
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, 1997 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): (714) 366-2183

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

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

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

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

The aggregate market value of the voting stock held by non-affiliates of Registrant as of February 28, 1998 was \$95,562,306. *

The number of shares outstanding of Registrant's Common Stock, \$.10 par value, as of February 28, 1998 was 7,908,386.

Portions of the Proxy Statement for Registrant's 1998 Annual Meeting of Stockholders, filed or to be filed pursuant to Regulation 14A within 120 days following Registrant's fiscal year ended December 31, 1997, are incorporated by reference into Part III of this Report.

PART I

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

Products, Inc. ("BMP") (collectively, the "Company") is a leader in the development, manufacture and sale of proprietary, disposable medical connection systems for use in intravenous ("IV") therapy applications. The Company's IV connectors are designed to prevent accidental disconnection's of IV lines and to protect healthcare workers and their patients from the spread of infectious diseases such as Hepatitis B 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 IV 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 IV 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 IV connectors. In addition, healthcare regulations promulgated by OSHA mandate that "universal precautions" be observed to minimize exposure to blood and other body fluids.

BACKGROUND

The Company's first products, the Click Lock and Piggy Lock, 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 IV connectors with exposed needles that are secured by tape or open luer lock connections. Such conventional products typically do not provide the protection from needlesticks, accidental disconnection and contamination that are provided by the Company's products. Although protected needle products manufactured by the Company and by others significantly reduce the risk of needlesticks, they nevertheless employ steel needles, which require special disposal procedures.

Recognizing the inherent risks associated with needle handling and disposal, even with protected needle systems, the Company developed the CLAVE, a needleless IV connection system that was introduced in 1993. The CLAVE IV connection system allows protected, secure and sterile IV connections without needles and without failure prone mechanical valves used in the IV 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 will not only decrease needlesticks but will also reduce 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.

IV USAGE AND INFECTION CONTROL

Primary IV 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 IV 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 IV 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 IV system connections are made by inserting an exposed steel needle attached to the primary IV line into an injection port connected to the catheter. Conventional secondary IV connections, so called piggyback connections, are made by inserting an exposed steel needle attached to a secondary IV line into an injection port or other IV connector. In a conventional IV 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 IV solution to the patient. The exposed needles can easily be contaminated by contact with unsterile objects or through contact with fluid in the IV 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 ${\tt IV}$ connectors.

Hepatitis B 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 provider is required to perform a series of tests on the healthcare worker for both Hepatitis B 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 IV connectors are designed to prevent accidental needlesticks from needles originating from primary and secondary IV connections.

PRODUCTS

CLAVE Products

A conventional IV line terminates with a male luer connector to which a needle would be attached to penetrate a latex-covered injection port to make a primary or secondary IV 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 IV line, through the CLAVE into the primary IV 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 IV 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 IV system, acute and chronic central venous IV system, acute care catheter, multi-lumen catheter, peripheral catheter and a variety of other standard devices. The resilience of the silicone compression seal permits repeated connections and disconnections without replacing the CLAVE.

The CLAVE Integrated Y site is designed to be integrated directly into primary and secondary IV sets, thus eliminating the need for special adapters, pre-slit injection ports, or metal needles when making piggyback IV connections. Currently, virtually all popular IV 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 IV 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 IV set manufacturers, such as B.Braun/McGaw division of B.Braun Medical, Inc. ("B.Braun/McGaw") and Abbott Laboratories ("Abbott") to build directly into their IV sets. Sales of the CLAVE Integrated Y site to date have only been to Abbott and accounted for approximately 4% of the Company's net sales in 1997.

The CLAVE is the Company's largest selling product line, and accounted for 65% of the Company's net sales in 1997.

The Company's first products, the Click Lock and Piggy Lock, were designed to overcome the limitations of conventional IV 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 cylindrical housing also acts as a guide to direct the needle accurately into the matching port, thus allowing an easy, quick connection while preventing the needle point from scratching the insides of the injection port on insertion and scraping off particles of plastic which could enter the patient's vascular system. The clear plastic housing and the audible click permit visual and aural confirmation that the connection has been made.

The Click Lock housing locks onto the Company's matching injection port located on either piggyback IV sets or extension IV sets manufactured by the Company. Matching injection ports are also sold separately for use on other manufacturers' extension sets and catheters. Using the appropriate IV set or separate matching injection port, the Click Lock can be used with any conventional primary IV system, acute or chronic central venous IV system, acute care catheter, multi-lumen catheter, implantable medication port, peripheral catheter and a variety of other standard devices. The Piggy Lock was developed as a less expensive, more convenient alternative to using a Click Lock and related IV set combination to make a secondary or piggyback IV connection. The Piggy Lock does not however replace Click Lock components used in non-piggyback or conventional catheter connections.

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 McGaw, Inc., predecessor to B.Braun/McGaw ("McGaw"), (the "McGaw 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/McGaw. The McGaw Protected Needle is similar to the Click Lock, and competes with the Company's IV connection systems. The McGaw MPN Agreement provides that the Company release McGaw from any claims for patent infringement resulting from the sale of McGaw Protected Needles prior to the effective date of the McGaw MPN Agreement, and for as long as the McGaw MPN Agreement is in effect. The Company began assembly of the McGaw Protected Needle during 1994. Sales of the McGaw Protected Needle under the McGaw MPN Agreement accounted for approximately 8%, and 5% of the Company's net sales in 1996 and 1997, respectively. 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 the another agreement with McGaw, McGaw also agreed to pay the Company a share of McGaw's revenues on SafeLine, a then-new needleless IV connector designed and manufactured by McGaw for use with pre-slit injection ports. Such payments commenced in 1996 and accounted for approximately 3% of the Company's net sales in 1996 and 6% in 1997.

Lopez Valve

The Company's Lopez Valve is a small "T" valve designed to be connected into nasogastric tube systems. The valve permits intermittent injection of medications or fluids through nasal passages without having to disconnect the nasogastric tube. By eliminating the need to disconnect the nasogastric tube, the Lopez Valve helps prevent the splashing of and risk of contact with potentially infectious stomach fluids and also saves valuable time.

RF100 and RF150

The Company has developed a family of inexpensive single-use needleless connectors for use in both piggyback and non-piggyback applications. The RF100, designed for use in piggyback applications, is a one-piece, needleless IV 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

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 could compete with the CLAVE as less expensive needleless IV connectors.

Budget Medical Products, Inc.

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 IV sets manufactured by the Company which incorporate lower priced safe medical connectors, and custom IV sets incorporating the CLAVE. During 1996 and 1997, BMP's net sales were approximately \$400,000 and \$1,800,000, respectively. Most of the increase in 1997 net sales was because of increased unit shipments of custom IV sets incorporating the CLAVE.

The Company is currently taking steps aimed at expanding BMP by increasing systems capabilities, improving manufacturing efficiency, reducing labor costs and enhancing distribution. As part of these steps, the Company is evaluating transferring its manufacturing to a low-labor-cost area outside of the United States, as well as a significant broadening of its market. There can be no assurance that these steps will achieve the desired results.

CLC 2000

The Company commenced marketing the CLC 2000 in November 1997 upon receipt of the Section 510(k) clearance from the Food and Drug Administration. The CLC 2000 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 CLC 2000 does not permit the use of needles, thereby ensuring compliance with current needle-free policies. The CLC 2000 also contains no natural rubber latex.

Generally, when an IV line is disconnected, there is a back-flow of blood into the catheter that is in the patient. That blood in time occludes ("clots"). Occlusion ("clotting off") of catheters requires expensive procedures to "flush" the catheter, or if those procedures are not effective, replacement of the catheter. The CLC 2000 was developed to eliminate clotting of catheters because of "back-flow" after the catheter is disconnected by expelling a portion of the fluid remaining in the catheter on disconnection out through the tip of the catheter while maintaining a constant positive pressure to prevent any back-flow into the catheter.

The Company is currently conducting trials with the objective of receiving FDA approval of its claim that the CLC 2000 does prevent the occlusion of catheters, and while the Company believes it can achieve such approval, there is no assurance that it will ultimately receive it, and pending receipt of such approval, makes no claim as to the actual ability of the CLC 2000 to prevent occlusion of catheters.

New Products

The Company is developing several of new products that it intends to introduce in 1998. 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 hospital and homecare providers.

The Company has entered into strategic supply and distribution

relationships with B.Braun/McGaw ("the McGaw Agreement") and Abbott, two major IV product suppliers, each of whom has a significant share of the IV set market under contract. The McGaw Agreement, which extends to July 2000, confers exclusive and nonexclusive

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rights to distribute certain CLAVE products to certain categories of customers. See Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations for the current status of the McGaw Agreement. Under the Abbott Agreement which extends to April 2002, Abbott also has rights to market certain CLAVE products together with its own products. The Abbott Agreement adopted fixed prices as of January 1, 1998 for sales by the Company to Abbott, which prices are expected to decrease in the future based on sales volumes.

B.Braun/McGaw and Abbott purchase CLAVE products packaged separately and in bulk for distribution in the hospital market and to certain homecare providers. CLAVE products purchased in bulk are assembled into B.Braun/McGaw and Abbott's primary and secondary IV sets. Both B.Braun/McGaw and Abbott purchase other CLAVE products, which are sold as accessories.

The Company currently has approximately 19 independent distributors in the United States who employ approximately 150 salespeople in the aggregate. In addition, the Company employs 31 product specialists who support the Company's distributors' salespeople, calling on prospective customers, demonstrating products and supporting programs to train distributors' and customers' staffs in the use of the Company's products. Distributors purchase and stock the Company's products for resale to hospitals and home healthcare providers.

Sales to B.Braun/McGaw of McGaw Protected Needles and CLAVE products accounted for approximately 30%, 28% and 36% of the Company's net sales in 1995, 1996 and 1997, respectively. Sales to Abbott accounted for approximately 7% and 16% of net sales in 1996 and 1997, respectively. Several independent distributors accounted for more between 5% and 10% of 1997 net sales. All other customers 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. The loss of B.Braun/McGaw or Abbott as a customer would be more significant because these customers have full-line contracts with numerous hospitals and homecare providers to supply all IV products and solutions to those customers.

The Company's products are distributed in several European countries, Canada, the Middle East, Australia, Japan and other parts of Asia. During 1995, 1996, and 1997, foreign sales accounted for approximately 2%, 3% and 3%, respectively, of the Company's net sales. During the second quarter of 1996, the Company entered into a distribution agreement with BOC OHMEDA AB ("Ohmeda"), a major distributor of medical products, for distribution of CLAVE in Europe. Since then, a number of other distribution agreements have been established in Europe, and the Company has placed two product specialists in Italy. The Company has distribution throughout most of Europe, and expects to add a number of additional product specialists in 1998. In January 1998, Ohmeda announced an agreement to sell its European distribution operations to a competitor of the Company; the Company is currently evaluating the impact of that. There is no assurance that the sale will be completed and there is no assurance as to the impact of that sale on future distribution through Ohmeda or whether it will have an adverse effect on the Company's ability to increase sales in Europe.

MANUFACTURING

Manufacturing of the Company's products involves injection molding of plastic 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 22 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,

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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 IV sets are assembled manually.

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 now 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.

The Company's products are currently sterilized in processes, which use either gamma radiation or ethylene oxide gas ("ETO"). Most of the Company's sterilization is by gamma radiation. Sterilization is performed by independent companies who have extensive equipment and procedures to prevent the release of ETO and radiation into the environment. Use of ETO in California is subject to hazardous material labeling requirements. The Company believes that it can continue to have its products sterilized by firms in California. The Company is also investigating other methods of sterilization that would be more cost effective and less time-consuming, and has commenced qualification of certain products for sterilization by electronic beam radiation ("e-beam"). E-beam sterilization is less expensive and quicker than either of the other two methods currently used by the Company.

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. As described under Item 1, Business, Products, CLC 2000, certain product performance claims for the CLC 2000 require FDA approval. That approval may be required pursuant to the PMA procedure. 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

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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.

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(08/94)/EN 46001 (10/93). Those quality standards are similar to the GMP regulations but incorporate the quality requirements for product design and development.

Manufacturers of medical devices must also be in conformance with EC Directives such as Council Directive 93/42/EEC ("Medical Device Directive") and their applicable annexes. Those are regulations that assure that medical devices are both safe and effective and meet all applicable established standards prior to being marketed in the EC. Once a manufacturer and its devices are in conformance with the Medical Device Directive, the "CE" Mark may be affixed to its devices. The CE Mark gives devices an unobstructed entry to all the member countries of the EC.

The Company has demonstrated conformity to the regulations of both EN ISO 9001~(08/94)/EN~46001~(10/93) 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 be in conformance or that additional regulations restricting the sale of its present or proposed products will not be promulgated by the EC.

COMPETITION

The market for IV 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 of the CLAVE through higher volume production.

In addition to competing with conventional IV connection systems and protected needle locking IV connection systems marketed by companies such as Baxter Healthcare Corporation ("Baxter") and Abbott, the Company's present and future products will compete with needleless IV connection systems like those marketed by Baxter, B. Braun Medical, Inc., IVAC 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

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B.Braun/McGaw are leading distributors of IV 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 IV product requirements. In order to penetrate more of these hospitals, the Company has established strategic supply and distribution relationships with B.Braun/McGaw and Abbott.

The Company believes the success of 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 these products were developed primarily by companies who currently do not have the distribution or financial capabilities of the Company. The Company believes these products have had a modest impact on its CLAVE business to date, and 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.

PATENTS

The Company has United States and certain foreign patents on the CLAVE, Click Lock and Piggy Lock IV 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 CLC 2000, CLAVE, Click Lock and Piggy Lock IV connectors. The expiration dates of the Company's patents range from 2005 to 2015.

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 1995, the Company initiated legal proceedings against Tri-State Hospital Supply Corporation alleging patent infringement; the cost of the litigation has been significant. See: Item 3, Legal Proceedings; Item 7, Management's Discussion and Analysis of Financial Conduction and Results of Operations; and Item 8, Financial Statements.

EMPLOYEES

At February 28, 1998, the Company had 130 full-time employees, consisting of 58 engaged in sales, marketing and administration, and 72 in manufacturing, molding, product development and quality control. The Company contracts an independent temporary agency to provide its production personnel; none of the personnel provided through the agency are employed by the Company. At February 28, 1998, the number of temporary production personnel was approximately 192.

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ITEM 2. PROPERTIES.

The Company owns two adjacent 39,000 square foot buildings in San Clemente, California. The Company is currently in the process of acquiring facilities for BMP. The Company is currently evaluating the adequacy of its existing facilities but does not believe that significant additions will be required in the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS.

In an action entitled ICU Medical, Inc. v. Tri-State Hospital Supply

Corporation, pending in the United States District Court for the Northern

District of California, the Company alleges infringement of two of the Company's patents by defendant's protected needle connector and Y-style extension sets. The Company is seeking a permanent injunction, and monetary damages in an amount to be determined. On February 28, 1997, the Court ruled on a number of motions filed by the parties. It denied a number of motions for summary judgment brought by the defendant, including the motion for partial summary judgment of non-infringement of one of the patents, and issued rulings on matters of enforceability that were generally favorable to the Company. On February 20, 1998, a hearing was held on additional motions filed by the parties including a motion contesting the validity of the patents. A ruling is expected shortly. Trial date is presently set for June 1, 1998.

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.

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 --- ------

Executive Officer

Richard A. Costello	34	Vice President of Sales
Evelyn L. Foss	42	Vice President of Marketing
Francis J. O'Brien	55	Chief Financial Officer, Secretary and Treasurer
KEY EMPLOYEE:		
Robert J. Brown	40	President, Budget Medical Products, Inc.

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Dr. Lopez is the founder of the Company and has served as Chairman of the Board, President and Chief Executive Officer since August 1989. He also served as Secretary, Treasurer and Chief Financial Officer from January 1994 to October 1994.

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.

Mr. Brown became President of Budget Medical Products, Inc. in 1997, after having been a product specialist since 1992.

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 National Market tier of The Nasdaq Stock Market 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:

High	Low
\$9 31/64 8 7/8 11 1/4 14 1/2	\$ 8 1/4 7 1/4 7 3/4 10 1/2
\$ 17 5/8 23 1/2 13 5/8	\$ 14 13 8 1/4 6 5/8
	\$9 31/64 8 7/8 11 1/4 14 1/2 \$ 17 5/8 23 1/2

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

As of February 28, 1998 the Company had 160 stockholders of record and

ITEM 6. SELECTED FINANCIAL DATA

ICU MEDICAL, INC.

SELECTED FINANCIAL DATA

Year ended December 31, _____ (in thousands, except per share data) 1997 1996 1995 1994 1993 INCOME DATA: 10,438 10,276 8,818 4,407 -----Cost of goods sold..... 12,817 -----17,587 14,161 11,006 7,724 6,974 9.725 8,236 5,600 3,877 2,784 Gross profit..... 5,600 8,236 Operating expenses..... ----------_____ 7,862 5,925 5,406 3,847 4,190 1,269 1,289 713 516 (12) 3,450 2,475 1,958 1,456 1,146 Income from operations..... Investment income and other..... (12) 1,146 Provision for income taxes..... -----Income from continuing operations...... \$ 5,681 \$ 4,739 \$ 4,161 \$ 2,907 \$ 3,032 ====== ---------------_____ Income from continuing operations..... Per Share \$0.54 \$0.53 Basic \$0.71 \$0.41 \$0.44 0.54 0.52 Diluted 0.71 0.40 0.42 ===== ====== ===== Weighted average number of shares Basic 7,946 8,722 7,906 7,048 6,945 8,029 8,842 8,040 7,296 7,244 Diluted ===== CASH FLOW DATA: Cash flows from operations....... \$ 8,666 \$ 6,513 \$ 6,997 \$ 938 \$ 3,263 BALANCE SHEET DATA: 12,712

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

OVERVIEW

The Company's principal product is its CLAVE needleless IV connection system. The following table sets forth, for the periods indicated, net sales by product as a percentage of total net sales:

CLAVE	000	000	01.9
Click Lock	7%	12%	20%
McGaw Protected Needle	5%	8%	13%
Lopez Valve	4%	4%	4%
RF100-RF150 ("Rhino")	7%	3%	2%
Budget Medical Products	6%	2%	-
McGaw SafeLine Revenue			
Sharing	6%	3%	-
Total	100%	100%	100%

The Company sells its products to independent distributors and through strategic supply and distribution agreements with B.Braun/McGaw, Inc. ("B.Braun/McGaw" in 1997 and "McGaw" in prior periods) and Abbott Laboratories ("Abbott") (the "McGaw Agreement" and the "Abbott Agreement," respectively). Most independent distributors handle the full line of the Company's products. B.Braun/McGaw and Abbott both purchase CLAVE products, principally bulk, nonsterile connectors; B.Braun/McGaw also purchases the McGaw Protected Needle and Abbott also purchases the Rhino, a low-priced connector specifically designed for Abbott. Through 1997, both agreements established minimum transfer prices and a revenue sharing formula under which the Company could receive more than the minimum transfer prices based on selling prices of products incorporating the Company's products. The McGaw Agreement provided for revenue sharing based on McGaw's selling prices of CLAVE products and the Abbott Agreement provided for revenue sharing based on Abbott's selling prices of both CLAVE products and Rhinos. Effective August 1, 1997, and January 1, 1998, respectively, the Abbott Agreement was amended to establish fixed selling prices for Rhinos and CLAVE products and eliminate revenue sharing for all sales after the respective effective dates. The Company expects to establish fixed selling prices and eliminate revenue sharing under the McGaw Agreement effective January 1, 1998.

On June 25, 1997, B.Braun Melsungen AG ("B.Braun") acquired McGaw from IVAX Corporation. B.Braun's U.S. operation markets an IV connection system that competes with IV connection systems of the Company and others. The current McGaw Agreement extends to July 2000. The Company and B.Braun have signed a letter of intent to modify the McGaw Agreement to extend it to 2002 and modify product pricing. Average monthly sales to B.Braun/McGaw since June 1997 have decreased somewhat from the levels in the first half of 1997, although they are still significantly above those for comparable periods of the prior year. There is no assurance as to future patterns of sales with B.Braun/McGaw, and, while the Company expects to conclude a definitive agreement with B.Braun/McGaw, there is no assurance that it will. If it does not, the current agreement will remain in effect.

The Company 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 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 felt in the third quarter of

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1996, the Company in mid-October 1996 announced to its independent distributors a new aggressive pricing strategy to protect and expand its market. Under this strategy, prices to independent distributors will eventually be reduced by up to approximately 40%, depending on the type of customer to which the distributor is reselling the CLAVE product. The average price reduction through the fourth quarter of 1997 has been less than the maximum 40%, although 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.

In 1997, the Company reported net sales of \$30,404,000, which was \$5,805,000, or 24%, higher than the net sales of \$24,599,000 reported in 1996. The most significant factor in the increase was a \$2,816,000, or 17%, increase in CLAVE net sales, including revenue sharing from B.Braun/McGaw on sales of CLAVE products. Net sales in all of the Company's other product lines increased over 1997, except for a 23% decrease in Click Lock, Piggy Lock and McGaw Protected Needle net sales. The Company's independent distributors accounted for 48% of the Company's net sales in 1997, with McGaw accounting for 36% and Abbott the remaining 16%. In 1996, the comparable percentages were 65%, 28% and 7%, respectively.

Total CLAVE net sales increased approximately 17% from \$16,723,000 in 1996 to \$19,539,000 in 1997. Unit shipments of CLAVE products in 1997 increased approximately 61% over 1996, with McGaw 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 1997 decreased approximately 27% as compared with 1996. That decrease reflects lower prices from independent distributors and lower prices on bulk, non-sterile CLAVE products sold to McGaw and Abbott, as well as a higher percentage of the sales mix being accounted by bulk, non-sterile CLAVEs.

Net sales to B.Braun/McGaw, including revenue sharing, amounted to \$10,971,000 in 1997, as compared to \$6,875,000 in 1996. CLAVE net sales to B.Braun/McGaw increased approximately 89%, principally because of an increase in unit shipments. Net sales of the McGaw Protected Needle declined 23% and management expects those to continue to decline as the market for safe connectors continues its shift to needleless technology. Based on B.Braun/McGaw's forecasts, Management expects increases in unit shipments to B.Braun/McGaw in 1998, although there is no assurance that this expectation will be realized. Under the McGaw Agreement, the Company receives revenue sharing payments on B.Braun/McGaw's sales of its SafeLine products; such payments commenced in 1996, and the Company recorded estimated revenue sharing of approximately \$1,767,000 in 1997, as compared with \$834,000 in 1996. Although Management anticipates that such revenue sharing will continue, the actual amount will depend on the volume and selling prices of B.Braun/McGaw's SafeLine products, which Management has no means of forecasting accurately.

Net sales to Abbott amounted to \$4,993,000 in 1997, as compared to \$1,755,000 in 1996. CLAVE sales were \$2,906,000, an increase of 151% from the \$1,156,000 in 1996. The balance of the sales were in the low-priced Rhino, which were \$2,087,000 as compared with \$599,000 in 1996. Management expects an increase in sales volume with Abbott in 1998, although there is no assurance that such increases will be realized.

Management expects that unit sales of CLAVE to its independent distributors in 1998 will be approximately the same as in 1997 or slightly lower. Although Management had expected that the price reduction commenced in October 1996 would eventually be more that offset by increased volume, this has not occurred to date for independent distributors in the aggregate. There is no assurance that independent distributors will achieve increased unit volume 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/McGaw. 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 1997 as compared to 1996, because of the safe connector market's continued shift to needleless technology, and Management expects that decline to continue.

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The Lopez Valve showed a 9% growth in 1997 net sales as compared to 1996 because of increased unit shipments. Management expects continued modest increases in Lopez Valve net sales in 1998.

The Company's Budget Medical Products subsidiary ("BMP"), which markets custom IV sets, recorded approximately \$1,828,000 net sales in 1997 as compared to \$400,000 in 1996, its first year of operations. Most of the increase in 1997 net sales was because of increased unit shipments of custom IV sets incorporating the CLAVE. BMP's production is relatively labor-intensive,

resulting in a generally lower gross profit margin than for the Company's other products. BMP had a small gross profit in 1997. The Company is currently taking steps aimed at expanding BMP by increasing systems capabilities, improving manufacturing efficiency, reducing labor cost and enhancing distribution. As part of these steps, the Company is evaluating transferring its manufacturing to a low-labor-cost area outside of the United States, as well as a significant broadening of its market. There can be no assurance that these steps will achieve the desired results. However, even if they are successful, Management expects that gross profit margins in BMP will be lower than those historically recorded by the Company because production of its products is relatively labor intensive.

During the second quarter of 1996, the Company entered into a distribution agreement with BOC OHMEDA AB ("Ohmeda"), a major distributor of medical products, for distribution of CLAVE in Europe. Since then, a number of other distribution agreements have been established in Europe, and the Company has located two product specialists in Italy. The Company has distribution throughout most of Europe, and expects to add a number of additional product specialists in 1998. Total sales to foreign distributors were \$908,000 in 1997 as compared to \$693,000 in 1996. Management expects that its sales to foreign distributors will continue to increase in the future. In January 1998, Ohmeda announced an agreement to sell its European distribution operations to a competitor of the Company; the Company is currently evaluating the impact of that. There is no assurance that the sale will be completed and there is no assurance as to the impact of that sale on future distribution through Ohmeda or whether it will have an adverse effect on the Company's ability to increase sales in Europe.

Gross margin for 1997 was unchanged from the 58% registered in 1996. 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 McGaw SafeLine revenue sharing first recorded in 1996 more than offset the effect of lower average unit selling prices.

The Company expects that its unit production costs will continue to decrease in 1998 as unit volumes increase, but that the gross margin percentage will stay at or slightly lower than that achieved in 1997 as average unit sales prices decrease.

Selling, general and administrative costs ("SG&A") increased by approximately \$1,017,000 to \$8,463,000 in 1997, as compared to \$7,446,000 in 1996. As a percentage of sales, SG&A costs were 28% in 1997 and 30% in 1996. 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 and expansion of the international sales efforts. An increase in corporate expenses also contributed to the increase in SG&A. Partially offsetting those increases was a decrease in the costs of patent litigation in which the Company is the plaintiff from \$1,615,000 in 1996 to \$512,000 in 1997. Management also expects SG&A costs, exclusive of the patent litigation costs, to increase in 1998, both in absolute terms and also slightly as a percentage of sales, because of growth in the Company, increased domestic and international sales and marketing costs, promotional costs of new products expected to be introduced 1998 and expansion of BMP. Management expects the patent litigation costs to increase somewhat from the level experienced in 1997, but the amount and timing of the costs will depend on the progress of the litigation, and no assurances can be given in this regard.

Research and development ("R&D") costs increased in 1997 by approximately \$471,000 to \$1,261,000, or 4% of net sales, as compared with approximately \$790,000, or 3% of sales, in 1996. The increase related to efforts to complete development on a number of new products. Management estimates that R&D costs in 1998 will continue at a higher level than in 1997 because of continuing efforts to complete new products and because of clinical evaluations of the new CLC 2000, including trials necessary for FDA clearance of certain performance claims for the CLC 2000. However, no assurance can be given that such costs will not differ from those estimates or that the R&D will be completed as expected.

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The operating margin increased to 26% in 1997, compared with 24% in 1996, principally because SG&A decreased as a percentage of net sales.

Investment income was essentially unchanged from 1996 to 1997.

The Company's effective income tax rate in 1997 was 37% as compared with 34% in 1996, principally because tax-exempt investment income decreased as a percentage of total taxable income. Management expects its effective tax rate in 1998 to be equal to or slightly higher than the 1997 rate.

Income from operations increased 33%, as the increase in operating expenses of 18% trailed the 24% increase in net sales and gross profit. On a percentage basis, that increase in income from operations was partially offset by the essentially unchanged income from investments and a higher effective tax rate, resulting in a 20% overall increase in net income. Net income per share increased \$0.17, or 32% due to the increase in net income, and the reduction in shares outstanding because of the purchase of shares for treasury. The acquisition of treasury stock after considering the investment income that would have been earned if the shares had not been purchased, increased earnings per share by approximately \$0.04 for the year 1997.

Comparison of 1996 to 1995

In 1996, the Company reported net sales of \$24,599,000, which was \$3,317,000, or 16%, higher than the net sales of \$21,282,000 reported in 1995. The increase was primarily attributable to a \$3,648,000, or 28%, increase in CLAVE sales, including revenue sharing from McGaw on sales of CLAVE products, and \$829,000 of revenue sharing on McGaw's sales of its SafeLine products, which payments were initiated 1996. Also contributing to the increase were sales by the Company's Budget Medical Products subsidiary formed in late 1995, sales of the low-priced Rhino and a modest increase in Lopez Valve sales. Those increases were partially offset by a 32% decrease in Click Lock and Piggy Lock sales and a 25% decrease in McGaw Protected Needle sales. The Company's independent distributors accounted for 65% of the Company's net sales in 1996, with McGaw accounting for 28% and Abbott the remaining 7%. In 1995, the comparable percentages were 68%, 30% and 2%, respectively.

Total CLAVE net sales increased approximately 28% from \$13,075,000 in 1995 to \$16,723,000 in 1996. Unit shipments of CLAVE products in 1996 increased approximately 43% over 1995, with independent distributors, McGaw and Abbott accounting for approximately 47%, 8% and 45%, respectively, of this unit growth. The aggregate average net selling price of CLAVE products in 1996 decreased approximately 10% as compared with 1995. That decrease reflects equally lower prices from independent distributors and lower prices on bulk, non-sterile CLAVE products sold to McGaw and Abbott.

Net sales to McGaw, including revenue sharing, amounted to \$6,875,000 in 1996, as compared to \$6,301,000 in 1995. CLAVE sales to McGaw increased approximately 14%, principally because of an increase in unit shipments. Net sales of the McGaw Protected Needle declined 25%.

Net sales to Abbott amounted to \$1,755,000 in 1996, as compared to \$406,000 in 1995. CLAVE sales were \$1,156,000, as compared with none in 1995, with the balance of the sales in the low-priced Rhino.

Net sales of Click Lock and Piggy Lock decreased 32% in 1996 as compared to 1995. The Lopez Valve and Swiss System showed a 23% growth in 1996 revenue as compared to 1995 because of increased unit shipments.

Gross margin for 1996 improved to 58% from the 52% registered in 1995. 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 McGaw SafeLine revenue sharing first recorded in 1996 more than offset the effect of lower average unit selling prices.

Selling, general and administrative costs ("SG&A") increased by approximately \$2,009,000 to \$7,446,000 in 1996, as compared to \$5,437,000 in 1995. As a percentage of sales, SG&A costs were 30% in 1996 and 26% in 1995. The increase was primarily due to the continuing costs of patent litigation in which the Company is the plaintiff; such costs were \$1,615,000 in 1996 and \$168,000 in 1995 (see Item 3, "Legal Proceedings"). Other SG&A expenses

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increased at a somewhat lower rate than the increases in sales except for those related to BMP, which were not incurred in 1995.

Research and development ("R&D") costs increased in 1996 by approximately \$626,000 to \$790,000, or 3% of net sales, as compared with approximately

\$164,000, or less than 1% of sales, in 1995. The increase accelerated during the year as the Company increased efforts to complete development on a number of new products.

The operating margin decreased slightly in 1996 compared with 1995, from 25% to 24%. The effects of the improved gross profit was more than offset by the patent litigation costs and higher R&D costs.

Investment income increased in 1996 to \$1,289,000 from \$713,000 in 1995 because of increased funds invested. Funds increased because of the net proceeds of approximately \$16,000,000 from the Company's July 1995 public offering of Common Stock and cash provided by operations.

The Company's effective income tax rate in 1996 was 34% as compared with 32% in 1995. A state manufacturing tax credit, recorded in the fourth quarter of both years, was lower in 1996 than in 1995, and that effect was partially offset by a higher portion of income being tax-exempt investment income in 1996.

Net income increased 14% because of higher sales and gross profit margins offset by higher rates of SG&A and R&D in relation to sales. Net income per share increased 8% due to the increase in net income, offset by the effect of additional shares issued in the public offering in July 1995.

LIQUIDITY AND CAPITAL RESOURCES

During 1997, working capital increased approximately \$2,406,000 to \$37,993,000 from \$35,587,000. The Company's cash and cash equivalents and investment securities, including liquid investments, increased to \$35,112,000 from \$31,759,000. Those increases were due primarily to \$8,666,000 of cash flows from operating activities offset by \$4,606,000 used to acquire treasury stock.

During 1996, working capital increased approximately \$1,825,000 to \$35,587,000 from \$33,762,000. The Company's cash and cash equivalents and investment securities, including liquid investments, increased to \$31,759,000 from \$30,172,000. Those increases were due primarily to \$6,513,000 of cash flows from operating activities and \$1,460,000 from stock options exercised (principally tax benefits), offset by \$5,108,000 used to acquire treasury stock.

Capital expenditures were reduced significantly in 1997, 1996 and 1995 as compared with the \$9,414,000 in 1994 when the Company purchased its San Clemente facilities and much of its automated production equipment. Management expects to increase capital expenditures significantly in 1998 to meet increased sales volumes and to automate production of new products, and to incur capital expenditures to acquire and build a facility for BMP in a low-labor-cost area outside the United States.

Management expects that sales of the Company's products will continue to grow in 1998. If sales continue to increase, accounts receivable and inventories are expected to increase as well. As a result of these and other factors, the Company expects the use of working capital to fund its operations to continue to increase.

The Company has not purchased treasury stock since August 1997, but 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 for the foreseeable future.

FORWARD LOOKING STATEMENTS

In this Management's Discussion and Analysis and elsewhere in this Report, Management has made numerous statements about perceived trends and its expectations and beliefs about various matters, which reflect the best information currently available to Management and assumptions which Management believes to be reasonable. They include without limitation statements about: demand for safe medical devices; sales and unit volumes of product generally and of

B.Braun/McGaw; contracts with buying organizations; concentration of revenues among a small number of customers; the development by others of competing products; decline in average selling prices and the possibility of increased unit volumes offsetting such decline; decreases in sales of McGaw Protected Needle, Click Lock and Piggy Lock; SafeLine revenue sharing; sales and unit volumes of sales to independent distributors; the effect of competition and competitive products on sales by independent distributors; pricing pressure from end users; Lopez Valve sales; BMP systems capabilities, manufacturing efficiency, labor costs, distribution, transfer of manufacturing, broadening of market, costs of increasing systems capabilities and future gross profit margins; European product specialists; foreign sales; status of agreements with Ohmeda; unit production costs, production volumes and their effect on gross margin; SG&A costs; sales, marketing and promotional costs; new product introduction; regulatory approval of clearance of new products and new product claims; patent litigation costs, R&D costs and completion of new products; clinical evaluation costs; effective tax rate; capital expenditures; repurchases of the Company's common stock; and, working capital requirements. These statements and similar statements are forward looking statements that involve a number of risks and uncertainties, including the possible failure of the factors described in such statements to materialize, the materialization of other factors and the caveats which accompany the statements. The Company further cautions that, in addition to the factors described in such statements, actual future results of operations are subject to other important factors, including among others the following: general economic and business conditions; the effect of price and safety considerations on the healthcare industry, such as product innovation, new technologies, marketing and distribution strength and price erosion; unanticipated market shifts and trends; the impact of legislation effecting government reimbursement of healthcare costs; any changes in corporate strategies and practices of B.Braun/McGaw, Abbott and the Company's independent distributors that might effect the resources and efforts that they devote to marketing the Company's products; the possible impact of the acquisition of the Company's customers; production problems; changes in product mix; changes in marketing strategy; the availability of patent protection and the cost of enforcing of defending patent claims; and other risks described from time to time in the Company's registration statements and reports filed with the Securities and Exchange Commission, including those described under "Risk Factors" in the Company's Current Report on Form 8-K dated November 14, 1996. Results of operations actually achieved in the future may thus differ materially from Management's current expectations. 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, 1997 and 1996, and the related consolidated statements of income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 1997. 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, 1997 and 1996, and the consolidated results of its operations and its consolidated cash flows for each of the three years in the period ended December 31, 1997, 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 30, 1998

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ICU MEDICAL, INC. ______

CONSOLIDATED BALANCE SHEETS

ASSETS _____

	December 31,		
	1997	1996	
CURRENT ASSETS:			
Cash and cash equivalents	\$ 2,962,276	\$ 2,059,663	
Liquid investments	32,150,000	29,700,000	
Cash and liquid investments Accounts receivable, net of	35,112,276		
allowance for doubtful accounts			
of \$323,620 in 1997 and \$293,032 in 1996		3,043,149	
Inventories	1,762,628	2,233,619	
Prepaid expenses and other	200,964	763,146	
Deferred income taxes	717,000	450,000	
Total current assets	41,149,804	38,249,577	
PROPERTY AND EQUIPMENT, at cost:			
Machinery and equipment	7,078,157	6,761,568	
Furniture and fixtures	1,521,580	1,319,920	
Molds	2,873,321	2,679,014	
Construction in process	183,029	417,327	
Land, building and building improvements	5,001,297	4,993,228	
	16,657,384	16,171,057	
LessAccumulated depreciation		(5,242,487)	
	9,596,953	10,928,570	

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

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ICU MEDICAL, INC.

CONSOLIDATED BALANCE SHEETS

LIABILITIES AND STOCKHOLDERS' EQUITY

December 31, 1997 CURRENT LIABILITIES: Accounts payable Accrued liabilities Total current liabilities 82,000 DEFERRED INCOME TAXES 227,000 COMMITMENTS AND CONTINGENCIES STOCKHOLDERS' EQUITY: Convertible preferred stock, \$1.00 par value Authorized--500,000 shares; Issued and outstanding--none Common stock, \$0.10 par value-Authorized--20,000,000 shares; Issued -- 8,867,162 shares in 1997 and 1996 886,716 886,716 Additional paid-in capital 39,447,125 (4,848,465) 39, 455, 511 (9, 320, 352) Treasury stock -- 1,100,776 shares in 1997 and 566,711 shares in 1996 Retained earnings 16,924,995 11,263,528 Total stockholders' equity 47,946,870 46,748,904 \$51,186,097 \$49,638,637

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

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ICU MEDICAL, INC.

CONSOLIDATED STATEMENTS OF INCOME

1997 1996 1995 \$24,599,005 10.438,066 NET SALES \$21,281,995 \$30,404,128 COST OF GOODS SOLD 12,817,048 17,587,080 14,160,939 11,006,381 Gross profit OPERATING EXPENSES:
Selling, general and administrative
Research and development 7,445,694 5,436,628 8,463,480 1,261,274 Income from operations 7,862,326 5,924,892 5,405,909 712,651 INVESTMENT INCOME 1,269,236 1,289,298 Income before income taxes 9,131,562 7,214,190 6,118,560 PROVISION FOR INCOME TAXES 3,450,000 2,475,000 1,958,000 NET INCOME \$ 5,681,562 \$ 4,739,190 \$ 4,160,560 NET INCOME PER SHARE Diluted \$0.71 \$0.54 \$0.52 WEIGHTED AVERAGE NUMBER OF SHARES 8.722.081 7,946,328 7,906,604 Basic Diluted 8,028,991 8,841,562 8,040,139

Years ended December 31,

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

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ICU MEDICAL, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	of Shares Outstanding	Stock Amount	Capital	Treasury Stock		Total
BALANCE, December 31, 1994	7,065,737	\$706,574	\$21,338,190	\$ -	\$ 2,614,732	\$24,659,496
Issuance of common stock Exercise of stock options and	1,460,000	146,000	15,861,697	-	-	16,007,697
related income tax benefits	137,100	13,710	816,578	-	-	830,288
Net Income	-	-	-		4,160,560	4,160,560
BALANCE, December 31, 1995	8,662,837				6,775,292	45,658,041
Acquire shares for treasury	(596,711)	-	-	(5,108,168)	-	(5,108,168)
Exercise of stock options and related income tax benefits Net Income	-	20,432	-	259,703	(250,954) 4,739,190	
BALANCE, December 31, 1996					11,263,528	
Acquire shares for treasury	(549,565)	-	-	(4,606,068)	-	(4,606,068)
Exercise of stock options and related income tax						
benefits, and other	15,500		8,386	134,181	(20,095)	
Net Income	-	-	-		5,681,562	5,681,562
BALANCE, December 31, 1997	7 766 206	6000 716	C20 455 511	0 (0 220 252)	\$16,924,995	\$47.946.870
DALANCE, December 31, 1997	=======	,	========			\$47,946,870 =======

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

ICU MEDICAL, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years ended December 31,			
	1997	1996	1995	
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net Income	\$ 5,681,562	\$ 4,739,190	\$ 4,160,560	
Adjustments to reconcile net income to net cash				
Provided by operating activities				
Depreciation and amortization	2,148,826	1,969,310	1,798,700	
Deferred income taxes, non-current	(145,000)	21,000	288,300	
(Increase) decrease in:				
Accounts receivable	(280,540)	(289,821)	(578,972)	
Inventories	470,991	(729,797)	1,366,342	
Prepaid expenses and other assets	562,182	125,279	(568,426)	
Increase (decrease) in:				
Accounts payable	(498,905)	853,805	290,878	
Accrued liabilities	993,399	(177,404)	134,920	
Deferred income taxes, current	(267,000)	1,000	105,000	
Net cash provided by operating activities	8,665,515	6,512,562	6,997,302	
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchases of property and equipment	(829,306)	(1,276,766)	(1,739,877)	
Proceeds from sales of investment securities	-	507,580	4,000,000	
Net change in liquid investments	(2,450,000)	(2,049,156)	(24,775,844)	
Net cash (used in) investing activities	(3,279,306)	(2,818,342)	(22,515,721)	
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from exercise of stock				
options and related income tax benefits, and other	122.472	1,459,841	830.288	
Proceeds from sale of common stock	122,472	1,455,641	16,007,697	
Purchase of treasury stock	(4,606,068)	(5,108,168)	10,007,037	
ratchase of creasury scock				
Net cash provided by (used in) financing activities	(4,483,596)	(3,648,327)	16,837,985	
NEW INCREASE IN CASH AND				
NET INCREASE IN CASH AND	002 612	45 002	1 210 500	
CASH EQUIVALENTS	902,613	45,893	1,319,566	
CASH AND CASH EQUIVALENTS, beginning of year	2,059,663	2,013,770	694,204	
CASH AND CASH EQUIVALENTS, end of year	\$ 2,962,276	\$ 2,059,663	\$ 2,013,770	
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			========	
Cash paid during the period for income taxes	\$ 2.861.991	\$ 1,406,620	\$ 1,304,677	
cash para during the period for income taxes	Q 2,001,991	\$ 1,400,020	7 1,304,677	

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

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ICU MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 1997, 1996 AND 1995

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

a. General

ICU Medical, Inc. (the Company - a Delaware Corporation) operates 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. A wholly owned subsidiary, Budget Medical Products, Inc., formed

late in 1995 is 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:

	1997 	1996
Raw materials Work in process Finished goods	\$1,060,325 459,618 242,685	\$1,179,126 457,885 596,608
	\$1,762,628	\$2,233,619
	========	========

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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d. Patents and Licenses

Patents and licenses, which are shown in other assets in the accompanying consolidated balance sheets, are stated at cost and are amortized using the straight-line method over 10 years which is the estimated useful life of the patent or license. At December 31, 1997 and 1996, the net book value of patents and licenses was \$383,228 and \$371,131, respectively, net of accumulated amortization of \$243,139 and \$166,214, 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

In February 1997, the Financial Accounting Standards Board issued SFAS No. 128, "Earnings 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.

2.6

1. Stock Options

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

m. Accounting Estimates

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

n. Reclassifications

Certain reclassifications have been made to the 1996 financial statements in order to conform with the 1997 presentation.

2. 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	1996
Corporate preferred stocks Federal tax-exempt debt securities	\$26,450,000 5,700,000	\$17,500,000 12,200,000
	\$32,150,000	\$29,700,000
	=========	========

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

	1997	1996	1995
Corporate dividends	\$ 612,066	\$ 71 , 176	\$ 58,465
Tax-exempt interest	574,603	1,072,711	524,431
Other interest	82,567	145,411	129,755
	\$1,269,236	\$1,289,298	\$712,651
	========	========	=======

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3. ACCRUED LIABILITIES

Accrued liabilities consists of the following:

	1997	1996
Accrued incentive compensation	\$ 577,129	\$210,849
Accrued vacation	117,375	152,407
Taxes payable	737,840	229,776
Other accruals	321,571	167,484
Total accrued liabilities	\$1,753,915	\$760,516
	=======	=======

4. COMMON STOCK AND COMMON STOCK OPTIONS GRANTED

In July 1995, the Company completed a public offering of 1,460,000 new common shares, raising proceeds of \$16,007,697, net of expenses of approximately \$505,000.

In 1993, the Company adopted the 1993 Stock Incentive Plan and Directors' Stock Option Plan (the Plans). In 1996, the Plans were amended to increase from 1,500,000 to 3,500,000 the number of shares reserved for issuance to employees and directors. 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 called for options to be granted to non-employee Directors every three years; fifty percent of each Director's options vest 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 a condition 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. The Directors' Stock Option Plan was terminated, reducing the number of shares reserved for issuance to 3,335,000.

A summary of the Company's stock option activity is in the following table. Options canceled in 1996 were replaced with options granted at exercise prices ranging from \$7.69 to \$8.19 per share (weighted average \$7.76 per share), and 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, 1997, 2,102,452 are time-accelerated options, which were issued under the 1993 Stock Incentive Plan. Of those options, 46,150 issued in 1993 at an average exercise price of \$9.56 expire in 2004; 141,000 issued in 1994 at an average exercise price of \$10.56 expire in 2005; 25,000 issued in 1995 at an average exercise price of \$11.50 expire in 2006; 617,824 issued in 1996 at an average exercise price of \$12.48 expire in 2007; and, 1,272,478 issued in 1997 at an average exercise price of \$9.02 expire in 2008. Of the remaining 45,000 options that are not time-accelerated, 15,000 at an exercise price of \$14.00 expire in 1998 and 30,000 at an exercise price of \$16.13 expire in 2001. In January 1998, 750,000 options with an exercise price of \$12.25 were issued. Also in January 1998, options granted from 1993 to 1996 to purchase 155,150 shares of common stock at prices ranging from \$8.00 to \$13.62 (weighted average \$9.26 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 870,000, 940,000 and 25,000 in 1997, 1996 and 1995, respectively. At December 31, 1997, 450,000 options had exercise prices in excess of the market price of the Company's common stock.

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

	Shares	Exercise Price Range				Weighted Average
Outstanding at December 31, 1994	1,295,775	\$ 0.29	-	\$16.25	\$10.49	
Granted	36,000	11.44	-	16.63	13.74	
Exercised	137,100	0.29	-	6.96	0.37	
Forfeited	19,450	9.50	-	15.13	11.12	
Outstanding at December 31, 1995	1,175,225	0.29	-	16.63	11.76	
Granted	958,300	7.19	_	23.00	13.73	
Canceled	105,000	15.35	-	16.25	16.13	
Exercised	234,325	0.29	-	14.63	2.00	
Forfeited	55,050	9.50	-	18.81	14.01	
Outstanding at December 31, 1996	1,739,150	5.75	-	23.00	13.82	
Granted	1,371,002	7.50	_	12.94	8.97	
Canceled	830,000	9.19	-	23.00	14.39	
Exercised	11,500	5.75	-	7.33	7.05	
Forfeited	121,200	8.19	-	15.63	9.54	
Outstanding at December 31, 1997	2,147,452	\$ 7.19	-	\$16.25	\$10.29	
	=======			=====	=====	
Exercisable at December 31:						
1995	255,825	\$ 0.29	-	\$14.00	\$ 2.75	
1996	26,500	5.75	-	14.00	10.98	
1997	31,000	9.50	-	16.13	14.88	
Available for grant at December 31, 1997	1,167,548					
	=======					

The Company applies APB Opinion No. 25 and related interpretations in accounting for stock options, 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 1997, 1996 and 1995 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 5.9, 6.4 and 6.0 percent, respectively; expected option life of 4.3, 3.4 and 2.5 years, respectively; expected volatility of 54, 49 and 44 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 1997, 1996 and 1995 was \$3.33, \$5.84 and \$4.50, respectively. The total estimated fair value is amortized to expense over the vesting period.

	1997	1996	1995
Proforma:			
Net Income	\$3,682,000	\$3,968,000	\$4,147,000
Net Income per share - basic	\$ 0.52	\$ 0.48	\$ 0.53
- diluted	\$ 0.51	\$ 0.47	\$ 0.52
Weighted average number of			
commmon shares - basic	7,120,000	8,260,000	7,891,000
- diluted	7,209,000	8,379,000	8,025,000

5. INCOME TAXES

The provision for income taxes for the years ended December 31, 1997, 1996 and 1995, is as follows:

	1997	1996	1995
Current:			
Federal	\$2,826,000	\$1,992,000	\$1,110,700
State	1,036,000	461,000	454,000
	3,862,000	2,453,000	1,564,700
Deferred:			
Federal	(311,000)	(3,000)	279,300
State	(101,000)	25,000	114,000
	(412,000)	22,000	393,300
	\$3,450,000	\$2,475,000	\$1,958,000
	=======	=======	========

The current tax provision includes the tax expense that results from allocating to stockholders' equity the tax benefit that the Company receives upon exercise of stock options by employees and directors. Because of that benefit, current income taxes payable were reduced from the amounts in the above table by \$8,000, \$1,032,000, and \$780,000 in 1997, 1996 and 1995, respectively.

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

	1997		1996		19	95
	Amount	Percent	Amount	Percent	Amount	Percent
Federal tax at the expected statutory rate State income tax Tax-exempt interest and	\$3,105,000 661,000	34.0% 7.2	\$2,453,000 443,000	34.0% 6.1	\$2,080,000 373,000	34.0% 6.1
dividends Tax credits	(316,000)	(3.4)	(382,000) (39,000)	(5.3) (0.5)	(145,000) (350,000)	(2.4) (5.7)
Provision	\$3,450,000 =====	37.8%	\$2,475,000 =====	34.3%	\$1,958,000 ======	32.0%

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The components of the Company's deferred income tax provision for the years ended December 31, 1997, 1996 and 1995 are as follows:

	1997	1996	1995
Allowance for doubtful accounts	\$ (13,000)	\$ (25,000)	\$ (24,000)
Inventory reserves	(105,000)	(23,000)	37,800
Accruals	(45,000)	122,000	159,500
State income taxes	(104,000)	(73,000)	115,000
Depreciation	(145,000)	21,000	105,000
	\$(412,000)	\$ 22,000	\$393,300
	=======	=======	=======

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

	1997	1996
Current deferred tax benefit:		
Allowance for doubtful accounts	\$140,000	\$ 127,000
		•
Inventory reserves	300,000	195,000
Accruals	115,000	70,000
State income taxes	162,000	58,000
	\$717 , 000	\$ 450,000
	========	
Long-term deferred tax liability:		
Depreciation	\$(82,000)	\$(227,000)
	========	========

6. MAJOR CUSTOMERS AND CONCENTRATIONS OF CREDIT RISKS

The Company manufactures disposable medical devices which are sold on credit terms principally throughout the United States to wholesale medical supply distributors, and in selected cases to hospitals and homecare providers. The distributors, in turn, sell the Company's products to hospitals and homecare providers. The Company has also entered into a sales and supply agreement with two medical supply manufacturers. For the years ended December 31, 1997, 1996 and 1995, the Company had sales of 10 percent or greater to two distributors and the two manufacturers as follows:

	1997	1996	1995
Distributor A	*	*	12
Distributor B	*	13	12
Manufacturer A	36	28	30

Manufacturer B 16 * *

* less than 10 percent

7. EMPLOYMENT CONTRACTS

The Company has employment contracts with certain key employees which include an incentive compensation agreement. Under contracts that expired on December 20, 1996, a cash bonus pool was provided equal to 10 percent of aftertax profits through 1995. Fifty percent of each period's incentive compensation was payable on December 20 of

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that period and the remaining 50 percent was paid on December 20 of the subsequent period. Incentive compensation expense for the years ended December 31, 1995 and 1994, was approximately \$465,000 and \$324,000, respectively. Under new contracts effective January 1, 1997, incentive compensation expense based on meeting certain operating performance goals was \$274,000.

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.

9. RELATED PARTY TRANSACTION

In 1996, the Company purchased 167,850 shares of its common stock from the Company's President for \$1,458,197, equal to its fair market value on the date of purchase.

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

		Quart	er Ended	
	March 31	June 30	Sept. 30	Dec. 31
1997				
Net Sales	\$6,824	\$7,190	\$7,700	\$8,690
Gross Profit	3,911	4,133	4,394	5,149
Net Income	1,338	1,253	1,445	1,645
Net Income Per Share	\$ 0.16	\$ 0.16	\$ 0.18	\$ 0.21
1996				
Net Sales	\$6,008	\$6,147	\$5,972	\$6,472
Gross Profit	3,704	3,472	3,200	3,785
Net Income	1,591	1,267	964	917
Net Income Per Share	\$ 0.18	\$ 0.14	\$ 0.11	\$ 0.11

Basic and diluted net income per share was the same in all periods.

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

None.

PART III

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, 1997, 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."

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ITEMS 11 THROUGH 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, 1997, and such information is incorporated herein by this reference.

PART IV

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

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

1. Financial Statements

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

	FORM 10-K
	PAGE NO.
Report of Independent Public Accountants	1 9
Consolidated Balance Sheets at December 31, 1997 and 1996	20-21
1996 and 1995	22
Consolidated Statements of Stockholders' Equity for the	
Years Ended December 31, 1997, 1996 and 1995	23
Consolidated Statements of Cash Flows for the Years Ended December 31, 1997,	
1996 and 1995	24
Notes to Consolidated Financial Statements	25-32

2. Financial Statement Schedules

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

	FORM 10-K PAGE NO.	
Schedule II - Valuation and Qualifying Accounts	37	

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

3. Exhibits

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

EXHIBIT NUMBER 	DESCRIPTION				
3.1	Registrant's Certificate of Incorporation, as amended.(1)				
3.2	Registrant's Bylaws, as amended.(1)				
10.1	Form of Indemnity Agreement with Executive Officers.(1)				
10.2	Form of Stock Option Agreement.(1)				
10.3	Registrant's Amended and Restated 1993 Incentive Stock Plan.				
10.4	Registrant's Directors' Stock Option Plan.(2)				
10.5	Manufacture and Supply Agreement dated September 13, 1993 between Registrant and McGaw, Inc. relating to the CLAVE product.(3)				
10.6	Manufacture and Supply Agreement dated September 13, 1993 between Registrant and McGaw, Inc. relating to the Protected Needle product.(3)				
10.7	Supply and Distribution Agreement dated April 3, 1995 between Registrant and Abbott Laboratories, Inc. relating to the CLAVE product.(4)				
10.8	Second Amendment to Manufacture and Supply Agreement dated May 31, 1995 between Registrant and McGaw, Inc.(5)				
10.9	Distribution Agreement dated June 1, 1996 between Registrant and BOC OHMEDA AB.(6)				
10.10	Registrant's Director's Stock Award Plan.(7)				
10.11	Amendment to Abbott and ICU Medical Agreement, dated September 9, 1998 between Registrant and Abbott Laboratories (8)				
21.1	Subsidiaries of Registrant.				
23.1	Consent of Arthur Andersen LLP.				
27.1	Financial Data Schedule.				
(1) Filed a	(1) Filed as an exhibit to Registrant's Registration Statement Form S-1				

- (1) Filed as an exhibit to Registrant's Registration Statement Form S-1 (Registration No. 33-45734) filed on February 14, 1992, and incorporated herein by reference.
- (2) Filed as an exhibit to Registrant's definitive Proxy Statement filed pursuant to Regulation 14A on March 22, 1993 and incorporated herein by reference.
- (3) Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended September 30, 1993, and incorporated herein by reference.
- (4) Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended March 31, 1995, and incorporated herein by reference.

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- (5) Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended June 30, 1995, and incorporated herein by reference.
- (6) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the year ended December 31, 1996 and incorporated herein by reference.
- (7) Filed as exhibit and Registrant's definitive Proxy Statement filed pursuant to Regulation 14A on April 11, 1997 and incorporated herein by reference.

- (8) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended September 30, 1998 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:

None

SIGNATURES

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

ICU MEDICAL, INC.

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

George A. Lopez, M.D.
Chairman of the Board

Dated: March 10, 1998

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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
	Chairman of the Board, President, and Chief Executive Officer, (Principal Executive Officer)	March 10, 1998
/s/ Francis J. O'Brien Francis J. O'Brien	Chief Financial Officer and Principal Accounting Officer	
/s/ Jack W. Brown Jack W. Brown	Director	March 10, 1998
/s/ John J. Connors John J. Connors	Director	March 10, 1998
/s/ Michael T. Kovalchik, III Michael T. Kovalchik, III	Director -	March 10, 1998
/s/ Richard H. Sherman	Director	March 10, 1998

ICU MEDICAL, INC.

VALUATION AND QUALIFYING ACCOUNTS _____

Additions

	Balance at	Charged to			Balance
	Beginning	Costs and	Charged to	Write-offs/	at End
Description	of Period	Expenses	Other Accounts	Disposals	of Period
For the year ended December 31, 1995:					
Allowance for					
doubtful accounts	\$195,048	\$ 82,000	ş –	\$ 22,061	\$254,987
			======		=======
Inventory reserves	\$320,411	\$254,700	\$83,901	\$357,574	\$301,438
-	======		=====	======	======
For the year ended December 31, 1996:					
Allowance for					
doubtful accounts	\$254.987	\$ 40,000	s -	\$ 1,955	\$293.032
			======		
Inventory reserves	\$301.438	\$ 50,000	s -	\$ 77.371	\$274.067
	======	======	=====	=====	
For the year ended					
December 31, 1997:					
Allowance for					
doubtful accounts	\$293,032	\$ 35,000	\$ -	\$ 4,412	\$323,620
	======	======	=====	======	=======
Inventory reserves	\$274,067	\$243,951	\$ -	\$ 18,403	\$499,615

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EXHIBIT INDEX

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

EXHIBIT 21.1

SUBSIDIARIES OF REGISTRANT

NAME STATE OF INCORPORATION

Budget Medical Products, Inc. California

CONSENT OF INDEPENDENT PUBLIC ACCOUNTANTS

As independent public accountants, we hereby consent to the incorporation of our report dated January 30, 1998 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, 1997 or performed any audit procedures subsequent to the date of our report.

/s/ Arthur Andersen LLP ARTHUR ANDERSEN LLP

Orange County, California January 30, 1998

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