

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

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 1998 or

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

For the transition period from to

Commission File No. 0-19974

ICU MEDICAL, INC.

(Exact name of Registrant as specified in its charter)	
Delaware	33-0022692
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
951 Calle Amanecer	
San Clemente, California	92673
(Address of principal executive offices)	(Zip Code)

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

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

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

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

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

The aggregate market value of the voting stock held by non-affiliates of Registrant as of February 28, 1999 was \$145,320,294.*

The number of shares outstanding of Registrant's Common Stock, \$.10 par value, as of February 28, 1999 was 8,184,993.

Portions of the Proxy Statement for Registrant's 1999 Annual Meeting of Stockholders, filed or to be filed pursuant to Regulation 14A within 120 days following Registrant's fiscal year ended December 31, 1998, are incorporated by reference into Part III of this Report.

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

Item 1. Business.

ICU Medical, Inc., together with its wholly-owned subsidiary Budget Medical 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. In September 1998, the State of California enacted the bloodborne pathogen standard under the state's occupational safety and health statute. The standard mandates use of needlestick prevention controls, including needleless systems. Final regulations are due August 1, 1999.

The Company currently sells its products through IV product manufacturers and independent distributors.

Background

The Company's first products, the Click Lock(R) and Piggy Lock(R), feature protected needles to prevent accidental contact with needles and include locking mechanisms to prevent accidental disconnections. These products were designed to replace conventional products and methods, such as 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 needleless 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 not only decreases needlesticks but also reduces the number of needles to be disposed of and certain safety risks inherent in needle handling and disposal. While the Company continues to manufacture and sell protected needle products, sales of those products are declining as the market penetration of needleless systems such as the CLAVE and other competitive needleless products increases.

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 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 employer 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 or non-latex rubber 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 11% of the Company's net sales in 1998.

The CLAVE is the Company's largest selling product line, and accounted for 69% of the Company's net sales in 1998.

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Click Lock and Piggy Lock Products

The Company's first products, the Click Lock and Piggy Lock, were designed to overcome the limitations of conventional 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 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. 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.

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. ("McGaw"), predecessor to B.Braun Medical, Inc. doing business as B.Braun/McGaw ("B.Braun/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%, 5% and 4% of the Company's net sales in 1996, 1997 and 1998, 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 another agreement with B.Braun/McGaw, B.Braun/McGaw also agreed to pay the Company a share of B.Braun/McGaw's revenues on SafeLine, a then-new needleless IV connector designed and manufactured by B.Braun/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, 6% in 1997 and 5% in 1998.

Lopez Valve (R)

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

RF100 and RF150

The Company has developed a family of inexpensive single-use needleless connectors for use in both piggyback and non-piggyback applications. The RF100, designed for use in piggyback applications, is a one-piece, needleless 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, called the "Rhino," was developed specifically for Abbott for use with pre-slit injection ports in piggyback and non-piggyback applications. Once the injection port is pierced, the protective housing opens much like a clothes pin, and locks over the pre-slit injection port thus reducing the potential for accidental disconnections. Although the Company

believes that the CLAVE has significant functional advantages over the RF100 and RF150, these products are alternative and less expensive needleless IV connectors.

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CLC 2000(TM)

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 needle-free policies of some hospitals and homecare providers. The CLC 2000 also contains no natural rubber latex.

The CLC 2000 is used on the IV line in the same manner as the CLAVE. 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. Flushing often requires use of expensive drugs and carries the risk of infection from bacteria in the occluded blood. Because of this risk of infection, the United States Food and Drug Administration has recently suggested use of procedures other than drugs to prevent occlusion of catheters.

The CLC 2000 was developed to reduce clotting of catheters because of "back-flow" after the catheter is disconnected. The CLC 2000 consists of a "T" shaped cylindrical housing, which contains a poppet that is depressed as the luer tip enters the CLC 2000. Fluid flows around the poppet and through the housing into the primary IV line and into the catheter. When the luer is removed from the CLC 2000, a portion of the fluid remaining in the housing is expelled out through the tip of the catheter while a constant positive pressure is maintained to prevent any back-flow into the catheter.

The Company is currently conducting trials with the objective of receiving FDA approval for certain performance claims for the CLC 2000. While the Company believes it can achieve such approval, there is no assurance that it will ultimately receive it.

The Company began marketing the CLC 2000 in November 1997. The Company is concentrating the marketing of the CLC 2000 where its "no back-flow" features are of maximum benefit in patient care. These are generally therapies which use small diameter, long-dwelling catheters such as oncology, dialysis and long-term infusion of medication. Sales to date have not been significant.

1o2 Valve(TM)

The 1o2 is the first one-way or two-way drug delivery system. It functions as a single unit, or in multiple "ganged" units as a manifold, for use throughout a hospital. It provides the safety features of an automatic one-way valve, yet allows aspiration, or two-way function by simply pushing a button. The 1o2 Valve can be used in place of products such as stopcocks and check valve manifolds. The Company commenced marketing the 1o2 in November 1998. The Company expects to commence shipments of the 1o2 Valve in the spring of 1999. Initially, the Company intends to focus marketing efforts on anesthesia and critical care usage.

Budget Medical Products, Inc.

During late 1995, the Company created Budget Medical Products, Inc. ("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, 1997 and 1998, BMP's net sales were approximately \$400,000, \$1,800,000 and \$3,200,000, respectively. Most of the increase in 1997 and 1998 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 one of those steps, in December 1998, BMP commenced assembly at its new 20,000 square foot facility in Ensenada, Baja California, Mexico, and intends to transfer most of its manual assembly to the new facility by mid-1999.

Set finder(TM)

The Company is currently taking steps to build expertise and capabilities for direct distribution of commodity-type, standard IV sets directly to healthcare providers at competitive prices. Distribution will be through Set finder, Inc., a wholly-owned subsidiary of the Company, in a way that will minimize working capital requirements. Set finder products will be assembled at BMP's facility in Mexico. The Company is planning to launch the Set finder business later in 1999. (Independent distributors will continue to distribute custom/proprietary IV sets manufactured by the Company.)

New Products

The Company is developing several new products that it intends to introduce in 2000 and later. The Company believes innovative products continue to be important to maintaining and increasing its sales levels.

Marketing and Distribution

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

The Company has entered into strategic supply and distribution relationships with B.Braun/McGaw and Abbott, two major IV product suppliers, each of whom has a significant share of the IV set market under contract. The Agreement with B.Braun/McGaw, which extends to December 2002, confers exclusive and nonexclusive rights to distribute certain CLAVE products to certain categories of customers. Under the Agreement with Abbott, which extends to December 2009, Abbott has rights to distribute certain CLAVE products and the Rhino.

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's 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 15 independent distributors in the United States who employ approximately 100 salespeople in the aggregate. In addition, the Company employs 36 product specialists in the United States 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 CLAVE products and McGaw Protected Needles and SafeLine revenue share accounted for approximately 28%, 36% and 35% of the Company's net sales in 1996, 1997 and 1998, respectively. Sales to Abbott accounted for approximately 7%, 16% and 29% of net sales in 1996, 1997 and 1998, respectively. Several independent distributors accounted for between 5% and 10% of 1998 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 could have a more significant adverse effect on the Company's business and operating results 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. Foreign sales

(excluding Canada) accounted for approximately 3% of the Company's net sales in each of the years 1996, 1997, and 1998. The Company has six product specialists in Europe and three in Canada.

Manufacturing

Manufacturing of the Company's products involves injection molding of plastic and silicone parts, manual and automated assembly of the molded plastic parts, needles and other components, quality control inspection, packaging and sterilization. The Company molds the majority of its requirements for components, performs all assembly, quality control, inspection, packaging, labeling and shipping of its products. Sterilization and sterility testing are performed under contract by independent companies.

The Company has a fully integrated medical device manufacturing facility in two adjacent buildings totaling 78,000 square feet in San Clemente, California. A mold maintenance shop supports the repair and maintenance needs of the Company's molding operation. In addition, the mold maintenance shop serves as a research and development prototype shop, and utilizes advanced computer assisted design systems and automated machining equipment. The state-of-the-art medical device molding facility includes an 8,000 square foot class 100,000 clean room in which all molding of the Company's proprietary medical components is performed. The clean room is equipped with 24 injection molding machines and ancillary equipment including robots designed to minimize human intervention. The Company uses sophisticated, highly automated assembly systems to assemble the CLAVE, CLAVE Integrated Y site, Click Lock, RF150 and the McGaw Protected Needle products. The assembly systems are custom designed and manufactured for the Company. The Piggy Lock, Lopez Valve, 1o2 Valve and IV sets are assembled manually. The CLC 2000 is currently assembled manually pending installation of automated assembly in 1999.

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

The Company opened a 20,000 square foot facility in Ensenada, Baja California, Mexico in December 1998. The Company performs manual assembly operations for BMP at the facility and the Company intends to move certain other manual assembly operations there over the next year.

The Company's products are currently sterilized in processes which use either gamma or electronic beam ("e-beam") radiation. Most of the Company's sterilization is by gamma radiation. Sterilization is performed by independent companies. The Company has qualified many of its products and components for sterilization by e-beam. E-beam sterilization is less expensive and quicker than gamma radiation sterilization.

Government Regulation

Government regulation is a significant factor in the development, marketing and manufacturing of the Company's products. The Company and its products are regulated by the FDA under a number of statutes including the Federal Food, Drug and Cosmetics Act ("FDC Act"). The FDC Act provides two basic review procedures for medical devices. Certain products may qualify for a submission authorized by Section 510(k) of the FDC Act, under which the manufacturer gives the FDA a pre-market notification of the manufacturer's intention to commence marketing the product. The manufacturer must, among other things, establish that the product to be marketed is substantially equivalent to another legally marketed product. Marketing may commence when the FDA issues a letter finding substantial equivalence. If a medical device does not qualify for the Section 510(k) procedure, the manufacturer must file a pre-market approval ("PMA") application. This requires substantially more extensive pre-filing testing than the Section 510(k) procedure and involves a significantly longer FDA review process. FDA approval of a PMA application occurs only after the applicant has established safety and efficacy to the satisfaction of the FDA. Each of the

Company's current products has qualified, and the Company anticipates that any new products that it is likely to market will qualify, for the expedited Section 510(k) clearance procedure. There is no assurance, however, that new products developed by the Company or any manufacturers that the Company might acquire, or claims that the Company may make concerning those products, will qualify for expedited clearance rather than the more time consuming PMA procedure or that, in any case, they will receive clearance from the FDA. Certain product performance claims for the CLC 2000 require FDA approval after extensive testing that is not yet completed. FDA regulatory processes are time consuming and expensive. Uncertainties as to time required to obtain FDA clearances or approvals could adversely affect the timing and expense of new product introductions. All of the regulated

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products currently manufactured by the Company are classified as Class II medical devices by the FDA. Class II medical devices are subject to performance standards relating to one or more aspects of the design, manufacturing, testing and performance or other characteristics of the product in addition to general controls involving compliance with labeling and record keeping requirements.

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

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 QSR 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

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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., Alaris Corporation and others. Although the Company believes that its needleless CLAVE has distinct advantages over competing systems, there is no assurance that it will be able to compete successfully with these products.

Manufacturers of products with which the Company currently competes, or might compete in the future, include large companies with an established presence in the healthcare products market and substantially greater financial, marketing and distribution, managerial and other resources. In particular, Baxter, Abbott and B. Braun/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 the CLAVE has, and will continue to motivate others to develop one piece needleless connectors, which may incorporate many of the same functional and physical characteristics as the CLAVE. The Company is aware of a number of such products. The Company believes those products were developed primarily by companies who currently do not have the distribution or financial capabilities of the Company, although some of those products may be distributed in the future by larger companies that do have such capabilities. The Company believes these products have had a modest impact on its CLAVE business to date, but there is no assurance that the Company's current or future products will be able to successfully compete with these or future products developed by others.

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 1o2, 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.

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In 1998, the Company settled legal proceedings that it brought against Tri-State Hospital Supply Corporation in 1995 alleging patent infringement. The cost of the litigation was significant. See: Item 3, "Legal Proceedings" and Item 7, "Management's Discussion and Analysis of Financial Conduction and Results of Operations."

Employees

At February 28, 1999, the Company had 222 full-time employees, consisting of 75 engaged in sales, marketing and administration, and 147 in manufacturing, molding, product development and quality control, including 52 in Mexico. The Company contracts with 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, 1999, the number of temporary production personnel was approximately 136.

Item 2. Properties.

The Company owns two adjacent 39,000 square foot buildings in San Clemente, California and a 20,000 square foot building on approximately 94 acres of land in Ensenada, Baja California, Mexico. The Company is currently evaluating the adequacy of its existing facilities in San Clemente and expects to add to those facilities during the next twenty-four months.

Item 3. Legal Proceedings.

In an action entitled ICU Medical, Inc. v. Tri-State Hospital Supply Corporation, brought in the United States District Court for the Northern

District of California, the Company alleged infringement of two of the Company's patents by defendant's protected needle connector and Y-style extension sets. The parties agreed to settle this matter in June 1998. Under the settlement agreement, Tri-State Hospital Supply Corporation ("Tri-State") stipulates that the patents are valid, enforceable and have been infringed by virtue of Tri-State's manufacture and sale of certain products. The parties agreed to treat the other terms of the settlement as confidential.

On April 7, 1998, in an action entitled Allen Petty, dba Carmel Development International v. ICU Medical, Inc., an Orange County, California, Superior Court jury rendered a verdict in favor of the Plaintiff and against the Company in the sum of \$795,448 in an action brought by the Plaintiff for commissions allegedly owed him. On June 23, 1998, the Court reduced the judgement to \$727,522

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

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

Item 4. Submission of Matters to a Vote of Security Holders.

Not Applicable.

Executive Officers of Registrant.

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

Executive Officers:	Age	Office Held
---	---	-----
George A. Lopez, M.D.	51	Chairman of the Board, President and Chief Executive Officer
Richard A. Costello	35	Vice President of Sales
Evelyn L. Foss	43	Vice President of Marketing
Francis J. O'Brien	56	Chief Financial Officer, Secretary and Treasurer

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

Part II

Item 5. Market for Registrant's Common Equity and Related Stockholder Matters.

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

1997	High	Low
----	----	---
First Quarter	\$ 9 31/64	\$ 8 1/4

Second Quarter	8 7/8	7 1/4
Third Quarter	11 1/4	7 3/4
Fourth Quarter	14 1/2	10 1/2

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

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, 1999 the Company had 143 stockholders of record and believes it has approximately 2,500 beneficial stockholders.

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Item 6 Selected Financial Data

ICU MEDICAL, INC.

SELECTED FINANCIAL DATA

Year ended December 31

(in thousands, except per share data)

	1998	1997	1996	1995	1994
	----	----	----	----	----
INCOME DATA:					
Net sales	\$39,842	\$30,404	\$24,599	\$21,282	\$16,542
Cost of goods sold	16,687	12,817	10,438	10,276	8,818
	-----	-----	-----	-----	-----
Gross profit	23,155	17,587	14,161	11,006	7,724
Operating expenses	13,141	9,725	8,236	5,600	3,877
	-----	-----	-----	-----	-----
Income from operations	10,014	7,862	5,925	5,406	3,847
Investment income and other	1,408	1,269	1,289	713	516
Provision for income taxes	4,200	3,450	2,475	1,958	1,456
	-----	-----	-----	-----	-----
Income from continuing operations	\$ 7,222	\$ 5,681	\$ 4,739	\$ 4,161	\$ 2,907
	=====	=====	=====	=====	=====
Income from continuing operations					
Per Share					
Basic	\$ 0.90	\$ 0.71	\$ 0.54	\$ 0.53	\$ 0.41
Diluted	0.86	0.71	0.54	0.52	0.40
	=====	=====	=====	=====	=====
Weighted average number of					
shares					
Basic	7,990	7,946	8,722	7,906	7,048
Diluted	8,423	8,029	8,842	8,040	7,292
	=====	=====	=====	=====	=====
CASH FLOW DATA:					
Cash flows from operations	\$ 6,574	\$ 8,666	\$ 6,513	\$ 6,997	\$ 938
BALANCE SHEET DATA:					
Cash and liquid investments	\$38,090	\$35,112	\$31,760	\$29,665	\$ 3,569
Working capital	43,817	37,993	35,587	33,762	12,712
Total assets	62,360	51,186	49,639	47,850	26,321
Long-term debt	-	-	-	-	-

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:

Product Line	1998	1997	1996
CLAVE	69%	65%	68%
Click Lock	4%	7%	12%
McGaw Protected Needle	4%	5%	8%
Lopez Valve and other	5%	4%	4%
RF100-RF150 ("Rhino")	5%	7%	3%
Budget Medical Products	8%	6%	2%
McGaw SafeLine Revenue Sharing	5%	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 and Abbott (the "B.Braun/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, non-sterile 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 B.Braun/McGaw Agreement provided for revenue sharing based on B.Braun/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, the Abbott Agreement was amended to establish fixed selling prices for Rhinos and eliminate revenue sharing, and effective January 1, 1998, both the Abbott and B.Braun/McGaw Agreements were amended to establish fixed selling prices on CLAVE products and eliminate revenue sharing on CLAVE products.

In June 1997, B.Braun Melsungen AG ("B.Braun") acquired McGaw from IVAX Corporation. In June 1998, the Company and B.Braun/McGaw concluded a new definitive agreement effective as of January 1, 1998. The new agreement extends the prior agreement for CLAVE products from June 2000 to December 2002, has extension provisions beyond then, and generally reduces prices.

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

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 an IV product manufacturer such as B.Braun/McGaw or Abbott or the loss of a large contract by such a customer could have a material adverse effect on the Company's business and 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 1996, the Company since October 1996 has been reducing prices. Management expects that the average price of its CLAVE products will continue to decline. There is no assurance that the Company's current or future products will be able to successfully compete with products developed by others.

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Comparison of 1998 to 1997

In 1998, the Company reported net sales of \$39,842,000 which was \$9,438,000, or 31%, higher than the net sales of \$30,404,000 reported in 1997. The most significant factor in the increase was a \$7,969,000, or 41%, increase in CLAVE net sales. Net sales in all of the Company's other product lines were equal to or more than those for 1997, except for a decrease in Click Lock and Piggy Lock net sales. The Company's independent distributors accounted for 36% of the Company's net sales in 1998, with McGaw accounting for 35% and Abbott the remaining 29%. In 1997, the comparable percentages were 48%, 36% and 16%, respectively.

Total CLAVE net sales increased approximately 41% from \$19,539,000 in 1997 to \$27,508,000 in 1998. Unit shipments of CLAVE products in 1998 increased approximately 88% over 1997, with B.Braun/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 1998 decreased approximately 25% as compared with 1997. That decrease reflects lower prices from independent distributors and lower prices on bulk, non-sterile CLAVE products sold to B.Braun/McGaw and Abbott, as well as a higher percentage of the sales mix being accounted for by bulk, non-sterile CLAVES.

Net sales to B.Braun/McGaw, including revenue sharing, amounted to \$13,961,000 in 1998, as compared to \$10,971,000 in 1997. CLAVE net sales to B.Braun/McGaw increased approximately 36%, principally because of an increase in unit shipments. Net sales of the McGaw Protected Needle were virtually unchanged, but management expects those sales to decline in the future as the market for safe connectors continues its shift to needleless technology. Management expects increases in unit shipments to B.Braun/McGaw in 1999, although there is no assurance that this expectation will be realized. Under an Agreement with B.Braun/McGaw, 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 \$1,995,000 in 1998, as compared with \$1,767,000 in 1997. 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 \$11,601,000 in 1998, as compared to \$4,993,000 in 1997. CLAVE sales were 3.24 times the amount in 1997. Most of the balance of the sales were in the low-priced Rhino, which were \$1,987,000 as compared with \$2,087,000 in 1997. Based upon the terms of the Abbott agreement as amended in January 1999, Management expects a substantial increase in CLAVE unit and dollar sales volume with Abbott in 1999, although there is no assurance as to the amount of such increase.

Management expects that unit sales of CLAVE to its independent distributors in 1999 will be approximately the same as in 1998 or slightly lower. Although Management had expected that the price reductions commenced in October 1996, which have aggregated 40% by the end of 1998, would eventually be more than 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 29% in 1998 as compared to 1997, because of the safe connector market's continued shift to needleless technology. Management expects that decline to continue.

The Lopez Valve showed a 24% growth in 1998 net sales as compared to 1997 principally because of increased unit shipments. Management expects continued increases in Lopez Valve net sales in 1999.

The Company's subsidiary BMP, which markets custom IV sets, recorded \$3,218,000 net sales in 1998 as compared to \$1,828,000 in 1997, its second year of operations. Most of the increase in 1998 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 and 1998. The Company is currently taking steps aimed at expanding BMP by increasing systems capabilities, improving manufacturing efficiency, reducing labor cost and enhancing distribution. Because significant innovation is required to achieve these goals, there is no assurance that these steps will achieve the desired results. However, even if

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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.

Total sales to foreign distributors were \$1,364,000 in 1998 as compared to \$908,000 in 1997. (Those amounts do not include distribution in Canada.) In April 1998, BOC OHMEDA AB ("Ohmeda"), the Company's principal distributor in Europe, sold its European distribution to a competitor of the Company, and the Company has terminated substantially all distribution by Ohmeda since August 1998. The Company is currently arranging alternative distribution in Europe, although there is no assurance that satisfactory alternative distribution arrangements will be made. The Company believes that the loss of distribution through Ohmeda did have an adverse effect on the growth of European sales. To enhance growth of the European distribution, the Company has hired four additional product specialists in Europe bringing to six the total in Europe. Management expects that its sales to European and other foreign distributors will continue to increase in the future.

Gross margin for 1998 was unchanged from the 58% registered in 1997. The shift in sales mix toward a higher percentage of the relatively higher-margin CLAVE products, continued increases in the benefits of the Company's extensive production automation, and the increased absorption of overhead by higher production volumes offset the effect of lower average unit selling prices.

The Company expects that its unit production costs will continue to decrease in 1999 as unit volumes increase, but that the gross margin percentage will be equal to or slightly lower than that achieved in 1998 as average unit sales prices continue to decrease.

Selling, general and administrative costs ("SG&A") increased by approximately \$3,631,000 to \$12,094,000 in 1998, as compared to \$8,463,000 in 1997. SG&A costs were 30% of net sales in 1998 as compared with 28% in 1997. The increase in SG&A costs was primarily due to increased sales and marketing costs related to the Company's domestic expansion of the CLAVE product line, growth of BMP, expansion of the international sales efforts, and legal fees. Management expects SG&A costs to increase in 1999, because of growth in the Company, increased domestic and international sales and marketing costs, promotional costs of new products and expansion of BMP.

Research and development ("R&D") costs decreased in 1998 by approximately \$213,000 to \$1,048,000, or 3% of net sales, as compared with approximately \$1,261,000, or 4% of sales, in 1997. Management estimates that R&D costs in 1999 will continue at approximately the same percentage of net sales as in 1998. However, R&D costs could differ from those estimates and the R&D may not be completed as expected.

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

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

The Company's effective income tax rate in 1998 was 37%, approximately the same as in 1997. Management expects its effective tax rate in 1999 to be equal to or slightly higher than the 1998 rate.

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

Comparison of 1997 to 1996

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 B.Braun/McGaw accounting for 36% and Abbott the remaining 16%. In 1996, the comparable percentages were 65%, 28% and 7%, respectively.

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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 B.Braun/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%. Estimated SafeLine revenue share was approximately \$1,767,000 in 1997, as compared with \$834,000 in 1996.

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.

Net sales of Click Lock and Piggy Lock decreased 22% in 1997 as compared to 1996. The Lopez Valve showed a 9% growth in 1997 net sales as compared to 1996 because of increased unit shipments.

BMP net sales recorded were \$1,828,000 in 1997 as compared to \$400,000 in 1996, its first year of operations. Total sales to foreign distributors were \$908,000 in 1997 as compared to \$693,000 in 1996.

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 and continued increases in the benefits of the Company's extensive production automation more than offset the effect of lower average unit selling prices.

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.

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.

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.

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.

Liquidity and Capital Resources

During 1998, working capital increased approximately \$5,824,000 to \$43,817,000 from \$37,993,000. The Company's cash and cash equivalents and investment securities, including liquid investments, increased by \$2,978,000 to

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\$38,090,000 from \$35,112,000; that increase was due primarily to \$6,574,000 of cash flows from operating activities and \$3,460,000 from exercise of stock options, partially offset by \$6,656,000 of purchases of property and equipment.

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, due primarily to \$8,666,000 of cash flows from operating activities, offset by \$4,606,000 used to acquire treasury stock.

Capital expenditures increased substantially in 1998 from the relatively low levels in 1995 through 1997. The increase related to the acquisition of land and construction of the facility in Ensenada, Baja California, Mexico of approximately \$2.3 million, acquisition of production tooling and machinery of approximately \$3.5 million, and purchase of computer and other office equipment of approximately \$0.9 million. Management currently expects that capital expenditures for production tooling and machinery in 1999 will substantially exceed 1998 levels to meet expected increased sales volumes and to automate production of new products and that capital expenditures, of an amount yet to be determined, will be incurred to add to facilities in San Clemente.

Management expects that sales of the Company's products will continue to grow in 1999. 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, except for \$400,000 of shares purchased in August 1998. It may purchase additional shares in the future. However, future acquisitions, if any, will depend on market conditions and other factors.

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

Year 2000 Compliance

Many older computer programs use only the last two digits to refer to a year. Therefore, they do not properly recognize a year that begins with "20" rather than "19." This is referred to as the Year 2000, or Y2K problem. The Y2K problem has been eliminated in many new programs and systems, which are said to be "Y2K compliant." The Company has completed its initial assessment of Y2K and believes, based on manufacturers' specifications and subject to completion of testing in 1999, that all its information technology ("IT") systems and applications and related hardware are Y2K compliant. The Company has not completed assessing Y2K compliance of its non-IT systems, principally manufacturing systems, but it believes that any non-compliance will not affect

the ability to use the related manufacturing equipment. The Company will attempt to assess in 1999 whether third parties with whom it deals, such as customers, vendors and governments have any Y2K problems that could affect the Company; such problems could result in interruptions in delivery of services and materials and payments, among other things. The Company has not developed Y2K non-compliance contingency plans, but will consider the need for such plans upon completion of the Y2K compliance assessments. Costs to assure Y2K compliance have so far been and are expected to remain nominal.

While the Company is not currently aware of any Y2K compliance problems in its own systems, Y2K compliance of those systems cannot be assured until completion of testing. Further, the Company cannot assure that the information it receives from third parties about their Y2K compliance will be meaningful or accurate. Failure to achieve compliance for the Company's systems, or failure of significant third parties, with which the Company deals to achieve Y2K compliance, could have a material adverse effect on the Company's operations.

Forward Looking Statements

Various portions of this Report, including Management's Discussion and Analysis describe trends in the Company's business and finances that Management perceives and states some of its expectations and beliefs about the Company's future. These statements about the future are "forward looking statements," and the Company identifies them by using words such as "believes," "expects," "anticipates," "estimates," "intends," "plans," "will," "continuing," "could," and similar expressions and by statements about aims, goals and plans. The forward looking statements are based on the best information currently available to Management and assumptions that Management

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believes are reasonable, but Management does not intend the statements to be representations as to future results. They include, among other things, statements about:

- . future operating results and various elements of operating results, including sales and unit volumes of products, production costs, gross margins, selling, general and administrative costs, sales and marketing costs, promotional costs, and research and development expense and income taxes;
- . factors affecting operating results, such as shipments to specific customers, product mix, selling prices, the market shift to needleless products, achievement of business expansion goals, manufacturing efficiencies, production volumes, overhead absorption, expansion of markets and distribution costs;
- . new contracts with buying organizations and dependence on a small number of customers;
- . competitive and market factors, including continuing development of competing products by other manufacturers, consolidation of the healthcare provider market and downward pressure on selling prices;
- . working capital requirements, capital expenditures and common stock repurchases; and
- . Y2K issues.

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

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

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

- . general economic and business conditions;
- . the effect of price and safety considerations on the healthcare industry;
- . competitive factors, such as product innovation, new technologies, marketing and distribution strength and price erosion;
- . unanticipated market shifts and trends;

- . the impact of legislation effecting government reimbursement of healthcare costs;
- . changes by the Company's major customers and independent distributors in their strategies that might affect their efforts that to market the Company's products;
- . unanticipated production problems; and
- . the availability of patent protection and the cost of enforcing and of defending patent claims.

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

Item 7a. Quantitative and Qualitative Disclosures about Market Risk.

Not Applicable.

Item 8. Financial Statements and Supplementary Data.

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REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

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

We have audited the accompanying consolidated balance sheets of ICU MEDICAL, INC. (a Delaware corporation) as of December 31, 1998 and 1997, and the related consolidated statements of income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 1998. 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, 1998 and 1997, and the consolidated results of its operations and its consolidated cash flows for each of the three years in the period ended December 31, 1998, 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 27, 1999

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ICU MEDICAL INC.

CONSOLIDATED BALANCE SHEETS

ASSETS

	December 31,	
	1998	1997
CURRENT ASSETS:		
Cash and cash equivalents	\$ 2,048,315	\$ 2,962,276
Liquid investments	36,041,283	32,150,000
Cash and liquid investments	38,089,598	35,112,276
Accounts receivable, net of allowance for doubtful accounts of \$341,553 in 1998 and \$323,620 in 1997	6,492,197	3,356,936
Inventories	1,990,647	1,762,628
Prepaid expenses and other	384,842	200,964
Deferred income taxes - current portion	991,000	717,000
Total current assets	47,948,284	41,149,804
PROPERTY AND EQUIPMENT, at cost:		
Machinery and equipment	8,224,753	7,078,157
Furniture and fixtures	2,044,472	1,521,580
Molds	3,709,882	2,873,321
Construction in process	1,703,407	183,029
Land, building and building improvements	7,190,733	5,001,297
Less--Accumulated depreciation	(9,108,980)	(7,060,431)
	13,764,267	9,596,953
DEFERRED INCOME TAXES	92,000	-
OTHER ASSETS	554,992	439,340
	\$62,359,543	\$51,186,097

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,	
	1998	1997
CURRENT LIABILITIES:		
Accounts payable	\$ 683,063	\$ 1,403,312
Accrued liabilities	3,447,993	1,753,915
Total current liabilities	4,131,056	3,157,227

DEFERRED INCOME TAXES	-	82,000
-----------------------	---	--------

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 1998 and 1997	886,716	886,716
Additional paid-in capital	40,241,288	39,455,511
Treasury stock -- 807,847 shares in 1998 and 1,100,776 shares in 1997	(7,117,001)	(9,320,352)
Retained earnings	24,217,484	16,924,995
	-----	-----
Total stockholders' equity	58,228,487	47,946,870
	-----	-----
	\$62,359,543	\$51,186,097
	=====	=====

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

ICU MEDICAL INC.

CONSOLIDATED STATEMENTS OF INCOME

	December 31,		
	1998	1997	1996
	-----	-----	-----
NET SALES	\$39,842,165	\$30,404,128	\$24,599,005
COST OF GOODS SOLD	16,687,212	12,817,048	10,438,066
	-----	-----	-----
Gross profit	23,154,953	17,587,080	14,160,939
OPERATING EXPENSES:			
Selling, general and administrative	12,093,890	8,463,480	7,445,694
Research and development	1,047,579	1,261,274	790,353
	-----	-----	-----
Total operating expenses	13,141,469	9,724,754	8,236,047
	-----	-----	-----
Income from operations	10,013,484	7,862,326	5,924,892
INVESTMENT INCOME	1,408,416	1,269,236	1,289,298
	-----	-----	-----
Income before income taxes	11,421,900	9,131,562	7,214,190
PROVISION FOR INCOME TAXES	4,200,000	3,450,000	2,475,000
	-----	-----	-----
NET INCOME	\$ 7,221,900	\$ 5,681,562	\$ 4,739,190
	=====	=====	=====
NET INCOME PER SHARE			
Basic	\$0.90	\$0.71	\$0.54
Diluted	\$0.86	\$0.71	\$0.54
	=====	=====	=====
WEIGHTED AVERAGE NUMBER OF SHARES			
Basic	7,989,534	7,946,328	8,722,081
Diluted	8,422,613	8,028,991	8,841,562
	=====	=====	=====

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

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ICU MEDICAL, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Number of Shares Outstanding	Common Stock Amount	Additional Paid-In Capital	Treasury Stock	Retained Earnings	Total
BALANCE, December 31, 1995	8,662,837	\$866,284	\$38,016,465	\$ -	\$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	234,325	20,432	1,430,660	259,703	(250,954)	1,459,841
Net Income	-	-	-	-	4,739,190	4,739,190
BALANCE, December 31, 1996	8,300,451	886,716	39,447,125	(4,848,465)	11,263,528	46,748,904
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)	122,472
Net Income	-	-	-	-	5,681,562	5,681,562
BALANCE, December 31, 1997	7,766,386	886,716	39,455,511	(9,320,352)	16,924,995	47,946,870
Acquire shares for treasury	(32,100)	-	-	(400,409)	-	(400,409)
Exercise of stock options and related income tax benefits, and other	325,029	-	785,777	2,603,760	70,589	3,460,126
Net Income	-	-	-	-	7,221,900	7,221,900
BALANCE, December 31, 1998	8,059,315	\$886,716	\$40,241,288	\$(7,117,001)	\$24,217,484	\$58,228,487

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

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ICU MEDICAL, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	December 31,		
	1998	1997	1996
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net Income	\$7,221,900	\$5,681,562	\$4,739,190
Adjustments to reconcile net income to net cash provided by operating activities --			
Depreciation and amortization	2,364,136	2,148,826	1,969,310
Deferred income taxes, non-current	(174,000)	(145,000)	21,000
(Increase) decrease in:			
Accounts receivable	(3,126,193)	(280,540)	(289,821)
Inventories	(228,019)	470,991	(729,797)
Prepaid expenses and other assets	(183,878)	562,182	125,279
Increase (decrease) in:			
Accounts payable	(720,249)	(498,905)	853,805
Accrued liabilities	1,694,078	993,399	(177,404)
Deferred income taxes, current	(274,000)	(267,000)	1,000

Net cash provided by operating activities	6,573,775	8,665,515	6,512,562
	-----		-----
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property and equipment	(6,656,170)	(829,306)	(1,276,766)
Proceeds from sales of investment securities	-	-	507,580
Net change in liquid investments	(3,891,283)	(2,450,000)	(2,049,156)
	-----	-----	-----
Net cash (used in) investing activities	(10,547,453)	(3,279,306)	(2,818,342)
	-----	-----	-----
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from exercise of stock options and related income tax benefits, and other	3,460,126	122,472	1,459,841
Purchase of treasury stock	(400,409)	(4,606,068)	(5,108,168)
	-----	-----	-----
Net cash provided by (used in) financing activities	3,059,717	(4,483,596)	(3,648,327)
	-----	-----	-----
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(913,961)	902,613	45,893
CASH AND CASH EQUIVALENTS, beginning of year	2,962,276	2,059,663	2,013,770
	-----	-----	-----
CASH AND CASH EQUIVALENTS, end of year	\$2,048,315	\$2,962,276	\$2,059,663
	=====	=====	=====
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			
Cash paid during the period for income taxes	\$3,726,700	\$2,861,991	\$1,406,620
	=====	=====	=====

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, 1998, 1997 AND 1996

1. Summary of Significant Accounting Policies

a. General

ICU Medical, Inc. (the Company - a Delaware Corporation) operates principally in one business segment engaged in the development and marketing of proprietary disposable medical devices designed to protect healthcare workers and patients from the spread of infectious diseases. The Company's devices are sold principally to distributors and medical product manufacturers throughout the United States. All wholly owned subsidiaries are included in the Consolidated Financial Statements.

b. Inventories

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

Inventories at December 31, consist of the following:

	1998	1997
	-----	-----
Raw materials	\$1,121,212	\$1,060,325
Work in process	509,180	459,618
Finished goods	360,255	242,685
	-----	-----
	\$1,990,647	\$1,762,628
	=====	=====

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, 1998 and 1997, the net book value of patents and licenses was \$507,948 and \$383,228, respectively, net of accumulated amortization of \$323,239 and \$243,139, respectively.

e. Research and Development

The Company expenses research and development costs as incurred.

f. Cash Equivalents

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

g. Net Income Per Share

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

h. Investment Securities

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

i. Income Taxes

The Company accounts for income taxes in accordance with SFAS No. 109, "Accounting for Income Taxes," which requires an asset and liability approach in accounting for income taxes payable or refundable at the date of the financial statements as a result of all events that have been recognized in the financial statements as measured by enacted tax laws. Additionally, SFAS No. 109 requires that deferred tax assets be evaluated and a valuation allowance be established if it is "more likely than not" that all or a portion of the deferred tax asset will not be realized.

j. Revenue Recognition

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

k. Post-retirement and Post-employment Benefits

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

l. Stock Options

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

m. Accounting Estimates

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

2. Liquid Investments

The Company's liquid investments, 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:

	1998 -----	1997 -----	1996 -----
Corporate preferred stocks	\$14,600,000	\$26,450,000	\$17,500,000
Federal tax-exempt debt securities	20,350,000	5,700,000	12,200,000
Certificate of deposit	1,091,283	-	-
	-----	-----	-----
	\$36,041,283	\$32,150,000	\$29,700,000
	=====	=====	=====

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

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

	1998 -----	1997 -----	1996 -----
Corporate dividends	\$ 516,264	\$ 612,066	\$ 71,176
Tax-exempt interest	757,822	574,603	1,072,711
Other interest	134,300	82,567	145,411
	-----	-----	-----
	\$1,408,416	\$1,269,236	\$1,289,298
	=====	=====	=====

3. Accrued Liabilities

Accrued liabilities consists of the following:

	1998	1997
	-----	-----
Accrued incentive compensation	\$ 702,617	\$ 577,129
Taxes payable	802,415	737,840
Other accruals	1,942,961	438,946
	-----	-----
Total accrued liabilities	\$3,447,993	\$1,753,915
	=====	=====

4. Common Stock and Common Stock Options Granted

In 1993, the Company adopted the 1993 Stock Incentive Plan and Directors' Stock Option Plan (the Plans). In 1996, the 1993 Stock Incentive Plan was amended to increase the number of shares reserved for issuance to employees from 1,275,000 to 3,275,000. Options granted under the 1993 Stock Incentive Plan expire eleven years from issuance and are time-accelerated options which vest upon the earlier of the Company attaining specific operating performance levels or ten years from the date of grant. The 1993 Directors' Stock Option Plan, under which 225,000 shares had been reserved for issuance, called for options to be granted to non-employee Directors every three years; fifty percent of each Director's options vested on the date of the first annual shareholders meeting following the grant and the other fifty percent on the date of the second such meeting. The Plans include conditions whereby options not vested are canceled if employment or directorship is terminated. All options have been granted at the fair market value of the Company's stock on the date of grant. Upon exercise of options, the Company is generally entitled to a tax deduction for an amount equal to the excess over the exercise price of the fair market value of the shares at the date of exercise.

In 1997, the Directors' Stock Award Plan, under which each non-employee Director is awarded 1,000 shares of Common Stock annually, was adopted. Further, grants under the Directors' Stock Option Plan were discontinued, reducing the number of shares reserved for issuance under the Plans 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, 1998, 2,689,152 are time-accelerated options, which were issued under the 1993 Stock Incentive Plan. Of those options, 42,700 issued in 1993 at an average exercise price of \$9.56 expire in 2004; 126,000 issued in 1994 at an average exercise price of \$10.83 expire in 2005; 21,000 issued in 1995 at an average exercise price of \$12.10 expire in 2006; 562,324 issued in 1996 at an average exercise price of \$12.96 expire in 2007; 1,086,899 issued in 1997 at an average exercise price of \$9.17 expire in 2008; and, 850,229 issued in 1998 at an average exercise price of \$12.42 expire in 2009. The remaining 30,000 options that are not time-accelerated are at an exercise price of \$16.13 expire in 2001. In January 1999, options granted from 1993 to January 1998 to purchase 1,085,990 shares of common stock at prices ranging from \$7.19 to \$15.38 (weighted average \$11.28 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 360,000, 870,000 and 940,000 in 1998, 1997 and 1996, respectively. At December 31, 1998, all options had exercise prices less than the market price of the Company's common stock.

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

	Shares	Exercise Price Range			Weighted Average
Outstanding at December 31, 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
Granted	910,229	12.06	-	16.38	12.16
Exercised	321,029	7.69	-	14.00	8.24
Forfeited	17,500	7.38	-	15.13	12.51
Outstanding at December 31, 1998	2,719,152	\$ 11.15	-	\$ 16.38	\$ 11.15
Exercisable at December 31:					
1996	26,500	\$ 5.75	-	\$14.00	\$10.98
1997	31,000	9.50	-	16.13	14.88
1998	430,621	8.00	-	16.13	9.08
Available for grant at December 31, 1998	267,319				

The Company applies APB Opinion No. 25 and related interpretations in accounting for stock options granted to employees, and does not recognize compensation expense because the exercise price of the options equals the fair market value of the underlying shares at the date of grant. Directors' stock options are treated in the same manner as employee stock options for accounting purposes.

Under SFAS No. 123, the Company is required to present certain pro forma earnings information determined as if employee stock options were accounted for under the fair value method of that Statement. The fair value for options granted in 1998, 1997 and 1996 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 5.7, 5.9 and 6.4 percent, respectively; expected option life of 4.7, 4.3 and 3.4 years, respectively; expected volatility of 52, 54 and 49 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 1998, 1997 and 1996 was \$6.05, \$3.33 and \$5.84, respectively. The total estimated fair value is amortized to expense over the vesting period.

	1998	1997	1996
Proforma:			
Net Income.....	\$3,328,000	\$3,682,000	\$3,968,000
Net Income per share - basic.....	\$.044	\$ 0.52	\$ 0.48
- diluted.....	\$ 0.42	\$ 0.51	\$ 0.47
Weighted average number of common shares - basic.....	7,558,000	7,120,000	8,260,000
- diluted.....	7,991,000	7,209,000	8,379,000

The components of the Company's deferred income tax provision for the years ended December 31, 1998, 1997 and 1996 are as follows:

	1998 -----	1997 -----	1996 -----
Allowance for doubtful accounts	\$ (6,000)	\$ (13,000)	\$ (25,000)
Inventory reserves	30,000	(105,000)	(23,000)
Accruals	(367,000)	(45,000)	122,000
State income taxes	69,000	(104,000)	(73,000)
Depreciation	(174,000)	(145,000)	21,000
	-----	-----	-----
	\$ (448,000)	\$ (412,000)	\$ 22,000
	=====	=====	=====

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

	1998 -----	1997 -----
Current deferred tax benefit:		
Allowance for doubtful accounts	\$146,000	\$140,000
Inventory reserves	270,000	300,000
Accruals	482,000	115,000
State income taxes	93,000	162,000
	-----	-----
	\$991,000	\$717,000
	=====	=====
Long-term deferred tax benefit (liability):		
Depreciation	\$ 92,000	\$ (82,000)
	=====	=====

7. 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, 1998, 1997 and 1996, the Company had sales of 10 percent or greater to one distributor and the two manufacturers as follows:

	1998 ----	1997 ----	1996 ----
Distributor	*	*	13
Manufacturer A	35	36	*
Manufacturer B	29	16	*

* less than 10 percent

8. Employment Contracts

The Company has employment contracts with certain key employees which include an incentive compensation agreement. Incentive compensation expense accrued based on meeting certain operating performance goals was \$326,000 in 1998 and \$274,000 in 1997.

9. Commitments and Contingencies

The Company is from time to time involved in various legal proceedings, most of which are routine litigation, in the normal course of business. In the opinion of management, after consultation with legal counsel, the resolution of

these matters will not have a material adverse impact on the Company's financial position or results of operations.

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

10. 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.

11. Quarterly Financial Data -- Unaudited -- (dollars in thousands, except per share data)

	Quarter Ended			
	March 31	June 30	Sept. 30	Dec. 31
1998				
Net Sales	\$9,982	\$10,430	\$9,618	\$9,812
Gross Profit	5,815	6,062	5,598	5,680
Net Income	1,660	1,719	1,823	2,020
Net Income Per Share:				
Basic	\$ 0.21	\$ 0.21	\$ 0.23	\$ 0.25
Diluted	\$ 0.20	\$ 0.20	\$ 0.22	\$ 0.24
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:				
Basic	\$ 0.16	\$ 0.16	\$ 0.18	\$ 0.21
Diluted	\$ 0.16	\$ 0.16	\$ 0.18	\$ 0.21

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

PART III

Item 10. Directors and Executive Officers of Registrant.

The information about Registrant's directors and disclosure of Form 3, 4 or 5 delinquent filers called for by Item 10, Part III of Form 10-K is set forth in Registrant's definitive Proxy Statement filed or to be filed pursuant to Regulation 14A within 120 days of Registrant's fiscal year ended December 31, 1998, and such information is incorporated herein by this reference. Pursuant to Instruction G(3) to Form 10-K and Instruction 3 to Item 401(b) of Regulation S-K, information about Registrant's executive officers called for by Item 10, Part III of Form 10-K is set forth in Part I of this Report in a separate item captioned "Executive Officers of Registrant."

Items 11 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, 1998, 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 Annual Report.

Form 10-K
Page No.

Report of Independent Public Accountants.....	19
Consolidated Balance Sheets at December 31, 1998 and 1997.....	20-21
Consolidated Statements of Income for the Years Ended December 31, 1998, 1997 and 1996.....	22
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 1998, 1997 and 1996.....	23
Consolidated Statements of Cash Flows for the Years Ended December 31, 1998, 1997 and 1996.....	24
Notes to Consolidated Financial Statements.....	25-33

2. Financial Statement Schedules

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

Schedule II - Valuation and Qualifying Accounts.....	37
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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.(2)
10.4	Registrant's Directors' Stock Option Plan.(3)
10.5	Manufacture and Supply Agreement dated September 13, 1993 between Registrant and McGaw, Inc. relating to the Protected Needle product.(4)
10.6	Supply and Distribution Agreement dated April 3, 1995 between Registrant and Abbott Laboratories, Inc. relating to the CLAVE product.(5)
10.7	Registrant's Director's Stock Award Plan.(6)
10.8	Rights Agreement dated July 15, 1997 between Registrant and ChaseMellon Shareholder Services, L.L.C. as Rights Agent.(7)
10.9	Manufacture and Supply Agreement dated January 1, 1998 by and between Registrant and B.Braun Medical, Inc. relating to the CLAVE product.(8)
10.10	SafeLine Agreement effective October 1, 1998 by and between Registrant and B.Braun Medical, Inc.(8)
10.11	Amendment to Abbott and ICU Medical Agreement, dated January 1, 1999 between Registrant and Abbott Laboratories.(9)

10.12 Amendment No. 1 to Rights Agreement, dated January 30, 1999, between Registrant and ChaseMellon Shareholder Services, L.L.C. as Rights Agent.(10)

21.1 Subsidiaries of Registrant.

23.1 Consent of Arthur Andersen LLP.

27.1 Financial Data Schedule.

- (1) Filed as an exhibit to Registrant's Registration Statement Form S-1 (Registration No. 33-45734) filed on February 14, 1992, and incorporated herein by reference.
- (2) Filed as an Exhibit to Registrant's definitive Proxy Statement filed pursuant to Regulation 14A on May 4, 1996 and incorporated herein by reference.
- (3) Filed as an exhibit to Registrant's definitive Proxy Statement filed pursuant to Regulation 14A on March 22, 1993 and incorporated herein by reference.
- (4) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended September 30, 1993, and incorporated herein by reference.
- (5) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended March 31, 1995, and incorporated herein by reference.
- (6) Filed as exhibit to Registrant's definitive Proxy Statement filed pursuant to Regulation 14A on April 11, 1997 and incorporated herein by reference.
- (7) Filed as an exhibit to Registrant's Registration Statement on Form 8-A dated July 23, 1997 and incorporated herein by reference.
- (8) Filed as an exhibit to Registrant's Quarterly Report on Form 8-K dated June 18, 1998, and incorporated herein by reference.
- (9) Filed as an exhibit to Registrant's Quarterly Report on Form 8-K dated February 23, 1999, and incorporated herein by reference.
- (10) Filed as an exhibit to Registrant's Registration Statement on Form 8-A/A dated February 9, 1999 and incorporated herein by reference.

(b) Reports on Form 8-K.

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

Item 5 - November 5, 1998

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SIGNATURES

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

ICU MEDICAL, INC

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

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

Dated: March 1, 1999

SIGNATURES

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

Signature -----	Title -----	Date -----
/s/ George A. Lopez, M.D. ----- George A. Lopez, M.D.	Chairman of the Board, President, and Chief Executive Officer, (Principal Executive Officer)	March 1, 1999
/s/ Francis J. O'Brien ----- Francis J. O'Brien	Chief Financial Officer and Principal Accounting Officer	March 1, 1999
/s/ Jack W. Brown ----- Jack W. Brown	Director	March 1, 1999
/s/ John J. Connors ----- John J. Connors	Director	March 1, 1999
/s/ Michael T. Kovalchik, III, M.D. ----- Michael T. Kovalchik, III, M.D.	Director	March 1, 1999
/s/ Richard H. Sherman, M.D. ----- Richard H. Sherman, M.D.	Director	March 1, 1999
/s/ Robert S. Swinney, M.D. ----- Robert S. Swinney, M.D.	Director	March 1, 1999

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SCHEDULE II

ICU MEDICAL, INC.

VALUATION AND QUALIFYING ACCOUNTS

Description -----	Balance at Beginning of Period -----	Additions -----		Write-offs/ Disposals -----	Balance at End of Period -----
		Charged to Costs and Expenses -----	Charged to Other Accounts -----		
For the year ended December 31, 1996:					
Allowance for doubtful accounts	\$254,987	\$ 40,000	\$ -	\$ 1,955	\$293,032
	=====	=====	=====	=====	=====
Inventory reserves	\$301,438	\$ 50,000	\$ -	\$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
	=====	=====	=====	=====	=====
For the year ended December 31, 1998:					
Allowance for doubtful accounts	\$323,620	\$ 40,000	\$ -	\$22,067	\$341,553
	=====	=====	=====	=====	=====
Inventory reserves	\$499,615	\$ 62,000	\$ -	\$96,150	\$465,465
	=====	=====	=====	=====	=====

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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	

Subsidiaries of Registrant

<u>Name</u> -----	<u>State of Incorporation</u> -----
Budget Medical Products, Inc.	California
ICU MedEurope Limited	United Kingdom
Set finder, Inc.	Delaware
BMP de Mexico, S.A. de C.V.	Mexico

CONSENT OF INDEPENDENT PUBLIC ACCOUNTANTS

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

/s/ Arthur Andersen LLP
ARTHUR ANDERSEN LLP

Orange County, California
January 27, 1999

<ARTICLE> 5

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