaw Protected Needle during 1994. Sales of the McGaw Protected Needle under the B.Braun MPN Agreement accounted for approximately 3% of the Company's net sales in 1999. 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 a May 1995 amendment 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 4% of the Company's net sales in 1999. The Company expects that agreement, which expires in June 2000, 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.

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 comprised of a small plastic piercing element that is recessed into a plastic 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 (TM)

The CLC2000 is a one piece, swabable connector, engineered with the only technology currently in the marketplace 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 the I.V. line in the same manner as the CLAVE. 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 procedures to "flush" the catheter, or if those procedures are not effective, replacement of the catheter. Flushing often requires use of expensive drugs and carries the risk of infection from bacteria in the occluded blood. Because of this risk of infection, the United States Food and Drug Administration has recently suggested use of procedures other than drugs to prevent occlusion of catheters.

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 small diameter, long-dwelling catheters such as oncology, dialysis and long-term infusion of medication. CLC2000 accounted for less than 2% of the Company's net sales in 1999.

### 1o2 VALVE (TM)

The lo2 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 lo2 Valve can be used in place of products such as stopcocks and check valve manifolds. The Company commenced marketing the lo2 Valve in November 1998, and commenced shipment mid-1999. Initially, the Company intends to focus marketing efforts on anesthesia and critical care usage. Sales to date have not been significant.

### 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.

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During 1997, 1998 and 1999, net sales of custom I.V. systems to medical product manufacturers and independent domestic distributors were approximately \$1,800,000, \$3,200,000 and \$5,300,000, respectively. Most of the growth in 1997 and 1998 net sales was because of increased unit shipments of custom I.V. sets incorporating the CLAVE.

#### SETFINDER (TM)

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 initially will also be 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, 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 2000 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.

Effective January 1, 2000, the Company reoriented its distribution operations 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 B.Braun and Abbott, two major I.V. product suppliers, each of whom has a significant share of the I.V. set market under contract. The agreement with B.Braun, which extends to December 2002, confers to B.Braun exclusive and nonexclusive rights to distribute certain CLAVE products to certain categories of customers. Under the agreement with Abbott, which extends to December 2009, Abbott has rights to distribute certain CLAVE products, the Rhino and the CLC2000.

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

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.

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Sales to B.Braun of CLAVE products and McGaw Protected Needles and SafeLine revenue share accounted for approximately 36%, 35% and 28% of the Company's net sales in 1997, 1998 and 1999, respectively. Sales to Abbott accounted for approximately 16%, 29% and 42% of net sales in 1997, 1998 and 1999, respectively. The loss of B.Braun or Abbott as a customer could have a significant adverse effect on the Company's business and operating results because these customers 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 13 independent distributors in the United States and Canada who employ approximately 125 salespeople in the aggregate and accounted for approximately 25% of the Company's net sales in 1999. (Canada is included by the Company as "domestic" for administrative purposes.) In addition, the Company employs 8 product specialists in the United States who support the Company's distributors. Independent distributors in Canada are supported by the same product specialists who work with the medical products manufacturers. Distributors purchase and stock the Company's products for resale to healthcare providers.

One independent distributor accounted for approximately 7% 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 corrected 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%, 3% and 4% of the Company's net sales in each of the years 1997, 1998 and 1999, respectively. The Company has four product specialists in Europe.

### 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 the majority of its requirements for components, performs all assembly, quality control, inspection, packaging, labeling and shipping of its products. Sterilization and sterility testing are 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. 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 an 8,000 square foot class 100,000 clean room in which all molding 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. The Company uses 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 Piggy Lock, Lopez Valve and I.V. sets are assembled manually. The CLC2000 and 1o2 Valve are currently assembled manually pending installation of automated assembly in 2000.

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.

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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.

The Company's products are currently sterilized in processes, which use either gamma or electronic beam ("e-beam") radiation. In 1998, most of the Company's sterilization was by gamma radiation. By the end of 1999, most of the sterilization had been moved to 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 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 the 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.

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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

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 future will conform or that additional regulations restricting the sale of its present or proposed products will not be promulgated by the EC.

### 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 B.Braun and Abbott.

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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 the 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, CLC2000, CLAVE, Click Lock and Piggy Lock I.V. connectors. The expiration dates of the Company's patents range from 2005 to 2016.

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."

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#### **EMPLOYEES**

At February 29, 2000, the Company had 274 full-time employees, consisting of 70 engaged in sales, marketing and administration, and 204 in manufacturing, molding, product development and quality control, including 103 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 29, 2000, the number of temporary production personnel was approximately 94.

### 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 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 its patent by the manufacture and sale of the CLAVE connector, and Medex seeks monetary damages and injunctive relief. The Company, based on advice of counsel, believes the suit against the Company is without merit and the Company intends to vigorously defend itself in the action. The Company has brought an action entitled ICU MEDICAL, INC. v. MEDEX, INC. in the United States District Court for the Central District of California against Medex, Inc. for infringing several patents of the Company by the manufacture and sale of certain blood access devices. The Company seeks monetary damages and injunctive relief. The Company intends to vigorously pursue this matter.

On April 7, 1998, in an action entitled ALLEN PETTY, dba CARMEL DEVELOPMENT INTERNATIONAL v. ICU MEDICAL, INC., an Orange County, California, Superior Court jury rendered a verdict in favor of the Plaintiff and against the Company in the sum of \$795,448 in an action brought by the Plaintiff for commissions allegedly owed him. On June 23, 1998, the Court reduced the

judgement to \$727,522 (\$673,142 plus certain expenses), but denied the balance of the Company's motion to set aside the jury verdict. The Company believes the verdict is against the facts in the case and is contrary to well established law, and has appealed to have the balance of the judgement overturned. In view of the Court decision in June 1998 and the uncertainties of the appeal process, the Company accrued a provision for this matter in its June 1998 financial statements.

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

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

Not Applicable.

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#### 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.	52	Chairman of the Board, President and Chief Executive Officer
Richard A. Costello	36	Vice President of Sales
Evelyn L. Foss	44	Vice President of Marketing
Francis J. O'Brien	57	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 Nasdaq:

1998	High	Low
First Quarter Second Quarter Third Quarter Fourth Quarter	\$ 16 1/4 16 3/16 15 1/4 22	\$ 12 1/2 13 5/8 11 7/8 12 3/4
1999	High	Low

First Quarter	\$21 5/16	\$ 15 3/8
Second Quarter	19 3/4	14 3/8
Third Quarter	19 3/4	13 7/8
Fourth Quarter	16 1/4	11 5/8

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 29, 2000 the Company had 125 stockholders of record and believes it has approximately 2,900 beneficial stockholders.

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#### ITEM 6. SELECTED FINANCIAL DATA

ICU MEDICAL, INC.

#### SELECTED FINANCIAL DATA

#### YEAR ENDED DECEMBER 31, ------(in thousands, except per share data) 1998 1997 1996 1995 1999 INCOME DATA: \$ 47,014 \$ 39,842 \$ 30,404 \$ 24,599 \$ 21,282 19,883 16,687 12,817 10,438 10,276 Net sales Cost of goods sold 10,438 10.276 \_\_\_\_\_ 14,161 11,006 27,131 23,155 17,587 13,743 13,141 9,725 Gross profit Operating expenses 8,236 \_\_\_\_\_ \_\_\_\_\_ 13,388 10,014 7,862 1,431 1,408 1,269 5,400 4,200 3,450 5,925 5,406 1,289 713 2,475 1,958 Income from operations 5,406 Investment income and other Provision for income taxes \$ 9,419 \$ 7,222 \$ 5,681 -----\$ 4,739 \$ 4,161 -----Net income Income from continuing operations Per Share \$ 1.16 \$ 0.90 \$ 0.71 \$ 0.54 \$ 0.53 \$ 1.08 0.86 0.71 0.54 0.52 Basic Diluted \_\_\_\_\_ Weighted average number of shares 8,155 7,990 7,946 8,690 8,423 8,029 8,722 7,906 8,842 8,040 Basic Diluted \_\_\_\_\_ CASH FLOW DATA: Cash flows from operations \$ 14,767 \$ 6,574 \$ 8,666 \$ 6,513 \$ 6,997 BALANCE SHEET DATA: \$ 38,442 \$ 38,090 \$ 35,112 \$ 31,760 \$ 29,665 Cash and liquid investments 43,817 37,993 35,587 33,762 62,360 51,186 49,639 47,850 Working capital 42,024 Total assets 75,364 Long-term debt 68,014 58,229 47,947 46,749 45,658 Stockholders' equity

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### 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	1999	1998	1997
CLAVE	68%	69%	65%
Click Lock	3%	4%	7%
McGaw Protected Needle	3%	4%	5%
Lopez Valve and other	5%	5%	4%
RF100-RF150 ("Rhino")	6%	5%	7%
Custom I.V. Systems	11%	8%	6%
B.Braun SafeLine Revenue Sharing	4%	5%	6%
Total	100%	100%	100%

The Company sells its products to independent distributors and through supply and distribution agreements with B.Braun, Abbott (the "B.Braun Agreement" and the "Abbott Agreement," respectively) and C. R. Bard, Inc. ("Bard"). Most independent distributors handle the full line of the Company's products. B.Braun and Abbott both purchase CLAVE products, principally bulk non-sterile connectors. B.Braun also purchases the McGaw Protected Needle and pays the Company revenue sharing payments on its sales of its SafeLine products. Abbott also purchases the Rhino, a low-priced connector specifically designed for Abbott and the CLC2000. Bard distributes the Lopez Valve under a five-year agreement signed in June 1999.

The B.Braun Agreement, except for the SafeLine Revenue Sharing, extends to December 2002, and has extension provisions beyond then.

In January 1999, the Company and Abbott agreed to a significant expansion of their agreement for CLAVE products. The new agreement has assurances of substantial increases in sales unit volume, accompanied by price reductions. The new agreement was extended from April 2002 to December 2009, and designates the Company as Abbott's preferred supplier for all Abbott's needlefree technology. In July 1999 the contract was amended to include the CLC2000.

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

Management believes the success of the CLAVE has, and will continue to motivate others to develop one piece needleless connectors which may incorporate many of the same functional and physical characteristics as the CLAVE. The Company is aware of a number of such products. In response to competitive pressure, the Company has been reducing prices to protect and expand its market. The price reductions to date have 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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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. It is also launching SETFINDER.COM, which will distribute commodity-type standard I.V. sets directly

to healthcare providers. There is no assurance that either one of these initiatives will succeed.

Effective January 1, 2000, the Company reoriented its manufacturing and distribution operations. Marketing and sales operations will be 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, will 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	1999	1998	1997
Medical product manufacturers	71%	64%	52%
Independent domestic distributors	25%	33%	45%
International	4%	3%	3%
Total	100%	100%	100%

#### 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 to \$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. Based upon the terms of the Abbott agreement as amended through January 2000, Management expects a substantial increase in CLAVE unit and dollar sales volume with Abbott in 2000, although there is no assurance as to the amount of such increase.

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. Management expects increases in CLAVE unit shipments to B.Braun in 2000, although there is no assurance that this expectation will be realized. Net sales of the McGaw Protected Needle decreased 13%, 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 \$1,751,000 in 1999, compared to \$1,995,000 in 1998. The Company expects that the agreement, which expires in June 2000, will be extended, but there is no certainty as to this matter. Although Management anticipates that such revenue sharing will continue, the actual amount will depend on the volume and selling prices of B.Braun's SafeLine products, which Management has no means of forecasting accurately.

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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 B.Braun and Abbott, 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. Management expects a continued decrease in the net sales of standard CLAVE products to the independent domestic distributors, but expects that decrease to be more than offset by sales of custom I.V. systems and new products such as the CLC2000 and the 1o2 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 their unit sales may be impacted by competition from existing and new competitive products or acquisition of CLAVE 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.

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. Management expects that decline to continue.

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. Management expects continued increases in Lopez Valve net sales in 2000.

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.) Since mid-1998, the Company has been arranging distribution in each country in Europe to replace and expand upon that handled by a single distributor that was terminated in August 1998. The Company now has distribution arrangements in most of the principal countries in Europe, although there can be no assurance that those distribution arrangements will be satisfactory. Net sales to European customers increased 79% in 1999. Management expects that its sales to European and other foreign customers will continue to increase in the future.

In the fourth quarter of 1999, the Company launched SetFinder doing business as SETFINDER.COM. The effect of SetFinder on 1999 results of operations was insignificant. The Company expects to spend a significant amount to continue to the launch and development of SetFinder in 2000. There can be no assurance that SetFinder will achieve sales and the amount of future operating profits or losses is dependent upon the future development of the SetFinder business, the outcome of which s not known at this time.

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.

The Company is currently taking steps aimed at improving manufacturing efficiency principally by reducing labor costs and minimizing investment in inventory. The original focus was on production of custom I.V. systems, which is relatively labor intensive; it has now been expanded to include all 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 these steps should reduce unit production costs in 2000. 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. However, even if they are successful, management expects that profit 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 2000, but that the gross margin percentage will be equal to or slightly lower than that achieved in 1999 as average unit sales prices continue to decrease.

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. Management expects SG&A costs to increase in 2000, because of growth in the Company, increased domestic and international sales and marketing costs, promotional costs of new products and expansion of the custom I.V. system business and SetFinder.

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. Management estimates that R&D costs in 2000 will continue at approximately the same percentage of net sales as in 1999. However, R&D costs could differ from those estimates and the R&D may not be completed as expected.

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

The Company's effective income tax rate in 1999 was 36%, down from 37% in 1998. Management expects its effective tax rate in 2000 to be equal to or slightly lower than the 1999 rate.

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.

### COMPARISON OF 1998 TO 1997

In 1998, the Company reported net sales of \$39,842,000 which was \$9,438,000, or 31%, higher than the net sales of \$30,404,000 reported in 1997. The most significant factor in the increase was a \$7,969,000, or 41%, increase in CLAVE net sales. Net sales in all of the Company's other product lines were equal to or more than those for 1997, except for a decrease in Click Lock and Piggy Lock net sales.

Total CLAVE net sales increased approximately 41% from \$19,539,000 in 1997 to \$27,508,000 in 1998. Unit shipments of CLAVE products in 1998 increased approximately 88% over 1997, with B.Braun and Abbott accounting for the entire unit growth. Unit sales to independent distributors were down slightly. The aggregate average net selling price of CLAVE products in 1998 decreased approximately 25% as compared with 1997. That decrease reflects lower prices from independent distributors and lower prices on bulk, non-sterile CLAVE products sold to B.Braun and Abbott, as well as a higher percentage of the sales mix being accounted for by bulk, non-sterile CLAVEs.

Net sales to Abbott amounted to \$11,601,000 in 1998, compared to \$4,993,000 in 1997. CLAVE sales were 3.24 times the amount in 1997. Most of the balance of the sales were in the low-priced Rhino, which were \$1,987,000 compared with \$2,087,000 in 1997.

Net sales to B.Braun, including revenue sharing, amounted to \$13,961,000 in 1998, compared to \$10,971,000 in 1997. CLAVE net sales to B.Braun increased approximately 36%, principally because of an increase in unit shipments. Net sales of the McGaw Protected Needle were virtually unchanged. Revenue sharing payments on B.Braun's sales of its SafeLine products was approximately \$1,995,000 in 1998, compared to \$1,767,000 in 1997.

Net sales of Click Lock and Piggy Lock decreased 29% in 1998 compared to 1997, because of the safe connector market's continued shift to needleless technology.

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The Lopez Valve showed a 24% growth in 1998 net sales compared to 1997 principally because of increased unit shipments.

The Company's net sales of custom I.V. systems were \$3,218,000 in 1998 compared to \$1,828,000 in 1997. Most of the increase in 1998 net sales was

because of increased unit shipments of custom I.V. systems incorporating the  ${\tt CLAVE}$ .

Total sales to foreign distributors were \$1,364,000 in 1998 compared to \$908,000 in 1997.

Gross margin for 1998 was unchanged from the 58% registered in 1997. The shift in sales mix toward a higher percentage of the relatively higher-margin CLAVE products, continued increases in the benefits of the Company's extensive production automation, 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 approximately \$3,630,000 to \$12,094,000 in 1998, compared to \$8,464,000 in 1997. SG&A costs were 30% of net sales in 1998 compared to 28% in 1997. The increase in SG&A costs was primarily due to increased sales and marketing costs related to the Company's domestic expansion of the CLAVE product line, growth of BMP, expansion of the international sales efforts, and legal fees.

Research and development ("R&D") costs decreased in 1998 by approximately \$214,000 to \$1,047,000, or 3% of net sales, compared to approximately \$1,261,000, or 4% of sales, in 1997.

The operating margin decreased to 25% in 1998, compared with 26% in 1997, principally because SG&A increased as a percentage of net sales.

Investment income increased 11% from 1997 to 1998, principally because of an increase in invested funds.

The Company's effective income tax rate in 1998 was 37%, approximately the same as in 1997.

Income from operations increased 27%, as the increase in operating expenses of 35% exceeded the 32% increase in gross profit. Net income increased 27%. Net income per share (diluted) increased \$0.15, or 21%. The percentage increase in earnings per share was less than that for net income, principally because the increase in the price of the Company's stock increased the dilutive effect of stock options.

### LIQUIDITY AND CAPITAL RESOURCES

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.

During 1998, working capital increased approximately \$5,824,000 to \$43,817,000 from \$37,993,000. The Company's cash and cash equivalents and investment securities, including liquid investments, increased to \$38,090,000 from \$35,112,000, due primarily to \$6,574000 of cash flows from operating activities and \$3,460,000 from exercise of stock options, partially, offset by \$6,657,000 used to acquire treasury stock.

Capital expenditures increased substantially in 1999 from the relatively low levels in 1995 through 1997. Most of the expenditures were molding machines, molds and automated assembly machines in the Company's San Clemente, California production facilities. In addition, in April 1999, the Company purchased a 28,000 square foot building near its other two buildings in San Clemente to accommodate its expansion. Production capacity in San Clemente significantly exceeds the Company's current production requirements.

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Management expects that sales of the Company's products will continue to grow in 2000. If sales continue to increase, accounts receivable and inventories are expected to increase as well. As a result of these and other factors, the Company expects the use of working capital to fund its operations to continue to increase.

In October 1999, the Company purchased 121,000 shares of its stock for treasury at a cost of \$1,650,000. The Company had not purchased treasury stock from August 1998 through September 30, 1999. 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.

#### YEAR 2000 COMPLIANCE

Many older computer programs use only the last two digits to refer to a year. Therefore, they do not properly recognize a year that begins with "20" rather than "19." This is referred to as the Year 2000, or Y2K problem. The Y2K problem has been eliminated in many new programs and systems, which are said to be "Y2K compliant." The Company has not encountered any Y2K problems, and believes that it is extremely unlikely that it will. Costs to assure Y2K compliance were nominal.

#### 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:

- o future operating results and various elements of operating results, including sales and unit volumes of products, production costs, gross margins, selling, general and administrative costs, sales and marketing costs, promotional costs, and research and development expense and income taxes;
- o factors affecting operating results, such as shipments to specific customers, product mix, selling prices, future revenue sharing payments to the Company, the market shift to needleless products, achievement of business expansion goals, manufacturing efficiencies, labor costs, investment in inventory, unit production costs, production automation, expansion of markets and distribution costs;
- o new or extended contracts with manufacturers and buying organizations 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;
- o working capital requirements, capital expenditures and common stock repurchases; and
- o Y2K issues.

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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, 1999, which is incorporated by reference.

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

- 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, 1999 and 1998, and the related consolidated statements of income, stockholders' equity and cash flows for the three years ended December 31, 1999. These consolidated financial statements and the schedule referred to below are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and schedule based on our audits.

We conducted our audits in accordance with generally accepted auditing standards. 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, 1999 and 1998, and the consolidated results of its operations and its consolidated cash flows for three years ended December 31, 1999, in conformity with generally accepted accounting principles.

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

statements and, in our opinion, fairly states in all material respects the consolidated financial data required to be set forth therein in relation to the basic consolidated financial statements taken as a whole.

/s/ Arthur Andersen LLP ARTHUR ANDERSEN LLP

Orange County, California January 28, 2000

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ICU MEDICAL, INC.

CONSOLIDATED BALANCE SHEETS

ASSETS

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	December 31,		
	1999	1998	
CURRENT ASSETS:			
Cash and cash equivalents	\$ 1,901,000	\$ 2,049,000	
Liquid investments		36,041,000	
Cash and liquid investments Accounts receivable, net of allowance for doubtful accounts	38,442,000	38,090,000	
of \$368,000 in 1999 and \$342,000 in 1998	7,129,000	6,492,000	
Inventories	2,056,000	1,990,000	
Prepaid expenses and other	402,000	385,000	
Deferred income taxes - current portion	1,345,000	991,000	
Total current assets	49,374,000	47,948,000	
PROPERTY AND EQUIPMENT, at cost:			
Land, building and building improvements	12,173,000	7,191,000	
Machinery and equipment	13,752,000	8,225,000	
Furniture and fixtures	2,524,000	2,044,000	
Molds	5,608,000	3,710,000	
Construction in process	2,866,000	1,703,000	
		22,873,000	
LessAccumulated depreciation	(12,483,000)	(9,109,000)	
	24,440,000	13,764,000	
DEFERRED INCOME TAXES	806,000	92,000	
OTHER ASSETS	744,000	556,000 	
	\$ 75,364,000 =========	\$ 62,360,000	

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

### CONSOLIDATED BALANCE SHEETS

### LIABILITIES AND STOCKHOLDERS' EQUITY

	December 31,		
	1999	1998	
CURRENT LIABILITIES: Accounts payable	\$ 965,000	6 693 000	
Accrued liabilities		3,448,000	
Total current liabilities	7,350,000	4,131,000	
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 1999 and 1998	887,000	887,000	
Additional paid-in capital	40,843,000	40,241,000	
Treasury stock, at cost 765,123 shares in 1999 and 807,847 shares in 1998	(7,153,000)	(7,117,000)	
Retained earnings		24,218,000	
Total stockholders' equity	68,014,000	58,229,000	
	\$ 75,364,000	\$ 62,360,000	

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

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ICU MEDICAL, INC.

### CONSOLIDATED STATEMENTS OF INCOME

	For the years ended December 31,				
	1999	1998	1997		
NET SALES COST OF GOODS SOLD		\$ 39,842,000 16,687,000			
Gross profit	27,131,000		17,587,000		
OPERATING EXPENSES: Selling, general and administrative Research and development	12,529,000 1,214,000	12,094,000 1,047,000	8,464,000 1,261,000		
Total operating expenses	13,743,000		9,725,000		
Income from operations	13,388,000	10,014,000	7,862,000		
INVESTMENT INCOME	1,431,000	1,408,000	1,269,000		
Income before income taxes	14,819,000	11,422,000	9,131,000		
PROVISION FOR INCOME TAXES	5,400,000	4,200,000	3,450,000		
NET INCOME	\$ 9,419,000	\$ 7,222,000 ======	\$ 5,681,000		
NET INCOME PER SHARE					
Basic Diluted	\$1.16 \$1.08	\$0.90 \$0.86	\$0.71 \$0.71		
WEIGHTED AVERAGE NUMBER OF SHARES					
Basic Diluted			7,946,328 8,028,991		

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

ICU MEDICAL, INC.

### CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Number of Shares Outstanding	Common Stock Amount	Additional Paid-In Capital	Treasury Stock	Retained Earnings	Total
BALANCE, December 31, 1996	8,300,451	887,000	39,447,000	(4,848,000)	11,264,000	46,750,000
Acquire shares for treasury Exercise of stock options and related income tax benefits,	(549,565)	-	-	(4,606,000)	-	(4,606,000)
and other Net Income	15,500	- -	8,000	134,000	(20,000) 5,681,000	122,000 5,681,000
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 related income tax benefits,	(32,100)	-	-	(401,000)	-	(401,000)
and other Net Income	325,029		786,000 -	2,604,000	71,000 7,222,000	3,461,000 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 Net Income	163,724	-	602,000	1,614,000	(200,000) 9,419,000	2,016,000 9,419,000
BALANCE, December 31, 1999	8,102,039	\$ 887,000	\$ 40,843,000	\$ (7,153,000)	\$ 33,437,000	\$ 68,014,000

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

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ICU MEDICAL, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the years ended December 31,			
	1999	1998	1997	
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net Income	\$ 9,419,000	\$ 7,222,000	\$ 5,681,000	
Adjustments to reconcile net income to net cash				
provided by operating activities				
Depreciation and amortization	3,917,000	2,364,000	2,149,000	
Deferred income taxes, non-current	(714,000)	(174,000)	(145,000)	
(Increase) decrease in:				
Accounts receivable	(637,000)	(3,126,000)	(279,000)	
Inventories	(66,000)	(228,000)	471,000	
Prepaid expenses and other assets	(17,000)	(184,000)	562,000	
Increase (decrease) in:	, , , , , , ,	, , , , , , , , , , , , , , , , , , , ,	,	
Accounts payable	282,000	(720,000)	(499,000)	
Accrued liabilities	2,937,000	1,694,000	993,000	
Deferred income taxes, current	(354,000)	(274,000)	(267,000)	
Net cash provided by operating activities	14,767,000	6,574,000	8,666,000	
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchases of property and equipment	(14,781,000)	(6,657,000)	(829,000)	
Net change in liquid investments	(500,000)	(3,891,000)	(2,450,000)	
Net cash (used in) investing activities		(10,548,000)	(3,279,000)	
CASH FLOWS FROM FINANCING ACTIVITIES: Proceeds from exercise of stock				
options and related income tax benefits, and other Purchase of treasury stock	2,016,000 (1,650,000)	3,461,000 (401,000)	122,000 (4,606,000)	
Net cash provided by (used in) financing activities	366,000	3,060,000	(4,484,000)	

NET INCREASE (DECREASE) IN CASH AND

(148,000)		(914,000)		903,000
 2,049,000		2,963,000		2,060,000
\$ 1,901,000	\$	2,049,000	\$	2,963,000
\$ 4,555,000	ş	3,727,000	\$	2,862,000
\$	2,049,000 \$ 1,901,000	\$ 1,901,000 \$ =================================	2,049,000 2,963,000 \$ 1,901,000 \$ 2,049,000 \$ 4,555,000 \$ 3,727,000	2,049,000 2,963,000 \$ 1,901,000 \$ 2,049,000 \$ \$ 4,555,000 \$ 3,727,000 \$

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

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### ICU MEDICAL, INC.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 1999, 1998 AND 1997

#### 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 proprietary 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:

		1999		1998
Raw materials	\$	962,000	\$	1,121,000
Work in process		287,000		509,000
Finished goods		807,000		360,000
	\$	2,056,000	\$	1,990,000
	===		===	

### c. Property and Equipment

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

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

The Company follows the policy of capitalizing expenditures that materially increase the life of the related assets; maintenance and repairs are 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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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, 1999 and 1998, the net book value of patents and licenses was \$448,000 and \$508,000, respectively, net of accumulated amortization of \$431,000 and \$323,000, respectively.

### e. Research and Development

The Company expenses research and development costs as incurred.

### f. Cash Equivalents

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

# g. Net Income Per Share

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 market value), less the number of shares that could have been purchased with the proceeds from the exercise of the options, using the treasury stock method.

### h. Investment Securities

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

# i. Income Taxes

The Company accounts for income taxes in accordance with SFAS No. 109, "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.

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

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

### 1. Stock Options

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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, 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:

		1997
\$ 14,800,000	\$ 14,600,000	<c. \$ 26,450,000</c. 
1,091,000	1,091,000	5,700,000 -
\$ 36,541,000	\$ 36,041,000	\$ 32,150,000
	20,650,000 1,091,000	20,650,000 20,350,000 1,091,000 1,091,000

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:

		1999		1998		1997
Corporate dividends Tax-exempt interest Other interest	\$	699,000 551,000 181,000	\$	516,000 758,000 134,000	\$	612,000 575,000 82,000
	\$	1,431,000	\$	1,408,000	\$	1,269,000
	==		==		==	

#### ACCRUED LIABILITIES

Accrued liabilities consists of the following:

		1999		1998
Accrued incentive compensation Taxes payable Other accruals	\$	1,368,000 2,299,000 2,718,000	\$	703,000 802,000 1,943,000
Total accrued liabilities	\$ ==	6,385,000 ======	 \$ ==	3,448,000

### 4. COMMON STOCK AND COMMON STOCK OPTIONS GRANTED

In 1993, the Company adopted the 1993 Stock Incentive Plan and Directors' Stock Option Plan (the "Plans"). In 1996, the 1993 Stock Incentive 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 Stock Incentive Plan expire eleven years from issuance and 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. The 1993 Directors' Stock Option Plan, under which 225,000 shares had been reserved for issuance, called for options to be granted to non-employee Directors every three years; fifty percent of each Director's options vested on the date of the first annual shareholders meeting following the grant and the other fifty percent on the date of the second such meeting. The Plans include conditions whereby options not vested are canceled if employment or directorship 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 were discontinued, reducing the number of shares reserved for issuance under that Plan to 60,000.

A summary of the Company's stock option activity is in the following table. Options canceled in 1997 were replaced with options granted at exercise prices ranging from \$8.19 to \$8.31 (weighted average \$8.24 per share).

Of the options outstanding at December 31, 1999, 2,833,368 are time-accelerated options, which were issued under the 1993 Stock Incentive Plan. Of those options, 40,700 issued in 1993 at an average exercise price of \$9.56 expire in 2004; 109,500 issued in 1994 at an average exercise price of \$11.00 expire in 2005; 15,000 issued in 1995 at an average exercise price of \$12.56 expire in 2006; 504,709 issued in 1996 at an average exercise price of \$13.58 expire in 2007; 1,016,292 issued in 1997 at an average exercise price of \$9.22 expire in 2008; 835,227 issued in 1998 at an average exercise price of \$12.40 expire in 2009 and, 311,940 issued in 1999 at an average exercise price of \$16.86 expire in 2010. The remaining 30,000 options that are not time-accelerated are at an exercise price of \$16.13 and expire in 2001. In January 2000, options granted from 1998 to January 1999 to purchase 96,940 shares of common stock at prices ranging from \$12.25 to \$18.31 (weighted average \$15.94 per share) became vested.

Dilutive stock options account for the difference in the number of shares used to calculate basic and diluted net income per share. Options which are anti-dilutive because their exercise price exceeded the average market price of the Company's common stock approximated 90,000, 360,000, and 870,000 in 1999, 1998 and 1997, respectively. At December 31, 1999, 2,133,428 options had exercise prices less than the market price of the Company's common stock.

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

	Shares		xercise P Range		eighted Average
Outstanding at December 31, 1996	1,739,150	\$5.7	5 -	\$ 23.00	\$13.82
Granted	1,371,002	7.5	0 -	12.94	8.97
Canceled	830,000	9.1	9 -	23.00	14.39
Exercised	11,500	5.7		7.33	7.05
Forfeited	121,200	8.1			 9.54
Outstanding at December 31, 1997	2,147,452	7.1	9 -	16.25	10.29
Granted	910,229	12.0	6 -	16.38	12.16
Exercised	321,029	7.6	9 –	14.00	8.24
Forfeited		7.3	8 -	 15.13	 12.51
Outstanding at December 31, 1998	2,719,152	7.1	9 -	16.38	11.15
Granted	330,000	12.7	5 -	21.44	16.90
Exercised	158,724	7.1	9 –	14.28	8.65
Forfeited	27,060	13.0	0 -	 21.31	 16.14
Outstanding at December 31, 1999	2,863,368	\$ 7.1		21.44	\$ 11.91
Exercisable at December 31:					
1997		\$ 9.5	0 -	\$ 16.13	\$ 14.88
1998	430,621	8.0	0 -	16.13	9.08
1999	1,357,656	7.6	3 -	16.13	10.84
Available for grant at December 31, 1999	1,464,379				

The Company applies APB Opinion No. 25 and related interpretations in accounting for stock options granted to employees, 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. Directors' stock options are treated in the same manner as employee stock options for accounting purposes.

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 1999, 1998 and 1997 was estimated as of the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions in the respective years: risk-free interest rate of 5.4, 5.7 and 5.9percent, respectively; expected option life of 4.1, 4.7 and 4.3 years, respectively; expected volatility of 58, 52 and 54 percent, respectively; and, no dividends. The Black-Scholes option valuation model was developed for use in estimating fair value of fully transferable traded options with no vesting restrictions, and, similar to other option valuation models, requires use of highly subjective assumptions, including expected stock price volatility. The characteristics of the Company's stock options differ substantially from those of traded stock options, and changes in the subjective assumptions can materially affect estimated fair values; therefore, in Management's opinion, existing option valuation models do not necessarily provide a reliable single measure of the fair value of the Company's stock options.

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For purposes of the following required pro forma information, the weighted average fair value of stock options granted in 1999, 1998 and 1997 was \$8.36, \$6.05 and \$3.33, respectively. The total estimated fair value is amortized to expense over the vesting period.

1999	1998	1997

Net Income		\$ 7,005,000	\$ 3,328,000 \$	3,682,000	
Net Income per share	- basic	\$0.89	\$0.44	\$0.52	
	- diluted	\$0.83	\$0.42	\$0.51	
Weighted average numb	er of				
common shares	- basic	7,891,000	7,558,000	7,120,000	
	- diluted	8,426,000	7,991,000	7,209,000	

#### 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.

#### INCOME TAXES

The provision for income taxes for the years ended December 31, 1999, 1998 and 1997, is as follows:

	1999	1998	1997
Current:			
Federal	\$ 5,093,000	\$ 3,694,000	\$ 2,826,000
State	1,375,000	954,000	1,036,000
	6,468,000	4,648,000	3,862,000
Deferred:			
Federal	(852,000)	(379,000)	(311,000)
State	(216,000)	(69,000)	(101,000)
50400			
	(1,068,000)	(448,000)	(412,000)
	\$ 5,400,000	\$ 4,200,000	\$ 3,450,000
	=========	==========	

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Current income taxes payable were reduced from the amounts in the above table by \$751,000, \$843,000 and \$8,000 in 1999, 1998 and 1997, 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:

	1999	1999 1998			1997	
	Amount	Percent	Amount	Percent	Amount	Percent
Federal tax at the expected statutory rate State income tax, net of	\$ 5,038,000	34.0%	\$ 3,884,000	34.0%	\$ 3,105,000	34.0%
federal benefit	794,000	5.3	754,000	6.6	661,000	7.2
Tax-exempt interest and						
dividends	(353,000)	(2.4)	(380,000)	(3.3)	(316,000)	(3.4)
Tax credits	(79,000)	(0.5)	(58,000)	(0.5)	-	-
Provision	\$ 5,400,000	36.4%	\$ 4,200,000	36.8%	\$ 3,450,000	37.8%
						======

The components of the Company's deferred income tax provision for the years ended December 31, 1999, 1998 and 1997 are as follows:

		1999		1998		1997
Allowance for doubtful accounts Inventory reserves Accruals State income taxes Depreciation	\$	(11,000) - (317,000) (26,000) (714,000)	\$	(6,000) 30,000 (367,000) 69,000 (174,000)	\$	(13,000) (105,000) (45,000) (104,000) (145,000)
	\$ (2	1,068,000)	\$ ==	(448,000)	\$ ==	(412,000)

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

1999	1998
\$ 157 <b>,</b> 000	\$ 146,000
270,000	270,000
799,000	482,000
119,000	93,000
\$1,345,000	\$ 991,000
========	
\$ 806,000	\$ 92,000
========	========
	\$ 157,000 270,000 799,000 119,000 

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### 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 \$32,059,000 of consolidated net sales in 1999, \$27,508,000 in 1998 and \$19,539,000 in 1997. Custom I.V. systems, many of which incorporate the CLAVE connector, accounted for \$5,251,000 of consolidated net sales in 1999, \$3,218,000 in 1998 and \$1,828,000 in 1997. 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, 1999, 1998 and 1997, the Company had sales of 10 percent or greater to two manufacturers as follows:

	1999	1998	1997
		0.50	
Manufacturer A	28%	35%	36%
Manufacturer B	42	29	16

#### 8. COMMITMENTS AND CONTINGENCIES

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

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 intends to vigorously defend itself. The Company has also brought a patent infringement action against that Company and intends to vigorously pursue this matter.

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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
1999				
Net Sales Gross Profit Net Income Net Income Per Share: Basic Diluted	· ·		5,876 1,946 \$ 0.24	7,944 3,069 \$ 0.38
1998 Net Sales Gross Profit Net Income Net Income Per Share: Basic	· ·	\$ 10,430 6,062 1,719 \$ 0.21	5,598 1,823	\$ 9,812 5,680 2,020 \$ 0.25
Diluted	\$ 0.20	\$ 0.20	\$ 0.22	\$ 0.24

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, 1999, 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, 1999, 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:

1. Financial Statements	
The financial statements listed below are set forth in Item 8 of this Annual Report.	
Report of Independent Public Accountants	
2. Financial Statement Schedules	
The Financial Statement Schedules required to be filed as a part of this Report are:	
Schedule II - Valuation and Qualifying Accounts	39

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

EXHIBIT

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

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)
- 21.1 Subsidiaries of Registrant.
- 23.1 Consent of Arthur Andersen LLP.
- 27.1 Financial Data Schedule.
- (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 Quarterly Report on Form 8-K dated June 18, 1999, and incorporated herein by reference.
- (9) Filed as an exhibit to Registrant's Quarterly 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.
  - (b) Reports on Form 8-K.

Registrant filed the following Report on Form 8-K during the last quarter of the period covered by this Report:

Item 5 - November 5, 1999

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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.

By: /s/ George A. Lopez, M.D.
George A. Lopez, M.D.

Chairman of the Board

Dated: March 9, 2000

### 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		
	<del></del>			
/s/ George A. Lopez, M.D.	Chairman of the Board, President,	March 9, 2000		
George A. Lopez, M.D.	and Chief Executive Officer, (Principal Executive Officer)			
/s/ Francis J. O'Brien	Chief Financial Officer	March 9, 2000		
Francis J. O'Brien	and Principal Accounting Officer			
/s/ Jack W. Brown	Director	March 9, 2000		
Jack W. Brown				
/s/ John J. Connors	Director	March 9, 2000		
John J. Connors				
/s/ Michael T. Kovalchik, III, M.D.	Director	March 9, 2000		
Michael T. Kovalchik, III, M.D.				
/s/ Richard H. Sherman, M.D.	Director	March 9, 2000		
Richard H. Sherman, M.D.				
/s/ Robert S. Swinney, M.D.	Director	March 9, 2000		
Robert S. Swinney, M.D.				

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SCHEDULE II

ICU MEDICAL, INC.

VALUATION AND QUALIFYING ACCOUNTS

		Additions			
Description	Balance at Beginning of Period	Charged to Costs and Expenses	Charged to Other Accounts	Write-offs/ Disposals	Balance at End of Period
For the year ended December 31, 1997:					
Allowance for					
doubtful account	\$ 293,000	\$ 35,000	\$ -	\$ 4,000	\$ 324,000
Inventory reserves	\$ 274,000	\$ 244,000	\$ - 	\$ 18,000	\$ 500,000
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 <b>,</b> 000	\$ 368,000

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### EXHIBIT INDEX

\$ 466,000

Inventory reserves

Exhibit Number	Description	Sequentially Numbered Page
21.1	Subsidiaries of Registrant	41
23.1	Consent of Arthur Andersen LLP	42
27.1	Financial Data Schedule	43

\$ 466,000

# SUBSIDIARIES OF REGISTRANT

Budget Medical Products, Inc.

ICU MedEurope Limited

NAME

SetFinder, Inc.

BMP de Mexico, S.A. de C.V.

STATE OF INCORPORATION

California

United Kingdom

Delaware

Mexico

# CONSENT OF INDEPENDENT PUBLIC ACCOUNTANTS

As independent public accountants, we hereby consent to the incorporation of our report dated January 28, 2000 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, 1999 or performed any audit procedures subsequent to the date of our report.

/s/ Arthur Andersen LLP ARTHUR ANDERSEN LLP

Orange County, California January 28, 2000

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